NEW WORK ITEM PROPOSAL	
Date of presentation **2008-10-14**	Reference number (to be given by the Secretariat)
Proposer **NEN**	**ISO/TC 215 / SC WG2** N 662
Secretariat **ANSI**	

A proposal for a new work item within the scope of an existing committee shall be submitted to the secretariat of that committee with a copy to the Central Secretariat and, in the case of a subcommittee, a copy to the secretariat of the parent technical committee. Proposals not within the scope of an existing committee shall be submitted to the secretariat of the ISO Technical Management Board.

The proposer of a new work item may be a member body of ISO, the secretariat itself, another technical committee or subcommittee, or organization in liaison, the Technical Management Board or one of the advisory groups, or the Secretary-General.

The proposal will be circulated to the P-members of the technical committee or subcommittee for voting, and to the O-members for information.

See overleaf for guidance on when to use this form.

IMPORTANT NOTE: Proposals without adequate justification risk rejection or referral to originator.
Guidelines for proposing and justifying a new work item are given overleaf.

Proposal (to be completed by the proposer)

Title of proposal (in the case of an amendment, revision or a new part of an existing document, show the reference number and current title)

English title **Health Informatics: Quality criteria for services and systems for telehealth**

French title (if available) **To be supplied**

Scope of proposed project

Quality criteria for services and systems for telemedicine (as a subdomain of telehealth) will be formulated.

Existing definitions:
-> Telehealth - use of telecommunication techniques for the purpose of providing telemedicine,
medical education, and health education over a distance
(ISO TR16056-1:2004(E) - 3.75 pag. 10),
-> Telemedicine - use of advanced telecommunication technologies to exchange health information and
provide health care services across geographic, time, social and cultural barriers
(ISO TR16056-1:2004(E) - 3.76 pag. 10).

The Dutch NTA (NTA 8028 - 2007/2008) covers a subdomain of telemedicine: healthcare processes in which at least two actors are actively involved. At least one of these actors belongs to a legally accredited professional group or is acting under the supervision of a person who belongs to such a group. One of the other actors can be the care consumer. This proposed technical specification, will limit its scope to the above described healtcare processes.

The criteria will deal with:
1. Quality at the level of care provision e.g patient orientation, effectiveness and efficiency of care;
2. Quality at the level of information provision e.g. control of data, user convenience, quality aspects of the information system;
3. Quality at the level of business processes – "industrial organization" - a.o. process description and organizational structure, responsibilities and administrative management.

In addition to that criteria for quality control will be described including:
-> The need for an internal quality system
-> The presence of a comprehensive audit trail system.

Whereas the EHR will be an essential element for the storage of data, the quality of the EHR itself is not the subject, the relation of the telemedicine services and the EHR however definitely is.

Therefore, the above mentioned 'quality of the information systems' includes the quality of the communication with the EHR.

Concerns known patented items (see ISO/IEC Directives Part 1 for important guidance)

☐ Yes ☒ No If "Yes", provide full information as annex

Envisaged publication type (indicate one of the following, if possible)

☐ International Standard ☒ Technical Specification ☐ Publicly Available Specification ☐ Technical Report

Purpose and justification (attach a separate page as annex, if necessary)

Purpose and justification

The demand for healthcare will further increase in the coming decades because of the ageing population, patient empowerment and increased possibilities for treatment and care.
Because of the demographic developments this increased demand can not be accompanied by a proportional increase in the number of healthcare professionals available.
Next to these logistic problems (employees, systems, distances…..) a mismatch between massive organizations and the need for more individually defined care can occur. There is a need for care closer to the patient (at home or at short distance). Thus there is a need for new, more efficient and effective forms of care delivery. ICT has the potential to support these new or renewed services in healthcare where the participants in the processes are not necessarily at the same location.

By using ICT, such new forms of care are being proposed and to a limited extent already operational. It is important to safeguard the quality of such new services that probably will be expanding rapidly. The criteria can on one hand support the bodies that develop and offer such services and on the other hand support the supervising and regulatory authorities such as i.e. the Health Care Inspectorate. People must be able to rely on the quality, integrity and safety of care and products.

The quality criteria for services and systems for telemedicine (as a subdomain of telehealth) laid down in this technical specification, could be part of the conditions for reimbursement.

Target date for availability (date by which publication is considered to be necessary)

Proposed development track ☐ 1 (24 months) ☒ 2 (36 months - default) ☐ 3 (48 months)

Relevant documents to be considered

ISO TS18308 EHR requirements
ISO 16056 TR parts 1 and 2
NEN NTA 8028 Health Informatics, Telemedicine
Standards Australia: TR 2961—2007, Telehealth standards scoping study
CEN EN 13940 a system of concepts to support Continuity of care
Work in Australia, Brasil, Canada and UK and possibly others, to be determined.

Relationship of project to activities of other international bodies

Similar proposal to CEN

Liaison organizations	**Need for coordination with:** ☐ IEC ☐ CEN ☐ Other (please specify)

Preparatory work (at a minimum an outline should be included with the proposal)

☐ A draft is attached ☒ An outline is attached. It is possible to supply a draft by April 2009

The proposer or the proposer's organization is prepared to undertake the preparatory work required ☒ Yes ☐ No

Proposed Project Leader (name and address)	**Name and signature of the Proposer** (include contact information)
To be announced	**NEN, the Netherlands**

Comments of the TC or SC Secretariat

Supplementary information relating to the proposal

☒ This proposal relates to a new ISO document;

☐ This proposal relates to the amendment/revision of an existing ISO document;

☐ This proposal relates to the adoption as an active project of an item currently registered as a Preliminary Work Item;

☐ This proposal relates to the re-establishment of a cancelled project as an active project.

Other:

Voting information

The ballot associated with this proposal comprises a vote on:

☒ Adoption of the proposal as a new project

☐ Adoption of the associated draft as a committee draft (CD)

☐ Adoption of the associated draft for submission for the enquiry vote (DIS or equivalent)

Other:

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

☒ **English translation of the Dutch Agreement NTA 8028, Roadmap for the work on this standard**

Date of circulation	Closing date for voting	Signature of the TC or SC Secretary
2008-11-17	**2008-02-17**	**Audrey Dickerson**

Use this form to propose:

a) a new ISO document (including a new part to an existing document), or the amendment/revision of an existing ISO document;

b) the establishment as an active project of a preliminary work item, or the re-establishment of a cancelled project;

c) the change in the type of an existing document, e.g. conversion of a Technical Specification into an International Standard.

This form is not intended for use to propose an action following a systematic review - use ISO Form 21 for that purpose.

Proposals for correction (i.e. proposals for a Technical Corrigendum) should be submitted in writing directly to the secretariat concerned.

Guidelines on the completion of a proposal for a new work item

(see also the ISO/IEC Directives Part 1)

a) Title: Indicate the subject of the proposed new work item.

b) Scope: Give a clear indication of the coverage of the proposed new work item. Indicate, for example, if this is a proposal for a new document, or a proposed change (amendment/revision). It is often helpful to indicate what is not covered (exclusions).

c) Envisaged publication type: Details of the types of ISO deliverable available are given in the ISO/IEC Directives, Part 1 and/or the associated ISO Supplement.

d) Purpose and justification: Give details based on a critical study of the following elements wherever practicable. *Wherever possible reference should be made to information contained in the related TC Business Plan*.

1) The specific aims and reason for the standardization activity, with particular emphasis on the aspects of standardization to be covered, the problems it is expected to solve or the difficulties it is intended to overcome.

2) The main interests that might benefit from or be affected by the activity, such as industry, consumers, trade, governments, distributors.

3) Feasibility of the activity: Are there factors that could hinder the successful establishment or global application of the standard?

4) Timeliness of the standard to be produced: Is the technology reasonably stabilized? If not, how much time is likely to be available before advances in technology may render the proposed standard outdated? Is the proposed standard required as a basis for the future development of the technology in question?

5) Urgency of the activity, considering the needs of other fields or organizations. Indicate target date and, when a series of standards is proposed, suggest priorities.

6) The benefits to be gained by the implementation of the proposed standard; alternatively, the loss or disadvantage(s) if no standard is established within a reasonable time. Data such as product volume or value of trade should be included and quantified.

7) If the standardization activity is, or is likely to be, the subject of regulations or to require the harmonization of existing regulations, this should be indicated.

If a series of new work items is proposed having a common purpose and justification, a common proposal may be drafted including all elements to be clarified and enumerating the titles and scopes of each individual item.

e) Relevant documents and their effects on global relevancy: List any known relevant documents (such as standards and regulations), regardless of their source. When the proposer considers that an existing well-established document may be acceptable as a standard (with or without amendment), indicate this with appropriate justification and attach a copy to the proposal.

f) Cooperation and liaison: List relevant organizations or bodies with which cooperation and liaison should exist.