Validation of CAD/CAM systems

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Introduction
In preparation of the ISO meeting on Validation Dental CAD/CAM this paper was written. During the procedures that might lead to a proper work title and the scope of a preliminary work item (PWI) on validation of CAD/CAM systems, the following ISO conditions apply:

- Consensus by resolution of substantial objections is an essential procedural principle;
- Sufficient time is given for discussion, negotiation and resolution of significant technical disagreements;
- Discipline with respect to deadlines and timetables must be ensured;
- To avoid rediscussion standpoints must be known at an early stage of the work;
- Initial costs are beared by Dutch Mirror Group.

Abbreviations

WG	Working group
PT	Project team
PWI	Preliminary work item
NP	New work item proposal
WD	Working draft
CD	Committee draft
DIS	Draft international standard
FDIS	Final draft international standard
TR	Technical report
CAD	Computer Aided Design
CAM	Computer Aided Manufacturing
EDR	Electronic Dental Record
EAN	European numbering of goods
HIBC	Health Industry Bar Code
UMLS	Unified Medical Language System

The proposal for work in a new technical activity of dental CAD/CAM, which might require the establishment of a subcommittee, was made by the Dutch national body (NEN). Subsequently the proposal was circulated by the ISO general office in Geneva to all national bodies of ISO. The proposal for a new work item (NP) on the Validation of CAM/CAM systems was made by Dr. J.M. van der Zel, Computerized Dentistry, Academic Centre for Dentistry, Universiteit van Amsterdam and Vrije Universiteit, Amsterdam-NL.
The invited experts shall agree on the work title and scope as soon as possible at the first ISO/TC106 meeting in Rome on September 28th 2005. The scope is a statement precisely defining the limits of the work.
For example:
"Standardization of intra- and extra oral surface digitization of dental structures intended for the computer aided design and manufacturing of patient specific computer fabricated dental restorations under secure electronic data management. Excluded: digitization by X-ray."

The agreed title and scope shall be submitted to the plenary meeting of ISO TC 106 on October 1st 2005 for approval. A subcommittee can, in case of approval, be established on the condition that that a national body has expressed its readiness to undertake the secretariat. The

Dutch mirror group has agreed to undertake the secretariat in case of such approval, while Dr. J.M. van der Zel will undertake the executive secretariat and organization.

Remarks on title and scope

1. **Three areas**

The scope of the new standardization activity covers three areas:

a. Surface digitization of dental structures (part I),

This guideline is intended for use by manufacturers of CAM/CAM systems or components, custom dental device manufacturers and for testing purposes. A dental surface digitization system for CAM/CAM of dental restorations is a device used to record the topographical features of teeth, dental impressions, or stone models by analog or digital methods for use in the computer aided design and manufacturing of custom dental restorative prosthetic devices. The system is called a "system" because it typically consists of three integrated functions:

- a surface digitization device;
- a central processing module consisting of computer hardware and software;
- a manufacturing module consisting of a computer controlled machine.

The central processing module uses the image captured by the digitization module to produce a restoration in the manufacturing module (Part III).

Part I of this guideline is intended to:

- give specifications for dental surface digitization systems;
- ensure comparability of the characteristics of dental surface digitization systems;
- use methods with evidence-based process tools and artefacts.

The scope of this guidance includes dental surface digitization machines of any type with optical one-, two-, or three-dimensional sensors, but does not apply to impression materials or material milled, e.g. ceramic, resin, or metal. For these we refer to the ISO material standards. Sensors may allow swing-and-tilt movements by means of accessories.

This guideline provides the necessary additional specifications for the use of dental surface digitization:

- standards to be used as an alternative to gauge blocks;
- comparability of the characteristics where alternative standards are used;
- comparability of the characteristics where probing strategies differ for different sensors (different number of points, differences in coverage of the elements to be probed, use of accessories such as swing-and-tilt equipment);
- definition of the characteristics for varying operating conditions;
- guidance on how to take into account influencing quantities such as environmental parameters, mathematical filters, and surface characteristics of the artefacts.

b. Electronic data communication and dental record (EDR) (part II)

Part II of this guideline is intended to give specifications for dental CAM/CAM data formats of the resulting surface reconstruction and electronic dental records. The guideline is directed to maximize dental healthcare data collection, to enhance interoperability, improve efficiencies, streamline workflow and improve patient dental care. This guideline covers all types of dental CAM/CAM software and electronic data management in dental CAM/CAM services that focuses on quality and value and has five purposes. The first is to identify the content and logical structure of a Electronic Dental Record (EDR). The record carries all dental health related information about a patient over time. It includes such things as observations or descriptions of the patient (for example X-ray imaging reports), documentation about the actions carried out (for example, restorations), patient identifying information, and so on.

The second goal is to define the relationship of data coming from diverse source systems (for example, clinical laboratory information management systems, order entry systems), and the data stored in the Electronic Dental Record. Recalling that the EDR is the primary repository for information from various sources, the structure of the EDR is receptive to the data that flow from other systems.
Third, in order to accelerate the adoption of EDR's, this guideline provides a common vocabulary, perspective, and references for those developing, purchasing, and implementing EDR systems, but it does not deal either with implementation or procurement.
Fourth, this guideline describes examples of a variety of views by which the logical data structure might be accessed/displayed in order to accomplish various functions.
Fifth, this guideline relates the logical structure of the EDR to the essential documentation currently used in the dental care delivery system of custom dental devices in order to promote consistency and efficient data transfer. It maps to the clinical data currently in existing data systems and patient dental care records.

c. Computer fabricated dental restorations (part III)

The proposal is justified because CAM/CAM restorations are becoming a substantial part of the kaleidoscope of restorations offered to patients, while there are no generally accepted methods available to compare or validate the technical functionality of CAD/CAM systems and the medical devices they bring forth.

This guideline does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this guideline to establish appropriate safety and health practices and determine the applicability of regulatory requirements prior to use.

2. Work undertaken in similar bodies

Surface digitization

There has been a number of publications on the accuracy of digitization systems, but no efforts to come to a way of standard measurement was undertaken. Standardization work on optical coordinate measuring machines has been undertaken by VDI and has resulted in a standard ISO 10360. This might be useful as a starting point for a dental digitization standard.
As digitization is seen as an optical impression taking reference is made to the following documents:

EN ISO 4823:2000 Dentistry - Electrometric impression materials
EN ISO 6873:2000 Dental Gypsum products
EN ISO 13716:2000 Dentistry – Reversible hydrocolloid impression material systems

Electronic data communication and dental record

In dentomaxillofacial radiology consensus is reach by the general use of the DICOM 3 data format for filing, communication and interoperability.
The security of electronic patient data is an obligation of the dentist and should be given the highest priority as it is enforced by state law. That is why in different countries health care electronic data are not send over the internet but by secure intranet providers.

Computer fabricated dental restorations

Computer fabricated dental restorations restoration should be as close as possible to the stated and expected parameters formulated at the computer aided design stage. Custom dental device manufacturing should conform to annex II EEW 93/42 essential requirements.

3. Liaisons deemed necessary with other bodies

It might be useful to involve the Dental Informatics workgroup of professor Kordass (University of Greifswald, Germany) who have formulated some scope for work on

CAM/CAM. A liaison in the form of an nominated expert and communication of all relevant information might be useful.
The FDA has published a paper Guidance for Industry and FDA; Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations; Guidance for Industry and FDA; availability Internet site at http://www.fda.gov/ohrms/dockets.

4. Items to be included in the scope

Digitization in Dental CAD/CAM:

a. Definition of digitized data on which statistic analysis is performed: A surface digitization procedure starts with the generation of actually measured surface points, the *measured digitization data*.
   In most digitizing systems the measured points are mathematically processed by operations such as:
   1. Matching
   2. Filtering
   3. Weighing
   4. Selective removal
   5. Smoothing, etc.

   This results in the *processed digitization data (or surface data).* These data depend very much on the digitization protocol (e.g. number of passes), the extraction method of a surface from the raw data points, matching of point clouds.
b. Accuracy: Highly relevant. Can be done on a ball and cube.
c. Reproducibility: Relevant. With repeated measurements. Number of repetitions.
d. Reproduction of detail: Although relevant in traditional impression taking, there are two reasons why reproduction of detail might not be considered:
   1. Custom dental devices are not designed to a "perfect" fit, as expected from impression materials, but to a "clinically acceptable" fit.
   2. Because adequate tactile measuring devices lack surface contact at certain concave areas.

Electronic data communication and dental record:

a. Data formats: STL, ASCI, DICOM3.
b. Interoperability: XML, UML, UMSL.
c. Electronic Dental Record and security: Depending on national legislation.

Computer fabricated dental restorations:

a. Reproducibility: Relevant for validation and verification of process.
b. Accuracy: Highly relevant. Can be done by producing a with standard geometry, die or thin-walled hollow cube, and measurement of the product with appropriate means.
c. Packing and registration: according to Annex II EEW 93/42 essential requirements, bar code (EAN, HIBC).

3. Envisioned publication type

This might become an international standard.

4. Purpose and justification

a. Aim of the validation

A standard on validation of dental CAD/CAM systems is eminent, because a substantial amount of restorations is produced by CAD/CAM. The potential market for CAD/CAM restorations is estimated to be 3 billion Euro. In order to give stakeholders a tool for

specifying, testing, comparing, validation and verification a standard on CADCAM systems is necessary.

b. Stakeholders' interests

Industry, patients, dentists, dental technicians, trade, governments and distributors are the main stakeholders and have different interests.

a. Industry: need to validate process and equipment specifications.
b. Patients: need guarantee for good fitting restoration.
c. Dentists: want evidence based treatment.
d. Dental technicians: want predictable and reproducible process.
e. Trade: needs specifications.
f. Governments: want assurances for security of patient data.
g. Distributors: need to have standard for comparison and description.

c. Feasibility of the activity

The essence of a standard lies in its application and use. At present more than a dozen vendors have a presence in the dental market. The installed base is responsible for more than 2 million restorations yearly. This makes a standard for CAD/CAM systems feasible.

d. Timeline

The CAD/CAM technology has come to maturity after several decades of development. As it is a future oriented activity it is likely that a standard will evolve further from its first establishment. To develop further it is necessary to obtain a state of the art in standardized terms to establish a status quo to act upon.

e. Urgency of the activity

The first urgency lies in a description of the functions of a surface digitizer. Another priority, which has different urgency in different countries, are patient privacy rules for data security. For validation and verification of the computer aided manufacturing process from computer aided design data, standardized artifacts can be defined and produced that prove the effectiveness of the manufacturing process.

f. Benefits

The benefits of the proposed standard will differ for each stakeholder.

g. Harmonization of existing regulations

Harmonization of existing rules and standards will be one of the major tasks of the group.

5. Relevant documents

Document	Title
EN ISO 13606	Health Informatics - Electronic Health Record Communication.
preen 12052	Health informatics - Digital imaging – Communication, workflow and data management.
ISO 10241:1992	International terminology standards
ISO 7498:1984	Information Processing Systems - Open Systems Interconnection - Basic Reference Model - Part 2: Security Architecture.
prENV 12924	Medical Informatics - Security Categorisation and Protection for Healthcare Information Systems.
ADA TR 1031	Internet Security Issues for Dental Information Systems.
VDI/VDE 2617	Part 6.2 Accuracy of coordinate measuring machines - Characteristics and testing of Characteristics - Guideline for the application of DIN EN ISO 10360 to coordinate measuring machines with optical distance sensors.
ISO 10360	Coordinate measuring machines with optical distance sensors.
ISO 14253	Geometrical product specification (GPS) – Inspection by measurement of work pieces and measuring equipment.

6. Cooperation and liaison

There should be in the task group as much as possible representation and to obtain impute from other groups by cooperation and liaison e.g. ADA, FDA.

Annex A

Literature on surface digitization

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XML

E1239 Guide for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Electronic Health Record (EHR) Systems
E1384 Guide for Content and Structure of the Electronic Health Record (EHR)
E1633 Specification for Coded Values Used in the Electronic Health Record
E2182 Specification for Clinical XML DTDs in Healthcare
XML 1.0 Recommendation, http://www.w3.org/TR/REC-xml
XHTML Basic Recommendation, http://www.w3.org/TR/xhtml-basic
XML Linking (Xlink) 1.0 Recommendation, http://www.w3.org/TR/xlink
XML Namespaces Recommendation, http://www.w3.org/TR/REC-xml-names
XPointer, http://www.w3.org/TR/xptr
XSLT, http://www.w3.org/TR/xslt
Informative Document: Using XML as an Alternative Message Syntax for HL7 Version 2.3.x

Electronic Dental Record

E1239 Guide for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Automated Patient Care Information Systems
E1633 Specification for the Coded Values Used in the Computer-Based Patient Record
E1714 Guide for Properties of a Universal Healthcare Identifier
E1715 Practice for an Object-Oriented Model for Registration, Admitting, Discharge, and Transfer (RADT) Functions in Computer Based Patient Record Systems
E792 Guide for Selection of a Clinical Laboratory Information Management System
E1238 Specification for Transferring Clinical Observations Between Independent Computer Systems
E1381 Specification for Low-Level Protocol to Transfer Messages Between Clinical Instruments and Computer Systems
E1394 Specification for Transferring Information Between Clinical Instruments and Computer Systems
E1460 Specification for Defining and Sharing Modular Health Knowledge Bases (Arden Syntax for Medical Logic Modules)
E1467 Specification for Transferring Digital Neurophysiological Data Between Independent Computer Systems
E1712 Specification for Representing Clinical Laboratory Test and Analyte Names
E1769 Guide for Properties of Electronic Health Records and Record Systems
IS 5218 1977 Information Interchange-Representation of Human Sexes

IS 1000 1981 SI Units and Recommendations for the Use of Their Multiples and of Certain Other Units
IS 2955 1983 Information Processing-Representation of SI and Other Units in Systems with Limited Character Sets
IS 8072 1984 Information Processing Standard-Open System Interconnection Transport Service Definition
IS 8601 1988 Data Elements and Interchange Formats-Information Interchange (Representation of Dates and Times)
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