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Background: We are pleased to post ISO/TC215-N2144 which is the updated Resolutions document from the 26th meeting of ISO/TC 215, Health Informatics which met 17 November 2015 in Lillehammer, Norway. Please inform the ISO/TC215 Secretariat of necessary corrections by 30 November 2016. Additional meeting documents (e.g., Closing Plenary report and WG/JWG presentations) will be posted shortly. Thank you.

Committee URL: http://isotc.iso.org/livelink/livelink/open/tc215
N2144 – Lillehammer RESOLUTIONS
(Replaced review version N2142)
26th meeting of ISO/TC 215, Health Informatics
17 November 2016  |  Lillehammer, Norway

RESOLUTIONS OFFICE OF THE ISO/TC215 SECRETARIAT


Further to Vienna 2012 TC215 Resolution 60 requiring the use of the Standards Knowledge Management Tool (SKMT) for the identification and use of relevant terms and the entry of relevant project metadata and, also, in relation to use of the ISO Online Browsing Platform (ISO OBP), TC215 approves *trialling* of the following process:

1. As early as possible and no later than 4 weeks after a new work item is approved, the project leader shall ensure that the new work item is registered in the SKMT along with metadata describing the new work item. **Task 1 was approved with the agreement that assistance is available from SKMT leads (Heather Grain and Andrew Grant) and TC Secretariat.**

2. Before a draft document is first submitted for CD, DTR, DTS or DIS ballot the project leader shall confirm that the proposed terms and definitions in the draft document have been checked to determine whether they are inconsistent with related terms and definitions in the ISO OBP and the SKMT. **Task 2 is optional at this time, but is strongly encouraged.**

3. Before the final text of a document is delivered to the TC215 Secretariat for publication the project leader shall confirm that all terms and definitions in the document are entered in SKMT with “Candidate” or “Standard” status. **Task 3 is optional at this time, but is strongly encouraged.**

4. The project leader for each project (‘Project’) approved and in current development shall confirm to the TC215 Secretariat by 28 February 2017 whether the Project and its current metadata are correctly reflected in SKMT. **Task 4 is optional at this time, but is strongly encouraged.**

5. ISO/TC215 working groups are encouraged to register preliminary work items and their metadata in SKMT to ensure that they are visible to others. **Task 5 is optional at this time, but strongly encouraged.**

6. Where the nature of a preliminary work item (‘PWI’) or approved project (‘Project’) changes the responsible working group or project leader shall ensure that the metadata for the PWI/Project is updated to reflect the changed nature of the PWI/Project. **Task 6 is optional at this time, but strongly encouraged.**

7. At the Preparatory or Committee Stage (i.e. prior to CD, CD, DTR, DTS or DIS ballot) project leaders are encouraged to ensure that proposed terms and definitions have been entered in SKMT with “Pending” status to ensure that they are visible to others. **Task 7 is optional at this time, but strongly encouraged.**

**Overview Discussion Notes**

− There was extended discussion regarding whether or not the SKMT tool and processes are ready for SMEs to be able to easily use. The SKMT leads (Ms. Heather Grain and Dr. Andrew Grant) feel that the education and tools are generally ready and have been available for some time.

− There is support for use of SKMT in TC215. However, it was noted that it is important consider that our SMEs are extremely busy volunteers and have not had the time and bandwidth to take the time to understand and learn SKMT.

− The outcome of the discussion includes the following four points:
1. TC215 members generally support increased use of SKMT over time provided appropriate education and training resources are available. However, there was agreement to ask project leads to, henceforth, register approved new work items into SKMT. The TC215 Secretariat will work with the project leads to facilitate new project entry.

2. WG3 has volunteered to run a defined pilot, in conjunction with SKMT Governance Committee and report (a) outcomes (b) open issues and (c) next steps back to the TC before the April 2017 China meeting.

3. WG3 is has embedded the following language into some of the WG3 Resolutions with the potential that similar guidance would be included in future TC215 Resolutions.

   a. **Note**: This language is specific to WG3 to which they have agreed. "c) confirmation the project is registered in the SKMT with appropriate metadata, and (d) confirmation all proposed terms and definitions have been checked against those in the ISO OBP and the SKMT."

**ISO Online Browsing Platform (OBP): [https://www.iso.org/obp/ui/](https://www.iso.org/obp/ui/)

(From Vienna 2012 resolutions)

60. Regarding the Use of SKMT—Resolved that ISO/TC215

TC 215 instructs all TC 215 Project Editors to examine the SKMT for relevant glossary terms early in the drafting process, and where appropriate, consider using terms and definitions already entered into the SKMT. For each project ensure that all relevant metadata is entered into SKMT prior to forwarding for ballot. Unanimous

Objections: As noted. Abstentions: None Discussion: See above inline Motion: APPROVED as noted

Lillehammer 2016 ISO/TC215 Resolution 52 [Secretariat-R02 Lillehammer] establishes a new Traditional Medicines Task Force (TMsTF); pursuant to 2014/ISOTC215 Berlin Resolution 56 [WG3-R06]

ISO/TC215;

— disbands the WG3 Traditional Medicine Task Force under WG3;
— establishes a new Traditional Medicines Task Force (TMsTF) under ISO/TC215;
— retains Dr. Khadzir (Malaysia/DSM) as chair and Dr. Haiyan Li (China/SAC) as secretary, until the new TMsTF is disbanded and the new TMs Work Group (WG) is established;
— instructs TC215 Secretary to issue a:
   o call for P members to join the new TC215 TMsTF (Note existing NMBs TMTF members will need to re-nominate members to the new transferred TMsTF under TC215);
   o Invite O members and will note differences in participation permissions between P & O members
   o call for new work item proposals;
— agrees that this TF will carry out the following tasks:
   o review NPs based on ISO NP review criteria (as listed in Form 4 and ISO Directives Annex C);
   o review possible projects (can be new or from existing ISOTC215 WGs) that are proposed within a 2-week period and issue decision to TC215 Secretary;
— once possible NPs are identified, TC215 secretary to launch under normal ISO NP procedures;
— if NP is approved, this triggers the formation of the TC215 Traditional Medicines Work Group and all related procedures to form a new WG;
— the TC215 secretary will then issue a call for NMB to provide a convenor and secretary to the newly formed TMs Work Group pursuant to 2014/ISOTC215 Berlin Resolution 56 [WG3-R06]

Objections: None Abstentions: Germany, Italy Discussion: None Motion: APPROVED
RESOLUTIONS CHAIRMAN’S ADVISORY GROUP 01 (CAG01)


Further to Bern 2015 ISO/TC215 Resolution 49 [CAG01-R01] Creation of an Ad-hoc Task Force to review and propose updates to the ISO/TC215 Strategic Business Plan and Amsterdam 2016 ISO/TC215 Resolution 07 [Secretariat-R07] Strategic business plan activity update and next steps, and in accordance with the outcome of the subsequent CIB ballot and the resolution of comments received;

ISO/TC215:

− Approves the updated version 4.11 of the ISO/TC215 SBP as a draft for submission to TMB and for public review, in line with ISO Directives.
− Thanks the members of the Ad-hoc Task Force and particularly its leader, Mr Jeremy Thorp (UK) for their excellent work in producing the updated SBP.
− Disbands the Ad-hoc Task Force.

Objections: None  Abstentions: None  Discussion: None  Motion: APPROVED


ISO/TC 215:

− Approves the following revised statement of TC215 scope:

  “Standardization in the field of health informatics to facilitate the capture, interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system.

  NOTE: This scope includes items that are also within the scopes of other committees; such areas will be addressed through cooperation including formal liaison relationships.”

− Notes that the proposed revision has been discussed with potentially affected committees including IEC/TC 62, IEC/SC 62A and ISO/TC 210 and incorporates wording agreed with them.

− Requests the ISO/TC215 Chair and Secretariat to submit the revised statement of TC215 scope to ISO/CS for TMB approval.

Objections: None  Abstentions: None  Discussion: None  Motion: APPROVED
RESOLUTIONS WG1: ARCHITECTURE, FRAMEWORK AND MODELS

For ISO/PWI DTR Health informatics – Methodology for enterprise business and information management needs analysis to support standards-based architectures [Vienna agreement, ISO lead]
ISO/TC215;
— approves the WG1 recommendation to progress to an 8-week NP ballot as submitted by Sweden (SIS);
— requests the project lead to provide the (a) complete form 4 and (b) text to the WG1 convenor and TC215 secretary no later than 22 December 2016;
— requests TC215 Secretary to review and submit these items to ISOCS to within 10 days of receipt of items.

Objections: None
Abstentions: US, Germany, Malaysia
Discussion: None
Motion: APPROVED
WGl Resolution 1 and 2 were voted together

Lillehammer 2016 ISO/TC215 Resolution 56 [WG1-R02 Lillehammer] ISO 13606 Parts 1, 2, 3, 4, 5 for DIS ballot
(Vienna agreement, ISO lead)
For
EN ISO 13606-1 Health informatics—Electronic health record communication—Part 1: Reference model
EN ISO 13606-2 Health informatics—Electronic health record communication—Part 2: Archetype interchange specification;
EN ISO 13606-3 Health informatics—Electronic health record communication—Part 3: Reference archetypes and term lists
EN ISO 13606-4 Health informatics—Electronic health record communication—Part 4: Security
EN ISO 13606-5 Health informatics—Electronic health record communication—Part 5: Interface specification
ISO/TC215;
— approves the recommendation of WG1 to submit all five (5) parts for DIS ballot;
— requests the project lead to provide the (a) Updated text (b) disposition of the CD comments (c) all graphics files to the WG1 convenor and TC215 Secretary no later than 24 February 2017;
— requests TC215 Secretary to review and submit these items to ISOCS to within 10 days of receipt of items.
— ISOCS will synchronize ballot cycle with CEN.

Objections: None
Abstentions: US, Germany, Malaysia
Discussion: None
Motion: APPROVED
WGl Resolution 1 and 2 were voted together

For ISO/DTS 20428 Health informatics—Metadata for describing structured clinical genomic sequence information in electronic health records [Vienna agreement, ISO lead]
ISO/TC 215;
— approves WG1 recommendation for title correction as listed;
— Current title: ISO/DTS 20428 Health informatics—Metadata for describing structured clinical genomic sequence information in electronic health records
— Change to: ISO/DTS 20428 Health informatics—Data elements and their metadata for describing structured clinical genomic sequence information in electronic health records
— requests the TC215 secretary to submit title change to ISOCS no later than 10 December 2016.

Objections: None
Abstentions: Malaysia, Switzerland
Discussion: None
Motion: APPROVED
WGl Resolutions 57, 58, 59 were voted as a block
**Lillehammer 2016 ISO/TC215 Resolution 58 (WG1-R04 Lillehammer)**
ISO/DTS 20428–submission for publication

*For ISO/DTS 20428 Health informatics—Metadata for describing structured clinical genomic sequence information in electronic health records* *(note new title Resolution above)* *(Vienna agreement, ISO lead)*

ISO/TC 215;
- approves the recommendation of WG1 of DTS with new title and revised text and updated disposition of comments be circulated to the TC for a 4-week review;
- requests the project lead to provide (a) updated text (b) disposition of DTS comments (c) all graphics files to the WG1 convener and TC215 secretary no later than **15 December 2016**;
- requests the TC215 secretary to circulate the documents to the TC within 10 days of receipt of materials;
- if there are no complaints or comments, the revised text and comments will be submitted for publication.
- requests TC215 Secretary to review and submit these items to ISOCS to within 10 days of receipt of items.

**Objections:** None  
**Abstentions:** Malaysia, Switzerland  
**Discussion:** None  
**Motion:** APPROVED

WG1 Resolutions 57, 58, 59 were voted as a block

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**Lillehammer 2016 ISO/TC215 Resolution 59 (WG1-R05 Lillehammer)**
ISO/DTR 19669 submission for publication

*For ISO/DTR 19669 Health informatics—Reusable component strategy for Use case development*

ISO/TC215;
- approves the recommendation of WG1 that ISO/DTR 19669 with its revised text and updated disposition of comments be circulated to the TC for a 4-week review;
- requests the project lead to provide (a) updated text (b) disposition of DTR comments (c) all graphics files to the WG1 convener and TC215 secretary no later than **15 January 2017**;
- requests the TC215 secretary to circulate the documents to the TC within 10 days of receipt of materials;
- if there are no complaints or comments, the revised text and comments will be submitted for publication.
- requests the TC215 secretary to submit the materials to ISOCS for publication preparation within 10 days of final TC approval.

**Objections:** None  
**Abstentions:** Malaysia, Switzerland  
**Discussion:** None  
**Motion:** APPROVED

WG1 Resolutions 57, 58, 59 were voted as a block
RESOLUTIONS WG2: SYSTEM AND DEVICE INTEROPERABILITY

Lillehammer 2016/TC215 Resolution 60 [WG2-R01 Lillehammer] Create Ad Hoc group on Health Informatics for Aging Communities;
ISO/TC215;
— approves the WG2 recommendation to create an Ad Hoc Group on Health Informatics for Aging Communities;
— to create a report “Health Informatics for Aging Communities” to be presented 1-year from now in Liverpool and to progress this work in coordination with WG1 and other TC215 SMEs;
— work in active liaison participation with Continua Health Alliance, IEC SyC AAL, JTC1 and others;
— appoint Group Leads Mr. Todd Cooper (US/ANSI) and Professor Il Kon Kim (Korea/KATS); project coordination from Dr. Sun-Ju Ahn, Korea
— create a report to include: (1) survey of national challenges and activities; (2) catalogue representative use cases; (3) assessment of relevant technology and standards; (4) conceptual framework or model; (5) recommendations and roadmap for future work e.g. Reference Standards Portfolios (RSPs), Joint Work Items.

Objections: None  Abstentions: Italy, Malaysia  Discussion: None  Motion: APPROVED

Lillehammer 2016 ISO/TC215 Resolution 61 [WG2-R02 Lillehammer] possible Olympics EHR initiative
ISO/TC215;
— supports, in principle, the concept of a standards-based interoperability demonstration to be introduced incrementally into the Olympic Games’ Medical Services infrastructure

Objections: Abstentions: Malaysia, Germany, Netherlands, UK, Italy, China, and Switzerland
Discussion: None  Motion: APPROVED

Lillehammer 2016 ISO/TC215 Resolution 62 [WG2-R03 Lillehammer] Japan Ophthalmic Instruments Association (JOIA) Std.001 added to WG2 as a PWI
For JOIA Std.001 “Common Specification for output data of Ophthalmic Examination Equipment”
ISO/TC215 approves;
— the recommendation of WG2 to add this item as a PWI to the WG2 work program.

Objections: None  Abstentions: Malaysia, Italy, UK, Canada, Switzerland, China
Discussion: None  Motion: APPROVED

Lillehammer 2016 ISO/TC215 Resolution 63 [WG2-R04 Lillehammer] Japanese Industrial Standards Committee (JISC) proposal to submit an item to standardize laparoscope/endoscope intervention added to WG2 as a PWI – informatics term needed
For JISC proposal to submit a standard for laparoscope/endoscope intervention description
ISO/TC215 approves;
— the recommendation of WG2 to add this item as a PWI to the WG2 work program.
— Informatics description needed – consult with JISC for clarification

Objections: None  Abstentions: Malaysia, China, Italy, Canada, Switzerland, Australia
Discussion: There is a need to clearly add the informatics aspects of this project to the title. There is additional information and this will be added to the PWI information.  Motion: APPROVED
Lillehammer 2016 ISO/TC215 Resolution 64 [WG2-R05 Lillehammer] proposal to submit ISO/TS 22077-5 Health Informatics – Medical Waveform format Part 5: EEG added to WG2 as a PWI

For ISO/TS 22077-5 Health Informatics – Medical Waveform format Part 5: Electroencephalography (EEG)

ISO/TC215 approves:

— the recommendation of WG2 to add this item as a PWI to the WG2 work program.

Objections: None  Abstentions: Canada, Italy, Malaysia, Switzerland, UK  Discussion: None  Motion: APPROVED


For ISO/DTR 20055 Health informatics – Person owned document repository for PHR applications and health information exchange;

ISO/TC215:

— REQUESTS WG2 Secretariat to circulate the current updated draft and disposition of comments to WG2 and nominated experts for a 4-week WG review and feedback to the project lead;
— requests the project lead to provide (a) updated text (c) all graphics files to the WG2 convener and TC215 secretary no later than 24 January 2017;
— requests the TC215 secretary to submit the documents to ISO/CS for DTR ballot within 10 days of receipt of materials;

Objections: None  Abstentions: Italy, Malaysia, UK  Discussion: None  Motion: APPROVED

WG2 Resolutions 65, 66, and 67 voted as a block


For ISO/DTS 21089 Health Informatics – Trusted End-to-End Information Flows

ISO/TC215:

— approves the recommendation of WG2 that ISO/DTS 21089 with its revised text and updated disposition of comments be circulated to the TC for a 4-week review;
— requests the project lead to provide (a) updated text (b) disposition of DTR comments (c) all graphics files to the WG convener and TC215 secretary no later than 15 January 2017;
— requests the TC215 secretary to circulate the documents to the TC within 10 days of receipt of materials;
— if there are no complaints or comments, the revised text and comments will be submitted for publication.
— requests the TC215 secretary to submit the materials to ISOCS for publication preparation within 10 days of final TC approval.

Objections: None  Abstentions: Italy, Malaysia, UK  Discussion: None  Motion: APPROVED

WG2 Resolutions 65, 66, and 67 voted as a block

Lillehammer 2016 ISO/TC215 Resolution 67 [WG2-R08 Lillehammer] new work item to WG work program

For ISO/TR Health Informatics – Healthcare Applications of Blockchain Technologies as a PWI for WG2 Work Program

ISO/TC215 approves:

— the recommendation of WG2 to add this item as a PWI to the WG2 work program.

Objections: None  Abstentions: Italy, Malaysia, UK  Discussion: None  Motion: APPROVED

WG2 Resolutions 65, 66, and 67 voted as a block
RESOLUTIONS WG3: Semantic Content

For ISO/PWI Health informatics, Graphical Symbols
ISO/TC215:
- approves WG3 recommendation to add the PWI to the TC215 WG3 work program
Objections: None  Abstentions: UK, Switzerland, Italy  Discussion: No  Motion: APPROVED

Lillehammer TC215/2016 Resolution 69 [WG3–R02 Lillehammer] ISO submission for WG3 PWI
ISO/TC215:
- approves WG3 recommendation to add the PWI to the TC215 WG3 work program
Objections: None  Abstentions: Italy, Switzerland  Discussion: None  Motion: APPROVED

Lillehammer 2016 Resolution 70 [WG3–R03 Lillehammer] ISO/NP TS 21564 submission for 8-week CD ballot
For ISO/NP TS 21564 Health informatics, Terminology Resource Map Quality Measures (MapQual)
ISO/TC215:
— approves WG3 recommendation to progress to a 8-week CD ballot;
— requests the project lead to provide to the WG3 convenor and WG3 secretary no later than 15 December 2016: (a) the complete, approved disposition of comments, (b) updated text, requests the WG3 secretary to submit these items to the TC215 secretary by 18 December 2016;
— requests the TC215 Secretary to launch an 8-week CD ballot within 10 days of receipt of materials.
Objections: See discussion  Abstentions: None
Discussion: See discussion notes in Resolution 51 [Secretariat R01 Lillehammer] for the details of how this discussion was resolved. In brief, WG3 will run a pilot project with (a) an SME experienced with using SKMT and (b) a new user and (c) document the results and report to the TC for review at April 2017 China meeting.
Motion: APPROVED as listed in notes.

For ISO/NP 13120 Health informatics, Syntax to Represent the Content of Healthcare Classification Systems - Classification Markup Language (ClaML)
ISO/TC215:
— approves WG3 recommendation to progress to a 8-week CD ballot;
— requests the project lead to provide to the WG3 convenor and WG3 secretary no later than 24 December 2016: (a) the complete, approved disposition of comments, (b) updated text, (c)confirmation the project is registered in the SKMT with appropriate metadata, and (d) confirmation all proposed terms and definitions have been checked against those in the ISO OBP and the SKMT;
— requests the WG3 secretary to submit these items to the TC215 secretary by 10 January, 2017;
— requests the TC215 Secretary to launch an 8-week CD ballot within 10 days of receipt of materials.
Objections: None  Abstentions: None  Discussion: None  Motion: APPROVED

WG3 Resolutions 70, 71, and 72 voted as a block.
For ISO/PWI TS Health informatics, Workforce Roles and Capabilities for Terminology and Terminology Services (TermS)
ISO/TC215:
- approves WG3 recommendation to progress to a 8-week NP ballot as submitted from Canada (SCC)
- requests the project lead to provide to the WG3 secretary no later than 24 December, 2016: (a) complete and approved form 4, (b) NP text, and (c) confirmation the project is registered in the SKMT with appropriate metadata;
- requests the WG3 secretary to provide these materials to the TC215 Secretary no later than 10 January, 2017;
- requests the TC215 Secretary launch an 8-week NP/DTS ballot within 10 days of receipt of materials.

Objections: None Abstentions: None Discussion: None Motion: APPROVED

WG3 Resolutions 70, 71, and 72 voted as a block.

Lillehammer TC215/2016 Resolution 73 [WG3–R06 Lillehammer] ISO submission for an 8-week NP ballot because the scope will be expanded
For Revision of ISO 17115:2007 Health informatics, Vocabulary for Terminological Systems
ISO/TC215:
— approves WG3 recommendation to progress to a 8-week NP ballot (because the scope will be expanded);
— requests the project lead to provide to the WG3 secretary no later than 24 December, 2016: (a) complete and approved form 4, (b) NP text, and (c) confirmation the project is registered in the SKMT with appropriate metadata;
— requests the WG3 secretary to provide these materials to the TC215 Secretary no later than 10 January, 2017;
— instructs the TC215 Secretary to launch an 8-week NP ballot within 10 days of receipt of materials.

Objections: None Abstentions: None Discussion: None Motion: APPROVED

WG3 Resolutions 70, 71, and 72 voted as a block.
RESOLUTIONS WG4: PRIVACY, SAFETY & SECURITY

Lillehammer 2016/TC215 Resolution 74 [WG4-R01]: ISO/DIS 17090-5 submitted for FDIS Ballot
For ISO/DIS 17090-5 Health Informatics – Public key infrastructure – Part 5: Authentication using healthcare PKI credentials under [VA agreement, ISO lead]
ISO/TC215:
— approves WG4 recommendation to progress to 8-week FDIS;
— requests PL to update and submit the disposition of comments and updated text, and graphics to WG4 convener and WG4 secretary no later than 22 December 2016;
— requests the WG4 secretary to submit these items to the TC215 secretary by 22 December 2016;
— requests the TC215 Secretary to submit to ISO/CS within 10 days of receipt of materials.

Objections: None  Abstentions: Italy, Malaysia, Netherlands  Discussion: None  Motion: APPROVED

For ISO/TC 215 FDIS 25237 Health informatics – Pseudonymization [Vienna agreement, ISO lead]
ISO/TC215:
− approves the recommendation of WG4 that ISO/FDIS 25237 with its revised text and updated disposition of comments be circulated to the TC for a 4-week review;
− requests the project lead to provide (a) updated text (b) disposition of comments (c) all graphics files to the WG convener and TC215 secretary by 18 November 2016;
− requests the TC215 secretary to circulate the documents to the TC within 10 days of receipt of materials;
− if there are no complaints or comments, the revised text and comments will be submitted for publication;
− requests the TC215 secretary to submit the materials to ISOCS for publication preparation within 10 days of final TC approval.

Objections: None  Abstentions: Malaysia, Italy, Switzerland  Discussion: None  Motion: APPROVED

WG4 Resolutions 75, 76, 77 voted as a block

Lillehammer 2016 ISO/TC215 Resolution 76 [WG4-R03] ISO/DTR 18638 title change
For ISO/DTR 18638 Health Informatics – Components of education to ensure health information privacy
ISO/TC215;
— approves WG4 recommendation for title correction as listed;
— Current title: ISO/DTR 18638 Health Informatics – Components of education to ensure health information privacy
— Change to: ISO/DTR 18638 Health informatics – Guidance on health information privacy education in healthcare organizations
— requests the TC215 secretary to submit title change to ISO no later than 10 December 2016.

Objections: None  Abstentions: Malaysia, Italy, Switzerland  Discussion: None  Motion: APPROVED

WG4 Resolutions 75, 76, 77 voted as a block

For ISO/DTR 18638 Health informatics - Guidance on health information privacy education in healthcare organizations [noting the title change above]

ISO/TC 215;

— approves the recommendation of WG4 that ISO/DTR 18638 with its revised text and updated disposition of comments be circulated to the TC for a 4-week review;
— requests the project lead to provide (a) updated text (b) disposition of DTR comments (c) all graphics files to the WG convenor and TC215 secretary no later than 13 December 2016;
— requests the TC215 secretary to circulate the documents to the TC within 10 days of receipt of materials;
— if there are no complaints or comments, the revised text and comments will be submitted for publication.
— requests the TC215 secretary to submit the materials to ISOCS for publication preparation within 10 days of final TC approval.

Objections: None   Abstentions: Malaysia, Italy, Switzerland
Discussion: None   Motion: APPROVED

WG4 Resolutions 75, 76, 77 voted as a block
RESOLUTIONS WG6: PHARMACY AND MEDICINES BUSINESS

Lillehammer 2016 ISO/TC215 Resolution 78 [WG6-R01 Lillehammer] ISO/DTS 19293 submission for DTS ballot
For ISO/DTS 19293 Health informatics - Requirements for the record of dispense of a medicinal product [Vienna agreement, ISO lead]
ISO/TC215;
— approves the recommendation of WG6 to proceed to 8-week DTS ballot;
— requests the project leader to submit the disposition of the NP ballot comments, updated text and all images/figures and all other electronic content in revisable format to the WG6 secretary by no later than 5 December 2016;
— requests the WG6 secretary to provide these items to the TC215 secretary by 7 December 2016;
— requests TC215 Secretary to launch an 8-week DTS ballot within 10 days receipt of all requested items.

Objections: No Abstentions: Germany, Malaysia Discussion: No Motion: APPROVED

Lillehammer 2016 ISO/TC215 Resolution 79 [WG6-R02 Lillehammer] ISO 11615 submission for publication
For ISO 11615 Health informatics—Identification of Medicinal Products (IDM)—Data elements and structures for the unique identification and exchange of regulated medicinal product information [VA, ISO lead]
ISO/TC215;
— approves the recommendation of WG6 that pr EN ISO 11615 with its revised text and updated disposition of comments be circulated to the TC for a 4-week review;
— requests the project lead to provide (a) updated text (b) disposition of comments (c) all graphics files to the WG6 Secretary no later than 10 February 2017;
— requests the WG6 secretary to send to the TC215 secretary no later than 11 February 2017;
— requests the TC215 secretary to circulate the documents to the TC within 10 days of receipt of materials;
— if there are no complaints or comments, the revised text and comments will be submitted for publication;
— requests the TC215 secretary to submit the materials to ISOCS for publication preparation within 10 days of final TC approval.

Objections: No Abstentions: Discussion: No Motion: APPROVED

WG4 Resolutions 79, 80, 81, 82 voted as a block

Lillehammer 2016 ISO/TC215 Resolution 80 [WG6-R03 Lillehammer] ISO/DTS 20443 submission for publication
For ISO/DTS 20443 Health informatics — Identification of Medicinal Products (IDMP) – Implementation guide for EN-ISO 11615 Data elements and structures for the unique identification and exchange of regulated medicinal product information [VA, ISO lead]
ISO/TC215;
— approves the recommendation of WG6 that pr EN ISO/DTS 20443 with its revised text and updated disposition of comments be circulated to the TC for a 4-week review;
— requests the project lead to provide (a) updated text (b) disposition of comments (c) all graphics files to the WG6 Secretary no later than 10 February 2017;
— requests the WG6 secretary to send to the TC215 secretary no later than 11 February 2017;
— requests the TC215 secretary to circulate the documents to the TC within 10 days of receipt of materials;
— if there are no complaints or comments, the revised text and comments will be submitted for publication.
— requests the TC215 secretary to submit the materials to ISOCS for publication preparation within 10 days of final TC approval.

Objections: No Abstentions: Discussion: No Motion: APPROVED

WG4 Resolutions 79, 80, 81, 82 voted as a block
Lillehammer 2016 ISO/TC215 Resolution 81 [WG6-R04 Lillehammer] ISO/DIS 11616 submission for publication
For ISO 11616 Health informatics – Identification of Medicinal Products (IDMP) – Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information [Vienna agreement, ISO lead];
ISO/TC215:
— approves the recommendation of WG6 that pr EN ISO/DIS 16116 with its revised text and updated disposition of comments be circulated to the TC for a 4-week review;
— requests the project lead to provide (a) updated text (b) disposition of comments (c) all graphics files to the WG6 Secretary no later than 10 February 2017;
— requests the WG6 secretary to send to the TC215 secretary no later than 11 February 2017;
— requests the TC215 secretary to circulate the documents to the TC within 10 days of receipt of materials;
— if there are no complaints or comments, the revised text and comments will be submitted for publication;
— requests the TC215 secretary to submit the materials to ISOCS for publication preparation within 10 days of final TC approval.

Objections: No Abstentions: Discussion: No Motion: APPROVED
WG4 Resolutions 79, 80, 81, 82 voted as a block

Lillehammer 2016 ISO/TC215 Resolution 82 [WG6-R05 Lillehammer] ISO/DTS 20451 submission for publication
For ISO/DTS 20451 Health informatics – Identification of Medicinal Products (IDMP) – Implementation guide for EN/ISO 11616 Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information [Vienna agreement, ISO lead]
ISO/TC215:
— approves the recommendation of WG6 that pr EN ISO/DTS 20451 with its revised text and updated disposition of comments be circulated to the TC for a 4-week review;
— requests the project lead to provide (a) updated text (b) disposition of comments (c) all graphics files to the WG6 Secretary no later than 10 February 2017;
— requests the WG6 secretary to send to the TC215 secretary no later than 11 February 2017;
— requests the TC215 secretary to circulate the documents to the TC within 10 days of receipt of materials;
— if there are no complaints or comments, the revised text and comments will be submitted for publication.
— requests the TC215 secretary to submit the materials to ISOCS for publication preparation within 10 days of final TC approval.

Objections: No Abstentions: Discussion: No Motion: APPROVED
WG4 Resolutions 79, 80, 81, 82 voted as a block

For ISO/DTR 14872 Health informatics – Identification of medicinal products (IDMP) – Core principles for Maintenance of Identifiers and Terms [Vienna agreement, ISO lead]
ISO/TC215:
— approves moving from current 36 month track to 48 month track (track 3);
— requests the TC215 secretary to submit the extension request with ISO/CS by 1 December 2016.

Objections: No Abstentions: Malaysia Discussion: No Motion: APPROVED
WG4 Resolutions 83 and 84 voted as a block
ISO/TC215:
— approves the following request to CEN:
— Pending approval from CEN, due to the urgency and priority of market need for this document (ISO/TS 19844:2016 ID:70594)), ISO/TC215 requests that CEN back-adopt the ISO published standard rather than wait the additional required 12 weeks for CEN vote and ISO/TC215 review.

**Objections:** No  **Abstentions:** Malaysia  **Discussion:** No  **Motion:** APPROVED

WG4 Resolutions 83 and 84 voted as a block
RESOLUTIONS FROM ISO/TC215 JWG1: INFORMATICS OF TRADITIONAL CHINESE MEDICINE

For ISO/PWI, Health informatics--Classification of Traditional Chinese Medicine datasets;
ISO/TC215
  — approves the recommendation of JWG1 to proceed to 8-week NP ballot as submitted by SAC;
  — requests the project leader to provide (a) a complete Form4 (b) update NP working draft to the JWG1 Secretary that includes clarification about the differences of this project to ISO/TS 16277-1:2015, ISO/TS 17938:2014, ISO/TS 17948:2014, and ISO/TS 18790-1:2015 no later than 16 December 2016;
  — Requests the JWG1 secretary to provide these items to the TC 215 Secretary no later than 23 December 2016;
  — Requests the TC 215 Secretary to launch an 8-week NP ballot no later than 27 December 2016.

Objections: None  Abstentions: Canada, Denmark, Finland, Germany, Italy, Netherlands, Sweden, UK
Discussion: None  Motion: APPROVED
JWG1 Resolutions 85 and 86 voted as a block

For ISO/NP 16843-5 Categorial structures for representation of acupuncture- Part 5: Cupping;
ISO/TC215;
  — approves the recommendation of JWG1 for an 8-week DTS ballot, pending outcome of a final 4-week review in JWG1;
  — requests the Project leader to provide (a) disposition of comments from JWG1 meeting (b)updated text to the JWG1 secretary no later than 16 December 2016;
  — requests the JWG1 secretary to circulate the documents to JWG1 members for 4-week review on TC215/JWG1 ISO Livelink site no later than 23 Dec 2016;
  — If TC215/JWG1 approves updated draft and comment disposition, then;
    o requests the project leader to provide (a) complete disposition of NP ballot comments and JWG1 meeting comments (b) revised working draft to the JWG1 secretary by 2 February 2017;
    o requests the TC 215 Secretary review and launch the ballot by 10 February 2017.

Objections: None  Abstentions: Canada, Denmark, Finland, Germany, Italy, Netherlands, Sweden, UK
Discussion: None  Motion: APPROVED
JWG1 Resolutions 85 and 86 voted as a block
RESOLUTIONS JWG7: Safe, effective and secure health software and health IT systems, including those incorporating medical devices

NOTE: The following ISO/TC 215 resolutions were forwarded from the JWG7 meetings in Frankfurt, Germany, October 2016, held in conjunction with the IEC/SC 62A parent committee meeting.

Recognizing the successful NP ballot for the revision of IEC 62304:2006,
ISO/TC 215:
− notes the request of Joint Working Group 7 to add IEC 62304 (2nd ed.) to the JWG7 work programme with a new title of “Health software – Software lifecycle processes”;
− appoints Patty Krantz-Zuppen (U.S.A.) and Rich de la Cruz (U.S.A.) as project leads.

Objections: None  Abstentions: Italy, Malaysia  Discussion: None  Motion: APPROVED
JWG7 Resolutions 87, 88, 89, 90 voted as a block

Recognizing the successful NP ballot for the revision of IEC 80001-1:2010,
ISO/TC 215:
− notes the request of Joint Working Group 7 to add IEC 80001-1 (2nd ed.) to the JWG7 work programme with a new title of “Safety, effectiveness and security in the implementation and clinical use of connected medical devices or connected health software – Part 1: Application of risk management”;
− appoints Todd Cooper (U.S.A.) and Philip Raymond (U.S.A.) as project leads.

Objections: None  Abstentions: Italy, Malaysia  Discussion: None  Motion: APPROVED
JWG7 Resolutions 87, 88, 89, 90, 91 voted as a block

Lillehammer 2016 ISO/TC 215 Resolution 89 [JWG7-R03] Addition of ISO 81001-1 to the JWG7 work program
Recognizing the successful NP ballot for ISO 81001-1 “Health software and health IT systems safety, effectiveness and security – Foundational principles, concepts, and terms”,
ISO/TC 215:
− Adds ISO 81001-1 to the JWG7 work programme;
− appoints Ms. Michelle Jump (USA/ANSI) and Dr. Trish Williams (Australia/SA) as co-project leads.

Objections: None  Abstentions: Italy, Malaysia  Discussion: None  Motion: APPROVED
JWG7 Resolutions 87, 88, 89, 90, 91 voted as a block


ISO/TC215:
– Note the results of the parallel ballot of IEC/DTR 80001-2-9 and advancement of the draft (as revised) for publication as an International Technical Report.

**Objections:** None  **Abstentions:** Italy, Malaysia  **Discussion:** None  **Motion:** APPROVED

JWG7 Resolutions 87, 88, 89, 90, 91 voted as a block

Lillehammer 2016 - ISO/TC215 Resolution 91 [JWG7-R06] Recognition of Sherman Eagles

Given the notice that Mr. Sherman Eagles, JWG7 co-convener, will step down from that leadership position when his IEC/SC 62A appointment expires in 2017

ISO/TC215:
– recognizes the significant contribution that Mr. Eagles has made to both ISO/TC 215 and IEC/SC 62A;
– recognizes the key role he has played in the development of the IEC IS 80001-1 standard and the (10) 80001-2-x technical reports;
– recognizes his leadership in the ISO/TC 215 Health Software Ad Hoc Group, the development of the group’s report and the resulting standards projects that will serve the global health informatics and medical device communities for many years to come;
– expresses its enduring thankfulness for these contributions and best wishes for his well-deserved retirement.

**Objections:** None  **Abstentions:** Italy, Malaysia  **Discussion:** None  **Motion:** APPROVED

JWG7 Resolutions 87, 88, 89, 90, 91 voted as a block

The ISO/TC215 Closing Concluded at 1545pm