Secretariat of ISO/TC 194
"Biological and clinical evaluation of medical devices"

2021-03-04

Brief minutes

Chairman Advisory Group Meeting ISO/TC 194

Date: Tuesday, 1st December 2020

Attendees:

Jeremy Tinkler, UK	Chair ISO/TC 194
Jim Anderson, US	Convenor WG 1
Scott McNamee, US	Convenor WG 2
Miki Kurosawa, JP	Convenor WG 3
James Morrison, AU	Convenor WG 5
Hana Hofman-Hüther, DE	Convenor WG 6
Christian Pellevoisin, FR	Convenor WG 8
Mike Wolf, US	Convenor WG 9
Conrad Julius, DE	Convenor WG 10
Alan Hood, US	Convenor WG 11
Anita Sawyer, US	Convenor WG 12
Jon Dahl, NO	Convenor WG 13
Ted Heise, US	Convenor WG 14
Ed Reverdy, US	Convenor WG 15
Robert Geertsma, NL	Convenor WG 17
Marcelo Antunes, BR	Head of delegation
Boopathy Dhanapal, CH	Head of delegation
Michelle Kelly, UK	Head of delegation
Ryusuke Nakaoka, JP	Head of delegation
Carsten Senholt, SE	Head of delegation
Jennifer Goode, US	Head of delegation
Hae Choe, US	Supporting staff US Convenor from AAMI
Klaus Zeier, DE	Committee manager ISO/TC 150
Klaus Frösel, DE	Chair of the German national committee "Cleanliness of medical devices in the manufacturing process"
Madlon Timme, DE	Supporting Klaus Frösel

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1 Welcome and opening of the meeting (12:00 p.m.)

Jeremy Tinkler, Chairman of ISO/TC 194, welcomed the participants and in particular Hana Hofman-Hüther and Conrad Julius, who recently have been appointed as new Convenor for WG 6 and WG 10 respectively.

He stated that the discussion of agenda item 6.2 will be brought forward, since both Klaus Frösel, chair of the German national committee on "Cleanliness of medical devices in the manufacturing process", and Klaus Zeier, committee manager ISO/TC 150, need to attend another meeting.

He asked all participants to briefly introduce themselves and indicate their role in ISO/TC 194.

2 Introduction and update on measures taken by ISO/CS with regard to physical meetings

Karl Wenzelewski briefly mentioned that ISO has extended its measures regarding physical meetings until February 28, 2021 and he assumed that this will not be the last date and that this is also important with regard to the planning of an ISO/TC 194 meeting in 2021 for which the invitation from China still exists.

Update: Effective from 16 March 2020, all ISO governance and technical physical meetings planned until 30 June 2021 must be held virtually.

3 Status and tasks of working groups

3.1 and 3.2 What has been accomplished since the last meeting?

What are the main concerns for your WG?

Jeremy Tinkler asked each of the Convenor to give a status report regarding the work of his/her working group and asked to start in numerical order.

WG 1

Jim Anderson, Convenor of WG 1, stated that Part 1 is based on the findings of the other parts and that TC 194 tries to be responsive to new information coming from the other parts of the 10993.

He is disappointed that ISO does not recognize that the 10993 series is a living and evolving document and therefore he is in favor of registering the revision of Part 1 as a PWI.

Arthur brandwood proposes to register a PWI to produce a technical report (TR) addressing the "Impact of new technologies on biological evaluation".

Robert Geertsma disagrees and states that he does not support the registration of a PWI that will not be worked on and votes for a PWI for the revision of Part 1.

James Morrison mentioned that a TR does not have to be that extensive and the revision of Part 1 can be a big project. Thus, when a working group wishes to stay in existence they have to commit to doing something. Therefore, if a working group wants to continue to exist, it should do something even if it is only a small document but a meaningful contribution to the field.

Jim Anderson stated, if a revision of Part 1 is agreed WG1 might consider how all the other parts could be folded in or the Work Item could focus on where there is a specific topic or interaction of concern e.g cytotoxicity.

Task: Either start a NP for the revision of ISO 10993-1 or setup a vote on a PWI for a TR "Impact of new technologies on biocompatibility evaluation"

WG 2

Scott McNamee, Convenor of WG 2, mentioned that Part 9 and Part 15 have been published and there are two main documents under discussion, ISO/TS 37137-1 (which is out for review) and ISO/TR 37137-2.

> **Remark:** Due to the missing permission from ASTM to utilize Appendix X4-Nomenclature of Absorbable and Related Terms from ASTM F2902-16 Standard Guide for Assessment of Absorbable the document was on hold. The permission was granted recently and the Part 1 is currently out for a two weeks review.

Working Group 2 received comments on Parts 13 and 14 and regarding the way forward, he mentioned that due to the lack of participation from ceramics experts, the working group has therefore not yet been able to initiate the revision of ISO 10993-14. He has sent a poll for experts but so far has not received any nomination.

With regard to ISO/TR 37137-2 he is not sure what the status of this document is. Karl Wenzelewski stated that Herbert Thelen has stepped down as project leader and a successor has to be found. Scott McNamee agrees to look for a successor and to inform the secretariat accordingly to start a CIB on the successor.

Task: Start a NP on the revision of ISO 10993-14 together with a call for experts from the field of ceramics.

WG 3

Miki Kurosawa, Convenor of WG 3, informed the participants that he had a meeting to discuss the comments received on the ISO/DIS 10993-2 and that it has been agreed to have an additional meeting with UK experts to finish the document to send it to the secretariat for submitting to ISO/CS for FDIS voting.

> **Remark:** A request from WG 3 to extend the timeframe to 36 month has been granted by ISO/CS

Jeremy Tinkler stated that there was a discussion on the DIS stage for further clarification and this could be used for a NP to revise Part 2 again.

Task: Wait for circulation of the FDIS and then discuss the NP on the revision of ISO 10993-2

WG 4

Karl Wenzelewski mentioned that he received an e-mail from Danielle Giroud, Convenor of WG 4, that she could not attend the meeting due to technical problems.

Jeremy Tinkler stated that the ISO 14155 has been published recently and that he will talk to Danielle Giroud about what to do with a PWI or a NP.

Task: Jeremy to discuss with Danielle Giroud the next steps.

WG 5

James Morrison, Convenor of WG 5, has met 4 time since the meeting in Berlin and the group is working on a comparative study. This work programme has turned out to be more extensive than expected and before doing an intra-laboratory repeatability study, an inter-laboratory reproducibility study and a test method correlation study, at least one pilot study is needed. At the next meeting the pilot study protocol and the supporting documents will be

discussed in order to make sure that the body of work is significant. . Five different methods will be used and the aim is to give the user a confidence in the significance of their results. This could lead to a revision of Part 5 but it is not the principle reason for the study.

WG 6

Hana Hofman-Hüther, newly appointed Convenor of WG 6, mentioned that parts of ISO 10993-3 are still under discussion and several members are in charge of writing specific parts for the revision of Part 3. However due to the step down of Albrecht Poth and her change of employment, the work could not be executed as intended.

Karl Wenzelewski stated that a working group meeting should be scheduled for early next year to discuss the comments received on the CD and to discuss the next steps on ISO 10993-3.

Task: Schedule a meeting of WG 6 early 2021

WG 7

Karl Wenzelewski mentioned that the revision of ISO/TS 10993-20 was cancelled by IOS/CS due to no progress and thus a NP could be started for a revision.

Task: Start a NP or PWI on the revision of ISO/TS 10993-20

WG 8

Christian Pellevoisin, Convenor of WG 8, mentioned that the working group worked on ISO 10993-10 and ISO 10993-23 and he waits for the publication of Part 23 as this document is a huge change in the biological evaluation of medical devices as an in-vitro approach was introduced to be used at first before testing in-vivo.

The working group also worked on ISO 10993-10 to eliminate irritation from this part.

He gave an outlook for the next years and stated that the working group want to monitor and support the implementation of the standard and to gather historical or new data to foster confidence and applicability of non-extractables. Discussion should be started on the applicability of Part 23 to specific irritation tests, e.g. eyes, vaginal, oral …

In order to discuss two points, a revision of Part 10 can start very soon. One is to address the quantitative risk assessment approach for skin sensitization and the other is to define the framework for evaluation of additional non animal methods (reference chemicals, historical data, materials, process spiking extracts and/or positive reference materials and to identify methods for and initiate a comparative study. A meeting is to be planned to discuss this.

Task: Set up a vote on a NP or PWI for the revision of ISO 10993-10.

WG 9

Mike Wolf, Convenor of WG 9, mentioned that since the publication of ISO 10093-4 the working group has not meet regularly and there is a need right now to see how the standard has been implemented internationally.

There are a number of issues when dealing with the standard as written today and there is room for refinement in terms its advice and practice, e.g. exposure ratios and certainly advance of in-vitro techniques used for studying haemocompatibility particularly in the area of testing thrombosis. There is some progress in the area of interpretation of results when fresh blood or animal blood is used.

Before publication of the standard a lot of discussion took place to perform a comparative study in terms particularly in the area of in-vitro techniques. There are areas for

improvement in Part 4 and thus a NP on the revision of Part 4 seems to be feasible.

Robert Geertsma asked on behalf of the Dutch mirror committee if there is any progress in the publication of the previous round robin study results. There was a promise to publish it but it seems that nothing has happened and he asked for further information. Mike Wolf replied that the burden is on his shoulder to bring that publication out and he stated that this publication will come out in 2021.

Robert Geertsma asked how the experts will be involved before publication and Mike Wolf stated that the experts will receive the text seeking for feedback before it will be published.

Task: Start a NP on the revision of ISO 10993-4

WG 10

Conrad Julius, newly appointed Convenor of WG 10, mentioned that his last contact with the group and Arne was in October 2019 where he had to leave for personal reasons. He stated that disbanding of WG 10 is not an option and he has some ideas and a PWI would be a good idea.

Karl Wenzelewski stated that he has received several enquiries on ISO 10993-6 which can be the basis for either a PWI or a NP. He will check with Conrad what the best solution will be.

Task: Either start a NP or a PWI on the revision of ISO 10993-4

WG 11

Alan Hood, Convenor of WG 11, informed that there are two projects; one is the revision of ISO 10993-17. 2020 has been a year of hard work for all WG experts and the editing group had produced a second CD, which has been circulated recently.

The second project is the revision of ISO 10993-7 and it has been agreed by the working group 11 to initiate a NP and he asked the secretary to send information to him on what is necessary to start the NP.

Jeremy Tinkler stated that there are two requests received from ISO/TC 198; one is the separation of the chemical analysis from the toxicology, the other is to establishresidual limits for hydrogen peroxide, which will be discussed under item 6.1. James Morrison pointed out that the role of WG11 should be to provide methodological standards, not vertical specifications.

Task: Continue revision of ISO 10993-17. Start a NP for a revision of ISO 10993-7.

WG 12

Anita Sawyer, Convenor of WG 12, stated that the ISO/FDIS 10993-12 was approved in August 2020 and went in October to the publication stage and according to the ISO project portal it is foreseen for publication in January 2021.

Part 12 is normatively referenced in the majority of the other ISO 10993 standards and a proposed PWI could be developed to document how Part 12 is adopted by the user or how the other standards in the ISO 10993 series can be revised to support Part 12 or if Part 12 needs to be amended according to the requirements in the other standards.

Jeremy Tinkler stated that we need some substantial background to write such a PWI to satisfy ISO/CS. Ted Heise noted that parallel requirements are needed on extraction for analytical chemistry tests. These may go into Part 18.

Task: Start to write a proposal for a PWI.

WG 13

Jon Dahl, Convenor of WG 13, stated that the Part 13 has been published in 2017 and will be out for review in 2022. The standard deals with toxicokinetic studies so more how to do a study than a toxicokinetic evaluation and thus a PWI on mathematical models for the evaluation of toxicokinetics can be setup.

Task: Start to write a proposal for a PWI.

WG 14

Ted Heise, Convenor of WG 14, stated that ISO 10993-18 has been published in January 2020 and ISO/TS 10993-19 in May 2020. He pointed to an error in the equation E.2 in Part 18, which will be corrected by an amendment beginning next year.

Another point is whether repeated testing is necessary when test procedures have been revised. Part 1 and Part 4 indicate that repeated testing is not necessary if the products provide evidence of safe clinical use in the past. The implications and definition of "history of safe clinical use" need to be clarified and this should be discussed in WG 15. Ted Heise was asked to share relevant information with Ed Reverdy.

Ted Heise addresses the need for a PWI on "Sample preparation on chemistry".

Task: PWI for "Sample preparation on chemistry". Discussion of "history of safe clinical use" in WG15.

WG 15

Ed Reverdy explained that at the moment an ad hoc group led by Arthur Brandwood is working on a TS on "Analytical chemistry" and some meetings have taken place.

Arthur Brandwood explained that the format and content of the document is well advanced but some technical details still need to be discussed. He stated that he needs a volunteer who has not been involved in the preliminary work to take an independent look at the document.

A further question is where the new document should/could be allocated to; in WG 15, which then decides in which working group it is best placed, or directly in WG 14. Jeremy Tinkler suggested that the document be returned to WG 15 to decide which is the best way forward.

Ed Reverdy mentioned that the work on the presented document on "Cleanliness" should also be allocated to WG 15 in advance and then it should be decided whether it should be worked on in WG 14 or possibly in a newly established working group.

Tasks: Start a NWIP for a new ISO/TS on “Analytic chemistry” and for an IS or TS on “cleanliness of medical devices”. Discuss the definition and implications of "history of safe clinical use".

WG 16

The Convenor, Kim Darnell had not been reappointed due to the planned transfer of work on pyrogenicity to WG 7. However concern was raised that WG7 was not an appropriate home for this subject and it was agreed that the convenor should be reappointed.

Anita Sawyer asked about the status of ISO/TR 21582 as people are waiting for the document to be published. Karl Wenzelewski stated that the document is with ISO at stage 30.99 which means "CD approved for registration as DIS" however for a TR it means "approved for publication" as no DIS or FDIS is needed for a TR.

Remark: ISO/CS informed the secretary that the document has been rejected due to formal reason. It was mentioned that a TR shall not contain any requirements which are indicated by "requires", "required", "needs" and " will need to". An answer to that statement was given by Jeremy Tinkler but no answer received yet.

Task: Start to write a proposal for a PWI to elaborate a TS on in vitro methods.

WG 17

Robert Geertsma explained that ISO/TR 10993-22 was published in July 2017 and asked whether the systematic review is due soon.

Karl Wenzelewski informed that a systematic review is not foreseen for a TR and that a TR theoretically has an unlimited lifetime. He added that it had been discussed in WG 17 to publish the document as a TS, but this had not found a majority and so it was decided to publish a TR as a preliminary stage.

Robert Geertsma said that he did not want to revise the TR, but if it would help to keep the working group alive, he would consider it. However, it would have to be clarified whether the revision of a TR is feasible, otherwise the upgrading to a TS would have to be considered.

Task: Committee manger to find out if a revision of a TR is possible.

Kommen

Remark: According to the information received from ISO/CS a revision of a TR is possible.

Kommen

4 Reappointment of Convenor and information from ISO/CS

Karl Wenzelewski referred to the votings which have been setup for the re-appointment of working group convenors as well as the appointment of new working working group convenors and the result received, however ISO/CS sent a reminder that all working groups with no active work items must be disbanded by decision of the committee.

He gave a background on the rules with regard to the disbandment of working groups. He referred to ISO/IEC Directives Part 1:2020 where it is very clearly mentioned that a working group has to be disbanded when no active work item is allocated to the group.

This can only be prevented by either initiating a revision or voting on a preliminary work item (PWI). In the ISO/IEC directives, Part 1:2020, 2.2 the preliminary stage is described as follows.

> Technical committees or subcommittees may introduce into their work programmes, by a simple majority vote of their P members, preliminary work items (for example, corresponding to subjects dealing with emerging technologies), which are not yet sufficiently mature for processing to further stages and for which no target dates can be established.
>
> All preliminary work items that have not progressed to the proposal stage in the IEC by the expiration date given by the TC/SC and in ISO within 3 years will be automatically cancelled.
>
> This stage can be used for the elaboration of a new work item proposal (see 2.3) and the development of an initial draft.

Arthur Brandwood suggested that the Convenors can figure out a piece of work that would be a technical report or similar that would be a more flexible way than to recommend a revision of each of the main standards.

Karl Wenzelewski states that each convenor should think about whether to seek a revision

of his standard(s) or to put a PWI to a vote to satisfy ISO or face disbanding the working group

He mentioned that each of the Convenors has to provide information either for a revision or a PWI.

> **Remark:** Karl Wenzelewski prepared a template that can be used for both cases and will be sent to the Convenors to be filled in.

A difficulty could arise because Working Group 15 has the function of a more or less advisory group that does not itself work on standards, but looks at new work items and, after preliminary discussions, assigns them to an existing working group.

Jeremy Tinkler mentioned that Arthur Brandwood is leading an ad hoc group on analytical chemistry and that could be a PWI or even a WI for WG 15.

There is

information in the ISO/IEC Directives about such a group, but they must also be disbanded when it has completed its task.

It should be noted that ISO/CS is paying more attention to compliance with the directives, while disregarding the structure and tasks of the respective committees. This has become worse and worse in recent years and does not contribute to standardization work being carried out to the satisfaction of all. In this context, it should be noted that the resolution adopted in Lund (No. 521) is no longer recognized by ISO, although it had existed for years.

Ryusuke Nakaoka proposed to make a sort of submission to ISO/TMB to tell them that it is not a good idea for this particular technical committee because we are responding to a rapidly changing regulatory situation globally. It is not to make standards and look away from this, for us is to make a standard and watch to see who barks and then to work trying what to do better.

Jeremy Tinkler asked if the Convenor will still be listed in the ISO Documents members list and what will happen with the documents.

> **Remark:** Karl Wenzelewski has checked with colleagues at DIN and it seems that all experts, including the convenor, have been deleted from the members list but that the documents are still available, however it could not be verified if for all or only for the secretariat. This means, when a standard will be revised in the future you have to find a “new” convenor as well as experts to start the work.

With regard to the missing re-appointment of Kimbrell Darnell as Convenor of Working group 16, Karl Wenzelewski was asked to contact him if he is willing to serve for an additional three years time as Convenor and if yes, to setup a voting for the re-appointment on the CIB.

5 ISO Directives Update 2020

Karl Wenzelewski referred to a presentation from ISO/CS which gives an overview about the changes made to the ISO/IEC Directive, Part 1:2020 “Consolidated ISO Supplement — Procedures specific to ISO”. See attached.

6 Any other business

6.1 Recommendation from ISO/TC 198 to initiate a conversation with ISO/TC 194 to explore the possibility of joint work with ISO/TC 198 (WG 16, Vaporized hydrogen peroxide sterilization) to establish H_2O_2 residual limits.

The information was given that such a meeting has been under discussion since the beginning of 2020, but nothing has happened yet.

Both chair and secretary have proposed dates, but no meeting has been held yet.

James Morrison pointed out that ISO/TC 194 has received similar requests from other committees in the past and it was always made clear that ISO/TC 194 is dealing with horizontal standards which gives information how to establish things rather then what are the establish things are. He thinks that dealing with hydrogen peroxide runs in the same direction as with ethylene oxide whereas EO is a specific issue as it is toxic whereas hydrogen peroxide is more a regulatory issue.

Arthur Brandwood states that this proposal makes him very nervous. He works specifically on hydrogen peroxide sterilizers and disinfectors and there is a lot of misunderstanding about the risks involved. Comparing hydrogen peroxide to ethylene oxide there are very different mist profiles. Hydrogen peroxide sterilization is increasingly used and there is a lot more development on hydrogen oxide sterilization techniques. If this document is to go ahead it will be important to ensure sufficient expertise to properly handle those risks. Otherwise any standard developed could be problematic for the industry.

6.2 New proposal regarding cleanliness of medical devices

Klaus Frösel (Head of German national committee on "Cleanliness of medical devices in the manufacturing process") had intended to introduce this subject. Since there was a problem with Zoom and Klaus Frösel could only connect by phone, Klaus Zeier took over the presentation of the proposal.

Klaus Zeier stated that the creation of DIN 5343 was derived from ISO 19227 "Implants for surgery - Cleanliness of orthopedic implants - General requirements". The German idea of a more general scope of ISO 19227 to include all implants or all medical devices was rejected for formal aspects.

So it was decided to establish a national committee to start a national project on the basis of ISO 19227.

Following intensive discussion it was agreed at DIN to submit the DIN 5343 to ISO in order to start an international project and to ask ISO/TC 194 to take over this project.

Klaus Zeier explained why ISO/TC 194 was chosen and what the intended scope of the new ISO standard will be.

ISO/TC 194 thanked Klaus Zeier for this presentation and the discussion was opened.

Jeremy Tinkler asked if this could be a WI within WG 14 or WG 15.

Ted Heise, Convenor of WG 14, welcomed the proposal and mentioned that it is an important topic but mentioned that WG 14 may not be the right place to discuss it as the WG is more focused on chemical characterization and has a much broader scope of material characterization. He can consider cleanliness as part of chemical characterization but wants to hear other options.

Ed Reverdy, Convenor of WG 15, said that cleanliness is extremely important and is a part of the sterility assurance. He pointed out that it does connect with ISO/TC 194 but not only for orthopedic devices but to all medical devices. He also referred to reprocessing and the cleanliness in between uses.

Klaus Zeier mentioned that the standard on orthopedic implants is already out and this is not what ISO/TC 150 is concerned with. ISO/TC 150 wants to broaden it to all medical devices. The document does not cover reprocessing as this is part of other standards. Only dealing with cleanliness in the sense of packaging it once it has been manufactured, but if it is sterile or non-sterile depends on the product. The document ends when the product leaves the manufacturing site.

It was asked, if the proposal goes forward, where this works belongs as ISO/TC 194 is about evaluation of finished medical devices whereas this proposal is talking about manufacturing of medical devices. There are other commitees/countries are working on cleanliness, e.g. ASTM and Australia and we have to think carefully where this actually belongs.

Klaus Zeier is aware of the work within ASTM and as ISO/TC 150 is considering to broaden the ISO 19227 to other implants however they cannot write standards for other medical devices and ISO/TC 194 is not perfect but the best solution out of the "non perfect" solutions.

Robert Geertsma mentioned that it was mentioned that the document ends after the manufacturing process which for him includes the sterilization and packaging and this will be the final product we are looking at. Other elements mentioned in the scope and table of contents belongs either to ISO/TC 194 or ISO/TC 198.

Klaus Zeier answered that this may be a bit of semantics as it depends what is meant by manufacturing process. This can include sterilization, depending if the device will be delivered sterile or non-sterile but in any case, packaging is still included. Understanding is that all the steps are covered until the device will be shipped.

Jeremy Tinkler concluded that there is some consensus that the subject is relevant and important. It seems that it is relevant to ISO/TC 194 and how it should best fit in the existing framework we have and it's clear that we have enough to move forward and how do we do that.

It seems that this topic should be brought forward to WG 15 to discuss the further process.

It was mentioned that committees which may be interested in this topic should be informed.

> Remark of the committee manager: If there are any more questions please contact klaus.zeier@din.de

Disbandment ISO/TC 194/SC 1

Ed Reverdy addressed the fact that ISO/TC 194/SC 1 had been disbanded and asked who would be responsible in the event of a revision.

Jeremy Tinkler mentioned that there is no revision at the moment and therefore no active working point. If this were to be the case in the near future, it would have to be discussed whether the work would be carried out in an existing working group or in a new one to be set up.

Robert Geertsma informed those present that the systematic review of ISO 22442-3 was pending and that further measures would be required on the basis of the results.

7 Future meeting locations

Karl Wenzelewski mentioned that as long as we get a monthly update on measures taken by ISO/CS with regard to physical meetings it is not yet possible to plan a face-to-face meeting for 2021.

He mentioned that a physical meeting is not in the cards for the first half of 2021 and it could be difficult for the second half as well. He states that the deadline for the invitation to a physical meeting is 4 months, so an invitation has to be sent out at the beginning of August at the latest.

Jeremy Tinkler mentioned that we still have an open invitation for a meeting in China. If we think in times of a year from that date, we are looking for end of summer or early autumn (third or fourth quarter of 2021). That might work and we should keep that date.

Christian Pellevoisin mentioned that France is prepared to host an ISO/TC 194 meeting in 2022 or later, depending on the next meeting in China.

Karl Wenzelewski mentioned that planning could go ahead if we will have no further measures from ISO/CS with regard to physical meetings.

> **Remark:** Effective from 12 March 2020, all ISO governance and technical physical meetings planned until 30 June 2021 must be held virtually.

Ted Heise asked if the two-year programme also applies to working groups; this was answered in the negative by the committee manager.

Arthur Brandwood said that the working groups were working very well and he assumed that a virtual meeting of ISO/TC 194 could be held with a predefined maximum number of delegates per country.

Jeremy Tinkle asked if we really need a TC meeting, as the discussions are mostly about the next meeting. A TC meeting is a formal act but usually there are discussions that do not affect the work in the WGs.

Arthur Brandwood replied that at the TC meetings we made decisions on when working documents should be submitted or completed and advance to the next stage (CD, DIS or FDIS). If this can be done without a TC meeting, that is fine with him.

Karl Wenzelewski said that ISO has a clear timetable by which the documents must have reached the next stage and that it is therefore the responsibility of the convenor of a WG to adhere to this timetable in order not to run the risk of the WI being removed from the work programme. In any case, the WG should formulate a recommendation on the way forward at a meeting.

Jeremy Tinkler mentioned that resolution can also be agreed on remotely without having a meeting.

8 Adjourn

Jeremy Tinkler thanked all participants for their attendance and contributions and closed the meeting.