BioHealth

Encouraging the Use of eHealth

Security and Identity Management

Standards

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BioHealth

- Initiated by Members of EFMI WG Cards
  - To enforce the use of security standards in eHealth
  - To provide feedback to SDOs on user requirements
  - To identify obstacles / channel “calls for actions” and provide feedback to the European Council
  - To inform on new security technologies in healthcare
- Funded by the European Commission in Europe INNOVA
Europe INNOVA

„The Network driving Europe’s Innovation“

- Aims at SMEs
- Develop new indicators and innovation models
- Cluster mapping to identify growing, declining and emerging business clusters on a statistical basis in a region
- Seeking ways for effective innovation financing
- Facilitating innovation management
- Europe Innova Standards’ Network
  - Demonstrating the competitive advantages of applying standards

http://www.europe-innova.org
Small and Medium Enterprises

- Definition SME: < 250 employees.
- 23 million SMEs in the EU provide around 75 million jobs and account for 99% of all enterprises.
- SMEs employ in the private sector 66% of E-25’s working force.
- SMEs account for 57% of the added value within Europe. Europe’s health sector employs 9.3% of the EC’s workforce.
- Europe’s health sector worth > 8.5% of its gross domestic product.
- The estimated size of the European eHealth market is €20 billion.
* **eHealth Lead Market Initiative 7.1.2008** MEMO/08/5
* Action Plan for European Standardisation 15.3.2007
* **M/403 EN Brussels, 6.3.2007: Mandate to the European SDOs**
* “Lisbon strategy for growth and jobs” Lisbon March 2000
Market for innovative products and services with high growth potential (R&D & innovation intensive, based on increasing public and private customer need/demand)

Where EU industry can develop competitive advantage to lead in international markets (EU knowledge and industrial basis to capitalise on investments in promising new technologies).

That requires action by the public authorities (as a regulator lifting obstacles, as a customer driving developments, as a facilitator).

Definition: EC - DG Enterprise
Standards

- Play a crucial role in the definition of market conditions.
- Help reduce the costs of the development.
- Facilitate meeting specific needs of the European market. Increase competitiveness.
- Remove barriers of trade at international level.

Enhance Innovation

Funded by the European Commission
Challenges

WG I Information Models
WG IV Technology for Interoperability
WG II Terminology and Knowledge Bases
WG III Security, Safety and Quality
Task Force Cards

WG 1 Health Records
WG 2 Messaging and Communication
WG 3 Health Concept Representation
WG 4 Security
WG 5 Health Cards

www.centc251.org
www.iso.ch/meme/tc215

Funded by the European Commission
Goals BioHealth

- Facilitate and enforce the use of security related standards in eHealth by
  - informing on security, standards and standardisation issues
  - enabling the access to the standards
    - user-friendly information
    - access information on standards
    - guidelines on standards
- Watch critically the introduction of new tools in eHealth safety and security and in ID management
Fact Finding and increased information
Community building and awareness raising
Dissemination
Strategy - SDOs

- Informing SDOs on
  - Gaps in security, safety, and privacy standardisation for eHealth
  - Special European requirements in eHealth security

- in
  - Harmonisation Meetings
  - SDO Working Groups

Funded by the European Commission
Informing on

- Data security,
- data protection, privacy,
- identity management
- new technologies and on critical issues connected to these

on the BioHealth portal
BioHealth

Security and Identity Management Standards in eHealth Including Biometrics - Specific Requirements having an Impact on the European Society and on Standardisation

The BioHealth project deals with security related standardisation in eHealth. It addresses all those concerned with eHealth; those working in healthcare as well as patients and citizens; healthcare insurers as well as governmental bodies or healthcare industry.

One of our objectives is to create an open environment that supports the promotion of standardisation results from standard committees to policy makers and to stakeholders.

BioHealth is informing you on relevant standardisation activities as well as on the standards. Guidelines will be set up providing support on their implementation. Good practices will also be shown.

We are close to the standardisation committees and committee experts and want to enable a maximum level of feedback from stakeholders in Europe into the relevant standardisation committees, so that their activities represent the broadest possible consensus.

BioHealth is sponsored by Europe Innova, a European innovation policy initiative in the context of the EC DG Enterprise and Industry. The end of the project’s activities is foreseen in August 2006.

The information is growing with the progress of the project. So, please check these pages regularly.

WE INVITE YOU TO TEST THE BIOHEALTH STANDARDS’ REPOSITORY

The BioHealth Standards’ Repository provides a directory of security and identity management standards relevant to eHealth published by European and international organisations such as CEN, ISO, ETSI, ASTM, etc. The description of the standards helps you decide whether a standard is of use to you.

You may search the directory by certain predefined categories such as potential and actual use or type of standard, but you can also search by typing in keywords. The result of your search is a catalogue of the relevant standards displaying standard references and the English titles. You can expand this entry to see further details such as a detailed description of each standard, the year of publication, category, function, actual and potential use and a link to the publishing organisation.
STANDARDISATION

ABOUT THE ISO/IEC INFORMATION CENTRE

The ISO/IEC Information Centre is jointly operated by ISO, the International Organization for Standardization, and IEC, the International Electrotechnical Commission. Its objective is to provide stakeholders with information about standardization, standards and related matters. This site of the ISO/IEC Information Centre serves as a portal to the main information given on various pages of the ISO and IEC Web sites e.g. the ISO and IEC Catalogues, provides an enquiry service for users and gives access to the Web sites of national standards organizations via WSSN, the World Standards Services Network. The Web site also provides information on the relationship between WTO, ISO and IEC with regard to world trade and on standardizing bodies which have accepted the WTO TBT Code of Good Practice for the Preparation, Adoption and Application of standards. In addition, the site contains and provides access to reference publications on standard development, distribution and use and on information sources.

AIM - Association for Identification and Mobility

AIM is a global trade association comprising providers of components, networks, systems, and services that manage the collection and integration of data with information management systems.

American National Standards Institute (ANSI)

The American National Standards Institute (ANSI) coordinates the development and use of voluntary consensus standards in the United States and represents the needs and views of U.S. stakeholders in standardization forums around the globe.

ASTM Committee E31 on Healthcare Informatics

ASTM Committee E31 on Healthcare Informatics develops standards related to the architecture, content, storage, security, confidentiality, functionality, and communication of information used within healthcare and healthcare decision making, including patient-specific information and knowledge.

Basis for European standardisation  "EC"

The legal basis for European standardisation, including the ICT domain, is Directive 98/34/EC.

CDISC - Clinical Data Interchange Standards Consortium

CDISC is an open, multidisciplinary, non-profit organization committed to the development of industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trial data and metadata for medical and biopharmaceutical product development. The mission of CDISC is to lead the development of global, vendor-neutral, platform independent standards to improve data quality and accelerate product development in our industry.

CEN - eHealth Focus Group

The CEN/ISSS eHealth Standardisation Focus Group has been set up at the end of 2003 in...
Biometrics in Hospitals

- Contamination
- Gloves
- Hands used to transport materials
- Accessibility
- Emergency
Recommendations

- Knowledge of RFID tags
- Legal restrictions on secret RFID tagging of consumer goods
- Possibility to deactivate tags
- Ethical obligations
- Unique identity for each case of use
- Apply security measures, e.g. mechanisms to deactivate RFID tags
Strategy - stakeholders

- Providing information and expert advice to developers, hospital managers and politicians on
  - Standardisation related to eHealth security
  - eHealth security & identity management standards and support for their implementation
  - Results of ongoing standardisation efforts
- Facilitating the use and practical implementation of standards via
  - BioHealth Repository: Online directory of standards relevant for eHealth (see next 2 slides)
  - New items for standardisation identified and reported to SDOs
Results: Information

- Report on current eHealth security & identity management standards
- Report on existing safety standards for authentication devices (in process)
- Report on potential physical implications caused by the biometric devices
- Newsletters on specific topics

repository via the BioHealth portal after registration
<table>
<thead>
<tr>
<th></th>
<th>Standard Number</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>[+]</td>
<td>CEN EN 13606:2006</td>
<td>Electronic health record communication</td>
<td></td>
</tr>
<tr>
<td>[+]</td>
<td>ASTM E1715-01</td>
<td>An object-oriented model for registration, admitting, discharge, and transfer functions in computer-based patient record</td>
<td></td>
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<tr>
<td>[+]</td>
<td>CEN EN 13940-1:2006</td>
<td>System of concepts to support continuity of care - Part 1: Basic concepts</td>
<td></td>
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<td>[+]</td>
<td>ISO TR 21089:2004</td>
<td>Trusted end-to-end information flows</td>
<td></td>
</tr>
<tr>
<td>[+]</td>
<td>ISO IEC 9796</td>
<td>Information technology - Security techniques - Digital signature schemes giving message recovery</td>
<td></td>
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<tr>
<td>[+]</td>
<td>ETSI SR 002 176</td>
<td>Electronic Signatures and Infrastructures (ESI); Algorithms and Parameters for Secure Electronic Signatures</td>
<td></td>
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<tr>
<td>[+]</td>
<td>ETSI TS 102 176 V1.2.1</td>
<td>Electronic Signatures and Infrastructures (ESI); Algorithms and Parameters for Secure Electronic Signatures</td>
<td></td>
</tr>
<tr>
<td>[+]</td>
<td>ETSI TR 102 038 V1.1.1</td>
<td>TC Security - Electronic Signatures and Infrastructures (ESI); XML format for signature policies</td>
<td></td>
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<td>[-]</td>
<td>CEN EN 13940-1:2006</td>
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<td>-----</td>
<td>-------------------</td>
<td>---------------------------------------------------------------------</td>
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<tr>
<td>Published</td>
<td>2006</td>
<td>Type</td>
<td>International Standard</td>
</tr>
<tr>
<td>Comment</td>
<td>Defines the classes of concepts and their descriptive terms regarding all processes of care, especially considering patient centred continuity of care, shared care and seamless care.</td>
<td></td>
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</tbody>
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<tr>
<td>Published</td>
<td>2004</td>
<td>Type</td>
<td>Technical Report (TR)</td>
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<tr>
<td>Comment</td>
<td>This standard offers a guide to trusted end-to-end information flow for health(care) records and to the key trace points and audit events in the electronic entity/act record lifecycle (from point of record origination to each ultimate point of record access/use). It also offers recommendations regarding the trace/audit detail relevant to each.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comment</td>
<td>This standard offers recommendations of best practice for healthcare providers, health record stewards, software developers and vendors, end users and other stakeholders, including patients.</td>
<td></td>
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<tr>
<td>Published</td>
<td>-</td>
<td>Type</td>
<td>International Standard</td>
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<tr>
<td>Comment</td>
<td>This standard describes the creation of a single signature using the private key. It</td>
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### BIOHEALTH REPOSITORY - STANDARDISATION ITEM DETAILS

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<th>Abbreviation</th>
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<td>Name</td>
<td>Information technology - Security techniques - Digital signature schemes giving message recovery</td>
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<tr>
<td>Type</td>
<td>International Standard</td>
</tr>
<tr>
<td>Publisher</td>
<td>ISO</td>
</tr>
<tr>
<td>Other Publisher</td>
<td>IEC</td>
</tr>
<tr>
<td>Source</td>
<td><a href="http://www.iso.org">http://www.iso.org</a></td>
</tr>
<tr>
<td>Description</td>
<td>This standard describes the creation of a single signature using the private key. It is an alternative to the RSADSI Public Key Cryptography Standards (PKCS). It is a version of the RSA algorithm but it includes other features such as padding and bit mixing to counter attacks on small subject values.</td>
</tr>
<tr>
<td>Function</td>
<td>-</td>
</tr>
<tr>
<td>Potential And Actual Use</td>
<td>Electronic Signatures + Security techniques</td>
</tr>
<tr>
<td>Category</td>
<td>Communication Standards</td>
</tr>
<tr>
<td>Status</td>
<td>international standard</td>
</tr>
<tr>
<td>Published</td>
<td>-</td>
</tr>
<tr>
<td>Stakeholders</td>
<td>Healthcare authority + IT Developer + Security manager + Service provider + Software Developer</td>
</tr>
<tr>
<td>Comment</td>
<td>This standard consists of 2 parts (part 1 was withdrawn): Part 1: Integer factorization based mechanisms Part 2: Discrete Logarithm based mechanisms</td>
</tr>
</tbody>
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[Give Feedback](#)
Community Building/ Informing the user

- National and Regional Meetings
  - Setting up meetings and information activities on regional, national and trans-national level
- Organisation of Networking Meetings
  - Prague, December 2006
  - Tallinn, June 2008
- Formation of Stakeholder Groups
  - Guidelines on the standardisation activities, their implementation and how to gain maximum benefit
- Dissemination
  - Project Presentation, BioHealth Portal, Publications, Posters
Community building and awareness raising

- BioHealth held over 30 informative sessions at national and regional meetings and conferences
- More than 20 presentations, 4 publications, and 4 posters are available
- 2 Networking Meetings (1 in process) and 6 international workshops (2 more in process) were/are being organised
- Regular exchange with stakeholder groups
- Two lectures on eHealth standardisation are being introduced in the curriculum of the university degree for hospital managers at the Semmelweiss University, Budapest
- BioHealth portal

BioHealth Seminar at the European Parliament 15.10.2007

Funded by the European Commission

HelmholtzZentrum münchen
German Research Center for Environmental Health
Results: Supporting implementation

- Guidelines (in process)
- Report on identity management products & implementation in eHealth security standards
- Giving account on the results of existing standardisation efforts
- Report on identity management products & implementation
  Training material on eHealth standardisation (in process)
- Concept of hosting (e)EHIC within NFC mobile handset or PPD has been adopted into CEN/ISSS WS/eEHIC
- Negotiation on the implementation of identity management and tracking measures for blood bottles (in process)
Results: Supporting standardisation

- Biometric Safety Compliance Template (in process)
- Educating Hungarian hospital managers on security standardisation
- Demonstrating standardisation in use cases and scenarios (in process)
- Missing standards identified, new work items initiated
- DG Enterprise and Industry Directorate-General recommends to meet the standardisation needs identified by BioHealth (see 2008 ICT Standardisation Programme)
- Use and sustainability of the BioHealth Repository are being negotiated within and outside of the Consortium
Consortium

- HelmholtzZentrum München - German Research Center for Environmental Health, Neuherberg (Munich) – Co-ordinator
- Bull Hungary, Budapest
- eHealth Competence Center, University of Regensburg, Regensburg
- IMA - Institute of Microelectronic Applications, Prague
- ITS Norway, Oslo
- National Research Council of Italy, Naples
Further information at

www.bio-health.eu

and

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