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: Reference Institute for Bioanalytics

JCTLM Member status: Stakeholder

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Period covered: 2015 – 2017

1. **Major achievement(s) in support of standardization in laboratory medicine**

   The RfB, organizes an External Quality Assessment Scheme (EQAS) for medical laboratories internationally and is accredited according to ISO 17043 since 2012. EQAS is performed regularly in accordance with the "Guideline of the German Medical Association for quality assurance in Medical Laboratory Examinations – RiliBAEK" (J Lab Med 2015; 39(1): 26-69). These directives were created by the German Medical Association in close cooperation with the national metrology institute (PTB), the scientific society (DGKL), and external assessment providers (e.g. RfB) since 1971 and prescribe the implementation of the traceability concept since 1987.

   Therefore, RfB performs the evaluation of the results of medical laboratories by use of reference measurement target values for a variety of reference measurements systems. The calibration laboratories of RfB are accredited according to ISO 17025 and ISO 15195 for 30 measurands (electrolytes, enzymes, metabolites and substrates, non-peptide hormones, drugs, proteins) and their services are listed in the JCTLM database. The service for HbA1c is established and it is planned to ask for nomination in the next cycle.
   The services of the calibration laboratories are offered to IVD manufacturers and EQA organizers.

   Since 2003 RfB organizes - under the umbrella of the IFCC - an External Quality Assessment Scheme (EQAS) for calibration laboratories in clinical chemistry (RELA) annually. RELA surveys are currently provided for 35 measurands. The participants are NMIs, calibration laboratories, and candidate laboratories. More than 50 laboratories participate, and each year RfB receives more than 350 results from these laboratories. All results of RELA 2003 to RELA 2016 are published on the website with open access (www.dgkl-rfb.de:81).

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

   In cooperation with PTB the calibration laboratories of RfB develop and optimize new reference measurement procedures (RMP) (total haemoglobin, pH in blood). Furthermore, it is planned to develop RMPs for antibiotics and valproic acid.
   Accreditation / publication followed by JCTLM-listing is planned for total haemoglobin, total bilirubin, total protein.

3. **Promoting traceability in laboratory medicine**

   Presentations and Workshops, Publication

04/15 ISO TC212, Work Group 2, Reference Systems, Brussels, Belgium
09/15 Workshop on Implementation of the Concept of Traceability in Clinical Laboratories in Latin America, Quito, Ecuador.
10/15 Rückführung und Messunsicherheit mit Blick auf massenspektrometrische Methoden, DGKL WG LCMS, Banz, Germany
11/15 Rückführung in der Labormedizin – Referenzmethodenwerte und ihree Messunsicherheit, VDI Symposium, Braunschweig, Germany
11/15 ISO TC212, Work Group 2, Reference Systems, Geel, Belgium
06/16 ISO TC212, Work Group 2, Reference Systems, London, UK
09/16 Mass Spectrometry as Key Element of EQA in Germany, MSACL, Salzburg, Austria
09/16 EQAS in Clinical Chemistry – Linking Routine Analysis to Reference Laboratories Results, WADA-BIPM, Paris, France
10/16 Use of Target Values in EQA, EQALM, Barcelona, Spain
05/17 ISO TC212, Work Group 2, Reference Systems, Minneapolis, USA
06/17 Basics of Traceability applied to Laboratory Medicine, JCTLM Webinar – WG TEP
10/17 EQA and Traceability – The German Approach, NCCL, Guangzhou, China
11/17 ISO TC212, Work Group 2, Reference Systems, Brussels, Belgium

- Kessler A, Mass Spectrometry – a Key Technique for Traceability in Clinical Chemistry, TrAC 84 (2016) 74-9, doi.org/10.1016/j.trac.2016.03.017
- Grote-Koska D, Klauke R, Brand K, Schumann G, Alkaline phosphatase activity – pH impact on the measurement result, Clin Chem Lab Med (2017); 55(7): e146–e149
- Grote-Koska D, Klauke R, Brand K, Schumann G, Reference Measurement Procedure for the Determination of Electrolytes in Human Body Fluids via ICP-OES Measurement, Metrologia, (submitted 10/2017)
- Klauke R, Kytzia HJ, Weber F, Grote-Koska D, Brand K, Schumann G, Reference measurement procedure for total bilirubin in serum re-evaluated and measurement uncertainty determined, Clin Chim Acta, (submission planned for 11/2017)

4. **Reference laboratory networks /collaborations focusing on developing /implementing reference measurement systems**
   The calibration laboratories of RfB participate annually in the internationally IFCC survey scheme for calibration laboratories (RELA) and the IFCC network compaign for HbA1c.

   In addition, members of the RfB are involved committees and working groups to implement traceability by reference measurement systems: DIN / ISO TC212 Working Group 2 (Reference Systems), AKB of DAkkS (Advisory Council of the German Accreditation Body), BÄK (German Medical Association), IFCC WG-PE (formerly C-RSE), and IFCC C-TLM.

   Members of the RfB actively support the JCTLM Review Team “Enzymes”, “Metabolite&Substrates”, and JCTLM WG-TEP.

5. **Open questions and suggestions to be addressed by JCTLM**
   No open questions

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.