

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: CNAS

JCTLM Member status: National Accreditation Body

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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) List of Medical Calibration Laboratories Accredited by CNAS

No	Certification Number*	Name of Laboratory
1	L00418	National Center for Clinical Laboratories
2	L04831	Standardization Laboratory of Mindray Bio-Medical Electronics CO., Ltd., Shenzhen
3	L06359	Reference Laboratory of Maccura Biotechnology Co., Ltd., Sichuan
4	L06943	Beijing Aerospace Hospital Reference Laboratory
5	L07756	Medical Calibration Laboratory of Guangdong Provincial Academy of Chinese Medical Sciences
6	L07884	Reference Laboratory of Beijing Institute of Medical Device Testing
7	L07887	Reference laboratory of Nantong University Hospital
8	L08362	Reference laboratory of Beijing Shijitan Hospital, CMU
9	L08403	Reference Measurement Laboratory of Shanghai Centre for Clinical Laboratory
10	L09987	Reference laboratory of MedicalSystem Biotechnology Co., Ltd., Ningbo

* Scopes accredited including :blood cell counting ,electrolytes,enzymes,metabolites and substrates,non-peptide hormones,proteins,vitamins and micronutrients

b) List of CNAS Accreditation Documents

1. CNAS-CL06 Requirements on the traceability of measurement results
2. CNAS-CL07 Requirements for measurement uncertainty

3. CNAS-CL25 Application of laboratory accreditation criteria in the field of calibration
4. CNAS-CL31 Requirements for in-house calibration
5. CNAS-CL32 Specific accreditation requirements for reference measurement laboratories in laboratory medicine
6. CNAS-CL33 Guidance on the application of testing and calibration laboratories competence accreditation criteria in the field of clinical enzymology reference measurement
7. CNAS-CL54 Guidance on the application of testing and calibration laboratories competence accreditation criteria in the field of blood cell analysis reference measurement
8. CNAS-CL59 Guidance on the application of testing and calibration laboratories competence accreditation criteria in the field of reference measurements of metabolites and non-peptide hormone
9. CNAS—AL11 Scopes for the accreditation of medical reference measurement laboratories

More information is available on the CNAS website www.cnas.org.cn

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.)

National standard (GB/T) R&D project: Conformity assessment -Quality control for use of biological reference materials that not having traceability.

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

a) List of Publications

1. JJF 1644-2017 The production of reference materials for clinical enzymology
2. FDIS GB/T XXXX Conformity assessment—Application guide for evaluation and expression of uncertainty in biological sample measurement
3. Biological and Medical Laboratories-Evaluation of Uncertainty & Case Analysis, Lyu Jing, Chen Baorong, Wang Huimin, Science & Technology Press, Beijing 2015
4. A Brief Review of the Regulations, Standards and Guidance Documents on Traceability of Measurement Results in Laboratory Medicine, Lyu Jing, Chen Baorong, Zhuang Junhua, Science & Technology Press, Beijing 2015

b) Training Course by CNAS

Two sustained training courses for 115 assessors of medical laboratory during the last two years.

4. Reference laboratory networks /collaborations focusing on developing /implementing reference measurement systems

CNAS has cooperated with NIM(National Institute of Metrology), NCCL(National Center for Clinical Laboratories) and BIMT(Beijing Institute of Medical device Testing) to establish the domestic EQA Scheme for medical calibration laboratories, currently including 19 measurands (ALT, AST, ALP, AMY, CK, LDH, GGT, GLU, Cr, BUN, UA, TP, ALB, HbA1C, TC, TG , Potassium, Sodium, Calcium and Magnesium), covered major reference measurement services in China.

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)

Suggestions : Because POCT devices are widely used, it is suggested that JCTLM may consider to promote the research on CRM/RM(s) for POCT.

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.