BT N 12848

Draft BT C006/2022

TECHNICAL BOARD

CEN/BT by correspondence

For decision

Issue date: 2022-01-12

Deadline: **2022-04-05**

SUBJECT

New CEN/TC on Quality in Medical Imaging along the patient pathway

BACKGROUND

On 17 December 2021, AFNOR submitted a proposal to CCMC for the creation of a new Technical Committee (CEN/TC) on 'quality in medical imaging along the patient pathway'. A detailed explanation is provided in the ‘proposal for a new field of activity’ form (Annex I).

Rationale

Medical imaging is a complex discipline that has evolved considerably in recent years. This discipline is at the crossroads of information technology and increasingly advanced medical techniques. Its essential role is the establishment of reliable diagnostics. Scientific progress has allowed this discipline to develop considerably with the rise of both teleradiology and interventional imaging; the latter has now developed to the point of replacing conventional treatments. In addition to these new applications, the general use of medical imaging is increasing, with annual growth of around 5%.

Professionals must adapt and be trained rapidly to the use of new tools and new technologies, and to face new challenges such as the development of teleradiology to provide the best services to patients.

Medical imaging is also regulated by the Council directive 2013/59/EURATOM laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

If there are many standards in the field of medical imaging, they relate to equipment including acceptance and constancy test, evaluation and routine testing, techniques or are dedicated to radiation protection. Indeed, there are already standards on image quality but there is no European standard dealing with quality in medical imaging and the patient pathway.

To contribute to these new developments and to the patient pathway, AFNOR proposes to establish a CEN technical committee to develop, as a priority, a standard covering the patient pathway in medical imaging. It includes patient tare before the examination (appointment making, patient reception, etc.), during the examination (safety, hygiene, confidentiality, etc.) and after the examination (transmission of results, archiving, etc.).

This proposed standard aims also to provide a common basis in Europe for the development of clinical audits at national level, as requested by the European directive. The clinical audits methodology will not be covered as it already defined at European level (see bibliography in annex 1).

The new CEN/TC will consider and will be complementary to existing initiatives which are mainly related to the radiation protection requirements of the Euratom directive in radiology. Indeed, the intention behind the creation of this technical committee is to go beyond radiation protection, which, while essential is already well taken into account. It aims to cover all aspects related to patient care and all medical imaging

techniques.

To sum up, the standardization of this CEN/TC on medical imaging structures, aims to:

- define the requirements for the management of a medical imaging patient pathway,
- optimize the procedures while covering justification aspects,·
- provide a European document that contribute to support clinical audit within the meaning of the Euratom directive intended as a basis for national procedures,
- consider teleradiology, as this new practice is on the rise.

AFNOR is committed to providing the secretariat of the proposed TC and to providing Professional Standardization Support to the Working Group to be created.

Criteria for approval

By Resolution BT 65/2017, BT decided that the following criteria are to be met for acceptance of such a proposal for new work (in a new area):

- Vote according to Internal Regulations Part 2 clause 6.1.4; Note: Possible votes are 'Agrees', 'Disagrees with comments' and 'Abstains'. Any vote indicating 'Deferred decision' will be counted as 'Disagrees with comments'.
- At least 5 members express commitment to participate. As a consequence, BT Members are requested to state explicitly, by means of the commenting field provided in the BT-balloting tool, whether or not they are committed to participate in the work

Information session

In order to give the opportunity to ask questions and raise issues, while the consultation is ongoing, AFNOR invites CEN members to participate in an informative webinar session. Two sessions are proposed. It is open to CEN member but is not limited to NSB staff: any representative or stakeholder CEN members would like to include are welcome.

These web sessions will be held on:

- Webinar 1: Thursday 3 February 2022 at 10h00

  Registration link :
  https://afnor.zoom.us/meeting/register/tJYudu6rpzooHtPw1kyA7a34Zny9KluwF4Hi
- Webinar 2: Thursday 17 February 2022 at 15h00

  Registration link :

  https://afnor.zoom.us/meeting/register/tJcrcO6urD0iE9Owg-YirbZVhfZ2DsbwFxjH

PROPOSAL(S)

BT,

- having considered the proposal for a new field of technical activity on 'Quality in medical imaging along the patient pathway' submitted by AFNOR as included in Annex I;
- considering that the following members have expressed commitment to participate:
  - <Members>
- decides to create a new CEN/TC XXX with the following preliminary title and scope:

  Title: 'Quality in medical imaging along the patient pathway'

  Scope:

  Standardization in the field of medical imaging and radio diagnostics.

  It includes medical imaging for diagnostic and interventional purposes. The objective is to ensure quality and risk management in patient care in any type of medical imaging structure (public and private departments, services and facilities)

It covers procedures using ionizing and electromagnetic radiation or ultrasonography, performed on human beings1 in person or remotely (teleradiology).

With the exclusion of:

- radiotherapy,
- conventional optical imaging (such as endoscopy or fund us),
- photography of patients or lesions,
- anatomical pathology.

– allocates the secretariat of CEN/TC XXX to AFNOR;

– asks the new CEN/TC XXX to submit its final title and scope for BT approval, following its first kick-off meeting.

2022-01-11 – JO

PROPOSAL for a NEW FIELD OF TECHNICAL ACTIVITY	
Date of circulation ……	CEN/TC / SC N …… (where appropriate)
Secretariat …AFNOR……	CENELEC/TC / SC (Sec) …… (where appropriate)
Type of technical body proposed (TC / SC / BTTF)	…TC……

IMPORTANT NOTE: Incomplete proposals risk rejection or referral to originator.

☒ The proposer has considered the guidance given in Annexes 1 and 2 during the preparation

Proposal (to be completed by the proposer)

Title of the proposed new subject
(The title shall indicate clearly and unambiguously, yet concisely, the new field of technical activity which the proposal is intended to cover.)

Quality in medical imaging along the patient pathway.

Scope statement of the proposed new subject
(The scope shall precisely define the limits of the new field of technical activity. Scopes shall not repeat general aims and principles governing the work of the organization but shall indicate the specific area concerned.)

Standardization in the field of medical imaging and radio diagnostics.

It includes medical imaging for diagnostic and interventional purposes. The objective is to ensure quality and risk management in patient care in any type of medical imaging structure (public and private departments, services and facilities).

It covers procedures using ionizing and electromagnetic radiation or ultrasonography, performed on human beings, in person or remotely (teleradiology).

With the exclusion of:

- radiotherapy,
- conventional optical imaging (such as endoscopy or fundus),
- photography of patients or lesions,
- anatomical pathology.

Standardization related to equipment and radiation protection is also excluded as it is already covered by several established committees, both at international and European level (in particular IEC TC/SC 62B "Diagnostic imaging equipment", IEC TC/SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry", as well as ISO/TC 85 "Nuclear energy, nuclear technologies, and radiological protection" and the corresponding European committee, CEN/TC 430).

Purpose and justification for the proposal.

Medical imaging is a complex discipline that has evolved considerably in recent years. This discipline is at the crossroads of information technology and increasingly advanced medical techniques. Its essential role is the establishment of reliable diagnostics. Scientific progress has allowed this discipline to develop considerably with the rise of both teleradiology and interventional imaging; the latter has now developed to the point of replacing conventional treatments. In addition to these new applications, the general use of medical imaging is increasing, with annual growth of around 5%.

Professionals must adapt and be trained rapidly to the use of new tools and new technologies, and to face new challenges such as the development of teleradiology to provide the best services to patients.

Medical imaging is also regulated by the Council directive 2013/59/EURATOM laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

If there are many standards in the field of medical imaging, they relate to equipment including acceptance and constancy test, evaluation and routine testing, techniques or are dedicated to radiation protection. Indeed, there are already standards on image quality but there is no European standard dealing with quality in medical imaging and the patient pathway.

To contribute to these new developments and to the patient pathway, we propose to establish a CEN technical committee to develop, as a priority, a standard covering the patient pathway in medical imaging. It includes patient care before the examination (appointment making, patient reception, etc.), during the examination (safety, hygiene, confidentiality, etc.) and after the examination (transmission of results, archiving, etc.).

This proposed standard aims also to provide a common basis in Europe for the development of clinical audits at national level, as requested by the European directive. The clinical audits methodology will not be covered as it already defined at European level (see bibliography in annex 1).

The new technical committee will consider and will be complementary to existing initiatives which are mainly related to the radiation protection requirements of the Euratom directive in radiology.

Indeed, the intention behind the creation of this technical committee is to go beyond radiation protection, which, while essential is already well taken into account. It aims to cover all aspects related to patient care and all medical imaging techniques.

To sum up, the standardization of this technical committee on medical imaging structures, aims to:

- define the requirements for the management of a medical imaging patient pathway,
- optimize the procedures while covering justification aspects,
- provide a European document that contribute to support clinical audit within the meaning of the Euratom directive intended as a basis for national procedures,
- consider teleradiology, as this new practice is on the rise.

Is the proposed new subject actively, or probably, in support of European legislation or established public policy?

☒ Yes ☐ No

If Yes, indicate if the proposal is

▪ in relation to EC Directive(s)/Regulation(s):

COUNCIL DIRECTIVE 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation

Proposed initial programme of work

The proposed programme of work shall correspond to and clearly reflect the aims of the standardization activities and shall therefore show the relationship between the subject proposed.

Each item on the programme of work shall be defined by both the subject aspect(s) to be standardized (for products, for example, the items would be the types of products, terminology, characteristics, other requirements, data to be supplied, test methods, performance requirements, etc.). Supplementary justification may be combined with particular items in the programme of work (e.g. output from a research project).

The proposed programme of work shall also suggest priorities, target dates and the most appropriate type of deliverable (e.g. EN, TS) for each item

The work programme will focus on the development of a European standard in relation to the medical imaging patient pathway and answering specific European needs in link with EU regulation. The first work item will cover specifications laying out a comprehensive approach towards quality in medical imaging.

The initial work programme will cover the following topics:

- Patient pathway in medical imaging procedures
- Corresponding technico-medical requirements
- Quality and risk management of medical imaging

The best pratices description will be used for clinical audits. Nevertheless, the clinical audits methodology will not be covered as it already defined at European level (see bibliography in annex 1)

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing CEN, CENELEC, ISO and IEC deliverables.
The proposer should explain how the work differs from apparently similar work, or explain how duplication and conflict will be minimized. If seemingly similar or related work is already in the scope of other committees of the organization, or in other organizations, the proposed scope shall distinguish between the proposed work and the other work. The proposer shall indicate whether his or her proposal could be dealt with by widening the scope of an existing committee or by establishing a new committee.)

The existing standards in the field of medical imaging relate to equipment including acceptance and constancy tests, evaluation and routine testing and techniques or are dedicated to radiation protection. There is no European or international standard dealing with quality in medical imaging and the patient pathway.

Thus, the following committees are not directly working on quality in medical imaging, but their work and deliverables can be tools contributing to it:

- On radiation protection: ISO/TC 85 "Nuclear energy, nuclear technologies, and radiological protection", and especially SC2 « Radiation protection » and the European corresponding committee mirror CEN/TC 430 standardize in the field of peaceful applications of nuclear energy, nuclear technologies and in the field of the protection of individuals and the environment against all sources of ionising radiations
- On medical imaging equipment: IEC TC/SC 62B "Diagnostic imaging equipment" and IEC TC/SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry"
- On healthcare in general: ISO/TC 304 "Healthcare organization management"
- Related to telemedicine:
  - ✓ CEN/TC 251 "Health informatics"
  - ✓ ISO/IEC JTC 1/SC 6 "Telecommunications and information exchange between systems"
  - ✓ ITU-T Study Group 16 "Multimedia"
  - ✓ ITU-T Study Group 17 "Security"

The work will also be carried out considering the European initiatives such as the European Commission tender project QuADRANT, dedicated to improvement in quality and safety of radiology, radiotherapy and nuclear medicine through clinical audit.

A listing of relevant existing documents at the international, regional and national levels. Any known relevant documents (such as standards and regulations) shall be listed, regardless of their source, and should be accompanied by an indication of their significance.

The main documents identified are listed below, without being limited to:

European regulation and publications related to quality in medical imaging

- Council directive 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation,
- Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields),
- ESPERANTO 2019 ESR Guide to Clinical Audit in Radiology and the ESR Clinical Audit Tool
- Patient Safety in Medical Imaging: a joint paper of the European Society of Radiology (ESR) and the European Federation of Radiographer Societies (EFRS) – 2019,
- UR 16260 - European guidelines on quality criteria for diagnostic radiographic images - European Commission 1996.

National standards in quality in medical imaging (CEN members)

- FD S99-133: 2002 Quality management guide, applied to medical imaging structures - AFNOR (France)
- AFNOR SPEC S99-200: 2019 Healthcare services on medical imaging - AFNOR (France)
- NF S99-300: 2021 A comprehensive approach towards quality in medical imaging – AFNOR (France)
- DIN 6870-100: 2012 Quality management system in medical radiology - Part 100: General – DIN (Germany)
- DIN 6870-2: 2012 Quality management system in medical radiology - Part 2: Radiological diagnosis and intervention - DIN (Germany)
- TS 12314: 1997 Hospitals-Part 14, Criteria for radiodiagnostic services – TSE (Turkey)

Standards identfiied in telemedicine (international and CEN members)

- ITU-T F.780.1: 2018 Framework for telemedicine systems using ultra-high definition imaging - IUT
- NEN 8028: 2011 Health informatics - Quality criteria for services and systems for telemedicine – NEN Netherlands

A broader bibliography is available in annex 1

Known patented items

☐ **Yes** ☒ **No** **If "Yes", see CEN-CENELEC Guide 8 and provide full information in an annex**

A simple and concise statement identifying and describing relevant affected stakeholder categories (including small and medium sized enterprises) <u>in particular those who are immediately affected from the proposal</u> (see Annexes 1 and 2) **and how they will each benefit from or be impacted by the proposed deliverable(s)**

Main categories of stakeholders are:

- **Industry and commerce:**
  - **Professionals and medical imaging structures**: to improve their practices while preserving time and energy for the best care of patients.
  - **Providers** of medical imaging structure because they are part of the ecosystem and contribute to the quality of medical imaging structures through innovation and the development of new technologies.
- **Consumers: Patients and their families**: to benefit from the relevance and quality of medical procedures, care and safety of practices for the patients
- **Government**: to benefit from the availability of complementary tools to ensure compliance with the European directives Euratom (2013/59).

Liaisons:

A listing of relevant external European or international organizations or internal parties (other CEN, CENELEC, ETSI, ISO and/or IEC committees) to which a liaison should be established (in the case of ISO and IEC committees via the Vienna or Dresden Agreements).

Internal parties:

ISO/TC 85, SC2 and CEN/TC 430 : Nuclear energy, nuclear technologies, and radiological protection

CEN/TC 251: Health informatics

External organizations:

ESR European Society of Radiology and especially QuADRANT project "Constant improvement in quality and safety of radiology, radiotherapy and nuclear medicine through clinical audit"

EFSR European Federation of Radiographer Societies

UEMS European Union of medical specialist

EuSoMII European Society of medical imaging informatics

Joint/parallel work:

Possible joint/parallel work with:

☐ CEN (please specify committee ID)
☐ CENELEC (please specify committee ID)
☐ ISO (please specify committee ID)
☐ IEC (please specify committee ID)
☐ Other (please specify)

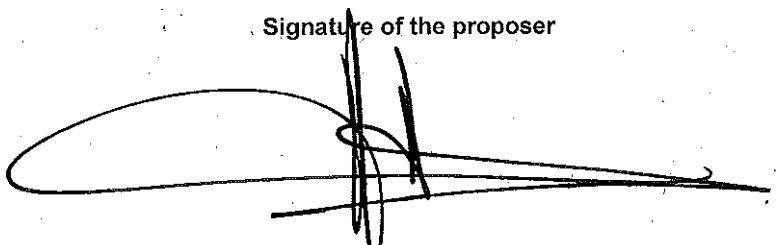
Name of the Proposer
(include contact details)

AFNOR
Contact details:
Ornella DONINEAUX
Standardization Project Manager
ornella.donineaux@afnor.org

An expression of commitment from the proposer to provide the committee secretariat if the proposal succeeds.

If the proposal is accepted, AFNOR is willing to undertake the secretariat of the new TC, and is committed to providing all resources to successfully run the secretariat.

Signature of the proposer



Franck LEBEUGLE
AFNOR Standardization Director

Annex(es) are included with this proposal (give details)

☒ **Annex 1: Bibliography of existing standards at the international, regional and national levels.**

Annex 1 " Bibliography of existing standards at the international, regional and national levels "

Organization	Country	Reference	Publication	Title
Medical imaging				
European and international standards				
ISO	ISO	ISO 12749-2	2013-09-00	Nuclear energy, nuclear technologies, and radiological protection - Vocabulary - Part 2: Radiological protection
CENELEC	CENELEC	Série EN 61223		Evaluation and routine testing in medical imaging departments - Acceptance and constancy tests - Imaging performance of equipments
National standards CEN/CENELEC members				
ASI	Austria	OENORM S 5245	2010-07-15	Diagnostic reference levels in X-ray diagnostics - Monitoring of the compliance
ASI	Austria	Série OENORM S 5240		Image quality assurance in X-ray diagnostics
DIN	Germany	DIN 6862-1 à 3		Identification and characterisation of radiological images in medical diagnosis - Part 1: direct and indirect radiography - Part 2: Passing on of radiographs and related records in digital radiography, digital fluoroscopy, cone-beam computed tomography and computed tomography - Part 3: Patient orientation in image generating procedures
DIN	Germany	Série DIN 6868		Image quality assurance in diagnostic X-ray departments
DIN	Germany	DIN 6870-2 et 100	2012-11-00	Quality management system in medical radiology - Part 100: General - Part 2: Radiological diagnosis and intervention
DIN	Germany	DIN 6878-1	2013-01-00	Digital archiving in medical radiology - Part 1: General requirements for the archiving of images
DIN	Germany	DIN 25300-1	2018-05-00	Processes in radiology - Part 1: Diagnosis of a imaging or image-based procedure
AFNOR		FD S99-133	2002-05-01	Quality management guide, applied to medical imaging offices/departments
AFNOR		AFNOR SPEC S99-200	2019-11-27	Healthcare services on medical imaging
AFNOR		NF S99-300	2021-07-16	A comprehensive approach towards quality in medical imaging

Organization	Country	Reference	Publication	Title
TSE		TS 12314	1997-11-04	Hospitals-Part 14, Criteria for radiodiagnostic services
National standards outside CEN/CENELEC				
SA	Australia	AS/NZS 4184.2.6 AMD 1	1995-00-00	Evaluation and routine testing in medical imaging departments - Constancy tests - X-ray equipment for computed tomography
SA		AS/NZS 4184.3.2	1998-00-00	Evaluation and routine testing in medical imaging departments Acceptance tests - Imaging performance of mammographic X-ray equipment
CSA Canadian Standards Association	Canada	CAN/HSO 42002	2019-09-01	Diagnostic Imaging Services
BNQ	Canada (Quebec)	CSA 5400-901	1972-10-23	Vocabulaire électrotechnique - Groupe 75 - Radiologie
JSA	Japan	JIS Z 4752-2-12	2009-05-01	Evaluation and routine testing in medical imaging departments - Part 2-12: Acceptance tests and constancy tests of film illuminators
Other documents				
NEMA National Electrical Manufacturers Association	USA	NEMA MITA CSP 1	2016-00-00	Cybersecurity for Medical Imaging
European Commission	EU	UR 16260 EN	1996	European guidelines on quality cirteria for diagnostic radiographic images
ESR and EFSR	EU	Insights into Imaging	2019	Patient Safety in Medical Imaging: a joint paper of the European Society of Radiology (ESR) and the European Federation of Radiographer Societies (EFRS)
ESR	EU	ESPERANTO 2019	2019	Esperanto ESR Guide to Clinical Audit in Radiology and the ESR Clinical Audit Tool

Organization	Country	Reference	Publication	Title
Telemedicine				
International standards				
ITU	ITU	ITU-T F.780.1	2018-10-00	Framework for telemedicine systems using ultra-high definition imaging
ITU	ITU	ITU-T X.1092	2013-06-00	Integrated framework for telebiometric data protection in e-health and telemedicine
NATO	NATO	STANAG 2517	2018-11-23	Development and implementation of telemedecine systems - AMedP-5.3 EDITION A
National documents				
VDE	Germany	VDE-AR-E 2757-2	2011-08-00	Service Staying at Home - Requirements for suppliers of combined services
VDE	Germany	VDE-AR-M 3756-1	2009-10-00	Quality management for Telemonitoring for medical applications
NEN	Netherlands	NEN 8028:2011 nl	2011-02-01	Health informatics - Quality criteria for services and systems for telemedicine
GOST	Russia	GOST 34244	2017-00-00	Telemedicine systems. General requirements for basic safety and essential performance of stationary telemedicine consultative and diagnostic centers