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.

<table>
<thead>
<tr>
<th>Organization:</th>
<th>Health Sciences Authority, Singapore</th>
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<tbody>
<tr>
<td>JCTLM Member status:</td>
<td>Member</td>
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<td>Period covered:</td>
<td>2015 – 2017</td>
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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.)

- **Accuracy-Based EQA Programme**

  HSA continues to organise an accuracy-based EQA programme for the local clinical laboratories, where metrologically traceable assigned (target) values determined by the Chemical Metrology Laboratory (CML) are used to evaluate the results of the participating clinical laboratories. The programme comprises two cycles per year.

  In 2017, a total of 17 analytes are offered in the HSA EQA programme. These include:
  
  (a) creatinine, glucose, total cholesterol, triglycerides (as ‘total glycerides’), urea, uric acid, LDL-cholesterol, HDL-cholesterol, calcium, sodium, potassium, magnesium, iron, and chloride in human serum
  (b) glycated haemoglobin (HbA1c) in human blood (two levels per cycle)
  (c) albumin and creatinine in human urine

  A total of 42 clinical laboratories, including all public and almost all private laboratories, participated in the HSA EQA programme.

- **Clinical Certified Reference Materials (CRMs)**

  HSA has produced the following clinical CRMs in 2015 - 2017:

  (a) HRM-3002B: Creatinine, glucose, total cholesterol, HDL-cholesterol, LDL-cholesterol, total glycerides, free glycerol, urea and uric acid in human serum
  (b) HRM-3003B: Haemoglobin A1c in human blood
  (c) HRM-3004A: Albumin and creatinine in human urine (expected to be ready in early 2018)
  (d) HRM-2011A: Sodium, chloride, copper, selenium and phosphorus in human serum
- **Reference Measurement methods Developed:**

  (a) LC-IDMS/MS method for glucose in human serum (listed in JCTLM database)
  (b) GC-IDMS method for free glycerol in human serum (listed in JCTLM database)
  (c) LC-IDMS/MS method for albumin in human serum and urine
  (d) LC-IDMS/MS method for creatinine in human urine
  (e) LC-IDMS/MS method for cortisol in human serum
  (f) LC-IDMS/MS method for progesterone in human serum
  (g) LC-IDMS/MS method for testosterone in human serum

- **CCQM Comparisons Related to Healthcare**

  HSA organised/co-organised the following comparisons:

  (a) CCQM-K109 & CCQM-P148 High polarity analytes in biological matrix: determination of urea and uric acid in human serum (in progress)
  (b) CCQM-K142 & CCQM-P179 Comparison of CRMs and value-assigned quality controls: urea and uric acid in human serum or plasma, co-organised with NIST (in progress)
  (c) CCQM-K139 & CCQM-P173 Elements in human serum (in progress)

  HSA participated in the following comparisons:

  (a) CCQM-K115 Peptide purity: synthetic human C-peptide
  (b) CCQM-K132 Low polarity analytes in a biological matrix: vitamin D metabolites in human serum
  (c) CCQM-P164 Pilot study on growth hormone determination in serum using isotope dilution mass spectrometry (in progress)

- **Publications Related to Healthcare**

  (1) Liquid chromatography–isotope dilution tandem mass spectrometry method for the measurement of urea in human serum and assignment of reference values to external quality assessment samples

  (2) Response to Letter to the Editor regarding “Achieving comparability with IFCC reference method for the measurement of hemoglobin A1c by use of an improved isotope-dilution mass spectrometry method”

  (3) Development of high accuracy methods for the certification of calcium, iron, magnesium and potassium in human serum

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)/measurands 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.)

- **Expansion of HSA EQA Programme**
Albumin in human serum will be added to the HSA EQA programme in 2018.

- **Development of Reference Measurement Methods**
  
  (a) LC-IDMS/MS method for estradiol in human serum  
  (b) Systematic study on the commutability of HbA1c in human blood CRMs  
  (c) Determination of total protein in human serum  
  (d) Determination of purity of peptides with cross-links  
  (e) Determination of purity of peptides using sulphur analysis

- **Development of Clinical CRMs**
  
  (a) Vitamin D metabolites in human serum  
  (b) Steroid hormones (cortisol, progesterone, testosterone and estradiol) in human serum  
  (c) Albumin in human serum

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) “Measurement uncertainty and metrological traceability in medical testing”, Cheow Pui Sze, oral presentation at the Technical Assessors Enclave, Singapore Accreditation Council, January 2015.


(c) “Certified Reference Materials for Clinical Measurements”, Qinde Liu, oral presentation at the Standards Adoption Workshop Biomedical Standards Industry Series 2015, November, 2015.

(d) 2016 HSA EQA Programme Symposium for participating clinical laboratories of EQA programme, January 2016.

(e) 2017 HSA EQA Programme Symposium for participating clinical laboratories of EQA programme, February 2017.

(f) “Measurement Uncertainty in Medical Laboratories”, Cheow Pui Sze, oral presentation at The 2nd APFCB-SACB-Siemens Specialty Meeting on Laboratory Excellence, October 2017.

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.)

Two HSA staff members are currently serving in the JCTLM Database Working Group:

(1) Dr Qinde Liu  
   Vice-Chair of Analyte Group 1  
   Member of Metabolites and Substrates Review Team  
   Member of Non-Peptides Hormones Review Team  
   Interim Leader of Non-Peptides Hormones Review Team for 2017 review

(2) Dr Richard Shin
Member of Non-Electrolyte Metals Review Team

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)

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 authorize 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.