Report of the 23rd meeting of the JCTLM Executive Committee 16-17 December 2021 Venue: Webex Video Conferences Time: 12:00-14:00 (UTC +1, Paris time)

List of participants: Dr G. Miller (JCTLM Chairman, IFCC) Dr R. Wielgosz (JCTLM Executive Secretary, BIPM) Dr G. Myers (IFCC) Dr S. Maniguet (JCTLM Secretariat, BIPM) Dr T. Liew (CIPM) Dr G. Jones (ILAC) Ms M. Bednarova (ILAC) Dr O. Liu (JCTLM DB WG vice-Chair, AG1) Prof. M. Panteghini (JCTLM DB WG vice-chair, AG2) Dr K. Phinney (JCTLM DB WG vice-Chair, AG3) Mr T. Fawcett (ICSH) Dr A. Kessler (IFCC) Dr Sang-Ryoul Park (CIPM) Dr S. Westwood (Blood cell Counting team Leader, BIPM) Prof. E. Theodorsson (JCTLM TEP WG Chair)

1 Approval of the agenda [JCTLM-EXEC/21-01]

The agenda was approved with an additional agenda item under 4.4 to discuss the international availability of reference materials as a part of the review criteria for JCTLM listing of reference materials.

2 Report of 22nd JCTLM Executive Committee Meeting

2.1 Review of action points arising from the 22nd meeting [JCTLM-EXEC/21-02]

2.2 Review of action points arising from mid-year meeting [JCTLM-EXEC/21-03]

The Committee reviewed the action items from the previous meeting that were still outstanding and would be completed after the meeting:

Action (A/19-05): JCTLM Secretariat to draft a procedure for an induction process for new EC members of JCTLM Executive Member Status for discussion at the next Executive Meeting.

Action (A/20-05): JCTLM Secretariat to finalize the procedure for an induction process for new EC members of JCTLM Executive Member Status for circulation and EC comments Action (A20-09): JCTLM Secretariat to request the service providers for total bilirubin measurement to clarify what procedure they employed to ensure traceability to the SI and what was the impact on their measurement uncertainty value.

3 JCTLM Governance

3.1 JCTLM Review Team Membership

The Committee reviewed the recommendations of the DBWG from its last meeting and supported the recruitment of new experts for serving as members of the review teams for

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Drugs, Nucleic acids, Electrolytes and Blood gases, Enzymes, Vitamins; confirmed that review team membership was dependent on active participation in the review process and was requiring individuals to have access to the necessary standards for the review of nominations. It further requested that a letter of suspension of membership should be sent to individuals who had been inactive over the last two review cycles, or who confirmed they had no access to the necessary standards for review of nominations.

S. Westwood would be stepping down after next year's review cycle and a new team leader for the Blood Cell Counting and typing review team would then need to be identified. The Committee agreed with the suggested approach, which would extend his term as leader of the review team to allow some overlap with the new person who would be identified from the current list of members of the team to take over the leadership.

Action:

Action (A21-01): JCTLM Secretariat to send a call for new experts' membership application in consultation with review teams leaders for Drugs, Nucleic acids, Electrolytes and blood gases, Enzymes, Vitamins by the Secretariat.

Action (A21-02): JCTLM Secretariat to contact individuals no longer compliant with mandatory requirements for JCTLM Review Team membership, and to send a letter of suspension of their term as a JCTLM review team member.

3.2 Representation on the Executive

Dr Miller informed the Committee that his term as Chairman of the JCTLM would end in December 2022. The Committee requested that the procedure for selection of a new President should be followed, which would require the Secretariat to inform the JCTLM Executive Committee members organizations of the need to nominate candidates for the post of JCTLM President. It was also reminded that the JCTLM Secretariat host organization would need to be re-elected at the same time.

Dr Myers informed the Committee that his term as IFCC representative in the JCTLM Executive Committee would end at the end of 2022 and a new IFCC representative will be elected by the IFCC Executive Board.

Action(A/21-03): JCTLM Secretariat to contact IFCC, BIPM, ILAC and ICSH by end of June 2022 for nominations of JCTLM President and Secretariat, for review and approval of applications during the next Executive meeting in December 2022.

3.3 JCTLM WG Chairs

Dr Wielgosz said that the term of the Chair and three vice Chairs of the JCTLM Database WG would come to an end at the end of 2022, noting that in accordance with JCTLM rules the responsibilities of the JCTLM DB WG Chairman would be taken over by the new JCTLM president who would be elected in January 2023.

Dr Phinney, Prof. Panteghini and Dr Liu confirmed their willingness to continue to chair the WG Analyte Group 3, 2 and 1, respectively.

The Committee also noted that the term of the Chair of TEP WG would expire end of 2022.

3.4 New JCTLM Database development

S. Maniguet reported that the development for the update of the JCTLM Database application with an external contractor had started in October and the launch of the new application was foreseen in the first semester of 2022.

Dr Wielgosz said that the BIPM was providing full financial support for this development of the new database so far, which would remain based on an Excel based technology for the nomination, review and publication process. He added that the cost for the optional development of a new web-based interface for supporting the process for submission and review of nominations for materials, methods and services had been anticipated in the call for tender process, and additional funding resources were still being investigated. The representative of the IFCC informed the members of the Committee that the IFCC Executive Board agreed on the approach to contact its IFCC Corporate Members to get extraordinary funding resources, which would be formalized via a communication letter. The ICSH representative also reported that the issue of getting extraordinary funding for the development of the JCTLM database was raised during the ICSH GA Video conference Meeting on 17 December and a resolution was adopted that ICSH would contact IFCC for presenting a joint letter to the IFCC corporate members.

3.5 Funding of the JCTLM Secretariat

Dr Wielgosz thanked the IFCC for its continuing support for funding the JCTLM Secretariat which was acknowledged on the BIPM and www.jctlm.org websites. As reported at the previous meeting the running cost for 2022 would be similar to 2021. This does not include the annual cost of the routine maintenance of the web system application for which new developments were being made and an extraordinary source of funding used. The BIPM will contact the IFCC Executive board with a summary of expenses for 2021 and predicted expenses for 2022 for the JCTLM Secretariat activities.

3.6 JCTLM Membership [JCTLM 21-04]

Dr Wielgosz reported that thirty JCTLM member organizations have already sent their biennial activity reports for the period 2020-2021 for consideration by the Executive Committee, and all of these were included in the document JCTLM-EXEC21-04. The Committee agreed to review and address the issues and questions submitted in these reports. It further requested an article on the highlights from these reports should be included in the next issue of the JCTLM Database newsletter.

Action (A/21-04): Dr Myers to review the JCTLM Member organizations' activity reports, on behalf of the EC, for consideration of any issues raised in these reports. Dr Myers to also prepare a brief report highlighting representative activities of JCTLM Member organizations for inclusion in the JCTLM Database newsletter.

4 Revision of JCTLM quality manuals

4.1 Update on procedure review and update

Dr Maniguet reported that the review of the JCTLM DBWG Quality Manual had been initiated in September and was still in progress. There were 4 new experts from the NMI community who were appointed in 2020 as members of the Quality System review team, as the review aimed at looking at opportunities to further align CIPM MRA review process for CMCs and JCTLM requirements, and where possible avoid double verification of information. This review focuses on the JCTLM acceptance and review criteria for listing materials, methods and services, and the process for demonstrating extent of equivalence with already JCTLM listed items. The revised procedures were foreseen to be presented for approval by the JCTLM Executive in December 2022, for an implementation in the 2023 review cycle. Dr Liew questioned how the availability of listed CRMs was being monitored by JCTLM. Some members of the Committee commented that it was the responsibility of the producer to notify the JCTLM Secretariat if a material ceases to be available. Dr Wielgosz added that following JCTLM procedures, the JCTLM Secretariat would contact a producer to confirm the availability of a CRM if a notification from a user was received questioning the availability of a CRM.

Dr Miller brought up for discussion the issue of the review criteria raised during the last DB WG meeting, and for which further guidance was requested by the DBWG. The issue of the appropriate level of metrological hierarchy required for a nominated method was discussed. This related to a nominated manufacturer's measurement protocol which was submitted for review as a reference measurement method in the JCTLM Database. From the discussion, the Committee agreed that reference to the guidance in ISO 17511 should be made in this case and the relevant JCTLM procedures should be updated to clarify that the subject of JCTLM review was limited to the highest available reference measurement procedures in a measurand calibration hierarchy.

The Committee also discussed the issue of the lack of clarity of the information submitted by an organization for addressing observed non-compliances from previous review cycles that was observed during last review cycle. It further requested that the relevant procedures documents should be amended to clarify the process and acceptance criteria for resubmission of materials and methods nominations for addressing reviewers' observations, to ensure that all necessary information is readily accessible for the reviewers and highlighted in the submission form.

The Committee discussed another issue concerning the lack of acceptance criteria in the procedures for the review of reference measurement services when a provider claims an extended reference measurement range to a lower limit than the published range of a formerly listed RMP applied by the laboratory. It was agreed that the provision of a validation report for supporting this extension of the reference measurement range would be required for assessment by the experts of the review team. The Committee requested that the relevant procedure document be amended to include the new requirement, with a limitation that this acceptance criteria would not apply for reference measurement services based on an implemented measurand-defined procedure where the experts of review team could at their discretion request the provision of adequate information required for confirming there are no modifications of applied procedure.

Action (A/21-05): JCTLM Secretariat to modify the relevant procedures to clarify JCTLM was operating the review of highest order metrological order material and method with reference to ISO 17511; to clarify the process and acceptance criteria for resubmission of materials and methods nominations for addressing reviewers' observations; to include the new requirement for submission of a validation report for supporting extension of the reference measurement range claimed to a lower limit than the acceptable range of the listed RMP.

4.2 Revision of JCTLM rules for regular participation in EQAS Scheme

As discussed in the mid-year review EC meeting in July 2021, a survey would be initiated amongst the listed calibration laboratories to understand their views on the required periodicity for RELA scheme participation, for further revision of the JCTLM procedures.

4.3 Inclusion of harmonization components in the JCTLM Database [EXEC21-16]

Dr Myers presented the document EXEC21-16 which included a proposal for a JCTLM nomination template for the submission of harmonization protocols developed in compliance with ISO 21151 requirements for possible inclusion in the JCTLM Database.

In the discussion that followed the Committee requested that this draft template should be further reviewed in parallel with ISO 21151 requirements for determining what suitable information should be published in the JCTLM Database and for clarifying whether listing the value assigned reference materials or panel patient samples used to establish harmonization protocols would be required.

Dr Wielgosz also reminded the Committee that the implementation of the harmonization protocols in the JCTLM database would require additional developments by the external contractor, for which additional resources for financing the development would be needed. The request for a first estimate of the cost for the development was being finalized based on the current template information, noting this would need to be re-evaluated following the confirmation of the template and clarification on the suitable and necessary information for publication in the JCTLM database. Dr Myers commented that he would approach the ICHCLR to investigate whether a possible contribution for funding this development could be anticipated by the consortium for harmonization.

The Committee anticipated the development of a new chapter of the JCTLM Quality Manual for describing the submission and review process for listing a harmonization protocol in the JCTLM Database. The formation of a task group of the QS RT on harmonization protocol was agreed, and G. Miller, G. Myers and DB WG Chairs agreed to participate.

Action (A/21-06): EC Members to review the draft version of the ISO 21151 nomination template for determining the acceptance and review criteria for listing harmonization protocols and/or associated reference materials.

Action (A/21-07): QS RT sub-group on harmonization protocols to draft the procedure documents for nomination and review of harmonization protocols in the JCTLM Database, for discussion at the next Executive Meeting in December 2022.

4.4 International availability of CRMs

Prof. Panteghini reported the case of a material nominated during the last review cycle which was confirmed by the producer to be only available for national customers. He added that he could see this as a critical issue for traceability in laboratory medicine when no other reference materials are listed in the JCTLM for the concerned measurand. The Committee noted this important point which raised the international accessibility of listed reference materials while JCTLM acceptance criteria requires that the reference material should be available to be listed with no additional requirement regarding the limitation on the geographical accessibility. It was agreed as first step forward that the producer should be requested to systematically indicate whether the material was restricted geographically and indicate this on the JCTLM database.

Action (A/21-08): JCTLM Secretariat to update the material nomination template to allow the producer to state whether the nominated material was restricted geographically.

5 Report from the JCTLM WG on Traceability Education and Promotion

Prof. Theodorsson reported on the annual activity of the TEP WG for the successful organization of the biennial online JCTLM Members and Stakeholders meeting on 13 December 2021, which was preceded by the JCTLM-ICHCLR-IFCC online Workshop on overcoming challenges to global standardization of clinical laboratory testing: reference materials and regulations, on 06 to 10 December. The Workshop was attended by about 400 participants and a set of recommendations discussed at the Workshop would be released for comment and publication in the course of 2022.

He added that the planning for 2023 JCTLM Workshop on EQAS schemes supporting traceability in laboratory medicine was progressing well, and the expected outcome was a set of recommendations for publication in a scientific journal.

The TEP WG was also involved in the production of educational materials on traceability in laboratory medicine for celebrating the World Metrology Day on Measurement in Health on 20th May 2021.

The TEP WG was also progressing with the development of a guidance document on metrological traceability in laboratory medicine for publication on the JCTLM website.

The Committee noted the need to discuss and better understand the naming and coding systems for measurands used across various parties involved in traceability in laboratory medicine and how best to determine the coding system to be used in the JCTLM database for better machine readability The formation of Task Group on Nomenclature and coding systems in view of digitalization was agreed, which would be led by Prof. Theodorsson, and A. Kessler, G. Jones and S. Maniguet agreed to participate.

Action (A/21-08a): Prof. Theodorsson to lead a Task Group to propose the coding system to be used in the JCTLM database for better machine readability.

The Committee also recognized the need to establish a task group for developing educational materials for organizations submitting nomination and individuals engaging in the activity of the review team.

6 Report from the Task Force Group of Reference Measurement System Implementation [EXEC21-05]

Prof. Panteghini said that the outcome of the first step of the activity the Task Force Group on Reference Measurement System Implementation was published in the December issue of Clinical Chemistry Journal (also included as meeting document EXEC21-05). He further suggested this publication, which was freely accessible, be published on the TF-RMSI webpage of the BIPM website and JCTLM portal.

He added that the TF RMSI was planning to use a similar approach for a new group of measurands in the next year.

The Committee thanked the JCTLM TF RMSI for its great work, and supported the proposal for continuing the activity for a new set of commonly tested measurands in laboratory medicine.

7 JCTLM DB WG: Approval of Recommendations

Dr Maniguet presented the summary of the nominations for reference materials, reference measurement methods and reference measurement services with the final DB WG's recommendations that had been submitted for review as part of cycle 18 for materials and methods and cycle 16 for services.

There were 184 new nominations made up of 113 material, 18 method and 53 service nominations that were distributed for consideration to ten JCTLM review teams in 2021.

Dr Miller said that the Database WG held two conference meetings on 14/15 December and successfully completed the review of all review teams' recommendations concerning these 184 nominations. All of these are summarized in the following sub-sections for each group of analytes including final Database WG recommendations.

He further indicated that in the interest of time, only specific outstanding nominations and general issues that were raised during the DBWG meeting would be discussed by the committee, considering that other reported issues were resolved during the DBWG Meeting sessions.

7.1 Approval of Cycle 18 RM and RMP and Cycle 16 RMS

7.1.1 Analyte Group 1

7.1.1.1 Non-Peptide Hormones [JCTLM-EXEC/21-12]

There were five nominations related to a certified reference material, a nomination for a reference measurement method and 18 nominations for reference measurement services that were reviewed by the review team for Non-Peptide Hormones, and of these a matrix material for Estriol (non-conjugated) in human serum at 5 levels concentration and a measurement service for Testosterone in human was being recommended for listing in the database.

The Committee approved the DB WG's recommendation for Non-Peptide hormones nominations.

7.1.1.2 Metabolites and Substrates [JCTLM-EXEC/21-13]

There were 75 nominations for certified reference materials and six nominations for reference measurement services that were reviewed by the review team for Metabolites and Substrates, and of these four reference measurement services for serum urea, glucose, uric acid and homocysteine were being recommended for inclusion in the JCTLM Database.

The Committee approved the DB WG's recommendation for Metabolites and Substrates nominations.

7.1.1.3 Drugs [JCTLM-EXEC/21-06]

There was a nomination for certified reference material and two nominations for reference measurement services that were reviewed by the review team for Drugs and were not being recommended for listing. It was noted that the nominated carbamazepine certified reference material was not recommended unless adequate responses to the reviewers' comments are provided by the producer for further assessment by the review team.

The Committee approved the DB WG's recommendation for the Drugs nominations.

7.1.2 Analyte Group 2

7.1.2.1 Proteins [JCTLM-EXEC/21-07]

There were six nominations for certified reference materials, a nomination for a reference measurement method and a nomination for a reference measurement service that were reviewed by the Proteins team, and of these a LC-MSMS method for analysis of amyloid beta 1-40 in human CSF was being recommended for listing.

It was noted that the nominated material for a recombinant human serum albumin solution was not recommended for listing until the producer responds to the reviewers' recommendation for changing the scope of the material in alignment with the conclusions of the certification report specifying that this material is to be used to establish a traceability chain for measurements of albumin in urine and not in serum.

It was also noted that the recommendation for listing the nomination for Total Haemoglobin reference measurement service was deferred until after receipt of the accreditation document and potential alignment of the linearity range with the linearity range of the JCTLM listed method.

The Committee approved the DB WG's recommendation for the Proteins nominations.

The Committee discussed the general issue of the CRP traceability chain(s) which was raised during the review of a nominated material. The formation of a task group involving all parties involved in the CRP reference measurement system was agreed, and Prof. Panteghini was appointed as the Chair.

Action (A/21-08b): Prof. Panteghini to lead a Task Group to review and comments on different traceability chains being developed for CRP measurements.

7.1.2.2 Enzymes [JCTLM-EXEC/21-08]

There were seven nominations related to certified reference materials and 14 nominations for reference measurement services that were reviewed by the review team for Enzymes, and of these two serum amylase and creatine kinase materials and nine services were being recommended for approval and publication in the JCTLM Database.

In addition, there were three certified reference materials for ALT, LD1 and CK-MM in buffer solution that were being recommended for listing, noting that the observed typographical error of the value for the lower limit of uncertainty range for LD1 and CK-MM should be corrected in the submission for consistency with the certificate prior to publication in the JCTLM database.

It was noted that a serum GGT and ALP material was not being recommended for listing until adequate responses to reviewers' comments are provided by the producer.

The Committee approved the DB WG's recommendation for Enzymes nominations.

7.1.2.3 Nucleic acid [JCTLM-EXEC/21-09]

There were 17 nominations for certified reference materials and 12 nominations for reference measurement methods that were reviewed by the review team for Nucleic acids and all of these were not being recommended for publication in the JCTLM Database. The Committee approved the DB WG's recommendation for Nucleic acid nominations.

7.1.2.4 Blood cell counting and typing [JCTLM-EXEC/21-14]

There were two nominations for reference measurement procedures for leukocytes and erythrocytes in whole blood that were not being recommended for approval after critical noncompliances regarding the lack of comparison with other procedures and the missing information supporting the procedure validation were observed. In addition, the review team observed the lack of reference to a paper in a peer-reviewed journal for the method.

The Committee approved the DB WG's recommendation for Blood Cell Counting nominations, noting that according to the guidance ISO 17511 the nominated method did not fit the metrological hierarchy for the measurand.

7.1.3 Analyte Group 3

7.1.3.1 Electrolytes and blood gases [JCTLM-EXEC/21-10]

There was a nomination for a reference measurement method and eight nominations for reference measurement services that were reviewed by the review team for Electrolytes and blood gases, and of these seven reference measurement services for serum/plasma calcium, magnesium, potassium, sodium or lithium from two providers were being recommended for listing in the JCTLM database.

The Committee approved the DB WG's recommendation for Electrolytes nominations.

7.1.3.2 Vitamins [JCTLM-EXEC/21-14]

There was a nomination for a reference measurement method and four nominations for reference measurement services for 25-hydroxyvitamin D3, and all of these were not being recommended for listing in the JCTLM database.

The Committee approved the DB WG's recommendation for Vitamins nominations.

7.1.3.3 Non-Electrolyte metals [JCTLM-EXEC/21-11]

There were two nominations for the first whole blood matrix CRM containing elements dedicated to replacement joints diagnostic tests that were reviewed by the review team for Non-electrolyte metals, and of these the certified value for Chromium in the material was being recommended for listing in the JCTLM database.

The Committee approved the DB WG's recommendation for Non-electrolyte metals nominations.

Action (A/21-09): JCTLM Secretariat to publish the nominations recommended for publication in the JCTLM Database and send out the report on the outcome of the review to the nominating organizations.

7.2 IFCC CDT method submission follow up

Dr Westwood reported on the consultation he undertook with the IFCC-WG-CDT representatives for discussing the corrective actions required for the IFCC-CDT method to be compliant with relevant ISO standards used by the JCTLM.

He commented there was a strong desire to find a pathway to integrate the method in the JCTLM Database and address the observed non-compliance concerning the uncertainty calculation raised in the review. He suggested that it could be possible to rework the method

data that had already been obtained in a supplemental publication to better address the issues around measurement uncertainty that had been raised. The Committee agreed that this would be a useful approach, especially if it could address the issues raised in the initial review and result in a resubmission to JCTLM.

Action (A/21-10): Dr Westwood to contact the IFCC-WG-CDT representatives on proposal to rework existing method data to further characterize method uncertainty.

7.3 Update on IFCC EQAS results

Dr Kessler reported on the IFCC EQAS Scheme activity for 2021. She highlighted the RELA Procedure Manual was currently being updated by the IFCC C-TLM to revise the RELA process and revise the limits of equivalence displayed on the graphs of results. A major project was initiated to coordinate the measurement activities via joint projects to demonstrate equivalence of results between RELA participants and NMIs. A survey distributed among the NMIs determined key measurands for Enzymes, Hormones and drugs that would be pertinent for RELA 2023 to 2025.

A key project for total Haemoglobin measurement has already started with RELA 2022 and discussion with linking to a CCQM comparison was underway.

7.4 Progress/ plans for Cycle 19 for RMs and RMPs and Cycle 17 for RMSs

As in previous review cycles, the same calendar would be applied for the next nomination and review cycle in 2022.

8 Reports from related activities / meetings

8.1 IFCC SD

There was no report from the IFCC SD. Dr Wielgosz informed the Committee that a BIPM observer, Dr Ralf Josephs, was now attending the IFCC SD.

8.2 ICSH GA

Mr Fawcett reported that the ICSH GA Video conference Meeting was held on 17 December. He added that the funding for the development of the JCTLM database was discussed during the meeting, and a resolution was adopted that ICSH would contact IFCC for presenting a joint communication letter to corporate members.

8.3 ILAC [JCTLM-EXEC/21-17]

Mrs Bednarova presented the document EXEC/21-17 for ILAC and JCTLM related activities for 2021, which highlighted the extended transition period for implementation of ISO 17025:2017 to 01.06.2021, ILAC contribution to the revision of ISO/IEC 17043 and ISO 15189, revision of ILAC G17:01/2021on guidelines for measurement uncertainty in testing, and ILAC GA resolution on extension of ILAC MRA for accreditation of biobanking according to ISO 20387. She also thanked Dr Jones for his excellent presentation, sharing experience and promoting JCTLM with accreditation audience at the European Accreditation Working Group on Health Care remote meeting in December 2022.

8.4 CCQM

Dr Wielgosz gave an update of the CCQM activities in 2021, notably the 26th CCQM Plenary Meeting on 26-28 April 2021, the publication of the CCQM Strategy document for 2021-2030, the completion of CCQM interlaboratory comparison studies for SARS-CoV-2 RNA

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copy number quantification, and monoclonal antibody quantification, and a Workshop for Infectious Diseases and Pandemic was held in October 2021 to develop a roadmap for metrology to support measurement associated with infectious disease and future pandemic readiness.

9 Liaison with ISO TC 212

It was noted that the revisions of ISO 15193:2009 and 15194:2009 were progressing according to the same revision schedule, with a possible publication in 2022.

10 Liaison with the WHO

It was agreed that BIPM would re-establish communication with the new WHO contact person.

11 Future meetings of the JCTLM

The Committee confirmed that the Database WG meeting and 24th Meeting of the JCTLM Executive Committee would be held in December 2022 (dates to be confirmed).

It was noted that the next edition of the international conference on research and quality assurance on Therapeutics and Diagnostics was being organized by NIM (China) and would be held as a hybrid meeting during July 2022.

The IFCC World lab in Seoul will be held on 26-30 June 2022.

12 Close

The Chairman closed the meeting on 17 December at 14:30.

Annex 1: Summary List of Actions

Outstanding Actions from the 22nd Executive Meeting:

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