UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

INETQI
INTERNATIONAL NETWORK ON QUALITY INFRASTRUCTURE

BEST PRACTICE IN LABORATORY POLICY DEVELOPMENT

GUIDANCE ON SUSTAINABLE LABORATORY INFRASTRUCTURE DEVELOPMENT

LAUNCHING EVENT

23 APRIL 2021

CONTEXT

More than 400 participants from 87 countries

Quality Infrastructure is a crucial element in promoting and sustaining economic development. It is also important for environmental and social wellbeing, thereby contributing to the Sustainable Development Goals (SDGs) as part of the 2030 Agenda for Sustainable Development, which sits at the heart of development plans and implementation strategies of many developing countries. Such a system relies on metrology, standardization, accreditation, conformity assessment, and market surveillance. Laboratories are also a key component.

Laboratories are necessary for proving the compliance of products and services with regulations and conformity with market requirements. The data and information that laboratories provide are essential for transparent and trustworthy decision making, especially those related to inspection and certification activities. Laboratories also ensure products and services meet the triple bottom line of social, environmental and financial considerations.

This demonstrates why developing or strengthening a Laboratory Infrastructure can be so critical. Laboratory Infrastructure comprises the laboratories (public and private), together with the scientific principles, practices and supportive laboratory quality control systems, i.e. proficiency testing, certified and other reference materials, that are required to quantify, underpin and enhance quality competitiveness, innovation, productivity, safety, health and environmental soundness and sustainability of goods, services and processes.

LAUNCHING EVENT

More than ever, the COVID-19 pandemic has demonstrated the need for effective testing capacities and related Laboratory Infrastructure. Against this backdrop, in April 2021, UNIDO and the International Network on Quality Infrastructure (INetQI) launched a guidance document, Laboratory Policy: A guide to development and implementation, that promotes Good Governance in Laboratory Infrastructure development to help ensure the efficiency, resilience and sustainability of the entire Quality Infrastructure system.

To celebrate the publication of this document, UNIDO invited stakeholders and partners to participate in a high-level panel discussion to address the need to establish a sustainable, fit-for-purpose and efficient laboratory capability that embodies international best practices. High-level speakers from the World Trade Organization, the International Laboratory Accreditation Cooperation, the International Bureau of Weights and Measures (BIPM), and the International Organization for Standardization, as well as representatives from Colombia and Namibia, shared their experiences and views on the need for sustainable Laboratory Infrastructure development and how this document will assist decision-makers in constructing a Laboratory Policy based on good practices.

This guidance document underpins and further complements the existing suite of Quality Policy guidance developed by UNIDO: Quality Policy Guiding Principles, Technical Guide and Practical Tool.

SPEAKERS

OPENING

Mr. Bernardo Calzadilla-Sarmiento
Managing Director, Digitalization, Technology and Agri-Business, UNIDO

Mr. Xiao Jianhua
Chair, INetQI

Ms. Sharonmae Shirley
Co-Chair, ILAC-IAF Joint Development Support Committee (JDSC)

KEYNOTE

Mr. Mike Peet
International Expert, Quality Policy & Quality Infrastructure, UNIDO

MODERATION

Ms. Merih Malmqvist Nilsson
International Expert, Quality Infrastructure, TBT, Accreditation & Standards

PANEL

Ms. Etty Feller
Chair, ILAC

Mr. Devin McDaniels
Economic Affairs Officer, WTO

Ms. Cristina Draghici
Secretary, Committee on Conformity Assessment, ISO CASCO

Mr. Andy Henson
Director, International Liaison and Communication, BIPM

Ms. Paloma Ellitson
General Manager, Testing and Inspection, Namibia Standards Institution

Mr. Javier Fernández
Quality Expert, Global Quality and Standards Programme (GQSP) Colombia, UNIDO

INSIGHTS FROM THE SPEAKERS

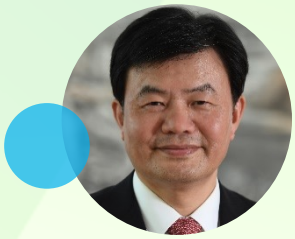
OPENING REMARKS

Mr. Bernardo Calzadilla-Sarmiento

Managing Director, Digitalization, Technology and Agri-Business, UNIDO

- Highlighted UNIDO's long track record in supporting the establishment of laboratories and helping them move towards accreditation and its subsequent mapping of the services offered by laboratories, available as a tool called the Laboratory Network.
- This work is an offspring of UNIDO's Quality Policy (QP) work with an emphasis on laboratories because of an observed fragmentation of the development of laboratories. There exists a multiplicity of institutions, no capacity for sustainability, and sometimes unclear roles and responsibilities. There also has been a supply-driven development and a mismatch between supply and demand.
- This is why UNIDO finds it important to have a Laboratory Policy (LP), which also provides a framework of Good Governance. The LP can help policymakers better address needs and have a comprehensive, consistent and sustainable Laboratory Infrastructure (LI) in line with private sector needs, directly impacting a country's development.
- Quality Infrastructure (QI) and laboratories must anticipate future developments, and here UNIDO has had a pioneering role, drawing attention not only to new technologies (e.g. Industry 4.0), but also to sustainability and how to incorporate the circular economy. We have to stimulate industrial development, ultimately coming from the UN, contributing to the SDGs.

"UNIDO is ready to support what comes next—the efforts in the future to build especially local experience and expertise—and to see what happens from the field, and from this experience…eventually develop other global public goods in close collaboration with our international technical partners."



Mr. Xiao Jianhua

Chair, INetQI

- LI is a key component of QI. We know QI is a crucial element in promoting and ascertaining economic development, as well as environmental and social wellbeing. It relies on metrology, standardization, accreditation, conformity assessment, and market surveillance.
- Laboratories are necessary for proving compliance and conformance. The competence and the impartiality of laboratories enable laboratories to generate valid results, therefore, they are critical for the results to be relied upon by businesses, regulators and consumers, and are used in other conformity assessment activities such as inspection and certification.
- Metrology, standardization and accreditation, as the key institutional components in the QI, are important for building confidence on the competence and the impartiality of laboratories. Sustainable LI, therefore, is essential for availability of competent and impartial laboratories to support effective operation of domestic markets, and its international recognition is important to establish its credibility in both local and foreign markets.
- To achieve such an LI, an LP is fundamental in order for all stakeholders to better understand the current situation, and to further improve the existing laboratory-related infrastructure.

"This publication is indicative of UNIDO's and INetQI's continued commitment for enhancing the Quality Infrastructure contributing to the achievement of the SDGs."

Ms. Sharonmae Shirley

Co-Chair, ILAC-IAF Joint Development Support Committee (JDSC)

- This launch is significant as laboratory services form the backbone of conformity assessment activities pivotal to the success of QI systems in developing economies. The LP guide will enable developing countries to leapfrog intrinsic hurdles in a free market environment, such as reliable test or measurement results from labs accredited by ILAC MRA signatories.
- The challenges faced by countries with immature laboratory infrastructure are, inter alia, unhealthy competition between public and private sector laboratories for both technical experts and market share; disproportionate application of duties and taxes to public and private sector labs, resulting in a wide disparity in pricing; unintended waste of resources; duplication and fragmentation of lab services in the public sector; and human capital constraints that lead to brain drain.
- A balanced national regional approach to laboratory design and operation will resolve procedural obstacles and realize wide-reaching positive outcomes, including legislator and regulator frameworks that boost a competitive accreditation-based laboratory sector that supports both regulatory needs and a robust QI. It also supports fair competition and sustainable public–private partnerships that enhance laboratory capacity and capability.
- UNIDO understands well that developing countries are best positioned to realize desired outcomes to achieve their own strategic goals.

"The Laboratory Policy is a tool that is user-friendly and provides pragmatic pathways to create Laboratory Infrastructure needed to catalyze economic growth in developing countries."

KEYNOTE

Mr. Mike Peet

International Expert, Quality Policy & Quality Infrastructure

Briefly walked participants through the key elements of the development of the *Laboratory Policy: A guide to development and implementation* publication, covering the following components:

Why LP is required?

- He mentioned that the need for increased quality of domestic products often leads to a deeper understanding of the essential role that laboratories play in verifying that goods and services comply with quality, safety and sustainability requirements.
- He noted that when an economy develops or strengthens its LI, it usually occurs in an environment where there are many other pressing demands on available public resources. This can result in the unintended wastage of scarce resources including the unnecessary replication of laboratory services.
- He stressed that investments in LI should not only seek to address immediate needs. It is important they are also channeled to areas where they could act as an enabler and multiplier for longer-term added value.

How was it developed?

- It was highlighted that the document draws on the wealth of experience and knowledge of UNIDO member countries, and QI experts. It was drafted, reviewed and finalized over many months using a broad consensus-building process including two expert group meetings and multiple opportunities for stakeholders to provide comments.
- He referred the audience to page 7 of the document to see the many people that were involved in the process and said that it was an honor for him to present their combined efforts.

What does it cover?

The document covers three areas that need addressing to develop and implement a Laboratory Policy successfully:

- Macro-level (policy level): the guide identifies the guiding principles for the formulation of a Laboratory Policy;
- Meso-level (institutional level): it looks at the elements needed to enhance trust in the test and measurement data laboratories provide, including the need for appropriate accreditation of its activities; and
- Micro-level (operational level): the guide identifies and considers common issues that have surfaced during support for the development and strengthening of laboratories in the past.

How should it be implemented?

- The document identifies and describes five discrete steps in the development and implementation of a Laboratory Policy.

What are the challenges and benefits of implementing such a policy?

- The document identifies the challenges and provides benefits of implementation at the (a) regulatory and institutional, (b) marketplace/customer, and (c) technical/laboratory levels.

Who should be involved?

- He ended the presentation by stressing that the success of a Laboratory Policy in guiding future development and/or strengthening of Laboratory Infrastructure depends on the strength of the dialogue and ongoing cooperation and collaboration between everyone requiring or providing laboratory services including Government officials, private sector and other impacted stakeholders and, last but not least, the various constituent organizations forming the Laboratory Infrastructure.

PANEL

Ms. Etty Feller

Chair, ILAC

- Quality plays an essential role in our lives, especially in this past year, which has taught us a lesson in modesty, in making the right choices, and the importance of testing in control of our lives in general and the medical area in particular.
- Accreditation is an ongoing process that gives beginners a roadmap and helps with preparing a gap analysis. The LP document will help countries, economies, governments, and regulators with the gap analysis and, most importantly, help to evaluate the risks associated with not implementing a LP.
- LP's impact is two-layered: In the short term, it is a new way of looking at laboratory work in an economy and of reviewing the processes performed in an economy. In the long term, it will help economies and especially regulators to write regulations and to implement regulations that will help them minimize risks in regards to imports, exports, market surveillance, etc.

"This document brings the links of all possibilities and allows mapping for each and every economy to get a clear picture of the situation in their economy and what are the steps they have to do to achieve the goal."

Mr. Devin McDaniels

Economic Affairs Officer, WTO

- Emphasized the centrality of LI and LP in improving the lives of ordinary people as meeting quality requirements is a major bottleneck preventing entrepreneurs in lower income countries from tapping into opportunity presented by international trade. When we address these QI issues and organize coherently, countries can reap the benefits of trade as an engine of growth, inclusiveness and poverty reduction in line with the SDGs.
- The WTO's role in this is about helping ordinary people to improve living standards, to create jobs and to support sustainability. The WTO Technical Barriers to Trade (TBT) Agreement has tried to further these objectives through development of international standards and QI to facilitate trade.
- Called for cooperating even more closely. The high demand for technical assistance and investment in LI and QI, and the many organizations and donors operating in this space, makes coordination challenging. If we want countries to reap the benefits of QI and LI, we can explore ways to increase and reenforce coordination of technical assistance provided by partner organizations for more effective implementation of the WTO TBT Agreement and better QI.

"We need to keep in mind that laboratory infrastructure goes much further than trade. It is the technical basis for keeping people and the environment safe and healthy, and is actually linked to the biggest threats we face today."

Ms. Cristina Draghici

Secretary, Committee on Conformity Assessment, ISO CASCO

- LP could help create an environment where laboratories can perform and operate impartially and competently so that trust in laboratory results is built and maintained.
- Among the objectives that this LP could put forward would be to ensure that relevant institutions are there to coordinate the development, dissemination and promotion of standardization activities. It could also promote the access/adoption/adaption of international standards to the local context.
- Additionally, this LP may ensure the provision and access to relevant national and international standards, promote harmonization, facilitate international recognition, and avoid duplication of efforts, all of which are important for ISO CASCO's work.
- A laboratory provides results and decisions are made based on these results, which are also the basis for other conformity assessment activities. The aim of a regulatory framework is based on preserving the health and safety of the population, also trying to encourage economic development and trade.
- All good reasons for supporting the idea of looking holistically at the QI, looking holistically at the development of laboratories, and using the existing international standards to further develop the LI.

"All of these laboratories in a network of laboratories, provide results which all contribute to the prosperity of a country, to supporting trade, and, in the end, to supporting the three pillars of SDGs, people, prosperity and planet."

Mr. Andy Henson Director

International Liaison and Communication, BIPM

- Of all the pillars of the QI, policy is really important in metrology, particularly at national metrology institute level because, while commercial laboratories are driven by the market, a national laboratory needs to meet all of its national requirements. That is not easy to fully understand and requires looking both outwards and inwards, and the policy helps with this.
- Each country is different: The blend of its economic activity, what is creating the wealth, how exports are oriented and in what commodities, and in what advanced manufacturing. It is also dynamic in that you know where you are today, but where are you going to be in 10 years? In having to try to understand that, you have to try to work out how to add the value.
- Inwards, policy helps with focusing limited resources. Having a policy presents an opportunity to improve human and physical resources, the technical cooperation of the laboratory, and the interaction in the market place, so that you are responding to demands and anticipating future demands. This gives a coherence to operating the lab, making investments, and deciding where to go next.
- In addressing how often to look at policy, it is important to understand that because it is a dynamic situation you need to periodically revisit where you are going, and the policy is a good tool for that.

"I very strongly welcome the UNIDO initiative on this document and we were very pleased to be able to contribute."

Ms. Paloma Ellitson

General Manager, Testing and Inspection, Namibia Standards Institution

- LP provides a tool whereby a country, through stakeholders, can bring national coherence for fit-for-purpose LI and it sets the framework for how a country can recognize and build onto existing LI and set new objectives for future development.
- Laboratory associations can play a key role in the awareness raising, promotion and coordination of the practical aspects of quality for laboratories. They can use technologies popularized during the pandemic to bring participants together to discuss results and reference material usage to increase understanding of results and to build participation.
- An LP can guide a process through information gathering in the form of a needs assessment which forms the basis of a stakeholder analysis and agreement on national needs, establishing national coherence. Practically, the laboratory association is a good platform to coordinate such a need analysis.
- The adoption of LPs creates this enabling environment within which laboratory associations can grow and benefit its members.
- When a laboratory association focuses on the national needs of the laboratory community, its relevance is established and its sustainability is improved through offering services that are relevant and address national coherence, while building on inclusivity and integrity of the National Laboratory Infrastructure. In this manner, the Laboratory Policy objectives can be realized.

"On behalf of the of National Laboratory Association of Namibia, I express my appreciation to UNIDO for the leadership role and visionary approach that has benefitted the region through this project and I commend the new initiative launched today."

Mr. Javier Fernández

Quality Expert, Global Quality and Standards Programme (GQSP) Colombia, UNIDO

- Colombia launched its QP in 2006 and its implementation established a solid basis for the LP. As a result of the 2006 QP, the National Accreditation Body of Colombia and the National Metrology Institute of Colombia were created and played a prominent role in the LP construction several years later.
- One of the main lessons learned is that a healthy and functioning QI can ease the process of drafting the LP and it is worth developing countries investing in it.
- It is also important to involve all incumbent stakeholders from the beginning in order to have a complete set of inputs for the later stages of the policy formulation.
- Taking into account different perspectives is vital. For example, market information gaps hindered the development of laboratory services in Colombia. In this regard, there were cases in which companies thought their required services were not available in the country and looked for them elsewhere, meanwhile national laboratories offering those services lacked the demand to make them economically sustainable.
- It is helpful to have a policy leader/a small group of leaders capable of coordinating efforts, balancing interests, taking decisions at the macro level and promoting institutional engagement.

"Thanks to that, the development of laboratory networks, the development of systems and search engines were considered to solve coordination gaps, just from the Laboratory Policy."

KEY TAKEAWAYS

- Laboratories are at the core of health care excellence, industrial transformation and sustainable development, and people, technology and data are key to make the system work effectively.
- The last year has taught us that we have to be openminded, flexible and realistic in our way of work. We will have a new normal that will be a hybrid of remote and face-to-face work, and at all levels of work, including the accreditation system, we will have to be aware of our options.
- Policy helps to focus limited resources including in buildings, equipment, and people, and helps with the external understanding of how to move forward and how to rely on others.
- Lessons learned for preparing an LP include that it is beneficial to: invest in QI to improve the process of drafting the LP, involve all stakeholders from the beginning of the process, take into account different perspectives, and have a policy leader.
- When we address QI issues and organize coherently, countries can reap the benefits of trade as an engine of growth, inclusiveness and poverty reduction in line with the SDGs.

Watch the recorded session here

Laboratory Policy: A guide to development and implementation

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