

IMPROVING CALIBRATION INFORMATICS

When NPHL COE was launched in 2017, all calibration reports were being generated manually. This required technicians to record all calibration data on a paper form, perform manual calculations to analyze the data and create a calibration certificate. This manual method was time-consuming and error-prone, significantly increasing workload for NPHL COE's technicians and diverting them from calibration work. In partnership with NPHL, APHL developed a series of innovative solutions that took advantage of existing capacity at NPHL COE.

One strategy was to utilize integration features inherent in volume calibration equipment to interface with the laboratory information management system (LIMS) at the NPHL COE. This integration enables the equipment's volume data to be automatically and electronically captured in the LIMS, allowing automatic analysis of the data. A calibration certificate can then be produced from a default template, significantly reducing time for volume calibration.

A second strategy involved on-site calibration of equipment for mass, temperature, time and rotational speed by NPHL COE staff, such as at a district or provincial laboratory. The solution needed to include the ability to perform calculations remotely and generate a standardized calibration report. Teams from APHL and NPHL developed a portal on the NPHL website to host a database with a screen that mimicked the calibration form for each parameter. The portal allows calibration technicians to input the required calibration data for each parameter, automatically prompts the required calculations to run and produces a calibration report.

These two solutions had an immediate, positive impact. The turnaround time (TAT) for laboratory equipment was significantly reduced; equipment calibration at NPHL went from 10 to five days and field equipment calibration decreased from seven to three days. With these reductions,

Improved informatics systems reduced turnaround time by more than 50%

standardized calibration certificates could be quickly issued to customers. In addition, overall management of calibration data at NPHL improved, and summary reports can now be obtained using a dashboard. The Kenya Accreditation Service has embraced the use of digital calibration certificates, enabling NPHL COE to offer this to clients promoting paperless processes.

NPHL COE PROVIDES REGIONAL BIOMEDICAL SUPPORT

Following the success of creating the NPHL COE and training of Kenya's biomedical engineers, several other East African countries approached NPHL to learn from the COE and adapt a similar approach.

The World Bank, through the East Africa Public Health Laboratory Network, approached NPHL and requested that the maintenance and calibration of laboratory equipment training curriculum be adapted for their purposes. The first training took place in 2018 at NPHL COE, where staff guided 16 participants from Kenya, Uganda, Tanzania and Burundi through the course. The second training took place in Bujumbura, Burundi in 2019 where NPHL COE staff facilitated the training for 15 participants from Burundi, Tanzania and Uganda.

With support from APHL, NPHL COE staff and trained Kenyan biomedical engineers have also been visiting countries within the region to mentor biomedical engineers on laboratory equipment management and maintenance.



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CALIBRATION TRAINING STRENGTHENS LABORATORY SYSTEMS

Kenya's NPHL COE Launches New System for Ensuring Sustainable Laboratory Quality

The new National Public Health Laboratories (NPHL) Centre of Excellence (COE) for Equipment Calibration, Certification and Training ensures the quality of results generated with public health laboratory equipment and offers traceability measurements to international standards. It uses five key parameters to evaluate the efficacy of laboratory equipment: volume, mass, temperature, time and rotational speed.

PROJECT HIGHLIGHTS

- Developed a training program to strengthen equipment maintenance and calibration
- Procured required equipment for NPHL COE and equipment maintenance and calibration toolkits for biomedical engineers
- Provided on-site mentorship at facilities for biomedical engineers
- Supported the production of national guidance on equipment management
- Supported development of quality manuals and standard operating procedures to meet the ISO 17025 accreditation requirement

FILLING A TRAINING VOID

While laboratory equipment is essential to any diagnostic testing that is conducted in laboratories, their appropriate inspection, timely maintenance and service is equally critical, without which both staff and patients may be at risk. Certified calibration is a means of ensuring laboratory equipment complies with specifications and safety regulations as specified by the equipment manufacturers, in addition to national and international policies and standards. Therefore, a significant factor in the accuracy of laboratory results and data is dependent on appropriate calibration.

In Kenya, calibration of public health laboratory equipment is the responsibility of the National Public Health Laboratories (NPHL), but they were not equipped to single-handedly ensure the proper maintenance and calibration of the country's public health laboratory equipment. There needed to be a sustainable, practical and cost effective method to distribute the workload, a way to train biomedical engineers at the county facilities to conduct the needed maintenance themselves.

To fill this training void, from 2016 to 2019 the Association of Public Health Laboratories (APHL) collaborated with NPHL, the American International Health Alliance (AIHA) and Kenya's Ministry of Health (MOH) and in 2017 successfully established a Centre of Excellence (COE) for calibration and certification of, and training on medical laboratory equipment—

THE FIRST OF ITS KIND WITHIN THE PUBLIC HEALTH SECTOR IN EAST AFRICA.



One of the NPHL COE calibration rooms

BRINGING THE NPHL COE TO LIFE

Facilities & Equipment

The first step towards making the NPHL COE a reality was to create a space with the appropriate facilities and resources. The COE consists of two calibration rooms, two rooms for storing testing equipment and an office. Because it is essential to maintain consistent environmental conditions in the calibration rooms, they were equipped with air conditioners to regulate room temperatures and environmental condition monitoring systems to alert calibration staff if the room conditions exceed environmental limits. Workbenches with anti-vibration properties were also installed, along with plumbing and electrical systems to provide reliable testing conditions. To enhance security of the center, a biometric access control system and a closed-circuit television system were put in place.



Officials and staff in front of NPHL COE at the Center's launch in 2017

The NPHL COE was recommended for ISO 17025 accreditation by the Kenya National Accreditation Service in October 2019, which will help ensure proper recognition at national and international levels as they pursue certification.

Creating the Curriculum

The next step for the NPHL COE was to develop training courses that the Center would offer. A technical working group—comprising MOH, CDC, APHL, AIHA and medical training institutions—was formed to guide the development of a curriculum for a biomedical refresher training focused on laboratory equipment maintenance and calibration. Trainings needed to include critical laboratory auxiliary equipment that have a significant impact on laboratory results including pipettes, microscopes, water baths, incubators and hot air ovens, refrigerators and freezers, thermometers, timers and centrifuges.

Training the First Biomedical Engineers

Once the curriculum was established, APHL and AIHA subject matter experts (from both Kenya and the US) conducted four, two-week-long trainings at the NPHL COE for selected biomedical engineers from laboratories around the country.

After returning to their labs, the trained biomedical engineers have helped reduce the workload of NPHL COE staff by performing calibration data collection and logging it into the NPHL COE web portal. NPHL COE staff use the portal to quickly review the data and generate a calibration certificate.

Training the Trainers

To ensure the biomedical refresher training would be sustainable when scaled up to the county level, it was essential that a small number of NPHL engineers take over the training from the APHL/AIHA subject matter experts. After a period of follow up and mentorships, twelve engineers from the original group of trainees were selected to become trainers and given an additional week of "train the trainer" instruction.