NEW WORK ITEM PROPOSAL

Date of presentation	Reference number (to be given by the Secretariat)
2004-09-04	
Proposer: The Dutch Mirror group'Dentistry'	ISO/TC / SC **N**
Secretariat: NEN	

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: Dental CADCAM systems

French title (if available):

Scope of proposed project

Special dental CADCAM standard(s) about the performance of these medical devices.

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)

Considering the fact there are over 1 million CADCAM restorations each year, the Dutch Mirror Group "Dentistry" asks TC 106 'Dentistry' to consider special ISO standards for dental CADCAM systems. CADCAM components such as the optical impression system, design software, fabrication machine and colorimeters are medical devices that have to perform to a certain level. The manufacturers need to prove (with reasonable assurance) the safety and effectiveness of the devices. There are many non-dental CADCAM standards that these manufacturers could use. However, the special demands for the dental application are not always covered by these standards. Many dental CAD/CAM related topics are already be covered by existing standards. Dental materials used for CADCAM restorations are already covered by standards about metal alloy, composite, ceramics and other horizontal standards.

Considering all these facts, the Dutch mirror group still believes that there is a need for special dental CADCAM standards. This has to do with the fact that the performance of these medical devices for the dental purpose is not proven yet and the fact that dentistry has specific requirements for this type of devices. The group recognizes the fact that there is a lack of dental definitions for tests on items such as accuracy, reproducibility and resolution. Furthermore, it might be of vital importance to standardize architecture, modeling of application software (e.g. open source CORBA) and communication protocols for open end systems (e.g. DICOM, DXF, STL). The Dutch Mirror Group asks ISO/TC 106 to install an ad-hoc working group. This group has explore the need for CADCAM standards for dentistry.

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

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 general 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: 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.

SHIPPED JAN 7 / 2010

NEN

Ter attentie van / for the attention of

RECEIVED JUL 17 2004

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Canadian Dental Association
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NEN-Voeding & Zorg

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Ellen Boer	+31 (0)15 2 690 342	+31 (0) 15 2 690 692	2004-07-07

Het bijgaande wordt u toegezonden
Please find enclosed

- ☐ ter kennisneming
- ☐ op verzoek
- ☐ volgens afspraak
- ☐ ter behandeling
- ☐ met dank retour
- ☐ voor commentaar
- ☐ als bijlage bij

- ☐ for your information
- ☐ at your request
- ☒ as agreed
- ☐ for your consideration
- ☐ returned with thanks
- ☐ for comments
- ☐ as an annex to

Dear Mr. Smith

Attached you will find the New Work Item Proposal on dental CADCAM from the Dutch Mirror Group.

Best regards,

Ellen Boer
Secretary of Dutch Mirror Group

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