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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

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.

The MI procedure implements the principles of justification and optimization, whether it uses ionising 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 procedures"* 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 ionising radiation and electromagnetic waves for the exposed persons, and the doses 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 exercised remotely (e.g. by teleradiology) under conditions defined by regulations and procedures. In this case, the assessment of the MI organization includes the procedures performed on-site and the procedures performed externally/remotely under the organization's control, and in particular their relevance and optimization.

All the activities are exercised 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 procedures. The performed MI procedures 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 skills required for safety, effectiveness, proper patient management of patients and a strong command of the MI procedures 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 composition and structure of the MI Organization shall be defined in a document which describes the roles and responsibilities of all the categories of professionals.

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 promote and create a positive safety culture.

5.2.2 Qualifications

The MI Organization shall ensure and document that all the professionals are qualified and authorized to practice. It shall possess documents proving that every professional has the necessary skills and command of the procedures they perform in order to meet the requirements within the professional scope pertaining to the quality of care and the safety of the patients treated in the MI organization.

The MI Organization shall enable and record the continuing professional development of the professionals in order to maintain and, if necessary, improve and develop their skills according to the best practices, ensuring a periodic review.

The training plan, including records and the monitoring of its quality and impact shall be described in a documented procedure.

Initial and periodic training shall be defined for the acquisition of any medical devices, taking into account their complexity, the practices and the number of users concerned. All equipment suppliers should ensure a training programme of appropriate length for the professionals is available throughout the life of the equipment. These mandatory training programmes shall be recorded and assessed using the training materials made available to the workforce.

While considering the professional scope, professionals are expected to be able to communicate and listen, show respect, kindness, and courtesy towards patients, and have ethical and professional attitude towards the different professionals.

Any delegations of activity shall follow processes that meet the applicable regulations.

5.2.3 Entitlements

Each professional shall be authorized by the MI Organization to perform the different types of MI procedures within their scope of competence and in accordance with the applicable regulations.

The same professional can be authorized for several operating positions and/or activities in the MI organization.

The MI Organization shall define its quantitative and qualitative entitlement criteria to determine the necessary level of activity per professional and for each of the types of procedures, in accordance with any existing recommendations.

Entitlement shall be adapted to the profile of the job and the formalities shall be limited strictly to meeting the needs. It shall be granted after practical exercise, according to internal procedures, for a limited duration.

Entitlements shall be renewed in the event of a change of equipment, significant changes to the MI Organization or a lengthy interruption of activity.

A documented procedure shall be put in place to describe the establishment and management of professional entitlements.

A mapping of the entitlements and continuous professional development (CPD) shall be drawn up and periodically reviewed.

In particular, the following documents are expected:

— a document describing the activities (types of MI procedures) carried out by the MI organization;

— job descriptions that describe the specific skills, competences, responsibilities, and tasks of the professional categories required to conduct each of these activities, and the mentoring time required for the entitlement of newly recruited professionals. All these job descriptions are used to match the workforce to the activities conducted. These job descriptions act as the supporting materials for individual entitlements;

— documents certifying the qualifications of the professional;

— initial training, including diplomas, and continuous professional development, in accordance with the applicable regulations. The MI Organization makes sure that the titles and diplomas of the professionals working in the MI Organization respect the applicable national regulations;

— validation of skills acquired through experience, in accordance with the applicable regulations;

— entitlement documents for each professional, listing the positions and the activities to which they can be assigned. Specific entitlements may be necessary.

Entitlements and their validation period shall be proportional to the risks related to the medical imaging activity.

EXAMPLE Formal definition of a training and entitlement process.

Step 1

—Training of all relevant staff including radiographers by the medical device supplier application specialists, on the basis of the technical clauses specifications of the medical device,

—Design of the procedures of the medical devices according to the internal policy.

Step 2

—Design of the tools used by the trained referent staff to train all the users of the medical devices: list of the tasks to be understood and performed at the end of the training, etc,

—Organization of the training of all the users of the medical devices by the referent staff, with the support of management: duration of supervision, working in pairs with trained referent staff, etc.

Step 3

—Internal entitlement for the position: design of an entitlement grid,

—Validation of the entitlement by the responsible person.

5.2.4 New arrivals and training

The introduction of newly arrived professionals and trainees shall be organized by the MI organization, with the sites concerned of the healthcare establishment, if necessary (for healthcare establishments, in coordination with the general induction processes specific to the site).

NOTE This applies to all the professionals of the MI organization, trainees, and students. It can also apply to professionals returning to their activity after a period of absence.

The introduction should include the work processes and procedures; the applicable information system(s); occupational health and safety, including the prevention of radiation and magnetic resonance imaging (MRI) risks; the effects of adverse incidents and accidents; ethics; confidentiality of patient information; quality management system.

Trainees shall be permanently supervised by senior members of staff. A specific training programme should be developed with the educational institutions concerned (universities, schools, etc.). Their role and responsibilities in the MI Organization shall be defined. The level of delegation shall be specified by the manager of the MI Organization in accordance with the applicable national regulations. The progress of each trainee shall be monitored and recorded along with the tutor responsible for such progress monitoring.

5.3 Premises and facilities requirements

The MI Organization shall specify supplies and maintain the premises required to guarantee the quality and safety of the MI procedures it performs, in accordance with the applicable regulations.

The premises and layout of the MI Organization shall be compatible with and safe according to the MI activities. They shall be sized to cope with the numbers of patients, and their dimensions shall meet the needs for confidentiality and sufficient space in the various clinical situations concerned.

EXAMPLE Disability, confinement to bed, emergencies, cognitive disorders.

The MI Organization shall take into account the different types of patients (e.g. paediatric patients, disabled patients…) and their needs.

Space required for the adequate conduct of each of these activities shall be defined to ensure the quality, safety and efficacy of the MI procedures performed on patients, and to protect the health and safety of the professionals working in the MI organization.

The MI Organization shall meet the appropriate requirements for health and safety, according to the type of procedure performed, for accessibility, confidentiality, and privacy, as well as the regulatory obligations applying to safety in establishments open to the general public (in particular, fire and electrical safety).

Access to sensitive areas of the MI facilities, e.g. especially rooms with medical devices, shall be controlled to ensure the professional and patient safety, confidentiality, security, and quality related issues.

The layout of the premises shall take account of the need for climate control, both for patients who are often unclothed and for the professionals, for ventilation and for lighting (especially in the areas where the examinations are interpreted).

The MI Organization shall also meet the applicable regulations pertaining to the layout and installation of equipment.

According to its services, the MI Organization shall offer:

— means of access adapted to the patient's circumstances and, if necessary, that are separated according to the patient types;

  EXAMPLE Non mobile hospital patients, mobile hospital patients, outpatients.

— a reception area for the general public that protects the confidentiality of patients and, if necessary, their carers;

— comfortable and suitable waiting areas;

— spaces for the performance of the MI procedures, with examination rooms, operator's areas, patient monitoring area, examination reporting areas, etc…

— separate and secure storage areas;

  EXAMPLE Documents, medicines.

— a room for waste management;

— office spaces;

— access to meeting room(s), for the examination of files or multidisciplinary meetings, as needed;

— a space for the professionals, in proportion to the size of the team, and including lavatory facilities, changing rooms, a rest area and, depending on the working hours, the provision of catering and more comprehensive washroom facilities;

— the expected signs, according to the applicable national regulations.

When the premises are closed and at times of restricted operations, access to the premises shall be controlled and limited to authorized persons. Measures shall be taken to mitigate the risks of theft and damage.

The energy supply and communication systems shall provide suitable working conditions.

EXAMPLE UPS (uninterruptible power supply), Internet bandwidth, telephone communications.

5.4 Imaging medical devices, healthcare products and other equipment

5.4.1 General

The equipment, hardware and software required to provide quality and safe care suitable for the medical procedures shall be available in the MI Organization and for use by the professionals. They shall be kept, including portable devices, in secured areas, and only be operated by qualified and trained professionals.

The MI Organization shall keep a written inventory of its equipment, hardware and software. The choice of equipment, hardware and software shall meet the specifications defined on the basis of the state of the art, the planned medical activities and their performance. These specifications shall be drawn up with the professionals concerned with the use of these equipment, hardware and software.

5.4.2 Imaging medical devices

Each imaging medical device shall be chosen according to the medical project and the procedures that the MI Organization performs. The acquisition of a new imaging medical device shall be accompanied by a training plan that is adapted to the needs of the organization and included in the specifications.

Every new imaging medical device shall be subject to documented acceptance when it is installed in order to check that it corresponds to the descriptions in the purchase or rental contract, and that it meets the safety requirements in accordance with applicable regulations and standards. This acceptance shall be conducted with the oversight of an MPE and/or the biomedical engineering department, if necessary, with input from other professionals within the medical imaging service, as required. The support of the information systems security manager can also be necessary.

The administrative formalities pertaining to these imaging medical devices shall be completed in accordance with the applicable regulations.

The MI Organization shall implement and document the internal and external quality control of these imaging medical devices in accordance with the applicable regulations.

The MI Organization shall have a documented programme both for preventive maintenance taking into account the manufacturer instructions, and for corrective maintenance, in accordance with the applicable regulations and standards. The program shall include the quality checks of the medical devices used by the MI organization. The equipment shall be kept in safe working order free of any danger. A register shall be kept with details of the medical equipment, its comprehensive service history and performance, in accordance with the applicable regulations.

The user manuals of the medical devices shall be available close to the devices concerned, or easily accessible and provided in the required language according to the national regulation.

A documented procedure shall describe the recommended conduct in the event of a failure and maintenance of the imaging medical devices.

A documented procedure shall describe the recommended conduct in the event of a new equipment or software, and in case of modification of the existing ones.

5.4.3 Healthcare products (medical devices implantable or not, medicines including contrast agents)

The MI shall select medical devices and medicines including contrast agents that are suited to the MI procedures according to its needs and other predefined criteria.

Their supply and accessibility by the professionals shall be ensured, including at night and during weekends.

The storage, traceability and the rules applying to the disposal of healthcare products shall be organized in accordance with the applicable regulations and the recommendations and described in a documented procedure.

EXAMPLE 1 Temperature, light, restricted access.

These storage rules shall be applied to all the healthcare products: checks of the batches, their expiry dates and storage conditions.

EXAMPLE 2 The temperature of the refrigerators.

Medical device vigilance and pharmacovigilance shall be applied. The respective responsibilities and the operating rules between the MI Organization and the pharmacy shall be formally defined in a procedure, if necessary.

5.4.4 Other equipment

The MI Organization shall provide the means of communication between healthcare professionals and patients, required for the proper treatment of emergencies, for example, the means of reading and processing images, such as computers with screens adapted to the required resolution and contrast according to the type of image being analysed and suitable software.

The MI Organization shall provide all other hardware required by the activity.

EXAMPLE Desks, chairs, tables for meetings.

5.5 Information systems and Data management

The MI Organization shall implement an information systems safety and security policy. In healthcare organizations, this policy shall be part of its general policy [8]. The structure of the MI Organization shall ensure the availability, the integrity and the confidentiality of the personal data in accordance with the applicable regulations.

EXAMPLE Patient and staff data, digital equipment data required to manage patients, data of the human resources management information systems

Each MI Organization shall ensure to fulfil the requirements for a Data Protection Officer (DPO) for accessing health data ensuring compliance with General Data Protection Regulation (GDPR) [9].

The DPO shall possess the necessary skills and up-to-date knowledge. Such as to ensure the implementation of the digital security measures, by taking actions to raise awareness and to train the professionals.

In healthcare establishments, the DPO shall work closely in collaboration with the Chief Information Security Officer (CISO), who is responsible for the overall information security of the establishment.

The information systems of the MI organization, whether they be medical devices or not, shall meet the recommended specifications and recommendations pertaining to health data and the applicable regulations. They shall be organized to guarantee optimal operation, reliability, and traceability, in order to provide care for patients, maintenance in operational condition and security.

The quality assurance, security and reliability of the digital systems shall meet the applicable regulations.

The MI Organization shall have a structure intended to ensure secure access to its professional software and patients' personal data, by using appropriate access authentication. Access entitlements shall be

defined according to the risks and the role of the professionals concerned. Connections shall be recorded and remain accessible subsequently.

Any additional patient database files shall be securely protected and declared in accordance with the applicable regulations.

The MI Organization shall have a documented procedure for securely filing the images and reports and shall be capable of exchanging and sharing its reports, images and other relevant information in accordance with communication standards. These exchanges shall be made in accordance with the data protection regulations, for example concerning the patient's consent.

The distribution of images and reports shall be controlled, both within the healthcare sectors and to patients and healthcare professionals outside the MI Organization who need to access it. The sharing and exchange of confidential personal data shall be securely protected according to the defined rules and in accordance with the regulations, which shall be made known to the professionals concerned.

In healthcare organizations, the information system of the MI Organization shall be connected and/or integrated to the information system of the organization.

In the event of interoperability with one or more external organizations, the MI Organization shall take measures to ensure the data security and confidentiality.

A plan for the continuity and recovery of digital activity shall be defined and implemented. The data backup and restore procedures shall be periodically tested. A plan for operation in degraded mode is part of the critical risk management and shall be periodically tested.

Patient data shall be backed up and archived and its security and confidentiality shall be ensured in accordance with the applicable regulations. The period of data storage and archiving shall be governed by national regulations.

For ongoing patient management, the availability of the patient's electronic medical record should be facilitated. Its content shall be taken into consideration at every stage of the patient's care and the examination report shall be included in the record, according to the patient consent.

NOTE This applies also to the non-digitalized patient's medical record.

External access to the information system for maintenance purposes or to work from outside the MI Organization should be available when needed and shall be protected according to the applicable best practices. The information system shall be protected against intrusions. The security conditions shall be checked and tested using a proven method and at a frequency determined by the MI Organization or the healthcare organization to which it belongs. The MI Organization shall ensure that cybersecurity penetration tests are conducted in accordance with the applicable regulations and to take any necessary corrective actions.

The organization of the security and backups of the information system shall be described in a documented procedure. which includes the recommended conduct in case of a cyber-attack.

5.6 Measures in hygiene and infection prevention

5.6.1 Hygiene control

The MI Organization shall furnish protective equipment for infection prevention and control to its healthcare professionals.

A documented procedure shall describe the technique and instructions for hand hygiene and dress code.

A documented procedure shall describe the techniques for other aseptic procedures performed in the MI organization, such as the technical conditions for performing vascular punctures; the technical conditions for performing aseptic procedures, such as biopsies or articular punctures; the preparation of the patient's skin for aseptic procedures; and the preparation of the equipment required to perform an aseptic procedure.

5.6.2 Management of infected and/or immune-compromised patients

A documented procedure shall describe the management of infected and/or immunodeficient patients.

In healthcare organizations, a documented procedure shall describe the information circuit that enables the clinical departments to inform the MI Organization of the state of contagiousness and/or immunodeficiency of a patient.

A documented procedure shall describe the recommended conduct when a professional is exposed to a biological risk.

5.6.3 Premises maintenance and cleaning

A documented procedure shall describe the management of the maintenance and cleaning of the MI Organization premises.

EXAMPLE 1 The method and frequency of cleaning are adapted to the function of the room and patient numbers.

The cleanliness of the premises shall be checked regularly.

The conditions applying to the verification of the cleanliness of the premises shall be defined and applied.

EXAMPLE 2 Means and frequency of verification, responsibility.

5.6.4 Other equipment maintenance and cleaning

A documented procedure shall describe the management of the regular cleaning of imaging medical devices, such as the remotely controlled table, bed and stand of the scanner, MRI coils, etc.

A documented procedure shall describe the management of the cleaning and disinfection of ultrasonic probes, in accordance with the rules of the applicable best practices.

A documented procedure shall describe the management of the cleaning and disinfection of items of reusable equipment.

The type and frequency of cleaning shall be adapted to the way in which the material and imaging equipment are used.

Sufficient quantities of suitable equipment shall be available to comply with hygiene rules.

Storage conditions shall be appropriate and checked.

The disinfected or sterilized medical and surgical equipment shall be monitored and tracked.

The stocks of sterile equipment and the expiry dates of single-use consumables, and of cleaning and disinfecting products in particular, shall be regularly and formally checked.

5.6.5 Linen management

A documented procedure shall describe the organization of linen management in order to prevent infections:

— separate clean and dirty linen routes;

— rules applying to the storage and transportation of the clean and dirty linen;

— rules applying to the handling of dirty linen;

— conditions of clean linen checks.

5.6.6 Waste and discharges control

A documented procedure shall describe the management of its waste and discharges in order to prevent infections.

The rules applying to the management of waste and discharges shall meet the applicable regulations.

Waste is sorted for example into:

— ordinary household waste, recyclable or not;

— healthcare activity waste incurring a risk of infection;

— sharp waste;

— waste for special disposal channels: electrical and electronic equipment waste, toner cartridges, X-ray films, residue from silver recovery recipients, etc.

To prevent the risk of contamination, waste from healthcare activities (syringes, dressings, compresses, sharp waste, items of small medical equipment, …) shall follow a special sorting, storage and disposal circuit that is different from the ordinary household waste circuit:

— sharp waste in special containers;

— contrast media in an adapted circuit;

— identifiable bin bags (different colours);

— storage in a secured place;

— special transportation and processing channels by specialized organizations;

— collection and destruction certificates.

More generally, environmental responsibility should be endorsed by the MI organization, adopting technologies that minimize the environmental impact of radiological procedures, and implementing environmentally friendly practices in the disposal of radiological waste.

5.7 Protection against ionising radiation

5.7.1 General

The MI Organization shall commit itself to ensure an effective radiation protection and safety culture, being aware of its importance and its overall objective to protect professionals, patients, and the public against the dangers resulting from practices using ionising radiation, meeting the national requirements, recognizing this culture is based on the principles of justification, optimization and dose limitation.

The first principle guarantees that benefits outweigh risks; the second ensures that patient's exposures are minimized with doses as few and as low as reasonably possible; and the third, focuses on individual exposure levels, taking measures to ensure they are respected and that diagnostic reference levels (DRLs) are taken into consideration.

The MI Organization shall be aware that dose limits are based on international studies on the effects of radiation and are set at levels to minimize harmful effects and so it shall ensure these to be understood by its relevant staff.

The protocols for each modality shall be adapted to clinical indications and examination types with due care to answer the referrer's question while delivering the dose as low as reasonably possible. The latter shall be traced in accordance with the national regulatory obligations and criteria.

5.7.2 Responsibilities

In accordance with national regulations, the MI Organization shall organize and formalize the roles and responsibilities related to radiation protection and use of equipment using radiation, in particular in order to ensure the safety of patients, professionals and the public.

EXAMPLE Medical Physics Expert (MPE), Radiation Protection Officer (RPO).

5.7.3 Education, training and entitlement

The MI Organization shall ensure that its staff has adequate education, information and competence in radiation protection, across all imaging modalities using ionising radiation, in accordance with their scope of practice.

The MI Organization shall ensure the adequate theoretical and practical training, periodically and when specifically needed, of its staff for the purpose of medical radiological practices, and its entitlement to work on the radiological equipment where they are positioned. Training programs shall be aligned with national recommendations and recognized best practices.

5.7.4 Dose monitoring

In order to ensure the protection of staff, patients and the public meets applicable regulations, guidance and the ALARA (as low as reasonably allowable) principle, the MI Organization shall ensure that documented procedures are developed and implemented describing how:

— staff radiation monitoring is managed and undertaken, including timely review of the results of such monitoring and any additional requirements for pregnant staff;

— environmental monitoring is managed and undertaken;

— patient dose monitoring is managed and undertaken, including the development and use of diagnostic reference levels (DRLs) and how special attention is applied to paediatric procedures, procedures for pregnant individuals, and high dose and recurrent procedures.

5.7.5 Premises (controlled and supervised areas)

The MI Organization shall be responsible for delineating controlled and supervised areas in accordance with legislation. It shall manage or restrict access in accordance with written procedures, ensuring that professionals, patients and the public are not accidentally or unintendedly exposed.

5.7.6 Categorization of professionals

The MI Organization shall ensure all exposed staff are individually classified, if necessary, monitored according to the regulated categorization and that records of monitoring results are maintained for the required legal period.

5.7.7 Protection procedures for professionals, patients and the public

The radiological safety management shall be based on optimization procedures and protocols.

In accordance with implemented radiation procedures and protocols DRLs shall be taken into account.

The limits of radiation exposure for the professionals and the public shall be respected, according to the national regulations.

If appropriate, in line with the national recommendation, shielding and other forms of protection shall be provided.

EXAMPLE When exposing children, a protective shield is provided to the parent or caregiver if their presence is necessary near the child.

Standard operation procedures (SOPs) shall be set up, notably.

A documented procedure shall describe:

— the implementation of the principle of justification;

— the implementation of the principle of optimization;

— the recommended shielding;

— the conduct when performing X-ray examinations on an individual who is, or may be, pregnant, and in the event of accidental or unintended exposure of a pregnant individual;

— the conduct for pregnant professionals;

— the management of the dose monitoring;

— the monitoring of the patients exposed to doses beyond the threshold for deterministic effects;

— the management of radiation protection incidents.

5.8 Safety with non-ionising radiation

5.8.1 General

The principles of justification, optimization and dose limitation outlined for protection against ionising radiation apply also to non-ionising radiation (Magnetic Resonance Imaging (MRI), ultrasound, or any other non-ionising imaging modalities).

The following paragraphs pertain specifically to MRI, given the specific risks associated with this modality.

The potential risks concern anyone (not just the patient) present in the MRI-environment.

The major safety considerations come from the behaviour of ferromagnetic objects when exposed to a strong magnetic field; the impact of the static magnetic fields, the time-varying gradient fields and radiofrequency (RF) magnetic fields on medical implantable devices and other electronic medical materials and its potential malfunction and damage; the RF related risks, such as tissue heating, which may lead into burns; and the acoustic noise, associated with the gradient coils.

The MI Organization shall comply with the legislation on physical agents and electronic fields [10] and recognize MRI safety as an essential principle for hosting an MRI unit.

It shall ensure that all professionals involved i.e. referring clinicians, radiographers, radiologists, and support staff are aware of the importance of MRI safety, and that appropriate procedures are established and followed.

The rules applying to ensure MRI safety shall be in line with national legislation and guidelines [11] and described in a documented procedure.

5.8.2 Responsibilities

In accordance with national regulations, the MI Organization shall organize and formalize the roles and responsibilities related to MR safety and use of MRI equipment, in particular in order to ensure the safety of patients, professionals and the public.

EXAMPLE MR Medical Director (MRMD), MR Safety Officer (MRSO), MR Safety Expert (MRSE).

5.8.3 MRI safety, education, training and entitlement

The MI Organization shall ensure that the entire staff working in MRI units are periodically, and when needed specifically trained, and assessed in MRI safety and authorized to work in MR environment.

Areas covered by the training programs shall include at least the management of risks and hazards associated with the static magnetic field, time-varying gradient fields, radiofrequency fields, as well as the management of some emergencies, such as the quenching risk, and the specificities of patient monitoring and management in this specific environment.

Training programs shall be aligned with national recommendations and recognized best practices.

MRI safety risk for the accompanying individuals, attending health care professionals, and others who find themselves only occasionally or rarely in the magnetic fields of MR scanners, such as security or housekeeping personnel, firefighters, police, etc. shall be analysed and appropriate educational information should be provided.

For security reasons the number of people entering the MRI unit shall be minimized.

5.8.4 Premises, equipment and access control

The MI Organization shall take measures to delineate and identify MR safety zones and ensure that only authorized, trained, and screened individuals (staff and patients) access them.

EXAMPLE 1 List of authorized professionals monitored screening checklist.

The risk zones shall be specifically demarcated, taking into consideration the power of the magnet. Physical barriers shall restrict access to these zones, and internal regulations governing staff and patient's entrance shall be displayed for everyone to see, remembering that the magnetic field is permanent.

The equipment in high-risk areas shall be MRI safe and labelled with the correct labelling.

EXAMPLE 2 Non-magnetic stretchers and wheelchairs, non-ferromagnetic IV poles, etc.

Everybody entering the MRI unit shall be systematically checked for non-MR compatibility.

EXAMPLE 3 Healthcare professionals, patients, carers, guides, cleaners, technical personnel, emergency personal.

The professionals shall recognize the importance of being screened and take active responsibility in the process.

5.8.5 Protection procedures for professionals and patients

A documented procedure shall describe:

— the monitoring of the steps ensuring patient safety before their MRI examination: patient questioning, examination, preparation (including for example gowning, hearing protection) and setup;

— the recommended conduct when performing an MRI scan on a patient with an implanted medical device, whether active (such as a pacemaker) or not, and with other foreign objects;

— the recommended conduct for pregnant staff and patients.

Patient supervision during an MRI examination shall be specifically organized.

5.8.6 Specific actions in the event of an unexpected incident in MRI

A documented procedure shall describe, based on risk analysis, the actions to be taken at least:

— for acute illness in patient during ongoing examination;

— if an object, taken in the examination room is attracted by the magnetic field and become stuck in the MRI device;

— in event of fire, power outages, water leaks or in case of quench and of helium leaks.

5.9 Identity vigilance

The patient's identity shall be checked at every step of their pathway, using an agreed protocol.

A documented procedure shall describe the rules applying to the organization of patient identity vigilance. These rules shall be established by the MI Organization and/or the identity vigilance units in healthcare organizations.

5.10 Artificial Intelligence (AI)

AI is playing an increasingly important role in Radiology.

EXAMPLE Image reconstruction and noise reduction, dose management and scan parameters optimization, image interpretation, workflow management, decision support, quality assurance, patient positioning or handling.

Requirements from international, e.g. AI Act [12], MDR [13], or national regulation, or suitable standards as well as chapters of this document, e.g. concerning, quality management, software usage or patient examinations shall be applied to AI applications, too.

General quality criteria for AI application or AI training in Radiology especially on patient data are for example: accuracy, objectivity, reliability, consistency, performance.

These topics shall be considered in documented procedures by the MI organization:

— data privacy and security;

— customisation based on MI Organization and clinical needs;

— ethical, social and legal aspects, for example for training data;

— responsibility and liability;

— transparency, proof of conformity or certification;

— explainability and traceability;

— influence on diagnostic or clinical decisions by healthcare professionals;

— training of healthcare professionals on AI applications and AI background;

— tools for AI quality checks and quality assurance;

— special questions as for continuous learning AI, data and system life cycle;

— AI governance, e.g. concerning compliance, strategy, policy for AI use, risk management, scalability and human resources.

6 Patient pathway for a MI procedure

6.1 Imaging referral for MI procedures

Each imaging referral for an MI procedure shall be written and authenticated by the professional who is responsible and takes care for it and who is authorized to do so according to national regulation and local MI Organization entitlement.

The expected complete content of the imaging referral includes the following items:

— the date (and time, if necessary);

— the administrative data (identity, date of birth, sex and gender, any necessary additional identification) about the patient;

— the name, first name and function of the referring party;

— the expected MI procedure and the anatomic region concerned;

— the clinical history, all relevant clinical information and the purpose (the question asked) of the MI procedure, with any special circumstances;

EXAMPLE Pregnancy, disability, advanced instructions.

— the risk factors and contraindications;

— the previous relevant MI procedures related to the referral;

— the degree of urgency, if necessary;

— the preferred date of the referred MI procedure, if necessary.

6.2 Justification and approval of the imaging referral

The MI Organization shall control the approval of the imaging referral.

The rules applying to the approval of the imaging referral shall be based on the principle of justification, considering European guidelines [1], national legislation and guidelines, and otherwise:

— the clinical context, previous MI procedures and risk factors, allowing for the risk-benefit ratio assessment;

— the availability of the right MI method;

and, as much as necessary, the need:

— for a multidisciplinary approval in a meeting;

— for a consultation (example: before an interventional imaging procedure; pre-anaesthetic consultation);

— to prescribe preliminary examinations (biology, another imaging examination) and/or medicine (contrast agent, other medicine required to perform the procedure).

The imaging referral shall be assessed by a medical doctor belonging to the MI organization, or by any other entitled health professional who approves or rejects the referral, or proposes substitution by another more appropriate MI procedure, and as necessary informs or discuss with the patient and the referring professional of the reasons for the changes.

The validation of the imaging referral can take place when the appointment is scheduled, or afterwards, as long as it takes place before the examination is carried out and shall be documented.

Certain imaging referrals should be completed by discussions with the referrer and/or the patient.

Urgent imaging referrals and life-threatening situations shall benefit from rapid approval processes.

6.3 Patient information and making an appointment

6.3.1 Patient information and informed consent

Where feasible and prior to the examination, patients shall be informed in accordance with the rules of medical ethics and the applicable regulations.

Patient information, obtaining the patient's consent, the protection of professional confidentiality, and the rules applying to the sharing of information between healthcare professionals and other professionals involved in their treatment in the imaging organization shall meet the applicable regulatory requirements.

The communication to the patient on the planned MI procedure shall be clear, fair and appropriate: its objectives, its preparation, execution and follow-up, its benefits, risks, contraindications, signs and symptoms that are to be reported, the patient's right to refuse a MI procedure, but also the risks to their health stated, and any costs to be paid by the patient. When relevant (e.g. high dose examinations) information on the potential dose and associated risks shall be given to the patient before the examination.

A document should describe the practical information about the examinations to be delivered to the patient.

If necessary, a consultation takes place before the examination, for example before interventional imaging procedures, or in case of specific risk factors.

The Radiology department shall provide contact information in case the patient needs more advice.

Patients under guardianship and disabled patients shall receive information adapted to their level of understanding and take part in the decision concerning them. The consent of the authorized carers shall be required, according to the national regulations.

6.3.2 Making an appointment

The system set up by the MI Organization to make appointments shall include:

— obtaining the identity of the patient (in accordance with the rules of identity vigilance) and other useful data (address, etc.);

— obtaining the identity of the referring party;

— identifying any risk factors and contraindications;

— taking into account the degree of urgency;

— providing information on the benefits and risks of the MI procedure, and on the practical aspects;

EXAMPLE 1 Preparation and execution of the MI procedure, post-MI procedure instructions, using means of providing the information adapted to the patient and risk.

— seeking the relevant previous MI examinations (images and report) that, if possible, is made available for the performance and interpretation of the MI procedure, subject to the patient's consent;

— giving a prescription to the patient, if necessary;

— providing information, other than medical;

EXAMPLE 2 Information on the payment and financial coverage of the procedures, any payment to be made by the patient, conditions of access to the site.

— notifying of any preliminary consultations, if necessary;

EXAMPLE 3 A consultation before an interventional imaging procedure, a pre-anaesthetic consultation.

— organizing the post-MI procedure care of the patient in a suitable unit, if necessary.

This entire process shall meet the requirements for the protection of the confidentiality of the information exchanged and of professional confidentiality.

The management of orders for examinations shall be described in a documented procedure.

6.4 Arrival of the patient in the MI organization

The MI Organization shall set up a structure to receive the patient, and have a documented procedure for the reception and registration of patients which provides for:

— the verification of the patient's identity;

— a special protocol for urgent imaging referrals, patients requiring infectious isolation measures, patients in detention, if applicable;

— the reception of persons requiring special treatment which is formally described;

EXAMPLE 1 Children, pregnant individuals, the disabled, the elderly and detainees.

— the protection of the patient's due privacy, dignity, safety and confidentiality;

— if a pre-interventional MI procedure consultation was necessary, verification of the justification is recommended;

— if a pre-anaesthetic consultation was necessary, verification of the anaesthetist's approval of the procedure;

— if biological tests were necessary, verification of the test results;

— if a specific preparation of the patient was necessary, verification that this preparation was made before the MI procedure;

EXAMPLE 2 Interruption or substitution of a pre-MI procedure treatment, special diet.

— validation that the patient and the carer has fully understood, as far as possible, the planned procedure, if possible, of the absence of any formal contraindications, and verification that any risk factors (pregnancy, in particular) have been taken into consideration;

— obtaining the informed consent of the patient, when possible and applicable;

— informing the patient of the possibility of receiving any information on request, including the result of the examination;

— accommodating the patient pending the MI procedure, and regularly informing them in the event of unusually long waiting times;

— the preparation of the patient and making the patient comfortable throughout the management process;

EXAMPLE 3 Undressing, injections, sedation.

— keeping the patient's belongings safe throughout the patient pathway.

6.5 Conducting the MI procedure

The MI Organization shall ensure that the following requirements are fulfilled:

— an easy identification by the patient of the role and identity of every team member of the MI organization;

— a definition of the conditions of execution of every MI procedure (see 3.1, 3.2, 3.3);

— the management and the monitoring of the patient for an MI procedure. Provisions shall be made for emergency MI procedures, and the rules defining priorities are defined.

Each imaging examination shall be carried out on the basis on a formal validation based on the relevance of the imaging referral according to the principle of justification.

A final verification of the identity of the patient, immediately before the MI procedure, of the contraindications of the MI procedure to be performed, and of the proper conditions of execution shall be made immediately before the MI procedure.

The demonstration of the adoption by the professionals involved of the principle of optimization shall take several forms:

— the use of documented protocols in the execution of all the examinations, including technical protocols for imaging devices;

— for MI procedures that use ionising radiation, the implementation of the principle of optimization is formally organized in order to keep the radiation dose as low as reasonably achievable, while still obtaining the diagnostic information that is of use to the patient;

— for MI procedures that use contrast agents and any medication, their optimized use in accordance with the applicable recommendations (type of contrast agent, volume and concentration);

— the formal definition of the procedures for managing persons at risk, and in particular children and pregnant individuals;

— the observation and analysis of the radiation doses in comparison with the Diagnostic Reference Levels (DRL) (national, local….);

— all actions taken and assessed in accordance with the instructions and characteristics of the MI medical devices used, in order to optimize the radiation and contrast agent doses administered in each procedure while obtaining diagnostic information and to protect the safety of the patients.

The rules of hygiene shall be adapted to the type of procedure.

6.6 Medical accidents and incidents

The MI Organization shall have a “just and learning culture” [4] and is capable to detect and react to medical accidents and incidents that may occur on its premises.

The MI Organization shall be responsible for a documented procedure, made known to all the persons concerned, describing the recommended conduct in response to typical medical accidents and incidents: allergic reactions, extravasation, life-threatening conditions, falls, unintended ionising radiation exposure, death, other.

The contact numbers of the emergency services shall be on display in the MI organization.

The professionals of the MI Organization shall be trained in the administration of emergency care and in the management of unintended emergency situations, in accordance with the applicable regulations.

A medical emergency trolley and the necessary equipment shall be available in the MI Organization and readily accessible.

The content of the trolley shall be defined in advance to respond to emergency situations; it shall be regularly maintained and checked. These checks shall be recorded.

NOTE In healthcare establishments, this function can be delegated to the anaesthesia department.

All the involved professionals shall know the existence, placement, and use of the emergency trolley, where it is stored.

The involved professionals shall know when and how to initiate and follow the emergency protocol.

Declarations of medical accident and incidents, including radiation incidents, shall be made according to the national regulations (see 7.10.3).

In case of accidents and incidents, the patient (or the concerned parts) shall be informed, and the information shall be recorded.

EXAMPLE Contact person, referring physician, referring department.

6.7 Monitoring patients after an MI procedure

The professionals shall be familiar with and have a good understanding of the MI organization's documented procedures for the post-MI procedure management of patients, and in particular:

— the transfer of patients to a suitable intensive care ward in the event of complications or a deterioration of their condition;

— patient surveillance and the recommended conduct if particular monitoring is required after injecting a contrast agent or another medicine, for example after an interventional imaging procedure;

— the procedure for informing the patient and the referring professional in the event of unfavourable and unexpected findings, taking account of the applicable recommendations;

— the organization of the return of the patient (depending on where they are expected, and the type of MI procedure performed);

— the procedures for the management of any biological samples, such as labelling, preservation, addressing and the procedures for dispatching them and receiving and treating the results.

6.8 MI procedure report

6.8.1 General

Each radiological examination shall be documented in a written report produced by the MI doctor or the responsible entitled healthcare professional.

NOTE According to the definition given in the Clause 3 "Terms and definition" the MI doctor, who is usually a physician, can also be a healthcare professional authorized to do so by their national regulations.

In healthcare organizations, and subject to the existence of a justified documented procedure that refers to an agreement between departments, certain specific MI procedures may not require a radiological report.

EXAMPLE Plain radiographs for orthopaedic examinations.

6.8.2 Content of the report

The report shall be a permanently accessible record that contains the following essential information:

— the unique identity of the patient, which typically contains their last name, first name, date of birth, gender, added for example by last name at birth, and ID parameters according to national regulations;

— the identity of the referrer, i.e. the medical doctor, dentist or other health professional who is entitled to refer individuals for medical radiological procedures [1].

— the department hosting the patient, where necessary;

— the date, and time[1] for repeated exams on the same day, and type of the MI procedure;

— the last name, first name and position of the reporting MI doctor(s) and, when relevant, other involved healthcare professionals; in cases of interventional imaging, this nominative information refers to the doctor(s) who performed the procedure and took part in the management of the patient;

— the indication for the radiological examination, based on the clinical history and previous investigations;

— a description of the modality and procedure used;

— the anatomic region concerned;

— the results and a comparison with previous MI examinations, when available;

— a conclusion and, if necessary, the recommended conduct.

The following information shall also be recorded in the report:

— the type of imaging medical device used to acquire the images; according to national regulations;

— information relating to patient exposure as required by national regulation;

— type and dose of contrast agents and other administered medicines;

— implanted medical devices;

— any samples taken (fluids and tissue);

— adverse events that may have occurred during or after the MI procedure, their management and the information received by the patient.

The reporting MI doctor shall make sure that the report answers the question raised by the referrer, as far as possible.

6.8.3 Validation of the report

The report of every MI procedure shall be approved by the MI doctor. In necessary the MI doctor can communicate an intermediate result.

[1] Time of the end of the examination(s).

6.8.4 Delivery of, and access to the report

The MI Organization shall define the appropriate methods of communication with the patient, the referrer and, if necessary, the other professionals concerned, in a documented procedure.

The report and the images of the examination, including reconstructed and processed informative images shall be stored in the patient's record in the information and archiving system, and made accessible to both the patient and the referrer.

Results shall be communicated in a timely manner, meeting the needs of the referrer, and adapted to the patient clinical situation. In an emergency, or if a serious condition is unexpectedly discovered, the referrer shall be directly contacted by the MI organization, preferably by the health professional who interpreted the examination, using any efficient means.

If needed, an exchange shall be organized to discuss the results.

A record shall be kept of the transmission of the results if the procedure cannot be derived from the Standard operating procedures (SOP's).

Regarding outpatients:

— Information about the method and timing of access to results shall be provided.

— They can receive verbal explanations of the results of their examination from the MI organization. This is preferably done by the health professional who interpreted the examination.

— The discovery of a serious pathology can require specific patient information, then tailored to each situation and shall require control over the patient's access to their results to ensure they do not discover unexpected findings without appropriate support.

— Emergency situations can require guiding the patient towards an appropriate care pathway.

6.8.5 Revised reports

Revision of reports shall refer to written instructions.

Any relevant changes made to the report subsequently shall be identified, while keeping the former versions.

The recipients of the report, including the clinician who is responsible for the patient, shall be informed accordingly of any changes.

A record shall be made of the transmission of the revised results. The traceability document shall show the date and time of the changes, the name of the person responsible for the changes, and contact details on the informed health professional.

When the reporting system cannot capture amendments, changes or alterations, a record of such shall be kept.

6.9 Specific organizational measures

6.9.1 Confidentiality

Confidentiality shall be protected at every stage of the patient's pathway, in line with GDPR [9].

Results shall be released in accordance with the rules of shared medical information and of professional confidentiality.

Personal data shall be protected in accordance with the applicable regulations.

The rules applying to the informing of third parties shall be based on the applicable regulations, with which the persons concerned are familiar.

6.9.2 Participation in out-of-hours service/emergencies

The MI Organization shall ensure the continuity of care.

The MI Organization shall participate in out-of-hours service according to its activity:

— a list shall be drawn up of the procedures that the MI Organization can perform during periods of out-of-hours service;

— a list shall be drawn up of the members of the MI team providing out-of-hours service and made known to all the persons and departments concerned (distribution, display on noticeboards, etc.).

If the MI Organization does not participate in out-of-hours service, or only participates partially, backup solutions shall be defined and made known to all the persons and departments concerned.

6.9.3 Organization of relations with stakeholders throughout the MI procedure

The MI Organization shall identify its stakeholders.

The MI Organization shall define its roles, relations and responsibilities with those stakeholders in written documentation.

EXAMPLE The emergency, anaesthesia and intensive care, and critical care departments.

The policy and procedures regarding the possible use of the radiological equipment by healthcare professionals who do not belong to the MI Organization shall be described in a documented PROCEDURE.

6.9.4 Interventional imaging

Interventional procedures are a particular variant of imaging procedures. All the general requirements in this document shall apply to these procedures, plus the following requirements, which are specific to interventional Radiology.

The standard operating procedures (SOPs) applying to interventional procedures shall be in place.

Specific risks in interventional procedures shall be taken into account.

For some locally defined high risk interventional procedures:

— consultation with the MI doctor who will perform the procedure,

— consultation with an anaesthetist, if necessary,

— decision on a collegial basis, with the exception of emergencies.

EXAMPLE 1 In staff meetings, in multidisciplinary meetings, by studying the patient file.

To ensure health and safety conditions the MI department shall specify:

— a list of the professionals authorized to perform the procedures;

— the adequate number of trained professionals;

— the expectations regarding the characteristics of the technical environment and the list and stocks of consumables;

— the rules of surgical hygiene;

— the possibility of resorting to anaesthesia;

— the checking procedure before the start of the intervention;

— the possibility of accessing surgical and resuscitation resources in the event of complications.

All these specifications shall take into account the level of complexity and risk associated with the different procedures ensured by the MI organization.

The MI Organization shall have procedures to control pain and, when applicable, monitor vital signs during and after the interventional imaging procedure.

The team shall systematically check that the rules applying to patient safety are obeyed before the start of the procedure.

Post-procedure monitoring shall be organized, defining:

— the rules applying to patient monitoring which shall be written and made known to the staff;

— the rules applying to the transmission of data between the interventional imaging room and the hospital ward;

— the interventional imaging procedures that require a consultation of the patient by the MI doctor after the intervention;

— post-therapeutic monitoring, which may be multidisciplinary, depending on the patient and the type of MI procedure, in order to assess the tolerance and efficacy of the MI procedure;

— the eventual specific monitoring required following the use of high doses of contrast agents and/or radiation exposure.

EXAMPLE 2 Patient and referrer information, kidney function monitoring, skin monitoring…

6.9.5 Teleradiology, remote primary reading and remote scanning

6.9.5.1 General

This document deals with the following scenarios with information transfer between healthcare professionals:

— Teleradiology: In this scenario remote justification, remote selection of examination modality and protocol and remote reporting is done by remote MI doctor.

— Remote primary reporting: In this scenario the first reporting is done by the remote MI doctor in a timely manner; remote justification is not part of the scenario.

— Remote imaging: In this scenario a remote radiographer controls and remotely manages the radiological examination of a patient.

Secondary reading (tele-expertise), or rereading at the request of patients, or image transfers without reporting by MI doctors are outside the scope of this document.

Remote MI doctors provide an authorized service based on an imaging referral, usually by onsite healthcare professionals, and usually take responsibility for the diagnosis or the recommendations they make, even not in the presence of the patient, according to the national regulations.

The remote MI doctors can be either affiliated to the same MI organization, to another MI organization, or to a third party.

Teleradiology, remote primary reporting and remote scanning shall meet the legal and ethical requirements, and best practices described in this document regarding the quality and safety of care as procedures performed on site by an MI team. The participating healthcare professionals shall conform to the requirements of the competent authority of the country where the patient is treated. The percentage of respective on site and remote activity of a remote professional or a healthcare organization shall be in accordance with national regulations. Verbal and written exchanges shall use the language recommended or specified by health care authorities of the country of the MI Organization where the patient is treated, otherwise defined in an agreement of the participating healthcare organizations and / or professionals.

NOTE The standard ISO 13131:2021 "Health informatics — Telehealth services — Quality planning guidelines" [14] provides helpful information for quality planning of telehealth services including a short example of remote primary reading, especially for larger projects.

6.9.5.2 Description of the teleradiology procedure

In the teleradiology scenario, depending on the national regulation, the remote healthcare professional shall examine and approve the written imaging referral of the referrer and its relevance, based on the necessary clinical input. If necessary, dialogue between the remote healthcare professional and the patient and/or the referring healthcare professional and/or the local radiographer shall be organized and recorded.

Depending on the national regulation the remote healthcare professional shall choose the protocol of the examination. According to the chosen protocol, the healthcare professional of the MI Organization shall perform the MI procedure in an optimal manner and, if necessary, with the support of other healthcare professionals of the onsite healthcare organization, e.g. in the case of administration of contrast agent and the treatment of adverse reactions. If necessary immediate information exchange can be established. The remote healthcare professional shall approve the quality of the completed procedure performed in keeping with the examination protocol adapted to the patient's state of health. The remote healthcare professional shall be responsible for the report, its transfer in a timely manner.

Responsibility may be further defined and regulated through contracts between the participants or descriptions of the remote interpretation procedure.

6.9.5.3 Structuring measurements of the MI Organization for teleradiology and remote primary reading

As far as possible, teleradiology and remote primary reading are organized along territorial lines shared between the referrers, the MI doctors and, depending on the national regulations, the competent authority, healthcare structures and optimized procedures.

NOTE A specific scenario can involve ensuring teleradiology services during the night from a significantly different time zone.

Specific additional requirements for teleradiology may apply based on outcomes from risk analysis.

The following topics for Standard operating procedures (SOPs) of teleradiology and remote primary reading shall be organized and agreed:

— concerning the participating professionals

  — the identity and qualification of the remote MI doctor and other professionals (in particular, on-site doctors and radiographers), and other participants who are mentioned in the agreement; the notification or entitlement of participating healthcare professionals to authorities according to national regulations;

  — the conditions applying to the training in teleradiology or remote primary reporting activities of new participating professionals;

- the guaranteed availability of the professionals concerned and the schedule of their availability;
- regular and sufficient meetings periodically organized between on-site and remote professionals;

— concerning the procedures and equipment

- conformity with the written protocols for the MI procedures concerned; special adaptions may apply;
- dependent on national regulations the procedures for informing the patients about teleradiology or remote primary reading and obtaining their consent;
- the procedures for the medical information exchanges between the participants, which are protocol driven, secured and recorded; providing the results to the referrer and to the patient shall meet the same principles as onsite practice;
- the conditions for medicines/drugs/medicaments (for example contrast agents) administration, if necessary. The MI Organization shall ensure the safety of the patient during and, if necessary, after the MI procedure, guaranteeing the availability of further emergency care in a timely manner;
- the technical operating conditions: use of well adapted equipment in accordance with the regulations, the corresponding trained and authorized professionals and organizational procedures, for which the referring MI Organization is mainly responsible;
- the technical means of making exchanges over a secure network with a suitable bandwidth that protects confidentiality, and the means of backing up data, which shall be controlled and made known to the healthcare professionals;
- quality assurance measurements concerning the equipment which is relevant for teleradiology or remote primary reporting, e.g. the availability of the electronic network and the required time for transfers of the necessary image numbers, assurance of the integrity and quality of the data transmitted for each teleradiology procedure;
- the format of the images transmitted by each of the partners shall meet the DICOM standard or at least its functionality and quality; the procedures for storing and filing the images, after reconstruction and processing, and the report shall be defined; for example, the storage in the patient's file in the system of the onsite MI organization;
- registration of the time taken by the different steps of the process; for example, the time between end of radiological examination and provision of the report information to the referring healthcare professional, or separated times for transmission of images and reporting;
- the backup solutions and workarounds in the event of a transmission chain failure shall be provided and made known to the professionals to avoid relevant disadvantages for patients. A quick return to service, adapted to the needs of the users, shall be ensured;
- the rules applying to the management of the identification of the remote professionals. Ghost reading without the identification of the reporting professional is a serious misconduct and shall not be allowed in any circumstances;

— the rules applying to patient identity vigilance in teleradiology and remote primary reading and the protocols for the transmission and disclosure of the images and reports.

In the scenario of teleradiology this document operating procedure (SOP) shall be added:

— implementation of the principles of justification and optimization especially with regards to remote activity.

When teleradiology or remote primary reporting are organized between different MI organizations, the legal ties between the MI organizations as well as the determination of shared responsibilities shall be formally defined, e.g. in a contract or an agreement. The requesting MI Organization shall remain responsible for its organization and operation. The teleradiology or remote primary reading activity shall be formally defined in the medical projects of the organizations concerned.

6.9.5.4 Remote scanning

NOTE 1 This procedure can be called tele-operation.

NOTE 2 The MI Organization can also use remote scanning for education and training purposes.

In the remote scanning scenario, depending on the national regulation, the remote radiographer is granted access to the onsite MI equipment to perform or assist the MI procedure.

In remote scanning the same quality and safety rules as to standard procedures shall apply.

The MI Organization shall ensure that every procedure is undertaken by both trained and qualified remote and onsite radiographers in close contact and communication with each other.

Responsibilities during the procedure shall be well described in a standard operating procedures (SOP), with the description of individual and shared responsibilities.

EXAMPLE MI procedure performing responsibilities; safety responsibilities.

6.9.6 Implementation of new practices

If the MI Organization wants to introduce a new practice, after discussions and consultations with the MI team, it shall check that the new practice is technically possible and offers benefits. It shall set up the means of entitlement of its professionals for this new practice and an appropriate protocol with education and training and ongoing scientific and technical support before the practice is routinely implemented.

Each MI Organization shall have a documented procedure for introducing new practices.

7 The quality management and risk management system of the MI organization

7.1 General

This chapter provides assistance for the introduction and/or improvement of its quality management system (QMS) and a basis for audits and certification, e.g. related to EN ISO 9001 [15].

The MI Organization shall manage the risks which can incur by its activities or can affect the process, result or participants of its activities, and continuously improve the quality of its activities.

To this end, and in conjunction with the establishment to which it belongs, where appropriate, the MI Organization shall implement a QMS that provides for the efficient operation and control of its processes (especially patient management and support).

The MI Organization shall formally define its quality policy, objectives, scope and governance especially concerning processes, activities and documentation, which are monitored and regularly assessed as part of its QMS.

The MI Organization shall monitor its areas of activity and incorporate changes in regulations and recommendations issued by relevant scientific societies. In the absence of a national guideline mentioned in this document, a process should be developed within the MI Organization to manage this and ensure learning is enabled.

The quality approach shall be structured on the basis of a policy developed under the authority of the senior management of the health care organization and of the MI organization. The quality policy shall be in line with the strategic priorities of the healthcare organization.

All the professionals in the MI Organization shall be involved if the initiative is to succeed.

The QMS shall cover all the diagnostic and therapeutic activities of the MI organization.

The QMS shall include policy and procedures covering the possible use of the radiological equipment by healthcare professionals who do not belong to the MI organization. They shall be described in a documented Procedure.

The MI organization's QMS shall utilize the PDCA (plan-do-check-act) principle, also known as the Deming cycle. This dynamic method comprises four successive steps. It aims to create a virtuous circle. Its implementation allows the quality of the organization to be improved in an efficient way, regularly and whenever necessary.

The rest of the document is based on the four key steps of this method as shown by the graphic representation (Figure 1).

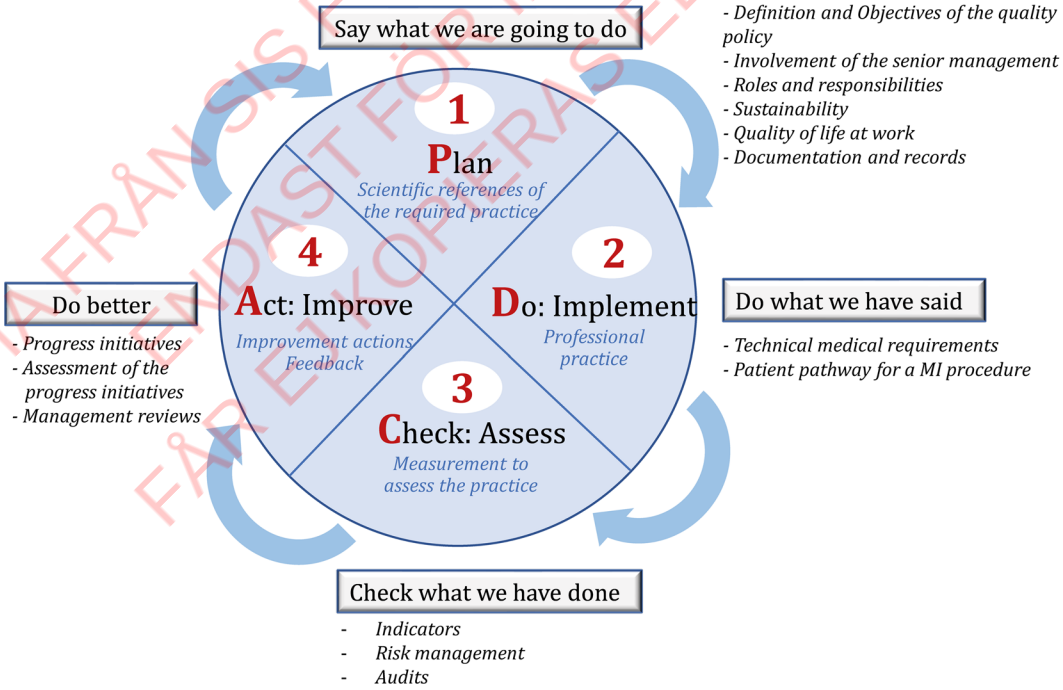

Figure 1 — The quality cycle

7.2 Definition of the quality policy

Within the general policy of the MI organization, the quality policy shall be made up of all the strategic priorities that contribute to the quality and safety of the MI procedure. The MI Organization shall develop, formally define, implement, and update its quality policy in line with the scope of the organization, the clinical services provided or intended and its operational context.

The quality policy shall:

— include the definition of relevant, precise and measurable quality objectives;

— take account of technical constraints and the applicable regulatory requirements;

— incorporate input that is of relevance to the quality and safety of the MI procedures. It shall exclude formalities that are of no interest to patients, patient related processes and involved persons;

— provide for the allocation of the resources required to achieve these objectives;

— determine the methods and tools used to measure the achievement of these objectives;

— include the establishment of a scientific and technical monitoring, and a legal monitoring in order to comply with national and European regulations.

The MI Organization shall inform its professionals of its quality policy. Outside the organization, this information shall be made available to concerned stakeholders, e.g. departments of the healthcare organizations or referrers for MI examinations.

7.3 Objectives of the quality policy

The MI Organization shall set quality objectives to meet the requirements defined in this document. The objectives shall be revised in management reviews at a predefined frequency.

The objectives of the quality policy shall be to:

— demonstrate its capability to constantly deliver MI services that meet the needs and expectations of patients;

— ensure patient safety and satisfaction;

— constantly control all the parameters that enable it to perform MI procedures in accordance with the legal and regulatory requirements, professional best practices and developments in medical knowledge and techniques;

— meet the needs and expectations of the referrers it works with;

— communicate about quality policy both within the organization and with the different stakeholders;

— be regularly reviewed in light of new evidence underpinning new practice and advancements in imaging technologies.

7.4 Involvement of the senior management of the MI organization

The MI Organization shall build its strategy and demonstrate its commitment, in particular by ensuring that:

— the policy and its objectives are defined;

— the resources required for the QMS are available;

— the QMS is effective;

— the benefits of an effective QMS and the importance of meeting its requirements are made known;

— the QMS achieves the expected results;

— the professionals are incited and encouraged to contribute to the efficiency of the QMS.

7.5 Roles and responsibilities in the MI organization

The QMS shall demand the close involvement and the responsibility of the management of the MI organization. The MI Organization shall have a specific line of responsibility (individual and/or groups of individuals that are specifically responsible for quality management).

The MI Organization shall define its internal responsibilities and authorities in the form of an organizational and functional chart of the entire MI organization.

The composition of the MI organization's team shall be defined in writing and made known to the stakeholders.

The duties and responsibilities of every member shall be defined and documented.

Healthcare professionals shall be engaged in the development of policies and QMS, aware of them and understand them.

A quality manager[2] belonging to the MI Organization shall be appointed by the organization's management, which delegates the responsibility for implementing the QMS to this individual and/or group. The quality manager shall make sure that the requirements contributing to the achievement of the objectives of the quality policy are met. This quality manager shall report directly to the management of the MI organization.

7.6 Sustainability

Sustainable Development Goals (SDG) of the United Nations emphasize the environmental, social and economic aspects of sustainable development. Many of them are of importance for the healthcare sector.

EXAMPLE 1 Good health and well-being (SDG 3), clean water and sanitation (SDG 6), affordable and clean energy (SDG 7), industry, innovation and infrastructure (SDG 9), responsible consumption and production (SDG 12).

In the field of economic and environmental aspects, specific sustainability aspects reducing the consumption of energy and resources in the MI Organization include, for example, energy consumption of devices like CT and MR or workstations and monitors, resource consumption especially in interventional Radiology, contrast agent consumption, consumables and waste management.

EXAMPLE 2 Switch off the electrical device or switch into low power modus while not in use, choice of energy efficient devices, fewer devices, more efficient use of equipment, no double examination[3], only justified examination[3], examination with less or without contrast agent[3], no paper, upgrade instead of new purchase, reuse or recycling of material, sustainability criteria for new procurement.

In their quality indicators, MI organizations shall include sustainability indicators.

[2] Person, or group of persons responsible for administrating and controlling the QMS within the MI organization, ensuring the organization meets applicable regulations and standards.

[3] Direct advantage for patients, too.

EXAMPLE 3 Energy consumption per scanner, energy consumption per workstation, energy consumption total, standby time of workstations, utilization rate per scanner, waste separation, life cycle of equipment.

MI Organization shall take into account social aspects as well access to imaging modalities for everyone, equal treatment of the patients, qualification and continuous education of the staff, diversity of patients and staff.

7.7 Quality of life at work

The MI Organization shall determine the working conditions and provide and maintain the suitable environment required for the adequate care of patients, and the proper performance of the MI procedures; as well as the suitable environment for its staff, contributing to a good work-life balance. It shall promote teamwork and encourage every one of its members to take initiatives with a view to providing quality and safe care.

The MI Organization shall aim to ensure that the content of work is designed in such a way that its staff is not subject to physical strain or mental stress that may lead to illness or accidents.

7.8 Documentation and records

The MI Organization shall determine which documents are necessary for the optimal care of patients, the control of the safety and quality of the MI procedures it performs, and the management of its QMS.

The records system aims to support every professional in the exercise of their activity and their decisions, through documented procedures that are of use in the management of patients. Following these procedures also aims to protect every professional when they are called to account. Every documented procedure shall be identified and controlled in the QMS. Exemptions from pre-established documented procedures are possible, if justified and recorded. In this case, the validity of the documented procedure shall be reviewed, or the need to make changes to the procedure shall be examined by the professionals concerned.

These documents shall be formally identified according to specific needs and risks. They shall be adapted to the size of the MI Organization and incorporated in the document management system.

Document review shall be undertaken at specified times depending on the type of the documents and updated as needed.

The list of the required documented procedures is provided in Annex A.

A documented procedure shall describe the rules applying to the control, protection and preservation of the documents.

When documents are created and updated, the MI Organization shall make sure that the following aspects are appropriate:

— the identification and description of the documents;

EXAMPLES 1 Title, date, author, reference number.

— their format and medium;

EXAMPLES 2 Language, software version, electronic or paper medium.

— the rules applying to creation, validation and/or approval (including the validity period);

— the process for implementation and audit of the process.

The MI Organization shall keep records that guarantee the traceability and the updating of the document system.

A documented procedure shall describe the rules applying to records control.

7.9 Measurement of indicators, assessment, and analysis

The MI Organization shall define and measure quality indicators, chosen according to its needs, the applicable regulations and the recommendations on best practices.

The MI Organization shall monitor the impact of its activity on patient diagnosis and outcomes. Within the organization, it shall also organize the assessment of certain procedures, especially innovative procedures, subject to the conditions defined with the whole team, in regard of guidelines and standard, in order to measure the quality of its practices.

The MI Organization shall also measure the satisfaction of patients, the referrers with whom it works or the departments that refers for MI procedures, and the employees of the MI organization.

The MI Organization management shall periodically and systematically review its QMS to make sure that it is appropriate, well adapted, effective and in line with its strategic priorities.

The MI Organization shall keep the records of these measurements, analyses and assessments.

The indicators can apply to (non-exhaustive list):

— the reporting time and delivery time to send the results;

— the accuracy of the reports;

— the satisfaction of patients and other stakeholders in the MI organization;

EXAMPLE 1 Referring healthcare professionals, the department's professionals.

— the hygienic control;

— the safety control;

EXAMPLE 2 Dose monitoring of patients and employees.

— the access rate to the imaging services;

EXAMPLE 3 work force, equipment and information system availability.

— the suitability of the human, material and financial means to achieve of the objectives of the MI organization;

— the assessment of suppliers.

The indicators shall be measured periodically and systematically.

The interested persons shall be informed of the results of the indicators.

The results of the quality indicators shall be used to improve the operation and/or the quality of the services of the MI organization, as part of the PDCA cycle.

7.10 Risk management

7.10.1 General

All the professionals shall be involved in pre-emptive and hindsight risk management, in particular with regard to healthcare-related vigilance.

Risk management shall include observation of the different forms of vigilance.

EXAMPLE Pharmacovigilance, medical device vigilance, protection against ionising radiation, MRI safety, and-identity vigilance.

In healthcare organizations, the risk management policy of the MI Organization shall be aligned with the establishment's policy, on a no-blame culture basis.

7.10.2 Pre-emptive risk management: risk map and risk control

The MI Organization shall identify the risks to be taken into consideration to:

— protect the safety of patients and professionals;

— improve patient care, taking also into consideration the patient experience;

— prevent or reduce the occurrence and the consequences of adverse events.

A risk map shall be drawn up and regularly updated in order to identify the risks, assess their criticality, give priority to any risks requiring an in-depth analysis and take the necessary actions to improve the organization.

The MI Organization shall set up a suitable process in the event of critical situations.

EXAMPLE Emergencies, problems with equipment.

The MI Organization shall regularly organize discussions about the MI procedures with the highest risks to improve the practices of the MI team.

7.10.3 Hindsight risk management

a) Declaration of adverse events

In order to improve the safety and quality of its services, the MI Organization shall identify, declare and process the organizational, human and technical dimensions of adverse events.

All incidents that could impede normal working, and accidents or incidents affecting the patients or the professionals of the MI Organization shall be considered to be adverse events.

The professionals shall be encouraged to declare adverse events and near misses. The principle of no-blame shall apply.

A documented procedure shall describe the means of declaring and managing adverse events, in keeping with the mandatory declarations required by healthcare-related vigilance according to the applicable regulations.

b) Management of claims and complaints

The MI Organization shall manage claims and complaints. They shall be investigated as quickly as possible and subject to in-depth analysis, if necessary.

Claims and complaints shall be followed up.

A documented procedure shall describe the means of receiving, analysing and processing claims and complaints.

c) Organization of a feedback process

The MI Organization shall set up a process for the selection, systemic analysis and follow up of patients and referrers feedback, adverse events and/or significant claims and complaints, and the access to the results.

The MI Organization shall set up a feedback process for the selected adverse events and near misses. The goal is to identify the technical, human and organizational root causes of these events in order to choose and take actions to make improvements, and then to assess their effectiveness. The chosen approach shall overpass the identification of responsibility and the immediately apparent cause of the adverse event.

This initiative shall be collective and bring together all the professionals concerned by the event, plus at least one person who is competent in the methodology of this type of initiative.

7.11 Progress initiatives

The MI Organization shall determine and take the necessary actions, known as corrective or preventive progress initiatives, in order to improve the quality and safety of the procedures it performs and the care it provides.

Potential nonconformities shall be subject to preventive actions.

Observed nonconformities shall be subject to corrective actions.

A documented procedure shall describe the organization of preventive and corrective actions.

7.12 Assessment of the progress initiatives

When an adverse event occurs, or when faced with a claim or complaint, the MI Organization shall:

— make sure that all the selected progress initiatives have been implemented;

— review the effectiveness of all the actions taken;

— update the identified risks, if necessary;

— make changes to the QMS, if necessary;

— ensure that the professionals are made aware of the events and actions taken.

When an adverse event directly affects the patient, the patient shall be informed of the effects and consequences of the incident and of the corrective actions taken.

Progress initiatives shall be recorded.

Where any audits, incidents or complaints lead to a documented action plan, the MI Organization should have documented escalation route to more senior managers for staff if actions are not being progressed according to plan by those responsible. This escalation route should include timescales for escalation post-action deadline that are risk-based.

7.13 Management reviews

For the management review, the MI Organization shall use the results of audits and QMS reviews in order to make sure that its QMS is still appropriate, well adapted, effective and in line with the strategic priorities of the organization.

This management review can be part of the general management review of the healthcare organization. It should include discussions between management representatives and the MI team about the issues and problems regarding quality and safety that the MI team faces.

The MI Organization shall compare the results of audits, indicators, declarations of adverse events and near misses, claims and complaints with the objectives defined in a management review.

The MI team shall take into account and exploits the received feedback.

The MI Organization shall analyse the results and draws conclusions in order to decide whether there are any needs or opportunities to be taken into consideration in order to improve the quality of service delivered to patients.

If necessary, the MI Organization shall define its new priorities with the professionals concerned. These priorities shall be the subject of structured and monitored action plans with a formal schedule.

The MI Organization shall keep the output data of the management reviews.

8 Audits based on this document

This document applies to all types of audits and assessments conducted within the MI organization. Their objective is to evaluate, monitor, maintain, and improve the quality and safety of the patient pathway throughout the entire MI process.

These audits shall be integral to the organization's quality system, which aims to ensure, through a systematic approach, its compliance with the requirements of this document, such as the implementation, effectiveness, and maintenance of its QMS.

The MI Organization shall conduct internal audits, including self-assessments, carried out by professionals within the MI organization. It shall also undergo external audits. These audits shall adhere to the general principle outlined by the BSSD [1], which defines "clinical audits" as "*a systematic examination or review of medical radiological procedures aimed at improving the quality and outcome of patient care through structured review. This involves examining medical radiological practices, procedures, and results against agreed standards for good medical radiological procedures, making modifications to practices as necessary, and applying new standards if needed.*"

The principle of clinical audit shall also apply to all the procedures performed by the MI organization.

This document is not intended to present the various audit methods, developed elsewhere, particularly by the ESR (Esperanto Guide) [16], and by the European Commission [17] but nonetheless aims to recall their general principles:

— clinical audits shall be conducted in accordance with national legislation, regulations, and rules;

— the audit criteria, scope, frequency, and methods for defining responsibilities and requirements for scheduling and conducting audits, reporting results, and maintaining records shall be defined and documented;

— the audit program shall consider the status and importance of the processes, technical and management areas to be audited, as well as the results of previous audits;

— the scope of audit can cover the entire activity of MI organization, or a part of its activity;

— audits shall be conducted regularly, offering reassessment;

— auditors shall be trained in audit techniques. Healthcare professionals with a deep understanding of the MI culture, systems, and processes shall be part of the clinical audit team;

— external audits shall involve a multi-professional team of peers, including a MI doctor and a radiographer, and depending on the procedures performed and the size of the MI organization, one or more additional auditors;

EXAMPLE A medical physic expert, a quality specialist.

— external audits, wherever resources permit, shall be conducted by independent auditors without any conflicts or ties of interest to the organization being audited;

— when nonconformities are identified, the personnel responsible for the MI Organization shall ensure that appropriate corrective actions are taken to eliminate the causes of the detected nonconformities.

Annex A
(normative)

List of the required documented procedures for this document

NOTE 1 All the professionals concerned are familiar with the documented procedures.

NOTE 2 This list is dependent on the specific activities of the MI Organization.

NOTE 3 It is recognized that some of these individual procedures can be combined in a single document.

Table A.1 — Correspondence between the required documented procedures and the subclauses of this document

General principles	
Implementation of the principle of justification	5.7.7; 6.2
Implementation of the principle of optimization	5.7.7; 6.5
Human Resources	
Composition and structure of the MI organization	5.2
Training plan	5.2.2
Management of professional entitlements, including job descriptions	5.2.3
Technical Medical Requirements	
Imaging medical devices, healthcare products and other equipment	
Recommended conduct in the event of an imaging medical device failure and maintenance	5.4.2
Recommended conduct in the event of a new equipment or software, and modification of an existing one	5.4.2
Procedure for storage, traceability, and disposal for healthcare products (medical devices implantable or not, medicines including contrast agents)	5.4.3
Information systems	
Procedure for securely filing the images and reports	5.5
Organization of security and backups of the information system	5.5
Hygiene and Infection prevention	
Technique and instructions for hand hygiene and dress code	5.6.1
Hygiene of aseptic procedures	5.6.1
Management of infected and/or immunodeficient patients	5.6.2
Recommended conduct when a professional is accidentally exposed to a biological risk	5.6.2
Organization of the maintenance and cleaning of the premises	5.6.3

	Organization of the regular cleaning of imaging equipment	5.6.4
	Cleaning and disinfection of ultrasonic probes	5.6.4
	Organization of the cleaning and disinfection of items of reusable equipment	5.6.4
	Organization of linen management	5.6.5
	Organization of the management of waste and discharges	5.6.6
Radiation protection		
	Recommended shielding for professionals, patients, and the public	5.7.7
	Recommended conduct for X-ray examinations of an individual who is, or may be, pregnant	5.7.7
	Recommended conduct for pregnant workers	5.7.7
	Collection and analysis of the doses in comparison with the Diagnostic Reference Levels (DRLs)	5.7.7
	Recommended conduct in the event of the accidental exposure of a pregnant individual	5.7.7
	Monitoring of the patients exposed to doses beyond the threshold for deterministic effects	5.7.7
	Management of radiation protection incidents	5.7.7
MRI Safety		
	Rules applying to ensure MRI safety, including the monitoring of the steps ensuring patient safety before their MRI examination	5.8.5
	Recommended conduct when performing an MRI scan on a patient with an implanted medical device	5.8.5
	Recommended conduct for pregnant staff and patients within MRI environment	5.8.5
Identity Safety		
	Rules applying for identity vigilance	5.9
Artificial Intelligence		
	Rules applying to the use of Artificial Intelligence	5.10
Patient pathway		
	Management of orders for examinations	6.3
	Reception and registration of patients	6.4
	Protocols for the execution of each of the examinations conducted in the MI organization	6.5
	Recommended conduct in response to the main medical accidents and incidents: allergic reactions, extravasation, life-threatening conditions, falls, unintended ionising radiation exposure, death…	6.6
	Recommended conduct for post medical imaging procedure patient management	6.7

Handling of the biological sample pathway	6.7
Method for delivery and access to the report	6.8
Standard Organization Procedures applying for Interventional Radiology	6.9.4
Standard Organization Procedures applying for Teleradiology, remote primary reporting and remote scanning	6.9.5
Implementation of a new practice	6.9.6
Quality and Risk Management	
Policy and procedures covering the possible use of the radiological equipment by healthcare professionals who do not belong to the MI organization	6.9.3; 7.1
Document and records control, protection and preservation procedure	7.8
Declaration and management of adverse events	7.10.3
Receiving and processing patient and referrer complaints and claims	7.10.3
Organization of corrective and preventive actions	7.11

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