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Topics

ISO/TC 150 (Implants for surgery)

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The ISO/TC 150 is an interdisciplinary TC due to handling all surgical implants; thus it requires active collaboration with the IEEE and other technical committees (TCs). Nowadays, the TC is greedy for new technologies and collaboration with TCs handling additive manufacturing and biotechnology. This paper reports on the current status of Subcommittee 1 (Materials) and its working groups, of which the author is a convener of Working Group 3.

1. Introduction

As of December 2, 2021, the ISO/TC 150 "Implant for surgery" consists of 26 participating countries and 20 observer countries. It consists of 8 working groups (WG) directly under the TC and 6 subcommittees (SC). WG 16 was formed as a result of a proposal by Japan (proposed by Mr. Ikeda of Kyocera Corporation) in SC 1/WG 3 on "Methods

for Testing Antimicrobial Resistance of Implant Surfaces," with the opinion that a WG should be formed to discuss various antimicrobial tests for implants in a comprehensive manner, and was co-convened by Mr. Ikeda and Dr. John Rose of the United States. On the other hand, WG 13, which deals with biodegradable metals, was suspended.

Mr. Hany Demian of the Food and Drug Administration (FDA) of the U.S. serves as the chair of the technical committee (TC). And, Mr. Klaus Zeier from Germany (DE), the secretariat country, has been appointed as the Committee Manager (CM). Among the SCs, the secretariat of SC 7 is Japan, and Dr. Ryusuke Nakaoka of the National Institute of Health Sciences serves as the CM. In addition, Prof. Kohei Murase of Osaka University is the TC 150 convener for JWG 1, Prof. Makoto Ota of Tohoku University is the convener for WG 14, and the author is the convener for SC 1/WG 3. The author is also the chairman of the Japanese National Committee and the head of the Japanese delegation.

This year, as last year, due to the COVID-19 pandemic, all of the meetings were either online or cancelled. The TC 150 Annual Meeting, which was cancelled last year, was held online on December 2-3, after the annual meetings of all scheduled subcommittees and working groups. In addition, SC 1, SC 7, JWG 1, WG 14, and WG 16, all of which are discussed in this paper, were held via online meetings.

Table 1. Structure of ISO/TC 150

JWG 1	Joint ISO/TC 150 - ISO/TC 261 WG: Additive manufacturing in surgical implant applications
WG 7	Fundamental standards
WG 8	Breast Implants
WG 10	Use and retrieval of surgical implants
WG 12	Implant coatings
WG 14	Models of tissues for mechanical testing of implants
WG 15	Neurosurgical implants
WG 16	Antimicrobial properties of implants
SC 1	Materials
SC 2	Cardiovascular implants and extracorporeal systems
SC 4	Bone and joint replacements
SC 5	Osteosynthesis and spinal devices
SC 6	Active implants
SC 7	Tissue-engineered medical products

2. Activities of TC 150

2.1 SC 1/WG 3 (Ceramics)

WG 3 was held on September 8 (Wed.) and 9 (Thu.) from 20:00 to 22:00 JST, with 38 participants, including 35 experts from eight countries: Brazil (4 members), France (1 member), Germany (2 members), Japan (13 members), China (1 member), India (2 members), UK (2 members), USA (10 members) and committee managers (one from Germany).

Attending from Japan were Mr. Ikeda, Dr. Sakoda, Mr.

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Asaoka, Dr. Kikuchi (combiner), and Dr. Hashimoto of JFCC, Prof. Otsuki of Nagoya University, Prof. Ishikawa of Kyushu University, Prof. Kawashita of Tokyo Medical and Dental University, Prof. Miyazaki of Kyushu Institute of Technology, Dr. Oyane of AIST, Mr. Kojima of JFCA, Ms. Koyanagi and Mr. Osugi.

Mr. Andy McCabe from the U.K. organized the meeting as co-convener with Dr. Kikuchi.

- (1) **ISO/PWI 13175-3**, Implants for surgery — Calcium phosphates — Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes Review of progress of task force and decision on further procedure

This project is being revised by PL Ian Dunkley, with Gary Fischman, Richard White, Masanori Kikuchi, Limin Sun, David Grossin, and Andy McCabe on the task force. He reported that it still takes time, for example, the diagram needs to be revised. A question was raised as to whether the compression test and the sphere indenter indentation test are effective in measuring what the user community actually wants to know, and it was suggested that SC 1 seek input from the broader community regarding measurement methods to determine the mechanical properties of porous calcium phosphate. The questionnaire was prepared by Hany Demian, Ian Dunkley and Gary Fischman and was to be submitted to the Committee Manager by 11/30/2021.

- (2) **ISO/PWI 4403**, Implants for surgery — Test method for flexural strength of porous calcium salt bone void filler after preconditioning in deaerated phosphate buffered saline
- (3) **ISO/NP**, Implants for surgery — Easy-to-Use test method for torsional strength of porous calcium salt bone void filler after preconditioning in deaerated phosphate buffered saline

For these two, we corrected them to the latest template, but they contained some non-revised parts even those were noted as revised in observation sheets, so we decided to correct them and send it back to Preliminary Consultation with the noting corrections more easily understandable.

- (4) **ISO/DIS 18531**, Implants for surgery — Calcium phosphate bioceramics — Characterization of hardening bone paste materials

PL Asaoka reconfirmed the responses to the previously collected comments, and the revisions were to be poured into the latest template. The latest draft and previous comments (and responses) were then circulated to the following project groups to collect comments and corrections again (with e-

meetings if possible) and circulate them to SC 1.

- (5) **ISO 23317:2014**, Implants for surgery — In vitro evaluation for apatite-forming ability of implant materials

PL Hashimoto gave an explanation of the overall proposed amendment, but after discussion it was determined that it was still not sufficient. (The international project group meeting decided at the previous WG 3 meeting was held only once, and only a revised version was presented by the domestic members based on the discussion at that meeting, which may have been regarded as a failure to gather sufficient opinions from the international project group participants.)

We agreed to have an e-meeting held by the project group by the end of 2021 and the issues would be resolved within that meeting. After an e-mail discussion among the domestic members, Dr. Ayako Oyane of AIST was appointed as the co-PL. A project group meeting was held on December 8 from 21:00-23:00 to begin revising the document. The next one is scheduled for the same time on January 28, 2022.

- (6) Preliminary consultation **ISO /PWI 6474-3**, *Implants for surgery – Ceramic materials – Part 3: Ceramic materials based on silicon nitride*

Standardization of silicon nitride ceramics for implants was proposed by Gary Fischman of the United States and was the subject of preliminary consultation. Basically, there was agreement on the standardization, but the numbering and branch numbering were discussed. Although the 6474 series is entitled as Ceramic Materials, it is limited to alumina and its composites. Further, calcium phosphate, hydroxyapatite, and zirconia are in separate series. (After an expert meeting with Gary Fischman, Junji Ikeda, and Richard White, the name of 6474 was changed at the time of the SR, and silicon nitride was standardized as a separate series.)

Following the formal proposal, experts will be sought in the future.

2.2 SC 1/WG 4 (Metals)

WG 4 was held on Monday, September 13 and Tuesday, September 14 from 20:00 to 22:00 JST with 18 participants from 6 countries: Brazil (3), Germany (1), Japan (2), France (1), UK (2), USA (7) plus committee managers and conveners. Ikeda and Kikuchi participated from Japan. Michael Roach of the United States led the meeting as convener.

- (1) **ISO/DIS 9584** Implants for surgery — Non-destructive testing — Radiographic examination of cast metallic surgical implants

PL Michael Roach reported on discussions in the Task Force. In the revision, it was proposed that the PWI re-launch the project after recruiting experts for the revision project and discard the ongoing ISO/DIS 9584:2020, since a comparison with related ASTM documents is necessary. It was decided that the committee manager would contact the ISO TPM prior to the SC 1 plenary meeting regarding this proposal, including whether a formal vote on DIS revocation would be required.

- (2) **ISO/DIS 5832-5**, Implants for surgery — Metallic materials —Part 5: Wrought cobalt-chromium-tungsten-nickel

The comment responses indicated by the experts were approved. Because of the technology-related changes made, the project leader will prepare the FDIS document and proceed to the FDIS ballot as soon as the ASTM copyright has been confirmed.

- (3) **ISO/DIS 5832-6** Implants for surgery — Metallic materials —Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy

The comment responses indicated by the experts were approved. Because of the technology-related changes made, the project leader will prepare the FDIS document and proceed to the FDIS ballot as soon as the ASTM copyright has been confirmed.

- (4) **ISO/DIS 5832-3**, Implants for surgery — Metallic materials —Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

There was no specific discussion as the FDIS is currently being voted on.

- (5) **ISO/PWI 5832-4**, Implants for surgery — Metallic materials —Part 4: Cobalt-chromium-molybdenum casting alloy

The contents of the response regarding the comments on the systematic review were discussed and the PWI was approved. The project team prepared a WD tailored to address the comments, and the revision project was initiated with a 24-month timeframe.

- (6) **ISO/PWI 5832-11** Implants for surgery — Metallic materials —Part 11: Wrought titanium 6-aluminium 7-niobium alloy

The contents of the response regarding the comments on the systematic review were discussed and the PWI was approved. The project team prepared a WD tailored to address the comments, and the revision project was initiated with a 24-month timeframe.

- (7) **ISO/PWI 5832-1** Implants for surgery —Metallic materials —Part 1: Wrought stainless steel

The contents of the response regarding the comments on the systematic review were discussed and the PWI was approved. The project team prepared a WD tailored to address the comments, and the revision project was initiated with a 24-month timeframe.

- (8) **ISO/PWI 5832-7** Implants for surgery — Metallic materials —Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy

The contents of the response regarding the comments on the systematic review were discussed and the PWI was approved. The project team prepared a WD tailored to address the comments, and the revision project was initiated with a 24-month timeframe.

- (9) **ISO/PWI 15374** Implants for surgery — Requirements for production of forgings

No discussion was scheduled, as no information was reported. Convener Michael Roach will check with project leader Karen McKinlay to see if there is anything to discuss at the next committee meeting. The committee manager informed that if no progress is made, the project will be terminated in November 2024 as three years old.

- (10) duplicate checking: **ISO 9853**, Implants for surgery — Non-destructive testing — Liquid penetrant inspection of metallic surgical implant

Jon Mosely, Boopathy Dhanapal, and Gary Fischman are completing duplicate checking in 2020 prior to the systematic review in 2024.

- (11) Future projects

An update on Cobalt limits / REACH was given.

- (12) Next Meeting

A virtual meeting is planned for spring 2022. Also, due to COVID-19, we are not/will not schedule the next face-to-face meeting, if a TC 150 face-to-face meeting is held, a face-to-face meeting will be held at the same time.

2.3 SC 1/WG 5 (plastic)

SC 1/WG 5 is convened by Ryan Siskey, USA. This year's online meeting was held from 20:00 to 22:00 Japan time on Friday, September 10 with 30 participants from 8 countries: Brazil (4), France (3), Germany (4), Japan (4), China (1), India (1), UK (4) and USA (9).

- (1) **ISO/PWI 14949**, Implants for surgery — Two-part addition-cure silicone elastomers

Jon Moseley and Heitor Neto Luz will proceed with the

deadline for duplicate checking with ASTM F2038 on October 30 of this year. At the same time, a call for experts was issued for SC 1 and a project team meeting was to be held via web meeting.

Committee managers were to be reminded to include textures and texture analysis when proposing new proposals.

- (2) **ISO/PWI 5834-2** Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 2: Moulded forms

Ryan Siskey presented a duplicate checking report on ISO 5834-2 and ASTM F 648, reporting on the most important sections that differed between the two documents. It was to be determined whether a revision could be made to include information identical to that duplicated in the standard revision. Mark Allen, Jon Moseley, and Ryan Siskey will work on the first draft of the document for revision, but will not solicit experts at this time.

Next, Ryan Siskey will be running a duplicate checking on 5834-1, which covers UHMWPE powder forms that also overlap with the 2021 revision of ASTM F648. The same procedure was to be followed for the other parts of the ISO 5834 series (-5, -3, -4).

- (3) **ISO/PWI 5833** Implants for surgery — Acrylic resin cements

Hany Damian proposed a revision of ISO 5833 based on duplicate checking with ASTM F 451 in 2020. Hany Damian, Jon Moseley, and Ryan Siskey to draft an amendment.

- (4) New delamination test

Mr. Sakoda of the National Institute for Health Research continued last year's presentation by bringing forward a new delamination test proposal with new data. It was decided to conduct a 4-week pre-consultation within WG 5 to gather comments on the draft. A project group meeting was then scheduled.

2.4 SC 1 (Materials)

SC 1 is chaired by Mr. Andy McCabe from the UK and Ms. Petra Bischoff from Germany is the CM. This year's meeting was held on Friday, September 17 from 20:00 to 22:00 Japan time with 20 participants from 7 countries: Brazil (2), Germany (2), Japan (3), UK (2), USA (9), India (1) and China (1). In addition, the committee manager and chairperson participate.

This year, the resolution was to accept the recommendation of the WG mentioned above. In addition to that, a resolution was adopted recommending that when PL

revising a document, the committee manager, convener, and chair recheck the contents to ensure that the revisions are correct before circulating it.

The contribution of Japan to SC 1 is that there are many PLs, including those for revision according to the decision of SRs. Most of the new proposals are on ceramics and came from Japan. The fact that Japanese bioceramics researchers have been leading other countries in this field shows a good sign in terms of international standardization. On the other hand, there are few new proposals, especially for metal and plastic materials. However, we believe that attention should be paid to future developments, as a delamination test of ultra-high molecular weight polyethylene has been proposed by Japan, and discussions on additive manufacturing of surgical implantation agents are underway in JWG 1, where a Japanese national serves as convener. Furthermore, Japan has won a convener in WG 16 on antimicrobial implants, and we believe that Japan's activities are becoming even more active.

3. Summary

As mentioned above, in several fields, including bioceramics, Japanese delegates proposes many projects, and active discussions for these projects are underway. In the TC as a whole, although the number of CM has not changed, the number of conveners has increased by one, to four. We would like to aim for more Japanese chairs (not only in the TC but also in the SC) and continue to promote Japanese proposals from new viewpoints that are scientifically more valid than those of other countries. On the other hand, the age of participants, including PLs, is gradually getting older, and it is considered necessary to recruit the next generation. To this end, we hope that the government, research periods, and universities will provide greater incentives for involvement in standardization activities.

Further, the inability to hold face-to-face meetings due to COVID-19 make more difficult for non-native speakers than natives because unofficial explanations and negotiation of the proposed projects cannot be done during breaks of that meeting. I feel that we need to think a lot about how to smoothly promote standardization of Japanese projects.