Draft template for biennial activity report from JCTLM Member organizations

All JCTLM Members are invited to attend the Members' and Stakeholders' Meeting, which is held once every two years, and submit a report of their activities in support of traceability in laboratory medicine over the preceding period.

For that purpose this template document provides guidance to JCTLM Members for drafting their biennial activity report. Organizations are invited to provide the information below for submission to the Executive Committee.

Organization: Shanghai Center for Clinical Laboratory

JCTLM Member status: Stakeholders Member

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Period covered: 2015 – 2017

1. **Major achievement(s) in support of standardization in laboratory medicine**
   (Please describe what activities your organization has undertaken related to the implementation of reference measurement systems in laboratory medicine during the last two years, including but not limited to information on: the production of certified reference materials; the development of reference measurement methods; or the establishment of calibration (reference) measurement services. Outline the measurement area(s)/measurands covered, and, provide a listing of the relevant technical/scientific publications.)

   a) SCCL has established 22 reference methods according to JCTLM publications, including Calcium, Lithium, ALT, Amylase, AP, AST, CK, GGT, LDH, HbA1c, Cortisol, Estradiol-17β, Estriol, Progesterone, Creatinine, Glucose, Total cholesterol, Urea, Uric acid, Thyroxion, Triiodthyronin and 25-OH-Vitamin D3. We participate in the annual RELA study organized by DGKL (www.dgkl-rfb.de:81) and our lab code is 54. Meanwhile the reference methods on red blood cells, white blood cells and hemoglobin are established according to ICSH recommendation.
   b) We developed the HBV DNA serum (liquid) reference materials and HCV RNA serum (lyophilized) reference materials which were certified as the Secondary Reference Materials by General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China. The certificate number is GBW(E)090627 and GBW(E)090628.
   c) On January, 2016, 7 enzymes have been approved by JCTLM to join the JCTLM calibration (reference) measurement services.
   d) On February, 2017, SCCL passed the CNAS accreditation on ISO17025/ISO15195. In addition to 7 enzymes, 2 new items by mass spectrometry, HbA1c and Creatinine, were also accredited. The certificate number is CNAS L6730. On April, we submitted the

application form to JCTLM WG2 for services database inclusion of our HbA1c and creatinine items.

2. Planned activity(ies) in support of standardization in laboratory medicine

(Please outline R&D project(s) and/or programme(s) planned by your organization in the next two years including information on: new measurement area(s)/meaurands of interest for your organization; new CRMs and renewals of materials; development of methods (new measurands and improved measurement technique/principle); and extensions of your calibration measurement service(s) portfolio.)

a) Development of reference materials, such as ALT, AST, etc., and get certified as the Secondary Reference Materials.
b) Establishment of reference methods on apolipoproteins, such as ApoA1, ApoB, ApoE, etc.
c) Establishment of reference methods on testosterone, homocysteine, according to JCTLM publications.
d) Inclusion more items to ISO17025/ISO15195 quality management systems, and application to JCTLM for database list.
e) Provision of reference measurement service for IVD manufacturers, research, trueness verification program in SCCL, etc., including HbA1c, enzymes, metabolites and substrates.
f) Organization of activities related to national and international traceability or harmonization, to make use of SCCL's role in PT provider and as member of Chinese Clinical Medicine Metrology Committee.

3. Promoting traceability in laboratory medicine

(Please describe activities your organization has undertaken during the last two years for promoting traceability in laboratory medicine including but not limited to a listing of your publication(s), presentation(s) and other communication(s) on traceability at international and national conferences or congresses, or other forums for clinical laboratory medicine)

a) On Sept.9, 2016, SCCL held the IFCC HbA1c Network Annual Meeting in Shanghai and simultaneously organized the forum named *HbA1c in Clinical Practice*, together with IFCC Committee on Education in the Use of Biomarkers in Diabetes (C-EUBD) and Shanghai Society of Laboratory Medicine. The speakers included C-EUBD Chair Prof. Garry John, Dr. Cas Weykamp, Dr. Emma English, Dr. Erna Lenters, Prof. Weiping Jia (Chair of Chinese Diabetes Society) and Prof. Wenxiang Chen (Director of NCCL).This forum promotes the standardization and quality management of HbA1c in China.
b) On Sept.27, 2017, SCCL held the forum on Quality Indicators in Clinical Laboratoy together with Shanghai Society of Laboratory Medicine. Prof. Mario Plebani from IFCC SD Executive Committee (SD-EC) member， Laboratory Errors and Patient Safety (WG-LEPS) Past Chair was invited to give a speech. This forum promoted the

application of quality indicators in Shanghai and further improve the quality management levels.

4. **Reference laboratory networks /collaborations focusing on developing /implementing reference measurement systems**
   (Please describe your participation in laboratory networks, forums or professional/technical committees linked to reference measurements system development/implementation, and contributions to JCTLM Working Group activities.)

   a) On Oct, 2011, SCCL joined the IFCC HbA1c Network and maintained certificate annually. Details are at the website: http://www.ifcchba1c.net/
   b) On May 30, 2016, A conference *Protein and Peptide Therapeutics and Diagnostics（PPTD）*was held in Chengdu by JCTLM，BIPM and NIM. Vice director of SCCL, Prof. Yi Ju, gave a speech named *The Accuracy of HbA1c Test Results: Practice on The Basis of Reference System and Trueness Verification Program (TVP)*. Prof Ju introduced SCCL's works on reference method based PT program, standardization of TVP to clinical laboratory, and the achievement of reduction of difference among methods.

5. **Open questions and suggestions to be addressed by JCTLM**
   (Suggestions on issues related to standardization and metrological traceability that should be considered by the JCTLM)

   a) During the development of reference method, reference materials are necessary to verify trueness, and we suggest that more attention be put on analytes that have no reference materials or not enough lots in storage.
   b) We hope the PT organizer can offer more analytes to meet the needs.
   c) More networks like IFCC HbA1c Network are expected in order to promote the application of reference systems in laboratory medicine standardization or harmonization.

Note: The information of this report will be accessible publicly on the relevant JCTLM Members webpage, unless the author of the report states otherwise. In the case the organization does not authorizes the publication of the report in part or full, the author will add a statement to clarify which part(s) of the report will /will not be rendered public.