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Foreword

This CEN REPORT has been prepared by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by SIS under mandate BC/CEN/03/255/97/23.6 by the European Commission and the European Free Trade Association. This work item was originally entitled Medical Multimedia and Related Interoperability Data Format but CEN/TC 251 decided to change the title to Interoperability of healthcare multimedia report systems in order to reflect more accurately the main focus.

This report has been produced by members of the Project Team 34 MULTIMED under the supervision of CEN/TC 251/WGIV: Technology for Interoperability.

This CEN Report is not a standard and does not contain the definition of a new data file format.

Defined terms are shown with the first letter of each word in capitals.

1 INTRODUCTION

1.1 Executive Summary

This CEN Report is concerned with the interoperability of systems for the creation, modification and presentation of digital healthcare multimedia report records. In addressing these issues the purpose of this CEN Report is:

- to examine the nature of healthcare reports as delivered and viewed using traditional methods
- to recommend methods for the presentation of electronic healthcare service reports using multimedia facilities
- to assess the suitability of existing and emerging standards and specifications
- to make recommendations for future work to enable the implementation of multimedia reports within the clinical process.

Reports presented using electronic multimedia facilities should, by comparison with commonly used existing methods, enable improved communication of the information obtained by service departments to those who request their services, thus leading to improved quality of Healthcare.

This report is intended to inform standards makers, systems designers and healthcare professionals about the nature of healthcare multimedia report records and show the way for the development of clinically viable implementations.

The domain of Healthcare Procedure Reporting is reviewed by means of scenarios which take account of previous CEN/TC 251 work and the views of clinicians and medical informaticians obtained by consultation. The two most common means by which Healthcare Service Reports are traditionally presented to clinicians are identified as a) report text on paper accompanied by optional supporting results in hardcopy form (e.g., X-Ray films) and b) live presentation, for example, as part of a case conference.

Multimedia Scenarios explain the application of multimedia facilities in the domain of Healthcare Service Reports and their subsequent use. Use cases illustrate the creation, amendment and subsequent use of healthcare multimedia reports. Conceptual models are derived from the use cases and illustrate the generic logical data structures required to record healthcare multimedia reports and the data presented. This CEN Report concludes that the clinical needs for healthcare multimedia reports may be served by presentation in two modes:

a) Navigation mode: The report text is presented in a form such as that supported by a Web Browser. A clinician can select as much or as little of the available material for presentation as is needed in the current clinical situation in the same way as is currently done when a written report on paper is accompanied by selected Healthcare Procedure Products such as images in hardcopy form. He/she also decides the order in which to view the available material.

b) Performance mode: The report is presented in a form similar to a lecture type presentation, for example, as part of a case conference and would appear to the recipient in the form of a video performance. The items and their order of presentation cannot be altered from that chosen by that report author (apart from changes implemented by the use of video like controls such as pause rewind, etc.), i.e. the material must be viewed in the way the author believes to be most appropriate.

In short, a Navigation Mode record specifies the layout and rendering for a set of procedure products in space. A Performance Mode record specifies how different Procedure Products are to be presented during a specified period of time.

This CEN Report uses the analogy of the performance of a piece of orchestral music as represented in the conductor's music score. In the case of a healthcare multimedia report Performance mode score there will be one line for each presentation channel, such as a defined region of a display window or sound channel. The score specifies the sequence and duration for the presentation of sets of healthcare information items, such as images and annotations, in a number of display regions, perhaps with synchronised sound such as a 'voice over' and annotation by fixed regions of interest and/or a pointer.

This CEN report explains the nature of the data to be presented as well as the presentation record data (score) for performance mode and Navigable record data for Navigation mode. It is noted that the report text may be required as the legally binding result of a healthcare service procedure. The availability of relevant existing standards to support the identified needs is reviewed and recommendations for enhancement of existing standards and creation of new standards are made.

This CEN Report concludes that Web-based and other standards/specifications, which support most of the identified requirements for the exchange of healthcare multimedia report (HCMR) records already exist. These standards/specifications also provide support of the identified presentation modes when interaction by the recipient is not required (e.g., no windowing of images, etc.). One of the deliverables of this CEN Project is a demonstration package that includes digital records of both Navigation mode and Performance mode HCMR presentation.

Standards do not, however, exist for the creation and amendment of the record of Multimedia Presentations in interactive form (record of the layout and rendering parameters of the presented procedure products). It is recommended that authoring tools be developed to enable the production of healthcare multimedia report records using the identified Navigation and Performance modes of presentation. These need to support both interactive and non-interactive forms to enable co-operation between medically qualified and non-medically qualified Healthcare Professionals in the task of producing multimedia reports. This should be implemented in collaboration with relevant groups, including CEN/TC 251, ISO/TC 215, HL7 and DICOM.

1.2 Digital healthcare multimedia reports

A digital multimedia document may be defined as a document that includes numerical representations of information that has been presented using different media. Such a document constitutes a digital record of a multimedia presentation. The monomedia items presented may include for example: text (structured or free), a static image (picture), a time series of images, a graphics entity (such as might delineate a Region of Interest), a voice sound clip. One such monomedia entity may be related to another. For example, a Region of Interest may need to be aligned in space upon the image to which it applies. A sound clip may need to be aligned in time with a time series of images (synchronised). Multimedia presentation systems are, of course, also capable handling a monomedia document (a document requiring presentation using one medium only e.g., text) and multimedia documents which do not invoke synchronisation.

Interoperability of systems for the creation, modification and presentation of digital healthcare multimedia report records depends on understanding and consistency in the representation of data. The key requirements for healthcare multimedia report presentation are:

a) that appropriate use is made of multimedia facilities to enhance the communication of information from reporting clinician to recipient and;

b) that the recipient sees and hears effectively the same things when he/she observes a presentation of the multimedia report as the clinician saw and heard when the report was recorded.

The understanding of the requirements for interoperability of healthcare multimedia report systems requires an understanding of the nature of the Healthcare Procedure Product data which is presented and the methods of presentation. This CEN report includes discussion of the nature of the logical data structures required to carry Healthcare Procedure Product data and healthcare multimedia report record data.

One of the main reasons for the need for specific Healthcare Standards is that medical images are of a different nature from images generally used by multimedia applications. A medical image, such as the image rendered from a regular array of X-Ray attenuation values acquired by a Computed Tomography (CT) modality, is a Digital Image. A Digital Image is a visual representation of a Digital Image Data matrix. In order for an application to present such an image on a screen two sets of data are required a) the Digital Image Data matrix and b) the rendering data. In the case of a CT image presentation to the reporting clinician on the display screen of a multimedia reporting system, facilities will be provided for him/her to adjust the rendering parameters. These are generally controlled by means of controls, called window controls, which select the range of X-Ray attenuation values to be displayed. By adjustment of these controls, the reporting clinician can select the most appropriate settings to demonstrate the image features referred to in the Report Words.

A number of stages in the life history of a Healthcare service report may be identified. First a report instance is created and associated with the request. Usually some or all of the report content is immediately recorded following the report instance creation. The report content is then built up by assembling and adjusting the

presentation of a number of components (Report Words, images, Curves, etc.). This process may be accomplished during one or more editing sessions during which there are no restrictions on the modifications which may be made to the report content (addition or removal of sections of Report Words, addition or removal of presented Healthcare Procedure Products, adjustment of presentation parameters). There may be a number of approval stages for the various components. Finally the whole report is approved (signed off) and is ready for dispatch. Usually the data will be sent out in a form that does not allow the recipient to alter the presentation parameters such as image windowing.

Subsequently it may be found that errors exist in the approved (signed off report). There are two commonly used methods for dealing with this situation:

a) No changes are made to the original approved report content but a section is added

b) The faulty report is withdrawn and is superseded by a new report instance without those errors which in turn is approved (Signed off).

From the above it is clear that applications for the creation, modification and presentation of multimedia report records must support constrained and unconstrained modification of the healthcare multimedia report record. In particular, applications for the presentation to report recipients will not allow any modification of the presentation.

1.3 Motivation

Significant developments in computer hardware, software and data communications used in Healthcare have taken place in the last few years. In particular, it is now possible to incorporate the results of Healthcare Procedures such as images and Curves within electronic reports, possibly using multimedia facilities. Systems can be implemented at reasonable cost using World Wide Web Technology and there is considerable interest in this area, which will impact on the Electronic Patient Record as well as the diagnostic imaging department.

It is believed that a review of the specific medical needs for multimedia reports and evaluation of existing and draft standards for use in this area will assist the healthcare informatics standards community in further standards development. A review will, in particular, help TC 251 in enabling the healthcare community to gain maximum benefit from the emerging technology.

From the standards development point of view, it is important to exploit the use of appropriate standards and to identify areas where more work is required to enable interoperability of systems.

In assessing the clinical requirements for healthcare multimedia reports and how these could be met, major problems exist. These are:

- There is no clear agreement about what a healthcare multimedia report is
- Implementations are rare
- Technologies develop rapidly
- Inadequate standards and specifications lead to interoperability problems.

1.4 Aims and Objectives

1.4.1 Aims

In addressing the problems listed above, this CEN Report aims to facilitate Interoperability of Healthcare Informatics Systems that support the use of Multimedia information. The report focuses on Healthcare (Procedure) multimedia reports such as Radiological procedure reports within the clinical process by:

a) identifying the needs for their implementation, and

b) reviewing existing and emerging standards and specifications in the light of the identified clinical needs, and

c) considering the requirements for further standardisation activities

1.4.2 Objectives

The overall objective is to make recommendations to CEN/TC 251 regarding future standards work required to enable the interoperability of Healthcare Multimedia systems for the creation, modification and presentation of healthcare multimedia report records, taking account of existing standards and existing and emerging technologies.

This CEN report has the following specific objectives:

Healthcare Multimedia Report: To define and explain the term Healthcare Multimedia Report (HCMR) in the context of this CEN Report.

Interoperability: To define and explain the term Interoperability in the context of this report

Healthcare Procedure Scenarios: To inform healthcare informaticians by documenting Scenarios of Healthcare Procedures such as diagnostic imaging procedures and intensive monitoring, illustrating the use of Imaging and other Medical Devices in the acquisition and processing of acquired patient data.

Healthcare Procedure Data: To describe the nature of the acquired and processed data produced by Healthcare Procedures. This will allow precise specification of the processes necessary for multimedia presentation of these data.

Healthcare Service Reports: To document scenarios of the production, recording and subsequent presentation of Healthcare Service Reports, with and without the use of multimedia facilities.

Healthcare Procedure Report Data: To discuss the nature of the data required to specify the presentation of a Healthcare Multimedia Report. Note that it is not intended to prescribe the method of presentation.

Unified Modeling Language Modelling: To develop Unified Modeling Language (UML) conceptual models based on the above scenarios.

Review of existing standards: To examine current relevant standards and determine to what extent they support the needs identified in this CEN Report.

Recommendations: To make recommendations regarding work required to improve interoperability of multimedia report systems, including recommendations for the extension of existing standards/specifications and the development of new standards/specifications.

1.5 Method of Work

1.5.1 Traditional Healthcare Service Report Scenarios

Scenarios of the creation and use of Healthcare Service Reports such as Radiological Reports were produced. These take into account the existing scenarios documents of CEN/TC 251/WG4 and CEN/TC 251/WG5 and the knowledge and experience of the medically qualified healthcare professional member of this CEN Report Project Team and views of various workers in the field. A scenario describes the processes that take place in the relevant domain and identifies the human actors, real world entities and logical data structures involved.

1.5.2 Scenarios of healthcare multimedia reports

Viable means for the clinical use of Multimedia Reports were identified:

1.5.3 Multimedia report use cases

Use cases of the creation, amendment and use of multimedia reports were produced based on the two related scenarios sections. These utilise both a textual format and diagrams to illustrate the sequence of events in a process showing how human actors, system facilities and logical data structures relate to each other.

1.5.4 Conceptual Modelling

Formal Unified Modeling Language (UML) conceptual models were derived from the use cases.

These high-level abstractions are also represented using UML system sequence diagrams. A system sequence diagram provides a model of a particular course of events within a use case where it is demonstrated how human actors interact with physical entities and multimedia entities and the events that are generated from this interaction. Use case and sequence diagrams are used to further derive a formal UML conceptual model (that is a representation of concepts of entities in the problem domain) using UML class diagram notation.

1.5.5 Logical data structures

The characteristics of a Healthcare Procedure Product logical data structure to support the forms of acquired and processed data covered by the scope of CEN/TC 251 WGIV are described at the end of section 8.

The characteristics of logical data structures for describing the Multimedia presentation of a specific set of Healthcare Procedure Product logical data structures are discussed in section 9.

1.5.6 Assessment of the applicability of relevant existing and emerging Standards and Specifications

The applicability of multimedia and other existing and emerging standards/specifications to support the identified requirements was assessed as a guide to the needs for further work.

1.5.7 Recommendations for use and/or extension of standards and Publicly Available Specifications

Recommendations are made for the use of (and possible extensions to) multimedia standards to serve the identified clinical needs. Areas where standards are lacking are identified, and need for further work items highlighted.

2 SCOPE

The scope includes issues concerning the interoperability of systems for the creation, modification and presentation of digital healthcare multimedia report records as described in the Introduction.

This CEN report concentrates on a limited set of multimedia documents, namely reports such as those of Diagnostic Imaging and Vital Signs studies. This set of documents constitutes a representative sample of complex healthcare multimedia reports within the scope of CEN/TC 251/WGIV. It is expected that the recommendations, which take into account this complexity, will support the management of less complex reports.

This CEN report has three main parts:

- Identification and modelling of the needs for interoperability of multimedia systems for the creation, modification and presentation of Healthcare Service Reports.
- Assessment of the applicability of appropriate existing and emerging standards and Publicly Available Specifications as at November 1998.
- Recommendations for the use and/or extension of Standards and Publicly Available Specifications.

The scope does not include the creation of implementable specifications or complete requirement specifications.