THE EUROPEAN UNION'S 10TH EDF PROGRAMME FOR NIGERIA

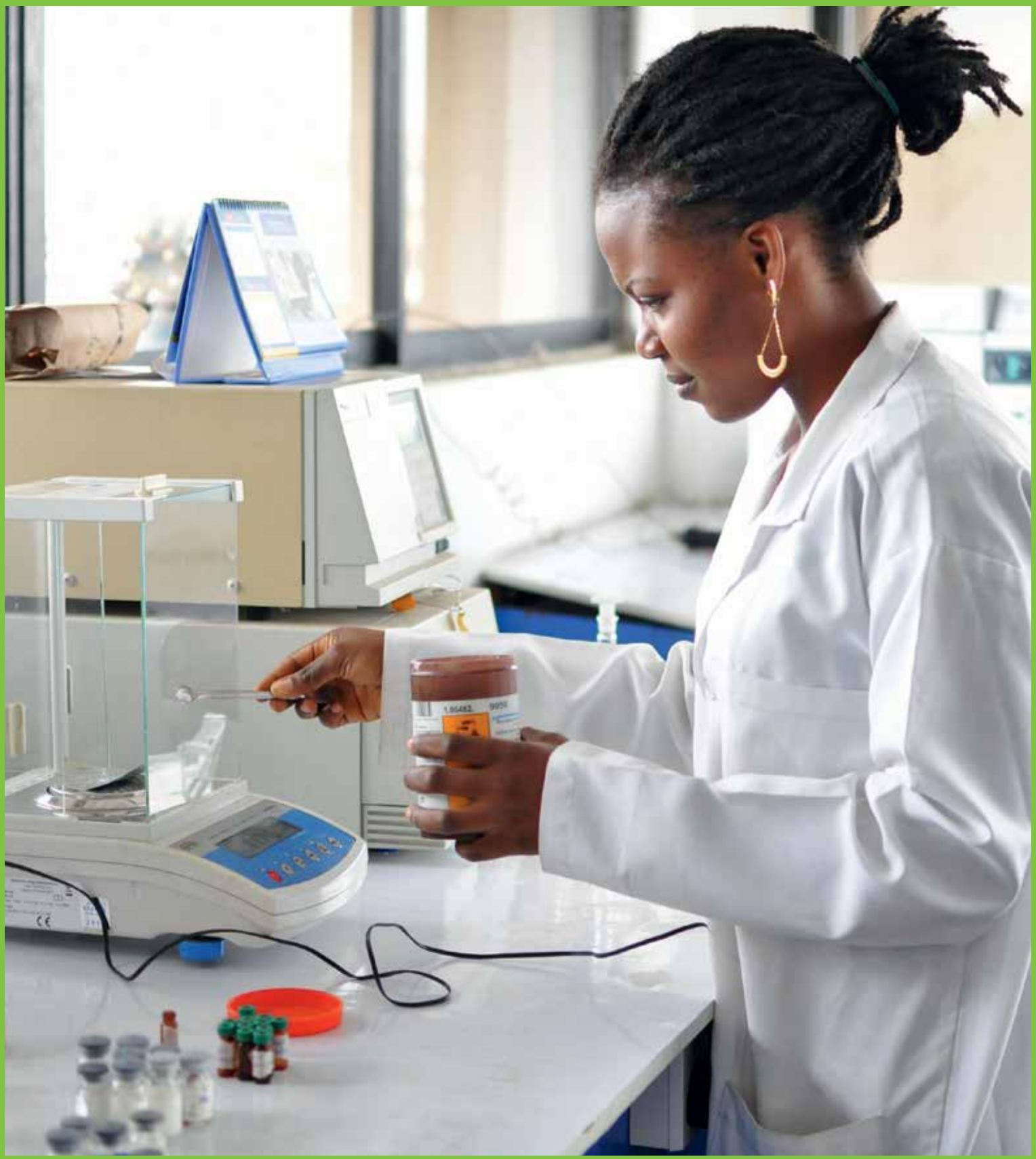
Roadmap to Accreditation

Enhancement of laboratory competencies in Nigeria

This project is funded by the European Union

FEDERAL GOVERNMENT OF NIGERIA

A project implemented by the United Nations Industrial Development Organization



Background

Trade has long been recognized as a potential engine for growth and wealth creation. Many developing countries continue to face difficulties in demonstrating compliance with quality requirements and trade rules, thus hindering them from accessing markets.

Nigeria's trade is dominated by crude petroleum exports. Diversification from oil exports to higher value manufacturing exports is a goal of the Nigeria Industrial Revolution Plan (NIRP), which is designed as a 5-year plan to accelerate the build-up of industrial capacity within Nigeria. The plan aims to increase the contribution of manufacturing to the Nigerian economy in sectors where Nigeria has comparative advantage - such as the agro-allied sectors; metals & solid minerals related sectors; oil & gas related industries; as well as construction, small and medium scale manufacturing and services. At the very heart of the NIRP is the drive to develop strong institutions to sustain industrialization in the medium to long term.

The United Nations Industrial Development Organization (UNIDO) is determined to contribute to the Agenda 2030 and the Sustainable Development Goals (SDGs) by promoting and accelerating Inclusive and Sustainable Industrial Development (ISID).

UNIDO is a key player in the fight to end poverty - while its activities contribute to numerous goals relating to people, prosperity, planet, peace and partnerships, its mandate is embedded in SDG 9: build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation. An infrastructure of strong institutions to support industrialization is the goal of the National Quality Infrastructure Project for Nigeria, which is funded by the European Union, supported by the Federal Ministry of Industry, Trade and Investment, and implemented by UNIDO.

Setting up a National Quality Infrastructure is one of the most positive and practical steps that a developing nation can take on the path forward to developing a thriving economy as a basis for prosperity, health and well-being. Within the Quality Infrastructure system, accredited conformity assessment services are used to demonstrate that a product, process or a service, meets specified requirements. These requirements are usually stated in technical regulations, international standards developed by organizations such as the International Organization for Standardization (ISO), national standards developed by organizations such as the Standards Organization of Nigeria (SON) and voluntary private standards. Conformity assessment services are usually performed by organizations specialising in one or other activities, of which the main ones are testing, inspection and certification.

Conformity Assessment Bodies may supply their services on a commercial basis, or they may be operated or mandated by the government. The requirements for conformity assessment activities themselves are also given in international standards, such as ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories.
The standard is for use by laboratories in developing their management system for quality, administrative and technical operations and covers aspects such as general management requirements as well as technical requirements of personnel and equipment. This helps to ensure consistency worldwide, as well as cross-border acceptance of results.

Recognizing the value of quality infrastructure for economic development, Nigeria has embarked on the development of institutions such as the National Accreditation Body, the National Metrology Institute and the development of numerous private and public-sector organizations delivering conformity assessment services which meet the global standards for such services as set-out by ISO. As the quality culture improves in Africa, tested and certified products are winning consumers' confidence, thus, increasing the demand for better and safe products. To prove and verify the quality of goods, conformity assessment certificates are sought for not only to demonstrate quality for domestic consumers but also to promote the export of Nigerian-made products to international customers.

Until now, certificates from Nigerian-based conformity assessment bodies have often not been internationally recognized, forming a barrier to trade. Hence, there is a need to increase the capacity of Nigerian bodies to verify conformance to standards and quality requirements and thus gain international recognition through accreditation. One way of doing this is to strengthen testing and calibration laboratories in Nigeria to offer high quality and reliable testing services for enterprises and regulators to facilitate trade. In order to do so, UNIDO has developed a holistic approach to strengthen conformity assessment bodies in developing countries, in a step-by-step approach.

Strengthening laboratories in Nigeria for accreditation

Laboratories must meet the requirements of ISO/IEC 17025 to qualify for accreditation.

It was found in 2014 that all but 2 of the about 100 laboratories contacted needed some technical support in the form of training and coaching on how to implement ISO/IEC 17025 to become ready for accreditation. Interaction with the laboratories indicated:

- Lack of understanding of accreditation;
- Low familiarity with the standard ISO/IEC 17025 and its contents;
- Little development or application of policies and procedures within the testing and calibration environment;
- Little understanding of Proficiency Testing (PT) or participation in PT Schemes;
- Lack of knowledge of ILAC measurement uncertainly requirements (ILAC P14); and,
- Widespread issues regarding traceability of measurement to the Bureau international des poids et mesures.

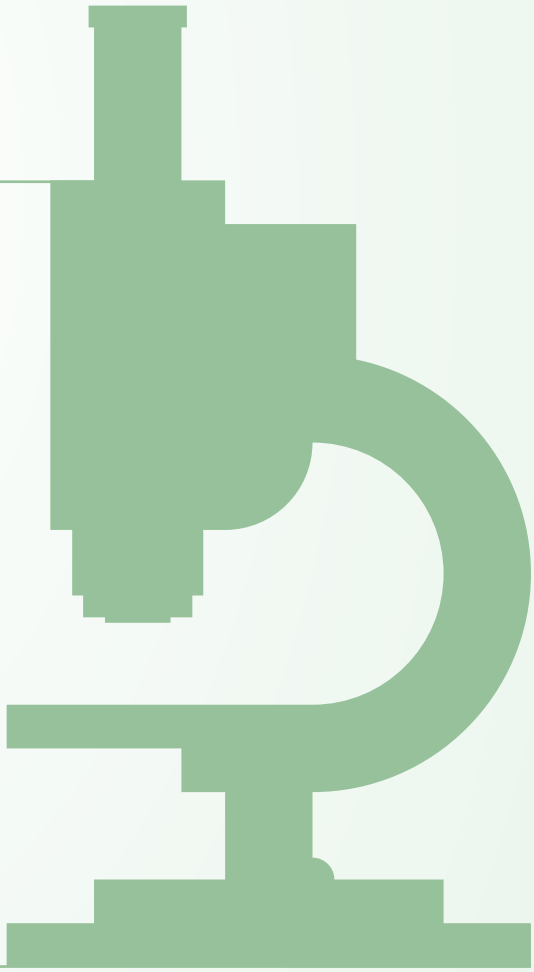
Gender balance

52 %
Laboratory Training

48 %
Laboratory Training

56 %
Assessor Training

44 %
Assessor Training



A project was established to prepare the Labs to the state of accreditation. The beneficiary area for this project covered major cities (Abuja, Ilorin, Kaduna, Enugu, Lagos, & Port Harcourt) in four geographic areas of the country. The three-phased training program was developed to train laboratory personnel on the standard and then assist them to implement management systems to meet the standard. However, the provision of short–term classroom-style training by itself would not be sufficient to assure the implementation of the standard's requirements by the laboratories. Therefore, the second and third phases involving medium-term (up to 12 months) follow-up, coaching and mentoring were made available to the laboratories by experts. These phases answered questions and assisted the laboratory staff to transition from an introductory academic understanding of the standard to a practical understanding and implementation of these concepts.

The project included 235 participants from 78 testing and calibration laboratories in these major cities. Scopes of the laboratories include the testing of: Food, Drinking Water, Pharmaceuticals, Cosmetics, Textiles, Physical and Chemical, and Environmental. A small number of the critical calibration laboratories also participated. Visits were made to the labs to determine their willingness, provide encouragement, and do a quick assessment and verification of needs.

In regard to the gender balance, the individuals in the laboratories that are leading these activities are for the most part those whom attended the laboratory training and the assessor training. The gender ratios in these two activities were 52% F / 48% M and 56% F / 44% M, respectively. Therefore, a gender balance that closely meets the target is expected.

The required training was delivered in three phases and included all aspects of ISO/IEC 17025.

PHASE 1

- Classroom-style courses.
- A **5-day ISO/IEC 17025 course** was given in each of the 5 cities to:
  - introduce the standard;
  - provide an understanding of the requirements of the standard;
  - and, demonstrate how to build policies and procedures for implementation of the standard.

  The model for this training is based on the successful approaches used for the establishment of accreditation bodies in Egypt and Pakistan.
- 3 days of focused training on typically more challenging topics.

The topics for the focused training were:

Uncertainty of Measurement

This is a very technical subject matter and is needed by those who work in the laboratories as analysts to be acquainted with the applicable test methods and the sources of error and ambiguity in these methods.

Statistical Quality control for Labs

The subject matter includes statistical measurement control and the use of laboratory control samples and drawing control charts. This will help ensure the quality control of testing done over time.

Method Validation

Topics explained included: How test methods are designed; Error sources and risks in measurement; Calculating errors and uncertainties; Mitigating the risks; Validation Plan & protocol; etc.

PHASE 2

The second phase dealt with the implementation of the theory and the building of management system policies and procedures in the participating laboratories. "On-the-ground" expert(s) were available to assist the trained laboratories on an as-needed basis to build the compliant systems. Two International experts and two national experts worked in parallel with many laboratories at the same time. Progress was varied depending on the sophistication, the motivation and the resources of the various laboratories. The two local individuals were used to handle the basic questions presented by laboratories and to encourage the labs to continue the work through regular follow-up, and to work with them on technical aspects of the correct test method application. This reduced costs and promoted local expertise. Complex questions with respect to implementation of the theory provided in the courses were referred to the international experts to encourage application of best practices and harmonization.

The team provided:

- Mentoring & coaching to the laboratories to create their quality systems;
- Advice to personnel in regard to the implementation of the newly-developed quality systems;
- Continued coaching on the determination of uncertainties, calculations for statistical process control as well as obtaining calibrations for equipment and accessing Proficiency Testing (PT) Schemes;
- Reports on the progress of each laboratory towards the development and implementation of their documented quality systems.

PHASE 3

Phase three will evaluate the preparation of each of the labs for accreditation, in terms of the results of their internal audits and the effectiveness with which they correct deficiencies they identify in their own systems. Criteria to Qualify for Pilot Accreditation are:

- Completion of operating policies and procedures that meet ISO/IEC 17025 requirements;
- Satisfactory completion of internal audits, management review and corrective action;
- Completion of uncertainty estimations;
- Documentation of calibration intervals for critical equipment; and,
- Validation of any non-standard methods.

The way forward

Over 60 of the original 78 laboratories remain committed and are continuing to strengthen their systems in preparation for accreditation some 18 months after the initial training. Approximately 20 of them are ready for accreditation and it is expected that many of the remaining 40 will achieve the same status.

Laboratories representing other sectors in the Nigerian economy have indicated interest in this initiative. Labs, particularly, in the mineral sector, are coming forward to participate. The compendium of laboratories under the Ministry of Mines and Steel Development, include approximately 30 laboratories in areas such as corrosion, chemical, geological, metallurgy and research. The quality of their output is important to this sector which may be a large contributor to the economy of Nigeria.

Areas where the experts continue to focus reflect areas where laboratories around the world have difficulty in the implementation of ISO/IEC 17025. Common areas of difficulty respect to the development and implementation of written documented policies and procedures include:

- Uncertainty calculations
- PT participation plan
- Implementing calibration requirements
- Internal Quality Control Process
- Action taken when bad results happen
- Corrective Action
- Impartiality provisions of ISO/IEC standards

Strengthening laboratories for accreditation is a complex process that requires time and resources. It takes commitment and perseverance for the participating laboratories and dedication, strong technical and people skills on the part of the experts that work with the laboratories. However, the desired outcome is being achieved for the Nigerian testing and calibration laboratories. UNIDO is strengthening testing and calibration laboratories in Nigeria to provide high quality and reliable testing services for enterprises and regulators to facilitate trade and provide safer products of higher quality to domestic consumers. To achieve this outcome, the project conducted interventions at several levels:

- Strengthened laboratories through intensive training on ISO/IEC 17025;
- Provided support and direction to laboratories in areas where difficulty is common;
- Mentored laboratories to build, write and implement management policies and procedures;
- Educated laboratory personnel on the conduct of internal audits in preparation for accreditation;
- Directed the laboratories to participate in PT Schemes or inter-laboratory comparisons.

By strengthening the Nigerian laboratory network through a harmonized approach Nigeria will have the conformity assessment services needed to meet international requirements, become accredited and contribute to Nigeria and West Africa's quality infrastructure development and export performance.


Building Trust for Trade
The National Quality Infrastructure Project for Nigeria


CERTIFICATION OF
PERSONS & INSPECTION
LABORATORIES
TESTING
NAB ACCREDITED TO ISO 17011
NAB ISSUE AECT ON ISO 15189
ISO 17025
ISO15189 – Medical LABS
Haematology
Parasitology

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