

Letter to the editor: Successful ISO 15189 accreditation in the Bethzatha Advanced Medical Laboratory in Ethiopia

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LETTER TO THE EDITOR

Many laboratories are taking a more focused approach to quality management system, i.e. the ISO 15189:2012 guideline (1). The Ethiopian standard agency (ESA) adopted ES ISO 15189:2013, in an effort to improve patient care through quality laboratory practices (2). In Ethiopia, a laboratory that meets this guideline can be accredited by Ethiopian national accreditation office (ENAO), indicating the highest level of confidence in the quality of services provided by the laboratory (3). Bethzatha Advanced Medical Laboratory was established as a private company in 1996, with a mission to provide quality medical laboratory services. It is well equipped with high-tech laboratory equipments (Fig.1). It has highly qualified professionals such as pathologist, clinical laboratory specialist, medical laboratory technologists and technicians. The laboratory is also structured into different departments.

Our medical laboratory was first recognized by SLMTA WHO-AFRO in 2012 as a 2-star laboratory. The second accreditation was an ISO 15189:2012 based accreditation. This accreditation process began in 2013 and was certified as ENAO-accredited in 5 analytes, i.e. glucose, creatinine, cholesterol, alanine amino transferase and aspartate amino transferase, in May, 2015.

Figure 1 Bethzatha Advanced Medical Laboratory in Addis Ababa

During the preparatory phase, first we offered awareness training for the top management about the benefit of accreditation. Secondly, we trained all the technical and non technical staffs about the 12 quality essentials. We designed a Quality Management System (QMS) based on a quality manual. The system was fully operational after trainings were offered to all personnel. Since the implementation of this QMS, a lot of progress could be seen that brings about a well organized structure, smooth work relations, and efficient services.

Metrological traceability is the property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty (4). International Laboratory Accreditation Cooperation (ILAC) and its associate member, ENAO, have mandatory policy on metrological traceability, i.e. medical laboratories are required to have an established calibration program for critical equipments that directly or indirectly affect examination results (5,6). As a result, most of the subsidiary equipments were calibrated by National Metrology Institute of Ethiopia (NMIE). At last, Beckman Coulter master calibrator (where traceability was achieved through National Institute of Standards and Technology's (NIST's) Standard

Reference Material (SRM)) was used to calibrate test methods.

Another critical criterion was Proficiency Testing participation (PT) (7) that made our journey to the accreditation process challenging. The German Society for International Cooperation (GIZ) provided us PT schemes on hematology and chemistry tests in support of the accreditation project since March 2013; however, it was terminated at the end of 2015. But, fortunately, our challenge was solved by the support of the Ethiopian Public Health Institute (EPHI).

Our laboratory monitors the progress of the QMS efficiently. The management reviews the pre-analytical, analytical and post-analytical processes. Using internal audit, as an assessment tool, the effectiveness of the action was evaluated.

To conclude, the management, and the staff in general, were dedicated and made an invaluable contribution towards the accreditation process becoming a success. Had we not obtained support of uninterrupted PT scheme from EPHI, things would not have been easy. Also, GIZ was a great help backing up our staff through trainings that facilitates the process of method verification and measurement uncertainty. Generally speaking, we have benefited enormously from the experiences we have been through in the

accreditation process. We hope our experience will inspire and shade a light to medical laboratories which might have not started the accreditation program yet.

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