[DITTA STA WG] TCON
Monday 15 January 2018, 14:00-15:00 Brussels time

PARTICIPANTS

Representative	Organisation
Annika Eberstein	COCIR
Marcio Godoy	Fujifilm
Antonios Katrantzis	Fujifilm
Weiping Zhong	GE
Mary Overland	GE
Susumu Uchiyama	JIRA
Naoki Morooka	Shimadzu
Shoji Toyofuku	Siemens
Maurizio Andreano	Siemens
Stephanie Kelly	Siemens
Wolfgang Leetz	Siemens
Habara Atushi	Toshiba

DRAFT AGENDA

- Welcome and adoption of draft agenda
- Preparation for the next meeting IMDRF WG on Standards / update on pre-draft guidance
- Ambitions for 2018
- AOT
- Conclusions and Actions

DRAFT MINUTES

- **Welcome and adoption of draft agenda**

Annika Eberstein introduced herself as new Technical & Regulatory Affairs Manager at COCIR since January. She can be reached at eberstein@cocir.org or phone 0032-483501119.

The draft agenda was adopted without modifications.

- **Preparation for the next meeting IMDRF WG on Standards / update on pre-draft guidance**

The group discussed the IMDRF draft guidance on Optimizing Consensus Standards for Regulatory Us. The draft document was circulated to group before the call as well as preliminary DITTA comments. The group discussed the comments, focussing on the following aspects:

- Recognition of standards for regulatory purposes should be emphasised
- Some disappointment was expressed that the document is now rather educational in nature than political with tangible recommendations for regulators
- IMDRF should consult with SDOs as they are also addressed in draft guidance. IMDRF in talks with ISO/IEC for a possible Memorandum of Understanding. It is planned that IEC/ISO will review document before publication (after Berlin meeting)
- Classification of standards needs to be clarified if section stays in text and process standard should be added as category
- Numbers (if available) of regulatory delegates in standards development committees should be included as reference in the guide (see survey done by working group at the beginning)

Next steps:

ASAP after the call: COCIR office will send out consolidated version of draft comments to the group
19 January: Deadline for feedback by members
23 January: Deadline for submission to IMDRF

- **Ambitions for 2018**

Maurizio showed the slides presented at the DITTA General Assembly (here attached). Besides the agreed priorities, he highlighted a potential workshop on international standards around the IMDRF meeting in September and a possible DITTA liaison to (or informal reports from) ISO/TC 215.

- **Conclusions**

The next call will be scheduled approx. for mid-February, a doodle with several suggestions will be circulated to the group with the draft minutes.

[DITTA STA WG] TCON
Tuesday 19 December 2017, 14:00-15:00 Brussels time

Participants

Maurizio Andreano	Siemens
Naoki Morooka	Shimadzu
Dave Osborne	GE
Mary Overland	GE
Peter Linders	Philips
Elisabeth George	GE
Peterson Oliveira	
Susumu Uchiyama	JIRA
Stephanie Kelly	Siemens
Wolfgang Leetz	Siemens
Marcio Godoy	Fujifilm
Riccardo Corridori	COCIR

IMDFR STA WG
Peter Linders reported about the draft document developed by the IMDRF STA WG, "Introduction, Scope, General principles", which has been circulated by Scott Coburn a few days before the call. The draft is expected to be revised and submitted for comments (deadline 20 January) before the Christmas break. Publication date: March 2018.
The WG agreed the document still requires some work to be fine-tuned.
Note: the paper was received during the Christmas Holidays and circulated on 4 January to the WG.

Memorandum IEC-ISO
IMDRF plans to sign a MoU with IEC and ISO (separately) around March 2018 meeting of IMDRF. Main purpose is to closer collaborate by exchanging information, attending meetings and contributing to work items. IMDRF would technically have Type Liaison A status.

Draft CD 20417 on labelling
The WG consider this draft an exercise, a pilot, that should serve IMDFR members to get used to the "standard" process

South Korea
South Korea has been accepted in IMDRF. SK is interested in the IMDFR STA WG and contacts should start soon.

MOU IMDRF/IEC
The WG discussed about the MOU between IMDRF and IEC and the benefits of involvement of IMDRF into standards. It was concluded that having regulators involved could increase the acceptability of standards.

IEC 62304
Wolfgang Leetz reported about the DITTA dislike for the 62304, reported also in the TC210 liaison report. The message was submitted also during the meeting in October in Hiroshima. While the initial position was to kill the project, the WG agreed that now DITTA can wait for the CDV and see how it looks like. Now that it is has been decided to divide it in 2 parts this seemed a better option.

Priorities 2018
The slides presented at the DITTA Annual meeting by Maurizio were used as basis for the discussion:

- IMDRF New Working Item: quality of International Standards
- 5th International Standardization Workshop
- Liaison with ISO TC215 (Members to think and provide their opinion)
- Monitoring

Next call
The next call is scheduled for 15 January, from 14.00 to 15.00 CET

[DITTA STA WG] TCON
Wednesday 11 October 2017, 14:00-15:00 Brussels time

Participants

1. Andreano Maurizio (Siemens)
2. Atushi Habara (Toshiba)
3. Delbeecke Bjorn (COCIR)
4. George Elisabeth (Philips)
5. Leetz Wolfgang (Siemens)
6. Linders Peter (Philips)
7. Morooka Naoki (Shimadzu)

1. **Adoption of the Draft Agenda and Draft Minutes (29 August 2017)**

The draft agenda and draft minutes were approved

2. Previous Action Points
3. Briefing IMDRF Ottawa

- Good line up of speakers. Opening keynote speaker Scott Colburn did not attend because of hurricane. Excellent participation (+100 people). Well received. A DITTA Thank You note needs to be send out.
- 2018: DITTA STA Workshop in March or September? September deemed better timing, Chinese delegation indicated this preference as well.

Action: Peter and Maurizio to come up with suggestion for thank you note

4. Preparation IMDRF WG on Standards Kyoto

- US FDA large delegation. PMDA confirmed. From EU only Matthias Neumann (Erik Hansson not likely to be in Kyoto). Draft agenda send out by Matthias but is restart for the group. Homework needs to be done in reading and drafting guidance materials. Not clear if some activities by regulatory only or if industry will be involved.
- Circulate documents for internal DITTA purposes with deadline for comments on Friday 20 October.

Action:
- **Maurizio to send agenda to Bjorn, who will circulate with 10-day comment period**
- **Maurizio to forward mail to Bjorn, who will remind Nicole to circulate work item extension + Notes Morooko-san**
- **Circulate message Kevin Day 2-page document. By end of next week comment deadline**

5. AOT
   a. Resignation Bjorn

- Bjorn has resigned from his position of COCIR Technical and Regulatory Affairs Manager. Last day of employment will be the 27th of October.

6. Next Meeting (Thursday 16 November, 14.00-15.00)

[DITTA STA WG] TCON
Tuesday 29 August 2017, 13:00-14:00 Brussels time

Participants

1. Andreano Maurizio (Siemens)
2. Deaven Dave (GE)
3. Delbeecke Bjorn (COCIR)
4. Godoy Marcio (Fujifilm)
5. Leetz Wolfgang (Siemens)
6. Linders Peter (Philips)
7. Morooka Naoki (Shimadzu)
8. Osborn Dave (Philips)
9. Overland Mary (GE)
10. Toyofuku Shoji (Siemens)
11. Uchiyama Susumi (JIRA)

1. **Adoption of the Draft Agenda and Draft Minutes (24 July 2017)**

The draft agenda and draft minutes were approved

2. Previous Action Points
3. IMDRF STA Workshop Agenda: Status

- Scott Colburn confirmed participation. The agenda was updated.

4. DITTA Liaison Report to ISO/TC 210

- Wolfgang Leetz is the successor to Linda Linsey as Liaison to TC 210. Wolfgang presented the structure of the report. The report will be redrafted based on member comments.

Action: Wolfgang to send to Bjorn for circulation (Nicole to send out final)

5. Risk Management Workshop (Hiroshima, TC 210)

- Meeting scheduled for Thursday 26 October in the afternoon.

6. AOT

a. Refurbishment

- Andrew is planning to submit proposal for PAS 63077 to become an international standard to the US National Committee. 63120 is officially acknowledged work in progress

b. ISO/TC 198 Sterilisation of Healthcare Products

- Maurizio gave a report on a new work item concerning the Sterilisation of Healthcare Products. The issue is alarming as a first assessment indicates that it duplicates the content of the 60601 series.

7. Next TCON (10 October 2017, 14.00-15.00)

[DITTA STA WG] TCON
Monday 24 July 2017, 15:00-16:00 Brussels time

Participants

1. Atushi Habara (Toshiba)
2. Braun Markus (Siemens)
3. Delbeecke Bjorn (COCIR)
4. Godoy Marcio (Fujifilm)
5. Leetz Wolfgang (Siemens)
6. Linders Peter (Philips)
7. Markus Braun (Siemens)
8. Morooka Naoki (Shimadzu)
9. Osborn Dave (Philips)
10. Overland Mary (GEHC)
11. Toyofuku Shoji (Siemens)

1. **Adoption of the Draft Agenda and Draft Minutes (26 June 2017)**

The draft agenda and draft minutes were approved

2. Previous Action Points

- Maurizio gave Wolfgang an older liaison report, which Wolfgang will take as a template.

3. Refurbishment

- The question was posed why no single document on refurbishment is under consideration and instead IEC 63120 and IEC 63077 would co-exist, although they both deal with refurbishment. Markus answered that the content of the IEC 63077 is already communicated with the world (e.g. Asian standards refer to its content, certain companies apply its processes) and only deals with imaging devices. He argued that it takes a long time to achieve a common understanding on refurbishment and that opening the scope would be time consuming. He suggested that, as the IEC 63120 currently has no content, that it could cover other branches (e.g. laboratory medical equipment). Peter stated to have no preference but merely observes that there are two initiatives with no connection, which could be united to avoid potential conflicts.
- It was decided to organize a TCON on Thursday 27 July with Thomas Fischer, Peter Linders, Maurizio Andreano and Markus Braun, among others, to discuss the issue.

Action: COCIR Secretariat to set up TCON

4. Programme STA Workshop Ottawa

- Peter and Maurizio will not attend the meeting. Peter made suggestions regarding the program of the DITTA STA workshop, which will be forwarded to members for comments.

Action: Bjorn to share document. Members to make suggestions by 25 July, 12.00

5. AOT
a. ISO/TC 210 Workshop Hiroshima

- A workshop on risk management could be organised for the ISO/TC 210 meeting in October 2017 for people who are not members to ISO/TC 210.

6. Next TCON (29 August, 13.00-14.00 Brussels Time)

[DITTA STA WG] TCON
Tuesday 26 June 2017, 15:00-16:00 Brussels time

Participants

1. Andreano Maurizio (Siemens)
2. Atushi Habara (Toshiba)
3. Delbeecke Bjorn (COCIR)
4. Godoy Marcio (Fujifilm)
5. Heidenreich Georg (Siemens)
6. Lewis Brian (Medec)
7. Linders Peter (Philips)
8. Morooka Naoki (Shimadzu)
9. Overland Mary (GEHC)
10. Ozawa Keiichiro (Fujifilm)
11. Toyofuku Shoji (Siemens)

1. **Adoption of the Draft Agenda and Draft Minutes (23 May 2017)**

The draft agenda and draft minutes were approved

2. Previous Action Points
3. 4 Blocker Update for DITTA SC (27 June)

- Goal: monitor global standards trends, define DITTA standards policy, identify and support IMDRF/AHWP
- Achievements: IMDRF standards WG Shanghai meeting, workshop standards at WHO accepted but not held (1-pager instead), DITTA members nominated candidate JWG7 co-convener, first draft for Ottawa standards workshop
- Risks: ISO/TC 215 and uncontrolled proliferation of documents on MSW, IT-networks, security; DITTA standards workshop at IMDRF September squeezed by RPS priority, IMDRF STA WG to be too "regulators only" minded
- Upcoming actions: elaborate agenda for DITTA STA Workshop, Ottawa, 18 September; clarify NWIP for GRP standard based on IEC/PAS 63077:2016; discuss standards status in EU liaison report for ISO/TC 210; review outcome of ISO/TC 215

Action:
- **Peter to modify 4-blocker and present at the DITTA SC of 27 June**
- **Bjorn to distribute to DITTA STA WG and DITTA SC**

4. DITTA STA Workshop Agenda – first draft to be presented at the DITTA SC (27 June)

- Maurizio presented a first draft DITTA STA Workshop agenda, which would be organized in three parts. The first part deals with the value of standards for conformity assessment, the second part with the quality of standards, and the third part would either deal with the presentation of IMDRF NWIP deliverables or best practices from ISO/TC 210, ISO/TC 194 and IEC/TC 62.
- Matthias Neumann (DE) was suggested as a speaker as well as Greg Leblanc; Scott Colburn was suggested as keynote speaker.
- Peter proposed to circulate an advanced draft agenda to the leadership of the IMDRF Standards WG group for their input.

Action:
- Maurizio to recirculate updated draft agenda to Bjorn, Peter, Morooka, Mary
- Bjorn to organize a separate call to discuss further

5. DITTA Liaison Report to ISO/TC 210

- Wolfgang is invited as the DITTA liaison person to collect items which DITTA should comment on, and start to prepare the liaison report.

Action: Maurizio to check with Wolfgang on the status of liaison report to ISO/TC 210

6. IMDRF Shanghai Meeting (6-8 June): update

- Peter, Morooka, Maurizio prepared notes with details (to be circulated)
- Positive discussions and outcome with clear next steps. While the report to be presented by Sept. addresses the scope of the original NWI, the group will present to the IMDRF MC a proposal for a work item extension (another 18month)

Action: Bjorn to circulate the joint meetings notes to DITTA STA group

7. Cybersecurity: follow-up

- Georg and members of the German National Committee discussed the NWIP on IT Security dealing with lifecycle activities of manufacturers which are not a product/safety issue under ISO 14971 (e.g. detecting and defending against unauthorized access) and presented it at the meeting of a subset of the ISO 62304 team at Austin last week. The NWIP was informally accepted but further discussion is necessary in different German Committees to get broader approval. DKE will have a proposal ready in the summer, which Georg will present at the Liverpool meeting. There will be no new content. Only existing material will be referred to. The NWIP will be ordered according to ISO 62304.

Action: Ozawa-san to follow up with Georg regarding the DITTA Webinar on Cybersecurity and discuss during DITTA SC of 27 June

8. Standards in the EU: current situation

- A seminar will be organized by CEN-CENELEC on 21 September under the heading of "The New Medical Devices Regulations and Related Standards: Ensuring a Successful Transition." The event will explore, inter alia, the framework under the new Regulations; analyse the impact, priorities and foreseen challenges for stakeholders; discuss the compatibility of harmonized standards and common specifications under the new framework; examine the role of harmonized standards under the new Regulations and identify ways in which different stakeholders may contribute to the transition.
- Speakers include representatives from the European Commission, notified bodies, competent authorities, CEN-CENELEC, and COCIR.

Action: Bjorn to prepare status summary by next TCON (including SMARRT, Global Garden, James Eliot, COCIR actions and strategy)

9. AOT

a. Meeting regarding IEC 60601-1-9

- Marcio Godoy indicated that ABIMED paper was submitted using DITTA`s rationale to withdraw -1-9 from the next ANVISA Normative Instruction. Only JIRA letter was attached. There was a TCON between ABIMED and ANVISA on 23/06 and the result was successful because ANVISA agreed with my requests, hence it will be discussed on the top-level meetings with includes INMETRO, Testing Labs Association and other stakeholders.

10. Next TCON (tbd)

Action: Maurizio to arrange participation of refurbishment expert (from DITTA GRP) at the next DITTA STA WG TCON to explain and help resolve the confusion between multiple standards efforts on refurbishment.

[DITTA STA WG] TCON
Tuesday 23 May 2017, 13:00-14:00 Brussels time

Participants

1. Andreano Maurizio (Siemens)
2. Atushi Habara (Toshiba)
3. Delbeecke Bjorn (COCIR)
4. Godoy Marcio (Fujifilm)
5. Heidenreich Georg (Siemens)
6. Keiichiro Ozawa (Fujifilm)
7. Leetz Wolfgang (Siemens)
8. Linders Peter (Philips)
9. Morooka Naoki (Shimadzu)
10. Northrup Andrew (MITA)
11. Toyofuku Shoji (Siemens)

11. **Adoption of the Draft Agenda and Draft Minutes (28 April 2017)**

Action: The draft agenda and draft minutes were approved

12. Previous Action Points

- ISO/TC 194 Revision 14155: Greg Leblanc is not involved in TC 194 and is not aware of activities coordinated at GMTA level. The revision will be a topic on the agenda of the upcoming AHWP meeting of WG5. Peter reported that the Netherlands abstained in the voting process.
- COCIR Webinar Standardisation: DITTA STA WG members are invited to attend the webinar. Bjorn will send the registration details.

13. DITTA Workshops at WHO Global Forum (10-12 May): Briefing

- Because the Standardisation Workshop was omitted from the program, the DITTA STA Leadership developed a one-pager on "Better Standards for Safer Products," which was handed out during the forum. The document will be uploaded on the DITTA website.

Action: Bjorn to send the one-pager to the STA WG

14. New Revision of INMETRO Regulation for Product Certification: Follow-up?

- Marcio reported that problems are ongoing (e.g. certification bodies do not know how to issue certifications) and that the issue will be addressed in June. The topic will also be discussed during a meeting with Advamed next week.

15. Cybersecurity: DITTA STA & MSW WG Leadership discussion

- Georg informed the WG that there is a special situation regarding placing medical devices on the market as to meeting acceptable safety levels, because the effect on the clinical IT environment (e.g. databases, servers) needs to be considered. The current trend in the revision of ISO 14971 on risk management is to have a broad interpretation of the concept "harm," which would also include hospital data damage. On the other hand, protecting a device from an attack could be handled in the context of software lifecycle activities in an extension or different standard from ISO 62304.
- Qualifying risk, checking acceptability and reassessing the medical device is valid under the safety requirements of ISO 14971, including for hospitals.
- It was noted that the term "security" is overused and causes a lot of confusion (e.g. EU MDR approaches "security" as a matter of "safety"). It would be better to have separate terms for different impacts and projects which need to be addressed.
- It was advocated to have a consistent approach with regards to all activities relating to cybersecurity (e.g. ISO 14971, ISO 81001-1 on health software and health IT systems safety).
- The German Technical Committee internally discussed ISO 62304 on software lifecycle processes, which content has not been mandated by the Shanghai resolution of 2013 which focused on the extension of the scope to software. It was noted that CD2 is of poor quality. It was agreed that amendment 1 to ISO 62304 should not be overwritten by CD2.
- It was proposed to hold a DITTA webinar on cybersecurity early September.

Action: Georg, Ozawa-san and Andrew to propose a date for a DITTA webinar on cybersecurity

16. AOT

a. IMDRF Shanghai (6-8 June)

- The DITTA delegation will be comprised of Peter Linders, Maurizio Andreano and Naoki Marooka.

17. Next TCON (Monday 26 June, 15.00-16.00)

[DITTA STA WG] TCON
Friday 28 April 2017, 14:00-15:00 Brussels time

Participants

1. Andreano Maurizio (Siemens)
2. Delbeecke Bjorn (COCIR)
3. Godoy Marcio (Fujifilm)
4. Linders Peter (Philips)
5. Osborn Dave (Philips)
6. Morooka Naoki (Shimadzu)
7. Toyofuku Shoji (Siemens)
8. Uchiyama Susumu (JIRA)

1. **Adoption of the Draft Agenda and Draft Minutes (4 April 2017)**

Action: The draft agenda and draft minutes were approved

2. Previous Action Points

- The Annual Report on IEC/TC 62 is accessible for DITTA members; Philippe Soly has been acknowledged as expert for WG6 in ISO/TC 210.

3. DITTA STA WG Activities 2017

- The four blockers, which contain an overview of the DITTA STA WG activities for 2017, were presented by Peter at the DITTA Steering Committee of Tuesday 25 May.
- Presented priorities were the organization of a workshop on standards at the Global Medical Device Forum organized by WHO (May 2017), nomination of expert on behalf of DITTA in ISO/TC 210 WG6 on Post Market Surveillance (May 2017), organization of a workshop in context of the IMDRF Plenary at Ottawa (September 2017), establishing liaison report to ISO/TC 210 where DITTA is a category a liaison member (October 2017), and aligning industry views on health informatics and health software (ISO/TC 215, IEC/TC 62A, Joint WG7), in cooperation with the DITTA MSW WG, ongoing.
- It is advisable to start planning DITTA STA WG Activities for 2018 timely.

Action:
- **Bjorn will attach the four blockers on 2017 Activities to the next TCON**
- **Bjorn will forward the 2017 priorities to Patrick Hope, DITTA Chair**

4. DITTA Workshops at WHO Global Forum (10-12 May)

- Wednesday 10 May (PPT deadline 3 May)
  - 09:00 and 09:45, Workshop Digital transformation of healthcare in LMICs
  - 13:30 and 14:15, Workshop Standards for Better and Safer Medical Devices:
    - The workshop will touch on aspects like what types of standards exist, how they are used for ensuring safet quality medical devices, and how they are used for market approval. Explain international standards versus national standard. Examples will be given of important standards (e.g. IEC 60601-series, ISO 13485, ISO 14971, ISO 16142). The development process of standards will be explained and the role of IEC and ISO.
    - Draft Agenda: latest update from IEC Central Office (Frans Vreeswijk, IEC SG, tbc), industry experience (Ludmilla Schlageter, VP Government Affairs & Healthcare Policy Western Europe and Western Africa, Siemens Healthineers), an authority testimony (Rainer Voelksen, Swissmedic, tbc), Questions & answers session.
  - 14:15 and 15:00, Workshop Medical Device Regulations for Regulators, Manufacture, And Users
- Friday 12 May
  - 9:45- 10:30 Plenary Panel Session 8, Priority medical devices for Cancer care and other non-communicable diseases (1 DITTA presenter for 5 min. presentation and then answer questions from moderator)
  - 13:30 to 15:00, session on Effective Cancer Treatment: Cobalt Vs. Linear Accelerators (1 DITTA presentation – 12 min. presentation followed by a round table) – DITTA presentation to be sent out by 3 May

5. Cybersecurity

- A NWIP on cybersecurity from ISO/TC 215 WG4 was recently launched.
- DITTA has no formal link with ISO/TC 215 but should consider requesting liaison status.

Action: Bjorn to invite leadership of DITTA MSW WG, i.e., Ozawa-san and Georg Heidenreich, to next DITTA STA WG to discuss cybersecurity

6. New Revision of INMETRO Regulation for Product Certification (Marcio Godoy)

- INMETRO regulation 54:2016 will become mandatory in May 1st, 2017 and all Brazilian certification body don`t know how to assess some requirements, hence they put on hold any product certification agreement for this regulation. The major problem is that this regulation states that a product certification agreement has to be signed prior to perform any test.
- A working group (ABIMED has 2 members) has been working on a new revision to clarify and create some rules (if needed) for the identified gaps. This new revision is to be released in 2 or 3 months.

Action:
- **Topic on agenda next call to see if there is a need for action**
- **Marcio Godoy to share material with Bjorn**

7. AOT

a. ISO/TC 194 Biological and Clinical Evaluation of Medical Devices: Revision of 14155 Good Clinical Evaluation

- Siemens was working in ISO/TC 194 but is no longer involved. The question was raised whether other companies are involved in this revision, which had as deadline 28 April 2017, as there is concern that there might be additional requirements for clinical investigation.
- GMTA is active in ISO/TC 194, particularly regarding the 14155 revision, and it was suggested that DITTA could ask if GMTA are actively pursuing the matter and what their position is.

Action: Maurizio to contact Greg Leblanc and share information with the DITTA STA WG to trigger discussion

b. IMDRF September Meeting Ottawa: Workshop Standardisation

- IMDRF STA WG led by Matthias Neumann will present its final report in September. The Shanghai meeting in June will provide indications on how to develop the program in Ottawa. The workshop would be organized from 12.00 to 16.00 but would continue without the participation of regulators after 13.30. DITTA will sponsor the lunch.

c. COCIR Webinar Standardisation

Action: Bjorn to check with Nicole if DITTA STA WG can subscribe to the COCIR Standardisation Webinar of 1 June on the Annual Report

8. Next TCON (Tuesday 23 May, from 13.00-14.00 Brussels Time)

[DITTA STA WG] TCON
Tuesday 4 April 2017, 15:00-16:00 Brussels time

Participants

1. Andreano Maurizio (Siemens)
2. Delbeecke Bjorn (COCIR)
3. Godoy Marcio (Fujifilm)
4. Leetz Wolfgang (Siemens)
5. Linders Peter (Philips)
6. Morooka Naoki Shimadzu)
7. Overland Mary (GEHC)

9. **Adoption of the Draft Agenda and Draft Minutes (7 March 2017)**

Action: The draft agenda and draft minutes were approved

10. IMDRF Meeting Vancouver (14-17 March): Update

- The IMDRF Management Committee was preceded by a DITTA Medical Devices Single Audit Program (MDSAP) Workshop. DITTA participated in the Tuesday afternoon session and delivered its view on different projects in IMDRF.
- Dr. Matthias Neumann presented the progress on the project for process improvement for standards development, which was adopted by Management Committee. Its content is unknown but there is agreement that there will not be a public consultation or output document.
- Two documents have been sent out by Gale Rodriguez last Tuesday 28 March and are circulating for comments regarding the Geneva meeting end February of the STA WG. The first document is on the proposed process for the next months to be further detailed at meeting in Shanghai. The second document is a rough outline for the final report of the focus group. The deadline for feedback is by 7 April. Morooko-san, Maurizio and Peter have been exchanging comments.
- The IMDRF Management Committee decided to revisit the list with essential principles of safety and performance in a new project in the Medical Device Single Review Program (SRP), which is a further development of the MDSAP but only deals with individual devices rather than Quality Management Systems. This is not an official project yet.

Action:
- **Members requested to send documents to Bjorn asap to be circulated to DITTA STA WG**
- **Peter to forward documents send by Gale Rodriguez**
- **Members to send comments by Thursday 6 April, COB**

11. IEC/SC 62 CAG: AM 2 for IEC 60601-1

- A meeting is taking place from 3 to 5 April in Dublin, Ireland to discuss the progress and planning of the second amendment of IEC 60601-1. Thomas Fischer (convenor WG 20), Norbert Bischof (Secretary of TC 62 and SC 62A and B) and Jos van Vroonhoven (Chair STP FG COCIR) are representing industry.
- IEC 60601-1-9 on Environmental Conscious Design will not be part of the second amendment activities.

12. IEC/TC 62 Annual Report

Action: Bjorn to figure out if Annual Report can be shared with DITTA Group

13. ISO/TC 210: WG 6 on PMS – DITTA Expert

- WG6 has been reactivated with a November meeting in 2016 in Delft and has drafted a rough outline on a post market surveillance technical report. The NWIP was only formally accepted after the meeting. A meeting is planned in Delft to see what has been delivered by the different subgroups.
- DITTA nominated Philippe Soly, who is also active in the European PMS field, as an expert to participate in the PMS group.

Action: Peter to draft letter and share with Wolfgang and Philippe Soly for agreement and will ask Patrick to send to ISO

14. ISO/TC 215: meeting & JWG7 co-convenor

- A Meeting of the Health Informatic Committee will take place in the third week of April and will be attended by Georg Heidenreich.
- Sherman Eagles as will retire as co-convener of IEC JWG7 (joint working group between IEC/SC 62A and ISO/TC 215). USNC nominated Ms. Patty Krantz to succeed Mr Eagles. For the leadership of an important body developing international standards, such as JWG7, the current leadership is deemed too US-flavored: the secretariat of both IEC/SC 62A and ISO/TC 215 is based in the USA, AAMI holds the secretariat of JWG7 (even when a (joint) WG isn't supposed to have a secretariat), the current co-conveners of JWG7 are both USA-based and the chair of ISO/TC 215 is USA-based. A more international character by appointing someone who is not USA-based is appropriate.
- The deadline for proposing candidates was last Friday 31 March. Germany nominated Georg Heidenreich and the Netherlands nominated Peter Linders as a candidate for co-convenor of JWG7, with the understanding that Peter Linders would withdraw if Georg is selected.
- A meeting of the Health Informatics Committee is scheduled to take place in the third week of April and will be attended by Georg Heidenreich.

15. IMDRF STA WG Meeting (6-8 June, Shanghai)

- The meeting at Shanghai will be a follow up of the Geneva and Vancouver meeting. The end goal is to have a recommendation report ready by the IMDRF Management Committee meeting in September in Liverpool. The meeting will deal with the impact of regulatory bodies on better standards, the better uptake for regulatory use and the engagement of regulators. It will also be discussed how this will look like and what and how IMDRF should do with its members (e.g. liaison with IEC).

Action: Bjorn to distribute agenda to the group

16. AOT

a. Draft NWIP based on IEC PAS 63077:2016

- Markus Braun (Siemens) is developing a draft NWIP building on IEC PAS 63077:2016. The document should be available by end April the latest.

b. DITTA STA Workshop in September

- A DITTA STA Workshop is scheduled for the September meeting of IMDRF in Liverpool in conjunction with the Health Authorities of Canada on Regulatory Product Submission.

c. Cybersecurity

- DITTA STA WG should understand how JWG7 plays a role regarding cybersecurity and how cybersecurity will impact standards.
- MITA established a cybersecurity Task Force.

Actions: next meeting slot reserved for cybersecurity

17. Next Meeting (2 May, from 15.00-16.00 Brussels time)

[DITTA STA WG] TCON
Thursday 7 March 2017, 15:00-16:00 Brussels time

Participants

1. Andreano Maurizio (Siemens)
2. Braun Markus (Siemens)
3. Deaven Dave (GEHC)
4. Delbeecke Bjorn (COCIR)
5. Godoy Marcio (Fujifilm)
6. Habara Atushi (Toshiba)
7. Linders Peter (Philips)
8. Michalek Gary (GEHC)
9. Morooka Naoki (Shimadzu)
10. Overland Mary (GEHC)
11. Toyofuku Shoji (Siemens)

18. **Adoption of the Draft Agenda and Draft Minutes (02 February 2017)**

Action: The draft agenda and draft minutes were approved

19. Recap of the IMDRF WG Standardization meeting (21-23 Feb. 2017, Geneva)

- Well attended by regulators (including China). Deliberated on how to proceed to next level and prepared meeting Vancouver 13-17 March, where Morooka-san and Peter Linders will represent DITTA.
- The group is targeting its final report to the IMDRF MC for Sept. (end of current NWI). It should include recommendations regarding based on the group's scope of "Improving the quality of international standards for regulatory use". Beyond that, the group agreed that a more permanent structure is need to improve regulators contribution to stadnards making and eventually have an IMDRF list of essential standards being recommended.
- The group laid out a "strategic plan" in this regard.
- Regulators agreed that not everything can be defined in regulations and that standards are essential.
- Representatives of IEC (lead by Frans Vreeswijk, General Sectratey & CEO) and ISO (lead by Kevin McKinley, Acting Secretary General) joined to exchange how cooperation can be deepened and what measures can be taken towards better international stadnards for regulatory use. It was a productive discussion, whereby the SDO urged the RA to make use of the existing ways of contributing. ISO/IEC will continue and enhance their activities to encourage each relevant TC/SC and the National Committees to ensure a proper participation of all concerned stakeholders (in particular RA, users, academics).
- ISO/IEC will consider if and how a Memorandum of Understanding between ISO/IEC and IMDRF could be formulated to achieve at least that, IMDRF RA experts do have full access to all relevant documents - IMDRF is consulted at the NWIP stage - IMDRF can provide an co-ordinated input into the standard development process at TC/SC level independent from National Committees - IMDRF can propose NWIP This all might be achieved also via a formal liaison status and will be checked.Next steps: Further analysis of the feasibility of an IMDRF Standardisation network + Analysis of potentially needed additional measures (e.g. review of the GHTF essential principles, guidance on good regulatory standards writing)
- Next meeting: Proposed in China (maybe first half June), to be be decided after Vancouver

Action:
- **Peter will ask Mr Neuman to make the presentation of the Chinese delegation available**
- **Meeting minutes will be distributed when available**
- **By end of week notes Maurizio will send notes to Peter for completion**

20. Standardization activities

a. Refurbishment standard

- DITTA GRP WG would like to transfer its IEC PAS 63077:2016 Good refurbishment practices for medical imaging equipment into an IEC IS standard. The idea would be not to change its scope, but to transfer the document as it is.
- In parallel, a NWI is being circulated building on the IEC 60601-1-9. While TC62 was decided not to make changes to -1-9 for the moment, the NWI intends to address the possibilities of circular economy. It is doing so, by taking -1-9 and expand it including e.g. the use of components for service and manufacturing.
- This initiative would not contradict the GRP standard. Rather, it would provide the framework, not only for refurbishment as a business model but also looking for reuse of components and parts in service business.

- Philips is fully supportive of such framework project but raised its concerns regarding the weak wording of the NWIP. Experts identified to the working group so far are: Habara-san from Japan (representing JIRA and Toshiba), Toyofuku-san and Markus Braun (Siemens), Tracy Fox and Mike Smith (GE), and Peter van der Linden and Jeroen van Nistelrooij (Philips). Five countries are required for support.
- Markus will draft the NWIP regarding IEC PAS 63077:2016 by end of April and share with the DITTA STA WG for review.
- Andrew Northup expressed his interest in convenorship of this working group.

Action: Markus will draft the NWIP by end April

b. Global Medical Forum (WHO)

- The third GMF organized in Geneva by WHO is scheduled for 10-12 May and includes workshops and plenary sessions where only regulators will speak. DITTA, as a liaison organisation with NGO status to the WHO, will potentially host one out of two workshops on standards development Topics suggested were standards development process and how it is intended to fit regulatory purposes or sterilization.

Action(s): if this will take place will be shared with group

c. Implementation 60601-1-9 (Marcio Godoy)

- The requirements -1-9 are not mandatory but they are one option to comply with environmental conscious design. Each Notified Body has a different vision and requires different information about the product, so it depends on Conformity Assessment Body which requirements are satisfying.

d. Handbook ISO 13485

- Over 400 comments were received on the handbook, most of them editorial but some countries submitted technical comments and their vote is now turning into a negative vote, which, however, is not sufficient to kill the document. The impact on the publication date is not clear but the handbook is scheduled to be available in March 2017.

21. AOT
22. Next TCON (3 April 2017, 15.00-16.00)

[DITTA STA WG] TCON
Thursday 02 February 2017, 15:00-16:00 Brussels time

Participants

1. Andreano Maurizio (Siemens)
2. Atushi Habara (Toshiba)
3. Delbeecke Bjorn (COCIR)
4. Godoy Marcio (Fujifilm)
5. Linders Peter (Philips)
6. Morooka Naoki (Shimadzu)
7. Osborn Dave (Philips)
8. Toyofuku Shoji (Siemens)
9. Van Vroonhoven Jos (Philips)

23. Tour de Table and introduction Bjorn Delbeecke, COCIR Technical and Regulatory Affairs Manager

- Bjorn previously worked at the Government Office of Siemens on trade related topics and the MDR, and on Circular Economy issues while active at EUROPEN – the European Trade Organization for Packaging and the Environment.

24. Adoption of the Draft Agenda and Draft Minutes (7 December 2016)

Action: The draft agenda and draft minutes were approved

25. Preparation of next IMDRF WG Standardization Meeting incl. SDO leadership (21-23 Feb. 2017, Geneva)

- Peter Linders, Maurizio Andreano and Naoki Morooka will represent DITTA at the IMDRF meeting.
- For GMTA, Eamonn Hoxey will not attend and will possibly be replaced by someone else (post-meeting note: the name of Mr. Claude Giroud was mentioned)
- The agenda suggests that all presentations will be given by regulators; Peter will suggest to Neumann to include industry in the agenda. It is necessary to align with GMTA and prepare slides to present or make verbal statements.
- Neumann plans to send out a summary list with identified problems by the end of week of 6 February, based on the "Berlin" list to which DITTA contributed. He wants to allow Singapore and China to provide also their comments.

Action:
- **Peter will reach out to Jeffrey Eggleston to schedule a call next week and will ask Matthias Neumann if materials to be presented can be shared**

a. Comments on letter by Matthias Neumann, Chair IMDRF SWG

- Dave reported that the Advamed Standards Working Group discussed the tone and content of the letter and considered it not appropriate. It was not coordinated amongst the IMDRF WG. They will provide written comments for Jeffrey Eggleston to take to the Geneva meeting.
- After a brief discussion, it was concluded that the letter probably reflects the opinion of the IMDRF SWG Chair Neumann, and DITTA should not give this too much weight.

26. Standardization activities:

a. Status of NP New Work Item Proposal 62A/1177/NP on Environmental conscious design of medical electrical equipment

- Philips informed the meeting that they do not support the content and language of the NWIP and recommended the Netherlands to vote negative. At the same time, it was stressed that Philips is in favour of a framework standard for circular economy.
- Siemens, stressed that the rationale behind this project is the increasing need to address circular economy, material restrictions, use of parts, etc. through a high-level standard to pro-actively assure market access, open business opportunities and address customer needs. Due to TC62 decision not to amend 60601-1-9 until approx. 2024, it was proposed to launch a new project outside the 60601-1 family.
- Envisioned is a framework standard to reduce the environmental impact during design & manufacture, maintenance, reuse and end of life of medical electrical equipment, systems and the parts and components.
- Different views should be discussed in the association, however, there is no association recommendation adopted on that matter so far.

- Siemens has taken the Philips concerns also to the German National Committee and discussed the matter. The committee asked the Secretary of SC 62A Charles Sidebottom to withdraw the NP, and discuss it further as PWI. The IEC central secretary however suggested that the rational given was not sufficient for a withdrawal, since:
    - The scope of the project can be further discussed and modified,
    - Any expert may be nominated by his National Committee to participate in the project at any time,
    - Possible long-term project plan and possibility of circulation of several CDs before going to CDV.

b. Update from DITTA liaison to ISO/TC 210

- Wolfgang Leetz could not attend due to travel
- Jos, convenor of ISO/TC 210/JWG1, and project leader for the revision of ISO 14971 described the intention to keep the basic principle of the standard unchanged and provide more guidance on the application thereof. No intention to add many new requirements; would not require major changes to your QMS if you comply with the current standard. The clause on post market surveillance and clause about the inclusion of clinical benefits in analyses will be clarified. Publication is aimed for mid-2019 to guarantee reference in amended 60601-1. For details please view ISO/TC 210 N851.
- The strategic business plan ISO TC 210 is outdated and needs to be revised. This will be done in the coming months.

27. AOT

- A final draft of the ISO 13485 handbook was circulated last week. Comments are due next week. It is scheduled to be published in March 2017.

Action:
- **Marcio to provide an update on discussion on implementation of IEC 60601-1-9 in Brazil during next TCON**
- **Members are requested to provide comments on ISO 13485 draft handbook**

28. Next TCON (Wednesday 8 March, 14:00-15:00)

[DITTA STA WG] TCON
Wednesday 07 December 2016, 14:00-15:00 Brussels time

Participants:

1. Frédéric Melchior (COCIR)
2. Gary Michalek (GEHC)
3. Gerd Neumann (Siemens)
4. Atsushi Habara (Toshiba)
5. Jan Ihlenfeld (Fujifim)
6. Wolfgang Leetz (Siemens)
7. Marcio Godoy (Fujifilm)
8. Maurizio Andreano (Siemens)
9. Richard Gardner (GEHC)
10. Peter Linders (Philips)
11. Shoji Toyofuku (Siemens)
12. Thomas Fischer (Siemens)
13. James Vetro (GEHC)
14. Klaus Stitz (MEDEC)

1. Adoption of the draft agenda and draft minutes 17 November 2016

Action: the draft agenda and draft minutes were approved

2. DITTA representative in ISO/TC 210 (Wolfgang Leetz, Siemens)

- Wolfgang Leetz introduced himself
  - Never previously participated in DITTA STA WG TCONs
  - Last 10-15 years, he has been in charge of standards at Siemens
  - His focus has been on IEC/TC 62 + ISO/TC 215
  - Less frequently on ISO/TC 210
- Siemens is ready to sponsor Wolfgang's attendance to ISO/TC210 meeting
- MITA has no official liaison with ISO/TC 210
- Eucomed has also no official liaison with ISO/TC 210
- In the case of GHTA, it is unsure if there is an official liaison report
- There is no "industry corner" at ISO/TC 210
- The normal practice is that the participants' names are not mentioned
- For standards projects, on the other hand, names are mentioned

Action:
- **Wolfgang was confirmed as DITTA representative in ISO/TC 210**
- **Gary will help in the transition between Linda and Wolfgang**
- **Klaus will introduce Linda to Wolfgang**

3. IEC 60601-1-9 (discussion with Thomas Fischer, Siemens)

- Kobe decision IEC 60601 family
  - How to update IEC 60601 family?
  - Chosen way forward: only the most urgent topics will be addressed in Edition 3.2
  - The rest will be addressed in Edition 4.0 in 2024
- IEC 60601-1-9 should not be updated before 2024
- There is a proposal to start a new standard out of IEC 60601 family
- At a later stage, IEC 60601-1-9 and the new environmental standard could be combined
- It is up to IEC/TC 62a to decide
- Possible content new standard:
  - A TCON between DITTA and COCIR has taken place
  - There is an agreement with + support from the IEC/TC 62a secretariat
  - Thomas developed an outline for the new environmental standard
  - Coverage: medical electrical equipment + medical electrical systems scope of new standard
  - It has been out for comments during 2 months
  - Feedback: 8 supportive opinions / 2 non-supportive opinions (but not neglecting the project)
  - The above-mentioned feedback was showed during IEC plenary meeting 2016 in Frankfurt
  - IEC/TC 62 a is waiting for input from ISO/TC 210
  - Next step will be to write a new work item proposal for the new environmental standard
  - Thomas will start the work in the beginning of 2017 in order to be able to hold a meeting of the maintenance team in March 2017
- In 2015, DITTA made a proposal to ISO/TC 210 to have a joined project

- During ISO/TC 210 Seattle meeting last year both merging solution + common project with IEC/TC 62a was welcomed
- It was expressed during the Kobe meeting that IEC/TC 62a was not unwilling to embark on a common project
- DITTA has not come up with a follow-up proposal
- The DITTA initial proposal for the new environmental standard had a wider scope than medical electrical equipment + medical electrical systems
- The outline prepared by Thomas is deviating from the DITTA proposal
- This year, there was no DITTA Liaison Report to ISO/TC 210
- For that reason, no discussions took place on the new environmental standard
- Question: is a broader basis needed?
- DITTA really needs to follow this up and there is a need to highlight which path to follow (DITTA's path or Thomas' path)
- Thomas kindly reminded that "this is standardisation, we never know what we will get"
- Thomas' intended is really to get the work started
    - Start the work in IEC/TC 62a
    - Later on, ISO/TC 210 might join
- DITTA IEC PAS GRP could be part of this new environmental standard
- There might be additional value in cooperating with ISO/TC 210
- DITTA GRP WG would like to transform IEC PAS into an IEC standard
- Question: does it make sense if pushing for a new environmental standard?
- It needs to be discussed with DITTA GRP WG
- DITTA GRP WG does not want to water down IEC PAS
- Successor of 60601-1-9 could be composed of 3 parts, one could of them could be GRP
- DITTA ENVI WG is also discussing what should be in
- For environment, there is IEC/TC 111 Environmental standardization for electrical and electronic products and systems
- The DITTA ENVI WG is working together with ISO on eco-design standard (ISO 14006 Environmental management systems – Guidelines for incorporating eco-design)
- It might be interesting to organise a TCON with the DITTA ENVI WG Chairs, DITTA STA WG Chairs and DITTA GRP WG Chairs in the beginning of next year in order to align

Action:
- **Thomas will send the proposal to Fred (beginning of next week)**
- **Fred will circulate the proposal to members for comments**
- **Fred will add Thomas + James Vetro to the distribution list**
- **Check if Wolfgang in distribution list**
- **Include DITTA ENVI WG + DITTA GRP WG in future communications about new environmental standard**

4. DITTA Annual meeting

- Maurizio attended the meetings in Chicago
- The attendance to the DITTA Annual Meeting was almost the same as for the DITTA Steering Committee Meeting
- For that reason, the DITTA STA WG presentation was skipped during the DITTA Annual Meeting
- The DITTA STA WG work in the context of the IMDRF work item on standardisation was recognised and greatly appreciated
- It is one of the most important matters currently on the table
- DITTA STA WG will also organise a workshop on standards in Canada during 2017
- Action items following the meetings have been identified by Maurizio
    - DITTA STA WG to liaise with ISO/TC 215?
    - DITTA STA WG to liaise with IEC/TC 62?
    - Question: any benefit or just duplication of work as COCIR is already liaising with ISO/TC 215 and IEC/TC 62?
- Distribute presentation in the context of IMDRF work item on standardisation + DITTA mapping document
    - distribution: article in DITTA newsletter with links to document in DITTA website Members area)
- Letter ISO/TC 210 (Peter Chair ISO/TC 210) to IMDRF (Fabio)
    - 2 informal letters have been sent to Fabio
    - There is no formal liaison and therefore Peter is reluctant to share the informal letters
    - Patrick Hope (new DITTA Chair) is free to ask Peter for more information
    - IMDRF IEC/TC 62 liaison officer

        - It needs to be clarified
        - Question(s): who is nominated? Is it the right person? Is IMDRF aware?
        - It is up to IEC/TC 62 to decide
            - Current name: Nicole Denjoy
        - Other question(s): Does IMDRF want to have a liaison with IEC/TC 62?
        - We still need to understand what it means
- DITTA's internal reporting might need to be reviewed

Action:
- **The Action items will be discussed at the next TCON**
- **Fred will circulate the DITTA STA WG presentations done by Maurizio**

5. Next TCON (19 January 2017 14:00-15:00 Brussels time)

- Discussion on DITTA STA WG action items
- Discussion on Thomas' Fischer proposal