

ISO/TC215, Health Informatics
29th ISO/TC215 Meeting
Closing Plenary Report
Maringá, Brazil
4 May 2018

WG4 : Health Informatics
Privacy, Security and Safety
Lori Reed-Fourquet, WG4 Convenor
Hideyuki Miyohara, WG4 Vice Convenor
Diana Warner, WG4 Secretary

Meeting Overview



- 21 Attendees
- 9 Countries
- 1 Liaison in attendance (TC292)

Strategic Planning

Published Since Liverpool



- ISO/TC 215 TS 20405 Health informatics --
Framework of event data and reporting
definitions for the safety of health software

Strategic Planning



- ISO DTS 11633-1, Information security management for remote maintenance of medical devices and medical information systems -- Part 1: Requirements and risk analysis

Comments resolved,

Fix editorial errors, then after completing the WG member review, proceed to publication.

Strategic Planning

Continuing Work



- NP22697 Application of privacy management to personal health information
 - NP Comments resolved
 - Continue Draft Development
- NP22696 Guidance for identification and authentication for connectable personal healthcare devices
 - NP Comments resolved
 - Continue Draft Development
 - Request review from WG 4 to JWG 7:see resolution

Strategic Planning



- Upcoming SR
 - ISO/SR 17090-3 Health informatics -- Public key infrastructure -- Part 3: Policy management of certification authority
 - WG4 confirmed that no correction is necessary
 - ISO/SR 17090-1 Health informatics -- Public key infrastructure -- Part 1: Overview of digital certificate services
 - WG4 confirmed that no correction is necessary
 - ISO/SR 21549 Health informatics – Patient healthcard data -- Part 1: General structure
 - WG4 confirmed that no correction is necessary

Strategic Planning

Continuing Work



- SR 27789 Audit trails for electronic health records
 - Continue Draft Development
 - Input the situation to HL7 Security WG in HL 7 WGM to be held in May 2018.
- ISO/PWI TR 11633-2 Health informatics -- Information security management for remote maintenance of medical devices and medical information systems -- Part 2: Implementation of an information security management system (ISMS)
 - Do not change scope
 - Since the contents of 11633-1 have been fixed, drafting work is started

Strategic Planning Liaisons Report



- TC292
 - Related topics do not currently exist
- JTC1SC27
 - Because liaison members are missing, only confirmation by report was carried out, but there is no big movement.

Thank You



Many thanks to our host
for a productive venue!

Resolutions



Ms. Warner to present Master Resolution Document

Resolutions



- **2018-32:** ISO/TC215 resolves to Approve ISO/NP 17090-4 *Health informatics - Public key infrastructure -- Part 4: Digital Signatures for healthcare documents* for an 8-week CD ballot by 25 June 2018.
 - *Objections: None*
 - *Abstentions: Italy, Switzerland*
 - *Discussion: None*
 - *Motion: **Approved***
- **2018-33:** ISO/TC215 resolves to Approve ISO NP 21332 *Cloud computing considerations for health information systems security and privacy* for a 4-week CIB ballot to approve the revised scope.
 - *Objections: None*
 - *Abstentions: Italy, Switzerland*
 - *Discussion: None*
 - *Motion: **Approved***
- **2018-34:** ISO/TC215 resolves to Approve ISO/NP 22696 *Health informatics -- Guidance for identification and authentication for connectable personal healthcare devices* for a 4-week JWG7 consultation by 25 June 2018.
 - *Objections: None*
 - *Abstentions: Italy, Switzerland*
 - *Discussion: None*
 - *Motion: **Approved***