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HEALTH INFORMATICS - ELECTRONIC HEALTHCARE RECORD COMMUNICATION - PART 3: DISTRIBUTION RULES

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English version

Health informatics - Electronic healthcare record communication - Part 3: Distribution rules

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by SIS.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

This is Part 3 of a multipart standard on *Electronic Healthcare Record Communication*.

The multipart standard consists of the following parts:

- Part 1: Extended Architecture
- Part 2: Domain Term List
- Part 3: Distribution Rules
- Part 4: Messages for the Exchange of information

This Prestandard was drafted using the conventions of the ISO/IEC directive part 3.

All annexes are informative.

Introduction

The need to distribute electronic healthcare records in whole or in part, whilst at the same time preserving security principles, has been the prime motivation behind the writing of this part European prestandard. However, the need for the opportunity for the subject of care to take a central role in their electronic healthcare record or its components being distributed both within and outside an information system to potential data users has taken priority over all other issues. The EU Data Protection Directive [95/46/EC] and the Council of Europe Recommendation on the Protection of Medical Data R(97)5 have also been central to the development of these distribution rules.

Serious consideration has been given to handling problems of access, not only to read from an electronic healthcare record but also to add information from within the same care team and document correctly. The problems are closely related since in many cases there are two systems interacting: one sending and the other receiving information.

This part European prestandard does not define the rules themselves (e.g. who should have access to what), these needing to be determined by local users, national guidelines and legislation. However it does define some of the requirements in relation to the architecture of the information system and in particular architectural component as described in part one of this four part European prestandard. It also places certain requirements on the functioning of information systems complying with this architecture and this part European prestandard in particular. These requirements when fulfilled enable compliance with the distribution rules defined by the data controller of the electronic healthcare record.

Distribution rules are a controlling mechanism, enabling access to and/or further distribution of the components to which they are attributed. Under the provisions and requirements of this European prestandard if a distribution rule is present then the data cannot be accessed or distributed unless the provisions of the rule are complied with. As a consequence it is possible to implement the distribution rules principles in such a fashion that the data may become unavailable thereafter. For both legal and healthcare reasons this should be prevented by the application of “fall back” rules with a “super user” type of access that will grant access to all data stored within the information system.

In order to provide the necessary flexibility required by the user community and avoid simple hierarchical constructs it is intended that where multiple distribution rules are present, they are processed individually and not as a combination. This method will provide for interoperability across country borders without weakening the rights of the subject of care. As a safeguard an access log has been included to ensure that if, for auditing or legal purposes, information is required on the distribution of data under the provision of distribution rules then this can be recreated in full. This access log and its entries are not intended to be communicated outside the information system to which it relates other than rendered in human viewable format.

If, for example, a data user be granted the privilege of having data distributed to them under the terms of a distribution rule that grants the right to modify or add to the architectural component covered by the rule then a

new version of those components is created. This new version may have further distribution rules added to it to provide for the new information needs. Version control within the architecture, as defined in part one of this four part European prestandard, provides for full recreation of the audit trail when used in conjunction with the relevant access log entry.

In clause 5, a set of data objects are shown that can be used to define rules that when implemented are interactive with other components and functions in an information system to control the distribution of data. Vendors are free to implement the distribution rules as they find best suited for their system, but they will have to follow the specifications in this document, including the data type definitions, when a distribution rule is distributed outside the originating electronic healthcare record system.

Annex A (Informative) shows the data structures when rendered into human viewable format for legal recreation and audit purposes outside the automated components of an information system.

Throughout this document Unified Modeling Language (UML) has been used. Reference is made to this technique in the Bibliography annex.

When national profiles are created using this European prestandard, then whilst the mandatory elements prescribed within the data objects will need to be included, the presence of optional elements within the national profile are left to national discretion.

If transnational interoperability is required, then all attributes are necessary and this European prestandard will need to be implemented in its entirety.