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**Medical Informatics - Methodology for the
development of healthcare messages**

**Méthodologie pour le
développement des messages dans
le domaine de la santé**

**Methodik für den Entwurf von
Nachrichten (Inhalte, Strukturen) im
Gesundheitswesen**

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CEN

**European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung**

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Foreword

Method for the development of healthcare messages

This CEN Report has been prepared under the direction of the European Committee for Standardisation (CEN) and is being submitted for approval by CEN/TC251 "Medical Informatics".

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Introduction

The main goal of WG3 is to develop standardised healthcare EDI messages. To ensure the overall consistency and coherence between the various standard messages (to be) developed, it is important that the message development activities conducted in a variety of domains are based upon the same approach and that the resulting deliverables are structured and presented consistently. The goal of this CEN Report is to describe the method to be used for the definition of character-based EDI messages to be used in healthcare, as currently no adequate method exists for this purpose¹.

The method builds upon and extends the approach as defined and used so far by WG3 (see CR 1350:1993 and the European Prestandard for the messages for exchange of laboratory information), and contains the following main components:

- establishment of the user requirements in the selected healthcare messaging domain.
- both an informal and formal specification of the messaging scenarios. This includes the definition of the communication roles, the messaging services (functions) to be supported by these roles and the major interrelationships between the EDI message types required to cover the needs for a particular domain.
- the formal definition of the information that is shared between the communication roles, through the Domain Information Model.
- the formal definition of the messages required to support the information exchange needs (General Message Descriptions), independently of the EDI-syntax used for the implementation.
- how to translate the General Message Descriptions into hierarchical structure specifications for implementation using a standard EDI-syntax,
- how to develop Implementable Message Specifications using a standard EDI-syntax (e.g. ASN.1 and EDIFACT).

The report specifies the method to be used by CEN/TC 251/WG3 in particular, but the underlying principles may be used by other CEN/TC 251 working groups and even outside the healthcare messaging domain.

The main clauses are clause 4 and 5. Clause 4 is a summary of the overall activities in the context of the development of standard messages, clause 5 defines each activity covered by the scope of this report in detail.

The annexes deal with issues arising related to the approach:

- annex A positions the message development approach in the context of the overall healthcare communications framework and in the overall context of standards,
- annex B describes a number of management issues related to the message development process (iteration, process management, quality assurance activities, project team organisation),
- annex C defines the attribute data types, used for the specification of the messages, in detail.
- annex D gives 2 additional approaches for the transformation of an object-oriented general message description into a hierarchical general message description.
- annex E deals with the aspects when moving to implementation (mainly profiling, i.e. customisation of the message specifications towards local implementation needs).
- annex F clarifies the scope of this method when considered in the context of more tightly coupled systems.
- annex G is a paradigm annex on how to read the models included in messaging standards based upon this approach

¹ Most methods are oriented towards the development of systems. This approach aims specifically at the definition of standardised EDI messages, in such a way that these specifications are complete, independent on the underlying implementations (implying a longer life-cycle for the specifications), easy to understand by the end-users and usable towards system developers.

- annex H is an executive summary of the approach.

How to read and use this document:

If you are new to the work of CEN/TC 251/WG3, and if you want to get the essential information about the way the Working Group develops standardised messages: after this introduction:

1. annex A,
2. annex H (executive summary)
3. clause 1 (scope),
4. clause 4 (message development overview).

If you know a little about the approach as used by the Working Group, and if you want to get more familiar with it:

1. annex A,
2. clause 1 (scope),
3. clause 4 (message development overview) or annex F (executive summary)
4. clause 5 (detailed message development activity description) or annex G (summary of symbols).

If you are knowledgeable about the approach and the activities of CEN/TC 251/WG3, and if you want to apply it for a specific message development task:

1. clause 1 (scope),
2. clause 4 (message development overview),
3. clause 5 (detailed message development activity description),
4. annex B (message development process management issues),
5. use annex C for issues arising related to attribute data types,
6. use annex D for the troubleshooting related to the construction of hierarchical GMDs,
7. use annex E for the modification of the resulting message specifications to more local information exchange needs,

If you want to use the deliverables resulting from a message development group which followed the approach:

1. annex H (executive summary),
2. clause 4 (message development overview),
3. clause 5 (detailed message development activity description) or annex G (summary of symbols).

1. Scope.

The scope of this CEN report is to specify a method for the development of European Standard message specifications for the electronic exchange of structured character-based information, between autonomous computer systems within and between organisations, for purposes related to healthcare. Such message standards are essential if healthcare services are to obtain the benefits of open systems and avoid the constraints of proprietary interfaces. The method specifies the activities of the message development process and the structure and the components of the resulting deliverables.

The scope of this report does not include method specifications for the development of other subject areas covered by working groups of CEN/TC 251, EWOS EG-MED and WEEB/MD9.

The scope covers the development process of standardised messages, starting from the user requirements up to the delivery of message specifications using EDIFACT and ASN.1, the two international syntax standards selected in view of CR 1350:1993, but the report does not exclude other syntaxes (e.g. SGML) from being used for the syntax specific message specifications.

The scope of the Report is limited to the specification of standardised messages, therefore it does not include in its scope areas such as conformance testing of messaging applications, the implementation method for messaging standards, the maintenance of the messaging standards. It does not include in its scope issues relating to data secrecy and data protection. It does not specify methods for establishing directories of coding schemes, for data sets or for messages. It does not include specifications related to the messaging standards approval process.

The method defined by this CEN Report supports and is validated for the development of message specifications for the electronic exchange of structured character-based information in healthcare, but it does not by its nature exclude the method to be used in a wider domain (i.e. other types of information or other domains).

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