

各種投票について（2018 年 5 月 24 日現在）

<投票済み>

1/19 〆切

- NP Revision ISO 10993-12:2012 "Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials"（ソウル会議決議の追認で、Scope 等の変更を伴わないため Form4 はなし）→賛成、エキスパート推薦（WG 12 メンバー）→成立（AWI に）

3/16 〆切

- ISO/CD 10993-18.2 "Biological evaluation of medical devices -- Part 18: Chemical characterization of materials" →コメント付き賛成→成立条件は満たしていたが、デルフトで討議→現在、DIS 登録作業中

3/16 〆切

- ISO/DTR 10993-19 "Biological evaluation of medical devices -- Part 19: Physico-chemical, morphological and topographical characterization of materials" →コメント付き賛成→成立予定

3/16 〆切

- ISO/DTS 21726 "Biological evaluation of medical devices -- Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of extractable substances from medical devices" →賛成→成立予定だが、フランスから反対票が投じられておりデルフトでも議論があった

4/9 〆切

- ISO/NP 10993-10 (Ed 4) "Biological evaluation of medical devices -- Part 10: Tests for skin sensitization" →賛成、エキスパート推薦（WG 8 メンバー）→成立

4/18 〆切

- ISO/NP 10993-17 (Ed 2) "Biological evaluation of medical devices -- Part 17: Toxicological risk assessment of medical device constituents" →賛成、エキスパート推薦（平井委員）→成立の見込み（Form 6 が未回覧）

5/11 〆切

- Request from IEC/TC 124 "Wearable electronic devices and technologies" for a liaison with ISO/TC 194（当該 TC から TC194 への liaison を受け入れるかを問う投票）→賛成→反対なし

5/15 〆切

- ISO/CD 22442-1 "Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management" →賛成→反対なし

<投票予定（新規）>

5/26 〆切

- ISO/FDIS 10993-1 “Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process”

7/17 〆切

- ISO/DIS 10993-9 “Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products”

7/17 〆切

- ISO/DIS 10993-15 “Biological evaluation of medical devices -- Part 15: Identification and quantification of degradation products from metals and alloys”

事務局長