

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: 2022 – 2023

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

As a professional national accreditation body, CNAS has accredited 29 medical reference laboratories at the end of 2023, the accredited scope covering 7 disciplines (hematology, enzymology, metabolites and substrates, protein, hormone, vitamin and microelements, electrolytes) and more than 40 reference measurement procedures/measurands. ISO 15193 is a mandatory requirements and its compliance must be assessed during the accreditation assessment procedure.

CNAS staff are the participating member of ISO/TC 212/WG2, which is responsible for the management of standards for reference system, many constructive comments from CNAS were adopted during the revision of ISO 15195, ISO 15193, ISO 15914 and the other relating standards. CNAS staff also formally participate the standardization activities in various technical committees in laboratory medicine, which are China National Technical Committee on Clinical Laboratory and IVD testing system (SAC/TC 136), two China National Metrology Technical Committees on biology and clinical laboratory (MTC 20 and MTC21), with all these active involvement in technical committees, CNAS will continue to contribute to the standardization and accreditation work of the reference system in laboratory medicine.

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

As a accreditation body, CNAS doesn't perform reference measurement procedures, but CNAS has specific requirements for the application of ISO 15195 and the relating reference measurement standards and has already applied them in the assessment of such reference laboratories, which includes application criteria of ISO 15195, requirements for application of accreditation, assessment requirements for reference measurement laboratory accreditation, requirements for assessments procedures and records, etc. CNAS adopted the related requirements of ISO 15194 into ISO 17034 accreditation system while facing the potential applicant in the IVD field.

CNAS is now leading the R&D projects focusing the CMC assessment, which will be concluded next year, with the result of this research program, CNAS will further demonstrate and ensure the reference measurement capability and building trust among different reference measurement laboratories and then contribute to the mutual recognition of the routine medical laboratory examination results for patients.

3. Promoting traceability in 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

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, 13 out of the 29 accredited reference measurement laboratories has been listed in the JCTLM database, among 247 JCTLM listed reference measurement services, 149 are from the CNAS accredited laboratories; for RMs, the ratio is 55 to 290, while none of Chinese producers is accredited against ISO 17034 in this field out of 37 accredited RMPs by CNAS in total.

5. Open questions and suggestions to be addressed by JCTLM

Close cooperation between JCTLM and ILAC need to be strengthened to gain more understanding and awareness of the importance and contribution of the medical reference measurement laboratory accreditation to the quality infrastructure of the national and international development of laboratory medicine. In addition, ISO 17034 might be more promoted in future.

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.