

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 Name: China National Accreditation Service for Conformity Assessment (CNAS)

JCTLM Member status: National and Regional Member

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Period covered: 2024 – 2025

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.)

As a professional national accreditation body, CNAS had accredited 34 medical reference laboratories by the end of 2025, with its accreditation scope covering 8 disciplines—hematology (hematopoietic cell counting), drugs, electrolytes, enzymes, metabolites and substrates, proteins, non-peptide hormones, vitamins, and trace elements—alongside over 40 reference measurement procedures/measurands.

CNAS staff actively participate in ISO/TC 212/WG2, the working group responsible for managing reference system standards, and have contributed numerous constructive suggestions during the revision of ISO 15195, ISO 15193, ISO 15914, and other related standards. Additionally, CNAS staff formally engage in standardization activities within laboratory medicine technical committees, including the China National Technical Committee for Clinical Laboratories and In Vitro Diagnostic Test Systems (SAC/TC 136) and the China National Technical Committee for Metrology in Biological and Clinical Laboratories (MTC 20 and MTC 21). Through this active involvement, CNAS will continue to advance standardization and accreditation efforts for reference systems in laboratory medicine.

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.)

As an accreditation body, CNAS does not perform reference measurement procedures. However, CNAS has specific requirements for the application of ISO 15195 and related reference measurement standards, and has applied these in the assessment of such reference laboratories, including requirements for ISO 15195

application standards, application for accreditation, assessment criteria for reference measurement laboratories, assessment procedures, and record-keeping. Meanwhile.

At present, the working group for studying and discussing medical reference measurement issues led by CNAS has been preparing the "Accreditation Guidance for Reference Measurement Laboratories". The next step will be to improve and supplement this document to promote its release and implementation. This document further clarifies the requirements for reference measurement procedures, metrological traceability of measurement results, and measurement uncertainty during the assessment process. It will help standardize medical reference measurement laboratory activities, enhance laboratory reference measurement capabilities, and promote standardization in laboratory medicine.

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)

CNAS conduct accreditation through peer assessment, which can promote traceability in laboratory medicine through the attestation of their conformance with the traceability requirements specified by ISO standards and other applicable normative documents.

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.)

CNAS set up the working group for studying and discussing the medical reference measurement issues, the WG members meet periodically to deal with specific technical or management issues in this field. The accreditation services performed by CNAS facilitated the reference laboratory networks /collaborations in China. According to statistics based on the JCTLM database, 18 out of the 34 accredited reference measurement laboratories has been listed in the JCTLM database, among 331 JCTLM listed reference measurement services, 232 are from the CNAS accredited laboratories

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)

No relevant suggestions.