UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

INETQI
INTERNATIONAL NETWORK ON
QUALITY INFRASTRUCTURE

LABORATORY POLICY
A GUIDE TO DEVELOPMENT AND IMPLEMENTATION

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Foreword

UNIDO has proven track record in the development of quality infrastructure (QI) in developing countries to improve their industrial and economic performance. This is one of the specialized services that UNIDO provides to promote inclusive and sustainable industrial development (ISID). This approach contributes to economic development and the well-being of people through the strengthening of a country's industrial base as a platform for social inclusiveness, economic competitiveness, environmental sustainability and integration into the global trading system. UNIDO, together with the International Network on Quality Infrastructure (INetQI), is committed to promoting and accelerating ISID to enhance the ability of the UNIDO member countries to meet market, environmental and societal needs to accelerate the achievement of the SDGs.

Successful and sustainable exports to the global marketplace are increasingly predicated by demonstrable compliance with international quality requirements for goods and services. The ability of developing countries and economies in transition to compete in global markets and participate in international value chains is often hampered by difficulties in proving compliance with technically sophisticated quality requirements. An appropriate and internationally recognised Laboratory Infrastructure (LI) helps both domestic and global producers, and consumers to overcome this challenge. It also helps ensure food safety and the protection of human, animal and plant health and the environment, thus ensuring that products and services meet the triple bottom line aligned to social, environmental and financial considerations.

Two years ago, UNIDO and INetQI spearheaded the development of the Quality Policy Guiding Principles. This offers policymakers the necessary guidance to create fundamental conditions to ensure good governance of its quality infrastructure (QI). This complementary document on Laboratory Policy (LP), a result of the strengthened partnership between UNIDO and INetQI, addresses the needs related to the development and strengthening of a key component of any QI, the Laboratory Infrastructure. This LP document also draws on the wealth of experience and knowledge of member countries, and has been drafted, reviewed and finalized through a broad consensus-building process.

An appropriate LP and the associated LI system can, as a subset of the QI, positively and substantially contribute to the UN Sustainable Development Goals (SDGs) as envisaged by the 2030 Agenda for Sustainable Development. LI related institutions and service providers will continually need to be strengthened and expanded to meet new technical requirements, help consumers make informed choices, encourage the measurement and testing of innovative solutions, and good practice. It also has the propensity to assist businesses and industries in their adoption of more sustainable technologies and processes. This document is indicative of UNIDO's and INetQI's continued commitment to promote and accelerate

inclusive and sustainable industrial development in developing economies with the aim to enhance their laboratory capacities in support of achieving the SDGs.

This publication supplements three previous UNIDO publications related to the quality policy, namely 'Quality Policy – Guiding Principles'; 'Quality Policy – Practical Tool' and 'Quality Policy – Technical Guide' and the more recent publication 'Rebooting Quality Infrastructure for a Sustainable Future'. Together, this set of documents is aimed at supporting QI and LI practitioners and policy makers to design and develop robust, holistic, and demand-driven QI and LI systems.

LI Yong, UNIDO Director General

Merih Malmqvist Nilsson, INetQI Chair

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The publication is the result of a collaborative effort of UNIDO and the International Network on Quality Infrastructure (INetQI), whose Members are:

BIPM	Bureau International des Poids et Mesures (International Bureau of Weights and Measures), BIPM
IAF	International Accreditation Forum, IAF
IEC	International Electrotechnical Commission, IEC
IIOC	Independent International Organisation for Certification, IIOC
ILAC	International Laboratory Accreditation Cooperation, ILAC
IQNET	International Certification Network, ILAC
ISO	International Standards Organization, ISO
ITC	International Trade Centre, ITC
ITU	International Telecommunication Union, ITU
OIML	International Organization of Legal Metrology, OIML
UNECE	United Nations Economic Cooperation for Europe, UNECE
UNIDO	United Nations Industrial Development Organization, UNIDO
WBG	World Bank Group, WBG
WTO	World Trade Organization

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This publication was edited by Mr. Richard King and the design and layout was developed by Ms. Radhika Nathwani.

Disclaimer

Executive Summary

Quality Infrastructure is a critical element in promoting and sustaining economic development, as well as in environmental and social wellbeing. Such a system relies on metrology, standardization, accreditation, conformity assessment, and market surveillance. Laboratories are a key component and 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, while ensuring products and services meet the triple bottom line of social, environmental and financial considerations.

Developing or strengthening Laboratory Infrastructure (LI) is not a trivial exercise. 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 replication of laboratory services (e.g. water and food testing laboratories in several government ministries when demand for these services is limited) and public laboratories competing with each other and with private sector laboratories.

Investments in LI should not only seek to address immediate needs. It is important they are also channelled to areas where they could act as an enabler and multiplier for longer-term added value, signalling the need to approach LI holistically. Each economy needs to consider its business environment, production capabilities and internal market needs. Demography, export and import activities, and global value chains are also important considerations. Government needs to take responsibility for the efficient and effective use of the available resources and provide overarching guidance for achieving their goals through cooperation with all stakeholders. This is where the need for a suitable Laboratory Policy (LP) arises.

Further issues that indicate the need for an LP can include:

- A growing concern for the safety of goods and services circulating in the domestic market;
- The need to increase the quality of domestic products both for the health and safety of the citizens and to meet international quality standards to stay in or enter foreign markets;
- An appreciation that laboratories play an essential role in verifying if national goods and services comply with quality, safety and sustainability requirements;
- Gaps in human talent, infrastructure, market development, regulatory framework and the demonstration of the technical capabilities of laboratories; and
- The lack of a policy to holistically and systematically address the weaknesses in the technical capacities of laboratories.

An appropriate LP has the potential to guide, in an integrated way, the development of the required

laboratory capability and capacity to address these issues, as well as other national and regional priorities. It can also assist in balancing current laboratory capacities and provide guidance on the efficient allocation of, often scarce, scientific and technical professional staff and other laboratory-related resources within the LI.

Given the investment associated with maintaining an LI, an LP can help focus available resources which can assist in delivering the many test results needed, cost-effectively and efficiently. With such a focus, a sustainable LI has the ability to underpin the health of people, protect the environment, guarantee the rights of consumers, support competitiveness of national producers, and access international markets, thus contributing to three of the Sustainable Development Goal (SDG) pillars—people, prosperity and planet.

An LP can be a valuable tool by which the government can unite all stakeholders around a common understanding of the current situation. It can guide all stakeholders in the 'what' of a country's LI. It can recognise and build on the existing laboratory-related infrastructure, and set objectives for how it can be changed, adapted and upgraded. Economies in general, and developing economies in particular, need to take ownership of their own needs and seek appropriate solutions.

There is no ready-made transferable model for an LP to suit the needs of all economies. The model eventually chosen has to be based on the particular needs and future goals of each economy. As a subcomponent of a QP, the LP principles contained in this document are designed to align with the QP principles and have been adapted and expanded to focus on LI issues specifically. They provide a standardized approach that promotes the development of an LP that best aligns with the particular stage in a country's development trajectory while encouraging appropriate benchmarking with others. Based on UNIDO's expertise in laboratory capacity building, the Laboratory Policy Guide is a useful resource to help countries develop and implement their own LP.

Table of Contents

Abbreviations and Acronyms

AB	Accreditation Body
AOAC	Association of Official Analytical Chemists
BIPM	Bureau International de Poids et Mésures
CA	Conformity Assessment (i.e. testing, inspection and certification)
CAC	Codex Alimentarius Commission
CIPM	Comité International des Poids et Mesures (International Committee for Weights and Measures)
CIPM MRA	CIPM Mutual Recognition Arrangement
CMC	Calibration and Measurement Capability
CRM	Certified Refence Material
DTI	Digitalization, Technology and Innovation
GLP	Good Laboratory Practice
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ILAC MRA	ILAC Mutual Recognition Arrangement
INetQI	International Network on Quality Infrastructure
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
ISPM	International Standards for Phytosanitary Measures
KCDB	BIPM key comparison database
LI	Laboratory Infrastructure
LMS	Laboratory Management System
LP	Laboratory Policy
MAD	Mutual Acceptance of Data
MSME	Micro, Small and Medium Enterprises
NGO	Non-Governmental Organization
NMI	National Metrology Institute
NQP	National Quality Policy
NSB	National Standards Body
OECD	Organization for Economic Cooperation and Development
OIE	World Organization for Animal Health
OIML	Organisation Internationale de Métrologie Légale (International Organization of Legal Metrology)

OIML-CS	OIML Certification System
PPE	Personal protective equipment
PPP	Public-private partnership
QI	Quality Infrastructure
QP	Quality Policy
REC	Regional Economic Community
SADC	Southern African Development Community
SDGs	Sustainable Development Goals
SI	International System of Units
SPS	Sanitary and Phyto-Sanitary (Measures)
TBT	Technical Barriers to Trade
TFA	Trade Facilitation Agreement
UN	United Nations
UNIDO	United Nations Industrial Development Organization
VIM	International Vocabulary of Metrology
WHO	World Health Organization
WTO	World Trade Organization
4IR	Fourth Industrial Revolution

1. INTRODUCTION

1.1 THE ROLE OF LABORATORY INFRASTRUCTURE

Quality Infrastructure (QI) is a system that combines initiatives, institutions, organizations (public and private), activities and people. It includes the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes. It is required for the effective operation of domestic markets, and its international recognition is important to establish its credibility in local and foreign markets. QI is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing. It relies on metrology, standardization, accreditation, conformity assessment, and market surveillance. Laboratory activities enable the assessment of conformity together with inspection and certification.

As a key component of the QI system, 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, while ensuring products and services meet the triple bottom line of social, environmental and financial considerations.

Developing or strengthening the Laboratory Infrastructure requires focus and insight. There needs to be a balance between the quantum of the intended investment and the expected short- and longer-term benefits. In many developing countries—where resources are sometimes limited—this often means difficult choices. Should the priority be building physical infrastructure like roads, bridges and hospitals? What priority should be given to the quality, safety and sustainability of products and services? Capital-intensive infrastructure projects can flounder due to inherent quality issues, adding additional and preventable costs and even posing a threat to life.

A robust needs analysis—one that considers a country's strategic development and policy objectives in parallel with its laboratory capacity requirements—is fundamental. An appropriate understanding of what laboratory services are available, and their ability to meet the expectations of regulators and the market place, is essential before making further investment decisions. It is also important to understand initial and ongoing investment implications, in relation to addressing the identified needs and potential benefits. Such information allows for a much richer understanding for evaluating further investment in laboratory capability.

Strategies that aspire to meet future market needs must also contend with at least two further challenges. First, how to demonstrably meet the Sustainable Development Goals (SDGs) as part of the 2030 Agenda for Sustainable Development. Indeed, the need for a sustainable Laboratory Infrastructure is implied, especially if noting that by definition:

"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."

Second, how to adapt to take full advantage of the technology of the Fourth Industrial Revolution (4IR). It is clear that laboratory infrastructure strategies that consider and leverage the opportunities offered by the SDGs and the 4IR will ultimately accrue significant further benefits.

1.2 LABORATORY INFRASTRUCTURE & SDGS

A sustainable Laboratory Infrastructure can help build economic prosperity, improve the lives of people and protect our planet, thereby contributing to the achievement of the 17 SDGs. For many developing countries, the 2030 Agenda for Sustainable Development sits at the heart of their development plans and implementation strategies. As such, both national and regional Laboratory Infrastructure institutions will play a key role through the calibration and testing services they provide, as well as other conformity assessment activities they enable, such as inspection and certification. A sustainable Laboratory Infrastructure, as part of a "rebooted" QI,[1] contributes to three of the SDG pillars: people, prosperity and planet.

[1] See UNIDO publication "Rebooting Quality Infrastructure for a Sustainable Future": https://tii.unido.org/news/rebooting-quality-infrastructure-sustainable-future

A Laboratory Infrastructure provides the technical foundation required for the functioning of modern societies. The Laboratory Infrastructure can support a range of policy objectives in areas that include:

- Industrial development;
- Technology and technological advancement;
- Trade competitiveness in domestic and global markets;
- Efficient use of natural and human resources;
- Food-safety;
- Health;
- Environmental protection; and the
- Mitigation of, and adaptation to, climate change.

1.2.1 BUILDING PROSPERITY

The UN's 2030 Agenda for Sustainable Development recognises international trade as an engine for economic development and poverty reduction, and a powerful motivator for specialisation, competition, economies of scale and innovation. It states:

"These powerful forces can, if properly harnessed, help make the world economy more sustainable and resilient to environmental risks while having positive effects on prosperity, jobs and equality."

A fit-for-purpose Laboratory Infrastructure can make domestic markets more effective, and facilitate their access to foreign markets. It also assists in the diversification of exports and promotes economic development more generally. For successful trade, manufacturers need to ensure that their products are of consistent quality,[2] comply with relevant standards and regulations, and meet the appropriate consumer requirements and specifications in their intended market. Meeting these needs often requires supporting laboratory data and reports that are trusted. The Laboratory Infrastructure is indispensable in the provision of this data, which is needed to address social and environmental aspects, without creating unnecessary barriers to international trade.

Laboratory Infrastructure (LI) makes important contributions to the prosperity pillar in the following ways:

» **Industry, Innovation and Infrastructure:** Manufacturers need to ensure that their products are of consistent quality, comply with relevant standards and regulations, and meet the appropriate consumer requirements and specifications in their intended market. Meeting these needs often requires supporting laboratory data and reports that are trusted. The LI is indispensable in the provision of this data, which is needed to address social and environmental aspects, without creating unnecessary barriers to international trade.

» **Decent work and economic growth:** The UN's 2030 Agenda for Sustainable Development recognises international trade as an engine for economic development and poverty reduction, and a powerful motivator for specialisation, competition, economies of scale and innovation. Increased participation in international trade can also unlock opportunities for expanding and improving the scope of work and associated working conditions for the local workforce. The LI provides crucial data to enable the attainment of the necessary quality, safety, performance and sustainability of products and services.

» **Affordable and clean energy:** The availability of the necessary calibration and testing laboratory capability supports governments and organizations in their ambitions for greater energy efficiency and transitions to clean energy. Moreover, it can help prevent unsafe, unhealthy or environmentally harmful products from entering the marketplace. Many renewable energy projects include a portion of foreign investment. These investors need to be confidence that each unit of energy produced is accurate.

1.2.2 MEETING THE NEEDS OF PEOPLE

Laboratory Infrastructure makes important contributions to the people pillar in several ways, including:

» **Food security and sustainable agriculture:** LI helps ensure food is safe for consumption, allowing people to live healthier lives and improve their social and economic wellbeing. It is also indispensable in supporting trade in agricultural products, often a key export for many developing countries.

» **Health and wellbeing:** Quality healthcare is underpinned by the measurements used in the diagnosis of health conditions. Laboratory Policy plays a key role in maintaining essential services and enhancing societal resilience to potential pandemics. A robust LP ensures that laboratories function well during a crisis, providing reliable test results that maintain public confidence in healthcare services. Appropriate measurements can ensure therapies are delivered safely and effectively. Guidelines and regulations on their own are meaningless. The measurements used to verify conformity or compliance need to be accurate, traceable to agreed reference standards, and use competently calibrated instruments.

» **Gender equality:** As countries further develop and strengthen Laboratory Infrastructure, including the use of technical assistance, an ideal opportunity is presented to integrate a gender perspective, including representation and decision-making roles, in the design and implementation of such initiatives.

1.2.3 PROTECTING THE PLANET

Laboratory Infrastructure makes important contributions to the third of the SDG pillars—planet—in several ways, including:

» **Water and sanitation:** The Laboratory Infrastructure provides the technical data needed to ensure water is safe for consumption. It also allows for pollution control and the promotion of water efficiency. Metrological services support the development of

[2] See UNIDO publication "Quality Infrastructure for Sustainable Development: https://www.unido.org/sites/default/files/files/2019-07/SDG-QI_BROCHURE_FINAL_0.PDF

reliable and internationally comparable metrics for tracking the level of reserves, the rate of extraction and the quality of national water sources. The calibration of water meters helps guarantee conservation and sustainable consumption.

» **Protecting life below water and on land:** Laboratory Infrastructure institutions and the services they provide are an essential contributor to the implementation of policies and actions aiming to achieve the sustainable use of marine resources (life below water) and the protection of ecosystems (life on land), in terms of measurement capabilities, monitoring, reporting and the verification of compliance or conformity.

» **Responsible consumption and production:** Laboratory Infrastructure institutions and their service offerings are indispensable in supporting the transition towards sustainable consumption and production patterns. They can provide accurate information about the materials, energy, water and land used, and associated emissions and wastage. These parameters are needed to develop and apply sustainability policies and to encourage eco-friendly behaviour.

» **Climate action:** Measuring climate-related variables is critical to understanding and monitoring climate change. The need for scientific observations of ever-increasing complexity and accuracy places stringent demands for precise and traceable measurements to internationally agreed units. These needs together with the measurement and assessment of greenhouse gas emissions related to human activity can only be realised through the use of an appropriate LI.

The same Laboratory Infrastructure institutions and their services also underpin the development of sustainable industry and infrastructure. Measurement and testing are particularly important in this, through assessment of the ecological performance and energy efficiency of materials, products and systems, including the:

» Environmental footprint of different categories of materials and products, and the definition of appropriate and measurable indicators, including for global supply chains;

» Ecological design of products and the optimization of the use of materials and energy over the product life cycle; and

» Energy efficiency of buildings, industrial plants, vehicles and electrical appliances.

1.3 LABORATORY INFRASTRUCTURE & THE FOURTH INDUSTRIAL REVOLUTION (4IR)

The Fourth Industrial Revolution (4IR) is increasingly unlocking greater interaction between physical and biological systems and digital technologies. These include artificial intelligence (AI), blockchain technology, supercomputing, cloud-enabled enterprise solutions, virtual reality (VR), biotechnology, robotics, 3D printing and the Internet of Things (i.e. connecting everyday items to the internet). The need for measurement and testing is also being impacted by these new developments. Machine learning, smart sensors, drones and virtual reality have all been successfully deployed.[3]

The 4IR is encouraging greater connectivity between people, technology and industry. There is also the potential for far-reaching impacts for laboratories, as they develop into smart laboratories. Such laboratories will increasingly harness the power of automation and informatics to change the way they service the needs of their customers. The kinds of technologies that will increasingly be deployed include:

» **AI and machine learning -** the use of digital imagery in a semi-automated processes to increase the speed and integrity of industrial testing.

» **Big Data -** to assist laboratories and the users of their services to determine areas for further improvement including optimal timing for laboratory quality assurance, and fit-for-purpose equipment maintenance and calibration activities.

The opportunities to use these and other 4IR advancements should be identified and used in developing more flexible solutions to addressing laboratory-related needs. The deployment of innovative laboratory solutions will also assist in ensuring that the LI is more efficient, effective and sustainable.

[3] See UNIDO Brochure - Advancing Conformity Assessment for the new digital age: https://tii.unido.org/sites/default/files/publications/UNIDO%20Conformity%20Assessment_Brochure_2020.pdf

1.4 THE CONTRIBUTIONS OF LABORATORY INFRASTRUCTURE

Given its importance, governments often aim to strengthen, upgrade and appropriately maintain the capacity of all parts of their Laboratory Infrastructure to ensure it is fit-for-purpose. A fit-for-purpose Laboratory Infrastructure can produce traceable and trusted test and measurement data and reports in a way that is efficient and effective. As such, it is widely recognized as an essential requirement for the protection of human health and the environment, for the facilitation of trade, enhancing exports, accelerating economic development and reducing poverty.

Table 1 (below) outlines some of the contributions of Laboratory Infrastructure in greater detail.

TABLE 1:

CONTEXT	CONTRIBUTION OF LABORATORY INFRASTRUCTURE
Market access to export markets (for products or subcomponents)	» Ensures accurate and comparable results by making test and measurement units traceable, through the use of appropriate calibration and reference materials. » Ensures a testing laboratory (or laboratories) are available at a reasonable distance and cost, while also delivering trusted and accepted results. » Allows exporters to receive results in a cost-effective and timely way, related to the testing and measurement requirements of target markets. » Underpins other conformity assessment activities[4] such as inspection and product certification.
Participation in global value chains	» Ensures the accuracy and comparability of calibration and test results. » Assists domestic suppliers in building trust with the other participants in the global value chain, particularly related to the reliability and trustworthiness of the Laboratory Infrastructure in which they operate.
Citizen, consumer and environmental protection	» Gives the ability to test and measure the properties and impact of materials and products, particularly those related to aspects of health and safety. » Provides important data to law enforcement authorities based on scientific evidence.

1.5 THE SCOPE OF THIS GUIDE

This document has been developed by UNIDO to guide the development and implementation of a Laboratory Policy. It provides laboratory-specific information which builds on an existing suite of three documents on Quality Policy already published by UNIDO:

» **Quality Policy – Guiding Principles**

» **Quality Policy – Technical Guide**

» **Quality Policy – A Practical Tool**

The guide intends to help policymakers and decision-makers understand the need for an LP and guide them in subsequent development using known practices. It also provides guidance in creating a conducive environment for the Laboratory Infrastructure that addresses the needs related to the different levels of development within countries. The guide approaches issues at three distinct but complementary levels, all of which are integral to the successful implementation of a fit-for-purpose laboratory development and maintenance system. These three levels are:

[4] For more information on conformity assessment see: https://www.unido.org/sites/default/files/files/2020-06/UNIDO%20Conformity%20Assessment_Brochure_2020.pdf

1. **Macro-level (policy level):** Identifying critical principles for the formulation of a fit-for-purpose Laboratory Policy;
2. **Meso-level (institutional level):** Exploring issues related to internationally recognised ways of enhancing trust in the test and measurement data from laboratories, including the use of accreditation;
3. **Micro-level (operational level):** Identifying and addressing the most common obstacles encountered by laboratories in developing, strengthening and sustaining the Laboratory Infrastructure.

2. BACKGROUND

2.1 REGULATIONS

2.1.1 INTERNATIONAL LEVEL

The World Trade Organization (WTO) is an international organisation that addresses issues related to the global rules of trade between nations. Its primary function is to ensure that trade flows as smoothly, predictably and freely as possible. As part of the family of instruments[5] developed by the WTO, three agreements recognize the crucial role of technical regulations, standards and internationally recognised conformity assessment procedures—such as testing, inspection and certification—and how these activities can impact trade flows, and therefore provide criteria to avoid unnecessary trade obstacles:

» **Technical Barriers to Trade Agreement (TBT):** Sets the rules for how technical regulations, standards and conformity assessment procedures are prepared, adopted and implemented. The TBT Agreement requires WTO members to use relevant international standards, guides or recommendations as the basis for their technical regulations, standards, and conformity assessment procedures to remove unnecessary obstacles to trade. The TBT Agreement also promotes mutual recognition of foreign conformity assessment results through negotiation and understanding between trade partners, based on relevant international guides and recommendations.

» **Sanitary and Phytosanitary Measures Agreement (SPS):** Requires governments to base their national SPS measures on international standards, guidelines and recommendations. The SPS Agreement states that when SPS measures are based on existing international standards, guidelines and recommendations, they are deemed to be necessary for legitimate objectives and presumed to be WTO-consistent.

» **Trade Facilitation Agreement (TFA):** Contains provisions for expediting the movement, release and clearance of goods. The TFA sets out measures for practical cooperation between customs and other appropriate authorities on trade facilitation including provisions on the use of testing and inspection results for customs clearance and goods release.

Organizations within a Laboratory Infrastructure have a key role to play in helping economies address the conformity assessment related requirements of all

[5] Other instruments developed by international organisations such as the WTO are Treaties, Prescriptive instruments, Policy / Political instruments, Incentive instruments Technical standards, mutual recognition agreements / arrangements and supporting instruments. For further information see the OECD publication "The Contribution of International Organisations to a Rule-Based International System: https://www.oecd.org/gov/regulatory-policy/IO-Rule-Based%20System.pdf

three of these international agreements. Regulations, including those intended to protect human health and safety, the environment, plant and animal life, and the prevention of deception in trade, often specify requirements that can only be proven by the provision of acceptable test or measurement results. Such results need to be provided by an institution acceptable to the regulatory authorities. Where laboratory services have been made widely available, proven their competence through accreditation and deemed acceptable by regulators, users can normally choose from accredited laboratories in the public or private sector. This greater choice means that users of the laboratory services necessary for them to prove can decide which they use based on preferred criteria, such as cost or speed of results.

2.1.2 REGIONAL AND NATIONAL LEVEL

The OECD notes that the intensification of global challenges including those related to the environment and human health and safety is leading to greater cross border regulatory co-operation.[6] They also understand that "the main task of regulators focuses on achieving specific domestic objectives such as safety, health, environment and consumer protection".[7] The need to consider and address regional or international issues is often part of implementing trade and other international and bi-lateral agreements at country level. Any subsequent alignment or other revision of regulations may include the need to adapt or develop the conformity assessment processes manufacturers or service providers need to implement as part of proving compliance with such regulations.

At a national level, it may be beneficial for the goals, institutions, roles and responsibilities for the supportive Laboratory Infrastructure—and Quality Infrastructure in general—be defined in legislation. Where they exist or are being developed, national legal and regulatory frameworks should seek to encourage and support the development of a robust, competitive and sustainable laboratory services sector to support regulatory and other strategic needs. Several factors can support this aim. One is encouraging the private sector to invest in and develop laboratory services. Another is ensuring government laboratories adopt a pricing model that allows the provision of services in a sustainable way over the long term and third, promoting the use of national and regional accreditation bodies for proving compliance with technical regulations. A fourth factor is that government may need to support such bodies in their pursuit and maintenance of multilateral recognition arrangements (at the regional or international level) to ensure that the accreditations they provide are internationally recognised.

[6] See OECD publication "International Regulatory Co-operation – Addressing Global Challenges": https://www.oecd.org/env/international-regulatory-co-operation-9789264200463-en.htm

[7] See OECD publication "International Regulatory Co-operation and Trade": https://www.oecd.org/gov/international-regulatory-co-operation-and-trade-9789264275942-en.htm

2.2 INTERNATIONAL STANDARDS

International laboratory standards can ensure repeatability and reproducibility of test and measurement results; this helps provide confidence in the ongoing quality of work and the validity of results.

2.2.1 GLOBALLY ACCEPTED STANDARDS

The globally accepted overarching standard for demonstrating the competence of laboratories and their laboratory management system is **ISO/IEC 17025,**[8] published by the **International Organization for Standardization (ISO)** and the **International Electrotechnical Commission (IEC)**. Its application is not limited to any sectors or differentiated with regards to internal versus independent laboratories. Laboratory activities according to ISO/IEC 17025 can be transparently integrated in specific programmes or complex frameworks. Testing and calibration laboratories are worldwide recognised according to this standard by accreditation.

ISO has also issued documents for the medical sector. Although voluntary, regulators are increasingly using them so they can conform to global standards. These documents include:

- **ISO 15189** – for medical diagnostic laboratories;
- **ISO 15195** – for reference measures;
- **ISO 15190** – for safety requirements; and
- **ISO 15195 –** for calibration laboratories using reference measurement procedures in laboratory medicine.

Organizations publishing industry-specific and widely-used laboratory standards also include:

- **ASTM International** (formerly known as the American Society for Testing and Materials);
- **Association of Official Analytical Chemists (AOAC) international methods:** and
- **Institute of Electrical and Electronics Engineers Standards Association (IEEE SA).**

There are many other industry or sector-specific standards organizations. Private standards play an important role in the marketplace addressing issues such as food safety, fair trade and sustainability of marine and forestry resources. Crucially, not all of these are considered as 'international standards' according to the WTO TBT Agreement.[9] It is important to note that the TBT agreement contains provisions to address the situation: "Whenever a relevant guide or recommendation issued by an international standardizing body does not exist or the technical content of a proposed conformity assessment procedure is not in accordance with relevant guides and recommendations issued by international standardizing bodies."[10]

2.2.2 INTERGOVERNMENTAL STANDARDS

Sometimes intergovernmental treaties or agreements have certain requirements of laboratories in specific sectors; particularly those with the potential risk to the wellbeing of humans, animals and plants. An example of this are the OECD Principles for Good Laboratory Practice (GLP). These are intended for laboratories and regulators of laboratories testing chemicals and drugs. [See Annex C (4)].

Three other intergovernmental organizations provide international standards in the areas of food safety, plant and animal health, and are recognised as international standard-setting bodies by the WTO SPS Agreement. Although standards provided by these organizations are voluntary, they are often used as the basis for national legislation. These organizations are:

- **Codex Alimentarius Commission (CAC):** Established by the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) to protect consumer health and promote fair practices in food. The commission develops and maintains the Codex Alimentarius, a collection of internationally recognised standards, codes of practice, guidelines, and other recommendations that also cover food production issues such as food quality, nutrition and labelling.
- **International Plant Protection Convention (IPPC):** Established by FAO member states, the IPPC develops international standards for phytosanitary measures (ISPMs) for safeguarding plant resources. These include pest surveillance and monitoring, import regulations, compliance procedures, and export certification all of which are aimed to prevent the introduction and spread of pests of plants and plant products.
- **World Organization for Animal Health (OIE):** Develops international standards to prevent and control animal diseases, and ensure the sanitary safety of world trade in terrestrial and aquatic animals and animal products.

[8] See UNIDO publication "Tested & Accepted, Implementing ISO / IEC 17025:2017": https://tii.unido.org/sites/default/files/publications/Guide%20ISO%2017025-2017.pdf

[9] The TBT Committee has established a set of six principles that help to identify whether a standard may be considered an international standard under the TBT Agreement: transparency, openness, impartiality and consensus, effectiveness and relevance, coherence and the development dimension.

[10] Agreement on Technical Barriers to Trade, Article 5, paragraph 5.6. WTO, Geneva

2.3 METROLOGY

Metrology is a key component of any Laboratory Policy and the foundation of any credible LI. Firms cannot manufacture a product or deliver a service that reliably meets requirements if their measuring instruments are not calibrated against a traceable measurement standard. The need for traceable measurement is particularly important when products are to be delivered as part of an international value chain. Measuring and testing instruments and equipment used in laboratories needs to be periodically calibrated; this is vital as part of providing data that is accurate and precise, trusted and repeatable. Given the importance of metrology, further information on the topic follows. The information is included purely to assist in understanding the need for establishing and maintaining an appropriate national and/or regional metrological capability to support the generation of credible measurements and tests by the LI.

Metrology is defined by the International Bureau of Weights and Measures (BIPM) as "the science of measurement, embracing both experimental and theoretical determinations at any level of uncertainty in any field of science and technology". It establishes a common understanding of units, crucial to human activity. Metrology is a wide-reaching field, but can be summarized through three basic activities: the definition of internationally accepted units of measurement, the realisation of these units of measurement in practice, and the application of chains of traceability (linking measurements to reference standards). These concepts apply in different degrees to metrology's three main fields: scientific metrology; applied, technical or industrial metrology; and legal metrology.

Modern metrology can be historically linked to the decision taken in France in the 18th century to harmonize units of measurement across the country. This is how in March 1791 the meter was defined. This led to the creation of the decimal-based metric system in 1795. Several countries adopted the metric system between 1795 and 1875. To ensure international conformity, the International Bureau of Weights and Measures was established through the Metre Convention. In 1960 the metric system was further strengthened with the creation of the International System of Units (SI).

Metrology provides reliable measurements as a basis for activities such as scientific research, technical development and production. Metrology is also needed to ensure goods, services and processes comply with quality, environmental, health and safety requirements, as well as meeting consumers' needs and expectations. Chemical metrology provides essential inputs for addressing food safety issues, such as tracing contaminants in food and foodstuffs. The intricate but invisible network of services, suppliers and communications on which modern society depends relies on metrology for their efficient and reliable operation. For example:

- The economic success of nations depends upon the ability to manufacture and trade precisely made and tested products and components;
- Satellite navigation systems and international time correlation make accurate location possible—allowing the networking of computer systems around the world, and permitting aircraft to land in poor visibility;
- Human health depends critically on the ability to make accurate diagnosis, and for which reliable measurement is increasingly important;
- Consumers have to trust the amount of petrol delivered by a pump.

Legal metrology—involving the regulation of measuring instruments and measurements—is also used in some fields to ensure consumer protection, a level playing field in trade, consistent measurements in the areas of health and the environment, and where required, legal proof of measurements.

The common definition of units—such as length, mass, volume, time and temperature—and the realisation and traceability of measurements made in practice to the reference standards, allows for reliable and accurate results. According to the International Vocabulary of Metrology (VIM), metrological traceability is defined as:

"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."

Metrological traceability links the result of any particular measurement to suitable reference standards which at the highest level of accuracy are linked to internationally accepted measurement reference standards. This concept ensures measurement results are both nationally and internationally comparable. Moreover, it gives much-needed confidence in the implications derived from these results, such as medical diagnoses, safety warnings and forensic conclusions. When a measurement result is traceable to internationally accepted SI units, it provides assurance that it can be trusted. This is achieved through the transfer of traceability from the national primary reference standards—usually maintained by a National Metrology Institute (NMI)—through the tertiary standards that are normally kept and used in public and private sector calibration laboratories. The measuring equipment used should then be regularly calibrated to ensure calibration and measurement results and supportive measurements are still accurate and trustworthy.

The CIPM Mutual Recognition Arrangement (CIPM MRA) is the framework through which National Metrology Institutes demonstrate the international equivalence of their measurement standards and the calibration and measurement certificates they issue. The outcomes of the Arrangement are the internationally recognized (peer-reviewed and approved) Calibration and Measurement Capabilities (CMCs) of the participating institutes. The CIPM MRA has been signed by the representatives of 106 institutes—from 62 Member States, 40 Associates of the CGPM, and 4 international organizations—and covers a further 154 institutes designated by the signatory bodies. Currently six Regional Metrology Organisations are recognized within the framework of the CIPM MRA:

» Intra-Africa Metrology System (AFRIMETS);

» Asia Pacific Metrology Programme (APMP);

» Euro-Asian Cooperation of National Metrological Institutions (COOMET);

» European Association of National Metrology Institutes (EURAMET);

» Gulf Association for Metrology (GULFMET); and

» Inter-American Metrology System (SIM).

To make measurements comparable, the quality of a measurement must be characterized by an expression of the measurement uncertainty. An internationally standardized procedure is necessary to interpret measurement results in science and technology correctly. Measurement uncertainty is a parameter characterizing the dispersion of the quantity values being attributed to a measurand. The Joint Committee for Guides in Metrology[11] (JCGM) has published the "Guide to the expression of uncertainty in measurement" (GUM), as the foundation for the determination of measurement uncertainties.

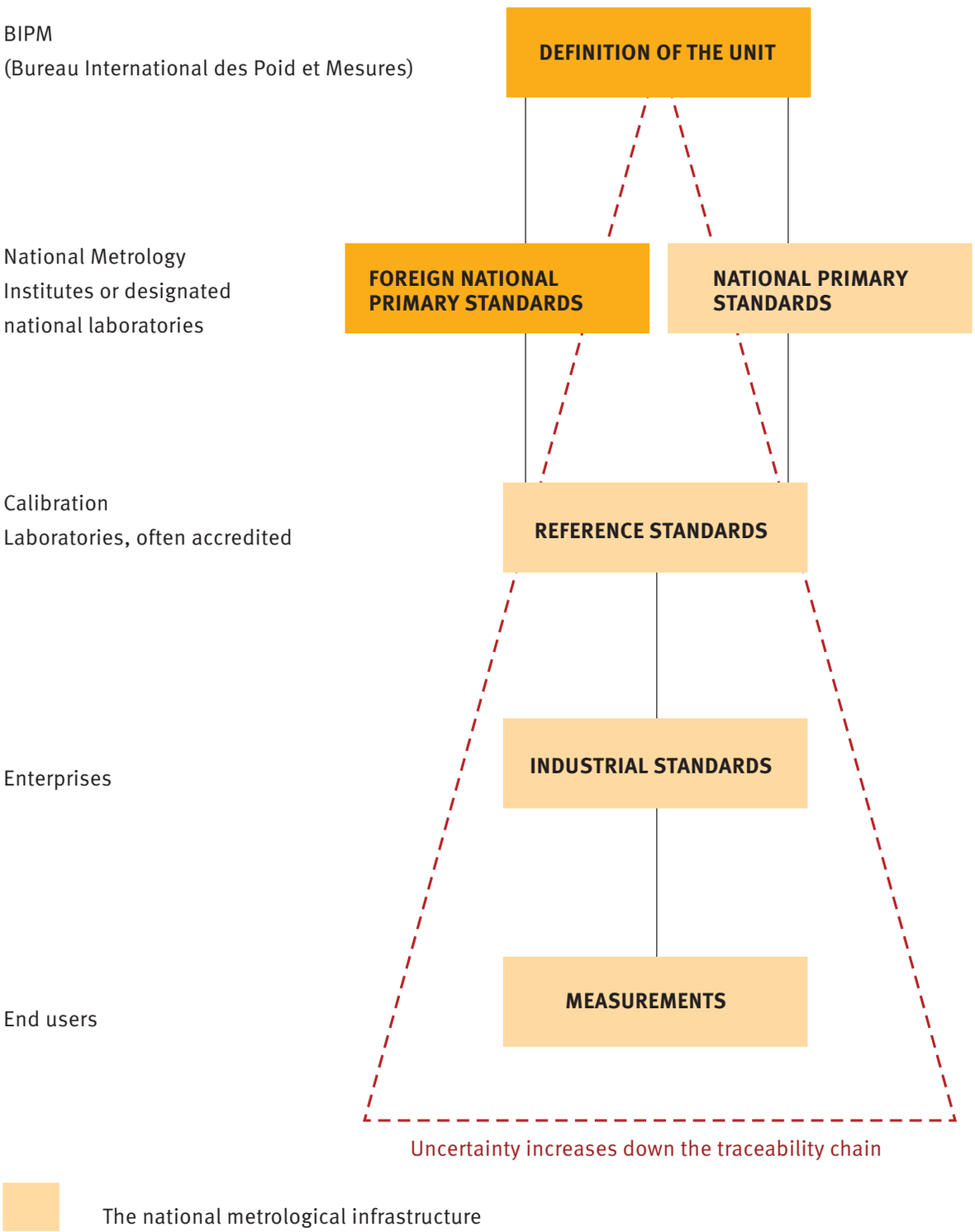
Where metrological traceability to the SI units is not technically possible, appropriate references—such as values of certified reference materials, results of reference methods, inter-comparison measurements or consensus standards—can also be used to demonstrate metrological traceability (for more details see ISO/IEC 17025; 6.5.3). In this case, measurements are traced back to the relevant reference, rather than to a SI unit. This still provides acceptable metrological traceability, because it establishes comparability between different laboratories.

[11] The JCGM is tasked with developing, maintaining and promoting global adoption and implementation of specific metrology instruments including the Guide to the Expression of Uncertainty in Measurement (GUM) and the International Vocabulary of Metrology (VIM).

FIGURE 1 REGIONAL METROLOGY ORGANIZATIONS (RMOS) RECOGNIZED WITHIN THE FRAMEWORK OF THE CIPM MRA

Source: BIPM, https://www.bipm.org/en/worldwide-metrology/regional/

FIGURE 2 THE TRACEABILITY CHAIN



2.4 ACCREDITATION

Conformity assessment service providers, including laboratories, need to give their customers the confidence that they are competent and impartial. Article 6 of the WTO TBT Agreement notes:

[To achieve] "confidence in the continued reliability of conformity assessment results… [verified compliance through accreditation] shall be taken into account as an indication of adequate technical competence".[12]

Accreditation is also being increasingly employed by national authorities to ensure the competence of laboratories and other conformity assessment bodies. Accreditation[13] is the proof—or 'attestation'—of the competence of a body to perform specific tasks, in accordance with the competence requirements in internationally harmonised standards. Internationally recognised accreditation of a laboratory and its activities—including testing, sampling, calibration, proficiency testing and reference material production—enhances confidence in the laboratory and the recognition of its results. In being appropriately accredited, a laboratory can show its customers it has been independently assessed as competent to deliver its accredited scope of tests, calibrations, or other services. Accredited test results and accreditation certificates provide the necessary assurance so that consumers, suppliers and purchasers have confidence in the quality and safety of goods and in the provision of services throughout the supply chain. Samples and products can be evaluated against specified requirements by accredited laboratories to check that products are fit-for-purpose and safe.

The role of an accreditation body[14] (AB) is to assess and attest the competence, impartiality and consistent operation of a laboratory including the suitability of the underpinning management systems. The criteria used are contained in relevant standards such as ISO/IEC 17025 (Testing and Calibration Laboratories), ISO 15189 (Medical Laboratories), ISO/IEC 17043 (Proficiency Testing Providers), and ISO 17034 (Reference Materials Producers), ISO 15195 (Calibration Laboratories in Laboratory Medicine). These criteria are normally supported by technical requirements specific to a scientific discipline. Several developing countries have national accreditation bodies that are internationally recognised. Where national ABs do not exist, or do not have recognition for the specific scope required, laboratories and users of laboratory facilities often need to seek such services in other countries to meet short-term needs.

On 2 November 2000, in Washington, DC, the International Laboratory Accreditation Cooperation (ILAC) converted numerous bilateral and two regional multi-lateral arrangements into a global multi-lateral mutual recognition arrangement. This was initially signed by 36 accreditation bodies from 28 economies. The aim was to facilitate trade by promoting the acceptance of accredited test and calibration results on exported goods. The ILAC Mutual Recognition Arrangement (ILAC MRA)—often referred to as the ILAC Arrangement—was the culmination of 22 years of intensive work. The ILAC Arrangement provides the significant technical underpinning for the testing, medical, calibration, proficiency testing and reference material results of the accredited laboratories of its members. The ability of these accredited laboratories to include the symbol of their chosen AB, together with the ILAC MRA Mark which they are licensed to use, helps provide increased confidence in the laboratory, while promoting acceptance of the results they provide. In 2019, ca. 76,500 laboratories were accredited by bodies organised within ILAC (International Laboratory Accreditation Cooperation) as signatories to the respective mutual recognition arrangement (MRA).[15]

[12] Agreement on Technical Barriers to Trade, Article 6, paragraph 6.1.1, WTO, Geneva

[13] While recognising that achieving and maintain accreditation by a laboratory is far from a trivial exercise, it is suggested, given the inherent benefits, that this remain a key objective, even if initially this is only for the main scope of activity.

[14] For more information see UNIDO publication "Setting up Accreditation Bodies in Developing Economies": https://www.unido.org/sites/default/files/2017-07/Accreditation_Bodies_final_0.pdf

[15] UNIDO publication "Tested & Accepted, Implementing ISO / IEC 17025:2017": https://tii.unido.org/sites/default/files/publications/Guide%20ISO%2017025-2017.pdf

FIGURE 3 OVERVIEW OF ILAC MRA AROUND THE WORLD

Source: ILAC, https://ilac.org/publications-and-resources/ilac-promotional-brochures/

3. WHY A LABORATORY POLICY IS NEEDED

Quality Infrastructure is a critical element in promoting and sustaining economic development, as well as in environmental and social wellbeing.[16] Such a system relies on metrology, standardization, accreditation, conformity assessment, and market surveillance. Laboratories are a key component and are often 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 other conformity assessment activities such as inspection and certification. When an economy develops or strengthens its Laboratory Infrastructure, 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:

» Replication of laboratory services, e.g. water and food testing laboratories in several government ministries when demand for these services is limited; and

» Public laboratories competing with each other and with private sector laboratories.

Sustainable access to laboratory support tools such as Proficiency Testing and Certified Reference Materials, and the procurement, servicing and maintenance of laboratory equipment, can also be problematic.

[16] See UNIDO publication "Rebooting Quality Infrastructure for a Sustainable Future": https://tii.unido.org/news/rebooting-quality-infrastructure-sustainable-future

Good governance requires public resources to be used responsibly. There is a need therefore to identify and differentiate between sustainable (profitable/cost recovery) services and those laboratory services that should be part or fully funded by government on an ongoing basis as a public service. Such a differentiation highlights the need for awareness among regulators regarding the true costs of providing the testing/calibration services required to prove compliance with technical regulations. Distortion of the market for laboratory services can be caused by public laboratories charging fees that are lower than the actual cost of their provision. Such a scenario does not encourage private sector investment in such services.

Investments in laboratory infrastructure and related resources should not only seek to address immediate needs. It is important they are also channelled to areas where they could act as an enabler and multiplier for longer-term added value. When addressing Quality and Laboratory Infrastructure needs, each economy needs to consider its business environment, production capabilities and internal market needs. Demography, export and import activities, and the global value chains an economy participates in, are also important considerations. A needs analysis of laboratory services should be undertaken, taking into account the context of the current stage of development, and the country's aspirations, strategies and goals for the future. Together with this knowledge, the government needs to take responsibility for the efficient and effective use of the available resources and provide overarching

guidance for achieving their goals through cooperation with all stakeholders. This is where the need for a suitable Laboratory Policy arises.

3.1 WHAT A LABORATORY POLICY CAN OFFER

An appropriate Laboratory Policy has the potential to guide, in an integrated way, the development of the required laboratory capability and capacity to address identified needs in support of national and regional strategic priorities. It can also assist in balancing current laboratory capacities and provide guidance on the efficient allocation of, often scarce, scientific and technical professional staff and other laboratory-related resources within the Laboratory Infrastructure.

It provides a valuable tool for the government to unite all stakeholders around a common understanding of the current situation. It should recognise and build on the existing laboratory-related infrastructure, including those situated in institutions of higher learning and national and regional research laboratories. These latter category of laboratories can provide a valuable resource in terms of further research and contributing to strengthening the technical competence of laboratory personnel. This is particularly relevant for laboratories situated in economies with a low level of QI and LI development. The LP helps set objectives for how the LI should be changed, adapted and upgraded to address the identified needs in an even more coherent and effective way.

While noting the need for appropriate international benchmarking and co-operation in establishing, strengthening and maintaining an LI, experience has shown that it is neither sufficient nor sustainable to blindly follow the approaches used in other economies. While learning from the mistakes of others within a similar context can provide valuable insights, attempts at complete emulation have rarely delivered the intended benefits. Economies in general, and developing economies in particular, therefore need to take ownership for addressing their own LI-related needs and seek appropriate and sustainable solutions in a synergistic way.

Further, an efficient, effective and sustainable Laboratory Infrastructure is the basis for proving the compliance of products and services in local, regional and global markets. It can also promote trade under fair competition and facilitate participation in global value chains. Laboratories and their customers—including those in or supporting value chains—increasingly require a policy that ensures coordinated, needs-driven development and sustainable delivery.

Given the investment associated with maintaining a Laboratory Infrastructure, a Laboratory Policy can help focus available resources which can assist in delivering the many measurements and test results needed in a modern economy, cost-effectively and efficiently. With such a focus, a sustainable Laboratory Infrastructure has the ability to underpin the health of people, protect

the environment, guarantee the rights of consumers, support competitiveness of national producers, and access international markets, thus contributing to three of the SDG pillars—people, prosperity and planet.

3.2 UNDERSTANDING THE NEED FOR A LABORATORY POLICY

International acceptability of laboratory results depends on demonstrable and continuous conformity with the requirements contained in various multi-lateral agreements and arrangements. These are usually based on agreed international standards for the competence of laboratories. Yet laboratories can face a number of issues which indicate the need for an LP.

Laboratories in any given economy often have diverse mandates and can be geographically dispersed. This often leads to technical isolation and minimal cooperation between laboratories, even when located in the 'non-competitive' public sector.

Some government departments may use laboratory services provided by other public Laboratory Infrastructure institutions without appropriate reimbursement. Costs related to the time and effort expended and the investment made in these facilities can be substantial. Such a tendency can negatively impact the financial support received from the laboratory's line ministry that is intended for the other fundamental services they are meant to deliver.

Further issues that indicate the need for an LP can include:

- A growing concern for the safety of goods and services circulating in the domestic market;
- The need to increase the quality of domestic products both for the health and safety of the citizens and to meet international quality standards to stay in or enter foreign markets;
- An appreciation that laboratories play an essential role in verifying that national goods and services comply with quality, safety and sustainability requirements;
- Gaps in human talent, infrastructure, market development, regulatory framework and the demonstration of the technical capabilities of laboratories; and
- The lack of a policy to holistically and systematically address the weaknesses in the technical capacities of laboratories.

In seeking to address TBT, SPS and TFA issues, regulatory test needs and the fulfilment of other market laboratory-related needs, the government must accept overall responsibility for the effectiveness and efficiency of the Laboratory Infrastructure system. The LP should ensure that an enabling environment is created and maintained that encourages the public sector laboratories to continuously innovate and be appropriately self-sustainable. However, developing this environment should by no means limit the business opportunities for private enterprise—particularly micro, small and medium enterprises (MSMEs)—wishing to provide calibration and testing services.

The increase in the occurrence of extraordinary events has already resulted in many adverse effects to the trading environment and subsequent health and safety measures adopted by many economies.[17] The LP can assist to keep trade flowing by boosting confidence in the quality and safety of the goods being traded, especially for essentials such as health supplies and food, while helping to avoid unnecessary barriers to import and export.

[17] See for example "digital transformation and industrial recovery in response to the COVID-19 pandemic": https://www.unido.org/news/new-publication-digital-transformation-and-industrial-recovery-response-covid-19-pandemic.

4. CHALLENGES AND BENEFITS FOR LABORATORIES

4.1 CHALLENGES FOR LABORATORIES

Laboratories can face a range of challenges, especially in developing countries. Through many years of providing support to laboratories, UNIDO and others have identified challenges that often cut across countries and regions. These include:

- A lack of communication between government and stakeholders when determining what Laboratory Infrastructure is needed and why;
- The various components of a country's Laboratory Infrastructure developing in an ad hoc and uncoordinated way, often due to a lack of understanding of how to sustainably address actual needs;
- A lack of supporting technical infrastructure—such as access to suitable and reliable transportation—making laboratories more expensive to run or difficult to access;
- A lack of the environmental conditions necessary to produce accurate and consistent results, often due to unstable power;
- Limited or no access to grade A reagents, certified reference materials and affordable proficiency testing services;
- A lack of access to suitable and affordable equipment calibration services;
- A lack of in-country after sales support for maintenance/servicing of laboratory equipment;
- Customs-related challenges in moving artefacts, proficiencytesting samples, reference materials across borders. This can result in such articles being held by customs officials until they expire; and
- Markets that do not demand an appropriate level of quality and safety, and thus lack the incentive to produce high-quality and safe products.

4.2 BENEFITS OF DEVELOPING A LP

Some of the many benefits of developing and implementing an LP can be similarly categorised to the grouping of challenges identified in Figure 4. Applying these same three groupings allows the identification of specific benefits, including:

- Better physical and human resources, improving the technical operation of a laboratory;
- Improved interaction of laboratories within the marketplace, so they can determine and appropriately respond to actual demand; and
- A more coherent and predictable environment for laboratories and other actors in the LI, as a result of national interventions.

Figure 4 below illustrates the three levels of challenges and the benefits of implementing an LP

Level	Challenges related to:	Benefits of implementing a Laboratory Policy:
TECHNICAL/ LABORATORY	Physical infrastructure & equipment	Capacity & capability addressed
	Human capital	Availability & capability addressed
	Demonstrating technical capabilities	Demonstrable & independently verified
MARKETPLACE/ CUSTOMER	Incentives & info to develop market for laboratory services	Incentives provided & info available
	Coverage of laboratory services	Fit-for-purpose & sustainable coverage
	Level of networking	Appropriate & ongoing level
REGULATORY & INSTITUTIONAL	Regulatory framework applicable to laboratories	Regulatory framework encourages use of public & private sector laboratories under fair competition
	Articulation of issues with regulators	Developed communication channels between regulators & Laboratory Infrastructure actors
	Technical regulations	Testing & measurement requirements in regulations appropriate & coherent

4.3 DEVELOPING A SUSTAINABLE LI

A Laboratory Infrastructure development and maintenance system can be considered at three levels:

1. **Macro-level (policy level):** Principles that guide the formulation of an LP, including good governance;
2. **Meso-level (institutional level):** Enhancing trust in test and measurement data from laboratories, including the use of accreditation; and
3. **Micro-level (operational level):** Best practices and minimum requirements to enable effective laboratory design and the achievement of valid test and measurement results.

4.3.1 MACRO-LEVEL

The development of laboratory capacity is often driven by a number of factors. These can include the needs of government, multinationals, and the public and private sectors. In many cases, the mobilization of funding from a variety of sources and making such funding available through processes that are as simple and efficient as possible are also key factors. Under these circumstances, the development of laboratory capacity does not always appropriately consider factors such as the availability and use of existing national laboratory facilities, and laboratory capacity situated in another institution or neighbouring country elsewhere. The overall demand regarding national and sectoral priorities is also an important consideration that is often neglected. The lack of suitable information on the supply and demand for existing laboratory capacity and services, and whether there are limitations caused by geographical concentrations of supply, only increase the difficulties in seeking appropriate solutions. In such cases the result is often unnecessary duplication, fragmentation or inter-agency competition. Other unintended results are that scarce scientific and technical resources, including experienced and capable laboratory personnel, are inefficiently allocated, and sub-optimal laboratory capacities and capabilities.

4.3.2 MESO-LEVEL

Many countries lack an LP that can guide them in developing sustainable testing and calibration capacity and capabilities. The absence of the strategic vision and direction provided by an LP is normally evidenced by the emergence of laboratory capability that is narrowly focused on meeting immediate needs. Such interventions are often overly dependent on donor assistance, and largely focused on expanding public-funded laboratories. Once the external funding ends, these interventions are frequently unsustainable.

A needs analysis of laboratory services—taking into account the context of the current stage of development, and the country's aspirations, strategies and goals for the future—will greatly assist both public and private laboratories in making better-informed investment decisions. There may be a need to develop a special kind of laboratory that requires high-levels of both initial and ongoing investment and specific expertise. In such cases, governments may need to either invest in providing such capability, or incentivise the private sector to do so.

Each economy should determine its own priorities related to LI development and ongoing associated needs. It is important to encourage appropriate relationships between public and private laboratories. Strategic redundancy in available laboratory capacity can be used in mitigating risks and reduce downtime. It is usual that some laboratory capability resides within the public sector, e.g. the NMI, forensic and certain reference laboratories. When the private sector is involved in the protection of national interests, the necessary checks and balances to ensure competence, impartiality and confidentiality must be in place. It is important to clarify in the LP under which circumstances such functions may be delegated and under what conditions (e.g. funding or cost recovery mechanisms, level of expected service related to response times, relationship with other conformity assessment services).

As part of the enabling environment created for all laboratories under the auspices of the LP it is important to address issues related to: a) the development and implementation of unambiguous procedures for the import and/or export of samples, reference materials, laboratory reagents and other such substances; b) facilitating the import of laboratory technology and equipment; c) representation of national views and opinions in the relevant international QI fora in an effective way (e.g. local mirror committees); d) the provision of financial assistance or grants in order to further develop national interest laboratory capacity; e) coordinate training and development for laboratory personnel, particularly international training and study tours; f) where demand dictates, encourage the local/regional production of reference materials; and (g) facilitate the provision and development of the necessary proficiency testing.

Many countries do not have a national accreditation body (AB). Laboratories in these countries usually need to address their accreditation needs through procuring the services of an AB situated elsewhere. In many cases, the internationally recognised AB services required to meet the immediate need can only be sourced from more developed countries. This has the disadvantage of requiring foreign currency to pay for these services. This can make it an expensive exercise when compared to solving the issue at hand. This is especially the case for smaller laboratories with a relatively low customer base.

The challenges of coherence and cost-effectiveness in developing laboratory capacity have also been recognised by the World Health Organization (WHO), through their work addressing health-related testing capability. In the preface to the WHO's 2011 *Development of National Health Laboratory Policy and Plan*, they note:

"Establishing a national LP and national laboratory strategic plan provides the framework for the coordinated development and delivery of quality and accessible national laboratory services… It [policies and plans based on its guidance] should systematically outline the major issues that need to be addressed, including organizational and management structure, human resources, laboratory infrastructure, care and maintenance of equipment, provision of laboratory supplies, a functional information management system, a quality management system and adequate financial support."[18]

While solely focused on medical laboratories, the WHO's guide provides valuable guidance that could be considered when developing a broader LP to address both national needs, and those of a Regional Economic Community (REC).

4.3.3 MICRO-LEVEL

Experience in assessing the needs of laboratories and providing appropriate technical assistance has helped identify a range of challenges at the micro-level. These challenges can be grouped into three distinct areas: the quality and amount of available human capital; the state of physical infrastructure and equipment; and finally, the demonstration of technical competence. These challenges dramatically reduce the ability of laboratories to coherently provide the type, range and number of tests and calibrations usually required to meet strategic objectives.

Some of the challenges identified in developing and strengthening laboratories include:

- Overlooking the need for insightful leadership that can ensure laboratory development, maintenance and strengthening is pro-actively guided by appropriate longer-term strategic intent. This also requires an understanding of the need to attract, retain and encourage the professional development of the type of staff necessary to ensure the laboratory produces valid results;
- Lacking a well-defined laboratory scope of activities, based on actual market needs;
- Failing to adopt a more business-like approach in servicing their customer needs;
- Failing to identify and effectively manage risks:
- Failure to appropriately address issues related to independence and probity, key characteristics of laboratory personnel. Each person and every institution should understand their role and serve without fear or favour;
- Failing to engage in appropriate marketing activities to promote their service offerings and technical abilities to current and potential future customers;
- Lacking appropriate and sustainable financial resources to cover the many operational needs, such as available supplies of laboratory consumables that are not usually addressed by donors;
- Lacking the equipment necessary to meet the identified needs, or equipment that is not functioning correctly as a consequence of problems with securing appropriate maintenance support;
- Failing to perform regular, technical results-focused internal audits by peer experts;
- Failing to effectively address customer complaints and non-conforming work;
- Failing to analyse data collected from monitoring processes for subsequent use in improving the laboratory's performance and capabilities;
- Lacking suitable safety methods and associated infrastructure including maintenance processes to manage hazardous materials such as chemicals, biological materials, and inflammable equipment;
- Lacking appropriate hazardous waste management systems;
- Having only limited quality control procedures;
- Having no—or only some—validated and / or verified test methods;
- Not using standard methods where these are available;
- Failing to perform routine/scheduled maintenance and calibration when required; and
- Failing to perform necessary verification checks.

4.4 LABORATORY ASSOCIATIONS

Establishing a national laboratory association representative of all laboratories in a country can help address many of these issues. Such an association can have numerous advantages, including providing a unified voice to government, industry and commerce, standards developers, accreditation bodies, and other national and international QI-related organizations. Laboratory associations can

[18]Development of National Health Laboratory Policy and Plan, WHO, 2011. Pg. viii

also assist in the organization of inter-laboratory comparisons and promote the exchange of best practice. With appropriate member collaboration, they can also facilitate exchanges of staff to assist smaller laboratories in conducting internal audits, make arrangements for similar laboratory equipment to be scheduled for servicing together to reduce costs associated with using out-of-country service providers, and combine member Reference Material and laboratory consumable needs to allow for bulk purchases and associated savings. Many countries already have laboratory associations, some of which were developed and initially supported by donor-funded projects. Experience has shown that unless government and the private sector assume a key role in maintaining the network, these quickly disappear once the project ends. In other cases, such associations would benefit from further strengthening and providing a clearer understanding of their role.

THE SADC REGIONAL LABORATORY ASSOCIATION (SRLA)[19]

In developing the QI of Southern African Development Community (SADC) Member States, the increasing need for the services of testing and calibration laboratories became clear. A number of SADC Member States formed their own national laboratory associations (NLAs) to mobilise support for their members by providing a platform for sharing experiences in implementation of laboratory management systems that a laboratory association provides. Since then, 13 out of 16 SADC Member States have formally established independent laboratory associations to support their laboratory activities. For Member States, reducing costs associated with trade and ensuring access to foreign markets is a high priority.

To help SADC nations meet the increasing demand for better and safer products, UNIDO collaborated with the SADC Regional Laboratory Association (SRLA). Through its Sustainable Quality Infrastructure for SADC (SQIS) project, funded by the Government of Finland, UNIDO is supporting 12 of the 16 SADC Member States.

The three central pillars of SQIS project activities are:

1. Strengthening the SRLA to provide strategic support to Member State NLAs;
2. Supporting Member State NLAs to offer sustainable services for their members; and
3. Strengthening testing laboratories' capacities.

The SRLA is an important stakeholder in the testing of products, using harmonised conformity assessment procedures compliant with the WTO TBT. With an increasing reliance on accredited testing and calibration, the SRLA is helping meet the higher demands of consumers and external markets and supporting trade. The overall objective of the SRLA is to improve collaboration and boost the technical and managerial skills of laboratory personnel in the region. Ultimately, the SRLA aims to assist member state laboratories in achieving accreditation to international standards, such as IO/IEC 17025.

[19] https://tii.unido.org/sites/default/files/publications/SRLA%20Brochure.pdf

5. GUIDING PRINCIPLES OF LP DEVELOPMENT

There is no ready-made transferable model for an LP to suit the needs of all economies. The model eventually chosen has to be based on the particular needs and future goals of each economy or, where appropriate, of a regional economic grouping. It should also consider the availability and advantages of using new technology including that which is now available through the 4IR. An initial needs analysis should provide the foundation for subsequent work, and as a minimum, cover:

- The current business environment;
- Manufacturing and production capabilities and aspirations;
- Domestic and target market needs—including any regulatory requirements;
- Feedback and expectations of QI users—including customers; and
- Broader citizen and environmental protection needs.

In developing an LP, it is important to gather input from a wide range of relevant stakeholders. It is important that all stakeholders who may subsequently be involved in implementation clearly understand the distinction between interdependence vis-a-vie independence amongst metrology institutions, accreditation bodies, standards bodies and laboratory associations. Such a group of stakeholders should ideally include representatives from:

- Laboratories, including those in academic and research/laboratory associations;
- Other NQI and SPS related institutions;
- Regulatory bodies;
- Business community (e.g. sector associations, importers, exporters);
- Consumer associations;
- Appropriate NGOs; and,
- Academia.

The provision of public sector funded laboratory capacity is usually mainly driven by legislation and regulatory needs. It is, therefore, automatically a government policy and implementation issue. In practice, this often generates unintended gaps as far as the provision of the laboratory services required to address other important and strategic needs. A more coherent and targeted provision of laboratory services that meet a set of specific and prioritised sector-driven needs would be far more cost-effective and efficient. This is particularly important when resources—especially for the ongoing servicing of the needs of regulatory authorities and the marketplace—are constrained, as is often the case.

A Laboratory Policy allows for the future development of the associated Laboratory Infrastructure to ensure it is strategically aligned, fit-for-purpose and sustainable. The Laboratory Policy assists in balancing

laboratory service provision. It addresses the capacity required to ensure health, safety, and protection of the environment together with increased access to international markets. Although a tailor-made approach on a case-by-case basis is necessary, the set of experience-based principles that follow are intended to allow each country to adapt and tailor these as appropriate. Adoption of these generic principles provides a standardized approach that promotes the development of an LP that best aligns with the particular stage in a country's development trajectory. They also encourage appropriate benchmarking with others. This can foster even greater participation and buy-in during the inception and implementation phases.

After an in-depth review of previous interventions related to the development of a Quality Policy (QP) throughout the world, the members of the International Network on Quality Infrastructure (INetQI) identified a set of guiding principles.[20] Given that a Laboratory Policy is a subcomponent of a QP, the Laboratory Policy Guiding Principles are designed to align with QP principles. The Laboratory Policy Guiding Principles below have therefore been adapted and expanded to focus on Laboratory Infrastructure issues specifically. The principles are:

1. **Coherence**: The need for a consistent approach to the development, strengthening and maintenance of a fit-for-purpose LI requires understanding and agreement on shared goals for both current and future LI capabilities;
2. **Integrity**: The way an LP is directed, overseen and implemented—at the national or regional level—is essential. It is crucial to create an environment where a laboratory can operate impartially and build trust and confidence in the results it produces;
3. **Inclusiveness**: All relevant stakeholders need to be involved in the process of drafting and implementing an LP and developing or strengthening the LI;
4. **Optimization**: In developing and implementing an LP, interventions should be focused on specific priorities, including market-driven demands, as identified through a needs analysis. The unnecessary duplication of laboratory resources should be avoided ; and
5. **Sustainability**: The LP should underpin appropriate political and economic objectives and guide the strengthening and further development and maintenance of laboratory capability and capacity. Sustainability also considers the ongoing levels of technical competence needed to continuously achieve the necessary impact.

Each of these principles—described and expanded upon in the following section—must be appropriately addressed during the creation of a national or regional Laboratory Policy.

[20] Quality Policy Guiding Principles, iNetQI / UNIDO, Vienna, Austria 2018

5.1 COHERENCE

In the context of LP, the concept of coherence is about being fit-for-purpose and consistent. This requires a complete approach, where relevant stakeholders have a shared understanding, agree on shared goals, and agree on both present and future capabilities. Taken together, coherence can support the achievement of a Laboratory Policy and wider Laboratory Infrastructure.

Importance of coherence

Coherence is important because, without it, resulting processes can become ineffective and inefficient for users. Governments have an inherent responsibility to promote the economic wellbeing of their citizens, ensure their safety and health, and protect the environment. Unfortunately, remedies that include addressing publicly funded laboratory-related needs have frequently evolved in an ad hoc way, especially where there is an over-reliance on donor support. In some cases, many ministries can be involved, each working to fulfil individual and usually legislated mandates. This can often lead to fragmentation, overlaps and gaps.

Strategies related to establishing, strengthening and maintaining Laboratory Infrastructure should take a high-level and long-term view, in contrast to simply addressing a particular situation or the immediate issue at hand. Laboratory coordination—at the inter-laboratory, the inter-ministerial and the inter-sectoral level—is crucial, especially when resources are scarce and overworked. There is also a need for appropriate coherence with other policies, including relevant regional ones that contain laboratory-related needs as well as a collaborative and cooperative approach to seek innovative solutions to better match the supply and demand for laboratory services.

Benefits of coherence

The benefits of adopting a coherent and cooperative approach to the LP development and implementation process can include:

» Focused and purposeful LP interventions based on the identified needs—minimising the risks of investing in short-term ad-hoc activities and encouraging long-term investment in sustainable laboratory resources;

» Alignment of available and planned laboratory capacity and capability with the applicable requirements of different regulators and addressing the needs of customers and consumers. This makes conformity-related activities easier to navigate, resulting in reduced effort and costs on the part of laboratory users; and

» Encouraging the use of calibration data and test results to address multiple conformity-related needs, so that additional results are only needed to address gaps in data and information. This could encourage laboratory service providers to expand their scope of work into areas of calibration and testing not previously addressed.

5.2 INTEGRITY

In this context, the concept of integrity is about embracing the principles of good governance. The way an LP is directed, overseen and implemented—at the national or regional level—is essential. It is crucial to create an environment where a laboratory can operate impartially and build trust and confidence in the results it produces.

Importance of integrity

Integrity is essential because it means users can have greater confidence and trust in the services you offer. It is also critical for addressing issues around undue influence and corruption. Factors that contribute to achieving and maintaining integrity can include:

» Good governance;

» Trustworthy, transparent and ethically-sound decision-making;

» Sound financial management;

» Integrity of data and IT infrastructure;

» Appropriate allocation of resources;

» Impartial market surveillance;

» Accurate monitoring;

» Building a strong institutional memory; and

» Taking full ownership of processes that include the need for impartiality and protecting the confidentiality[21] of information generated during laboratory activities.

Benefits of integrity

The benefits of integrity for LP development and implementation processes can include:

» Laboratories operating with integrity and impartiality, within relevant international standards of good governance;

» Increased levels of trust among users of laboratory services in local and international markets; and

» Reduced conflicts of interest between organizations and reduced overlaps in the mandates of public laboratories.

21 See ISO 17025: 2017 clauses 4.1 and 4.2 respectively.

5.3 INCLUSIVENESS

The concept of inclusiveness is about involving all relevant stakeholders in the process of drafting and implementing an LP and developing or strengthening the LI.

Importance of inclusiveness

Inclusiveness is important because it helps ensure there is a shared understanding of the content of a policy. It also supports the inclusion of relevant stakeholders [22] in the implementation and subsequent monitoring of the LP. The initial process of developing an LP should identify and engage all relevant stakeholders. [23] These should include:

» Stakeholders directly impacted by the LP—such as the Laboratory Infrastructure and other QI component organizations and their customers; and

» Stakeholders indirectly impacted by the LP—such as NGOs representing particular interests of the wider citizenry.

Relevant stakeholders can be identified through several groups:

» Laboratory Infrastructure or QI organization ownership—public, private, associations and, where appropriate, regional LI representation;

» Customer needs – products or services;

» Gender;

» Customer size—from large conglomerates to MSMEs; and

» Representatives of the wider community—NGOs and educational institutions.

As major users of laboratory services, it is important to involve the private sector in the development and implementation of an LP in a number of ways. First, by encouraging private sector organizations to provide sufficient and appropriate investment in the laboratory capacity needed to meet the needs of an economy. Second, by inviting private sector representatives to actively participate in decision-making on the type, range and amount of Laboratory Infrastructure capability required.

The involvement of civil society organizations should also be actively encouraged. NGOs—who are often a trusted voice in society—can assist in addressing issues such as consumer safety and the proper functioning of market surveillance.

The empowerment of women should also underpin LP development, by encouraging gender mainstreaming and gender parity, including supporting and encouraging laboratories owned and run by women. This is also significant because of the role of women in consumer purchasing decisions in the wider economy. Moreover, the views of women must be considered in the safety and quality of products.

Research and development institutions, innovation hubs and incubators should also be integral to this process. They can help to achieve a sustainable LI, providing insights on using 4IR technologies and innovations and on what future test and measurement requirements might look like.

Adopting such an inclusive approach has numerous benefits. First, it allows for a more holistic perspective of the current Laboratory Infrastructure landscape. Second, it helps foster a common understanding of the challenges and opportunities, as well as greater ownership of subsequent implementation plans and activities across a broader range of stakeholders. Finally, it can harness stakeholder's collective influence in the promotion of the need for laboratory capacity to meet the wider quality, safety and sustainability needs throughout society.

Benefits of inclusiveness

The benefits of inclusiveness in LP development and implementation processes can include:

» New and different perspectives on local and regional testing, measurement and calibration needs;

» Contributions to the resources required to initiate, strengthen and maintain an appropriate LI, to balance public-funding laboratory capacity with what can be provided by the private sector;

» Input on the new technology and innovations, including future testing and measurement needs;

» Input on new technology that can be used in laboratories to achieve greater efficiency, effectiveness and sustainability of the LI, such as smart sensors, drones, machine learning and real-time data analysis; and

» Feedback on what is needed to ensure that laboratory-related services offered continue to meet the needs of intended users and consumers.

[22] The OECD Draft Best Practice Principles on Stakeholder Engagement in Regulatory Policy may provide further input for policymakers seeking to engage with stakeholders in the development, implementation and monitoring of Laboratory policy. See: http://www.oecd.org/governance/regulatory-policy/public-consultation-best-practice-principles-on-stakeholder-engagement.htm

[23] Ibid. The OECD understand stakeholder engagement to involve three processes: information / notification; consultation and participation noting that they often complement and overlap each other.

5.4 OPTIMIZATION

The concept of optimization is about the most efficient use of laboratory-related resources. In developing and implementing an LP, interventions should be focused on specific priorities, including market-driven demands, as identified through the needs analysis. The unnecessary duplication of laboratory resources should be avoided.

Importance of optimization

An optimized approach to Laboratory Infrastructure is vital for several reasons. Investments should address strategically determined and demonstrable needs. Synergies need to be identified and used to provide LI support to underpin future economic goals more cost-effectively. Private enterprise-supplied measurement, testing and calibration services should be encouraged where they can deliver a more efficient and cost-effective laboratory service.

Optimized laboratory resources can help with cost-effective access to local, neighbouring countries and other international markets with goods and services of the requisite quality. They also help ensure the protection of the health and safety of people and the environment. For these reasons, an LP should seek to identify and promote appropriate linkages wherever possible. It is also important to note that addressing the testing needs of a particular sector requires careful consideration of any inherent technical complexities. These can vary significantly for each sector. For example, different sectors may require different testing capabilities and associated resources, such as different technical staff.

In the past, there have been significant efforts in developing generic and basic measurement and testing capabilities within laboratories. The development of such capability was expected to provide an initial platform to subsequently also address other, more specialised, and ever-expanding measurement, testing and calibration needs. In reality, this has often resulted in capability that is narrowly focused and underutilised. In many cases the result has been significant discrepancies between what is actually required as compared to what can be reliably delivered.

In developing the LP, priority sectors and particular market-driven needs must be clearly identified and codified. The availability of such information dramatically assists in identifying and optimizing the level of national and inter-regional Laboratory Infrastructure that is appropriate at a certain time for each of these sectors and associated value chains. Due consideration of the current levels of operation and acceptance in the marketplace and the intended trajectory for further laboratory capacity and capability development are also important. The priority sectors and market needs should be reviewed periodically as part of subsequent monitoring and evaluation processes. Such processes are also required to ensure continuous improvement and the prevention of over-regulation.

Benefits of optimization

The benefits of optimization in LP development and implementation processes can include:

- The ability to address immediate test and measurement priorities and Laboratory Infrastructure gaps, while creating a suitable foundation for future laboratory capacity and capability activities as a country moves further along its chosen development trajectory;
- Enterprises are better able to access local and foreign markets and minimise or avoid threats to public health, safety and the environment, because of the availability of fit-for-purpose LI;
- Greater use of value chain and life-cycle approaches, which help align laboratory service supply and demand with a set of national priority sectors and associated goods and services;
- Focused efforts on addressing specific laboratory development, strengthening and maintenance needs, including the technical and professional competence and capacity required at a particular time for each of the selected areas in a proactive way;
- Assists in re-focusing laboratory resources towards cost-effectively and efficiently addressing particular requirements—including those of any trading blocs they are members of—to promote greater intra-country trade; and
- Promotes a wider understanding of future laboratory needs and helps in proactively identifying the further strengthening activities required to satisfy new and emerging Laboratory Infrastructure requirements.

5.5 SUSTAINABILITY

The concept of sustainability refers to the capability, adaptability and long-term availability of suitable Laboratory Infrastructure. The LP should underpin appropriate political and economic objectives and guide the strengthening and further development and maintenance of laboratory capability and capacity. Sustainability also considers the ongoing levels of technical competence needed to continuously achieve the necessary impact.

Importance of sustainability

Sustainability is a multifaceted concept. In the context of this guide, the sustainable provision of Laboratory Infrastructure services is needed. It can support the transformation of processes used for manufacturing and service provision to a more sustainable form, as part of achieving the SDGs. It is also essential to consider and promote the use of new technology as a change agent in addressing these needs. Sustainability of the national Laboratory Infrastructure will also ensure the efficient and effective use of laboratory resources in the longer-term. The presence of an efficient, effective and sustainable Laboratory Infrastructure can contribute to:

» People's health and safety;

» Equitable trade and increased prosperity; and

» The protection of our natural resources, environment and planet.

The SDGs call for a profound transformation of existing production and consumption patterns. The goal is to achieve a better quality of life, which includes the availability of quality goods and services, but in a vastly different form to those available today. This requires a substantial reduction in the ecological footprint of economic activities. An associated and emerging global trend is the movement towards the 'circular economy'. This will undoubtedly impact laboratory functions and activities too. The LP should guide and support the attainment of these transformations in production and consumption.

New technologies are sometimes, albeit sporadically, piloted in developing countries through donor-funded assistance projects. Lack of subsequent traction is often attributed to lack of post-project support, including ongoing funding. The relatively low absorption capacity of national institutions and their staff due to them having multiple responsibilities can also be an issue. The LP must enable the government to clearly articulate its commitment to creating and maintaining an environment that encourages innovative solutions in addressing LI-related needs. This includes the need to provide the necessary assurance and associated stability to establish and maintain international trust in the laboratory activities they are expected to deliver under national and REC mandates.

Another critical issue is that women are commonly underrepresented in the science, technology, engineering and mathematics (STEM) subjects. Under-representation in these fields often leads to women's views and needs not being adequately reflected. To develop a gender-responsive LP, female subject experts should be consulted and invited to participate in the LP development process. To do so, gender roles and assumptions and stereotypes about women's capabilities and capacities may need addressing.

The LP should address four types of sustainability relevant to the LI:

» **Future needs of people, prosperity and planet:** All services should ensure human health, promote economic activity and preserve the environment.

» **Financial sustainability:** An appropriate level of income should be generated, where possible. This will help ensure the continuous provision of laboratory service offerings. Complementary to this, the government should retain the responsibility for funding those essential laboratory services that address wider public interest issues. It should also support appropriate international liaison activities and the costs associated with obtaining and maintaining international recognition for the laboratories under their responsibility.

» **Professional and technical competency:** Ongoing capacity for competent professional and technical staff should be developed to meet the identified needs in support of suitable key technical staff succession and retention plans.

» **Adaptability:** Services can address future issues by developing the capacity to adapt, such as proactively embracing innovation and digitalisation.

Benefits of sustainability

The benefits of a sustainable LP can include:

» Ensuring the long-term health and wellbeing of people and the planet;

» Making sure the laboratory-related needs of producers are appropriately met;

» Enhancing economic competitiveness;

» Developing safe and reliable physical infrastructure;

» Providing a responsible approach to the environmental impact of the LI;

» Ensuring the Laboratory Infrastructure can respond in a timely and innovative manner to the implications arising from the 4IR; and

» Allowing better coordination and focus of efforts to address challenges due to unforeseen circumstances, such as global pandemics.

6. VISION AND OBJECTIVES OF AN LP

6.1 VISION

Articulating a vision for an LP can help guide national or REC laboratory development activities. Several factors need to be considered in this:

- The need to consider all users, avoid conflicts of interest and enhance trust in results;
- The economic feasibility at both macro- and micro-levels;
- The need to acknowledge that there are different types of laboratories often with distinct mandates, roles and responsibilities.

What is eventually included in an LP is ultimately the decision of a country or REC. A possible vision for guiding national or REC laboratory development activities is:

"The development of a fit-for-purpose and sustainable laboratory infrastructure that provides timely and cost-effective services in supporting sustainable economic growth, global competitiveness, environmental resilience, the wellbeing of citizens and other sustainable development priorities."

This vision embeds the following key elements:

- **Fit-for-purpose:** Establishes the government's commitment to building an appropriate laboratory-related culture that supports all aspects of national life.
- **Enhancing LI:** Demonstrates the intention to enhance the required test and measurement capability and capacity of a country. It also shows the ambition to establish a Laboratory Infrastructure where both public and private sectors can provide timely and cost-effective calibration and testing services for the benefit of their society.

6.2 OBJECTIVES

6.2.1 LABORATORIES (INFRASTRUCTURE AND SERVICE)

Appropriate and sufficient calibration and testing capability are needed to ensure products and services can demonstrably meet required specifications. Such services—especially to MSMEs—require the government to establish, maintain and improve the laboratory services within the public-funded domain. It is important to note that, as an economy evolves, constituent Laboratory Infrastructure institutions and their laboratories may not necessarily adjust to new challenges and opportunities at the same pace. Enhancing such capacity should also not diminish the funding made available for equipment maintenance and other ongoing operational expenses.

The evolution of the Laboratory Infrastructure requires constant adjustment and adaptation. The government should create an environment that facilitates the development of private sector laboratories. They should also ensure services that the private sector laboratories can offer are appropriately used in public procurement and technical regulation activities. This presupposes that they can independently demonstrate their technical capability. In their use of accreditation against a suitable scope of testing activity, or in the case of a calibration laboratory, the requisite Calibration and Measurement Capability (CMC) should be encouraged and accepted.

Regarding state purchases, the government should demand independent proof of conformity of delivered products and services with relevant standards, including the appropriate use of laboratory data and reports. Establishing an incentive—such as preferential treatment for enterprises that distinguish themselves in the process of helping laboratories to improve—should be part of the adopted approach.

Policy-related objectives:

» Provide a clear definition of roles andresponsibilities for laboratory services in the country;

» Prevent inefficient use of public funds;

» Promote appropriate coordination and cooperation amongst laboratories;

» Prevent replication of public laboratory facilities and encourage appropriate centralization of laboratory services for addressing regulatory requirements;

» Promote private sector involvement in the provision of testing and calibration services;

» Prevent competition of public labs with private sector labs;

» Promote or facilitate the establishment of public-private partnerships (PPPs) for the provision of test and measurement capabilities required for regulatory functions;

» Stimulate the demand for the provision of private sector calibration and testing services;

» Streamline the requirements for establishing private sector laboratories, through initiatives such as fiscal incentives, tax reductions on revenue and exemptions of import duties and expedited customs clearance for laboratory equipment;

» Facilitate access to proficiency testing/ interlaboratory comparison schemes;

» Facilitate access to equipment supplies/service/ maintenance and calibration;

» Facilitate the import and export of Certified Reference Materials (CRMs) and the chemicals used for quality control purposes within a laboratory;

» Facilitate and expedite import of perishable materials (particularly important for proficiency testing samples);

» Promote more effective and flexible procurement processes for laboratories noting that many public laboratories in developing countries only procure consumables annually and therefore cannot address subsequent changing needs;

» Promote a culture of quality among private sector laboratories;

» Promote the use of new technology such as IT-infrastructure, machine learning, smart sensors, remote assessments of products and services;

» Support and facilitate capacity building in laboratory management and scientific and technical best practices through the use of training grants and technical assistance for private laboratories, with a gender-inclusive approach; and

» Encourage the establishment of national and regional networks of cooperation for developing knowledge and innovation hubs and laboratory clusters.

6.2.2 LABORATORIES (HAZARD AND RISK ASSESSMENT/MANAGEMENT)

Many laboratory operations include significant hazards, regardless of whether they undertake testing, pathology, calibration or research. It is often assumed that the laboratory staff are not only aware of these hazards and associated risks, but also know how to mitigate them effectively. Often it is left to the individual laboratory staff member to control these risks as part of their testing work. It is therefore often important to ask a series of questions of staff, including:

» Do they have the necessary expertise and knowledge to identify hazards associated with their day-to-day responsibilities?

» Do they know the best way to control the risks?; and, if so

» Does the pressure to complete their work distract them from paying due attention to safety?

In a laboratory, there are a number of risks to safe operation that need to be appropriately addressed as part of developing and implementing an LP. These include:

» Use of controls such as safety cabinets, filters, and ventilation to maintain a safe working environment in a laboratory;

» Use of gas cylinders, their safe placement in the laboratory and periodic inspection;

» Electrical hazards and associated risks, especially where high voltages are used;

» Environmental hazards due to the use of central air conditioning systems in microbiology laboratories and the periodic inspection of air conditioner filters;

» Fire hazards and associated risks;

» Special training of laboratory personnel in the care and use of personal protective equipment (PPE) during the handling and use of chemicals and microorganisms; and

» Wastage and disposal of chemicals and other hazardous material.

Policy-related objectives:

» Ensure legislation addresses the use, handling and disposal of laboratory chemicals and other hazardous material;

» Establish periodic risk assessments as an integral component of a laboratory's safety and other review procedures; and

» Establish training programmes for laboratories—in both the public and private sectors—that addresses the need for and implementation of safety audits, risk assessment and risk management techniques.

6.2.3 REGULATORY ACTIVITIES

Laboratory tests and other services are often required to prove to regulatory authorities that products and services meet regulatory requirements. Both public and private laboratories can provide these if they are accredited or peer-assessed to an equivalent standard for the required tests as a measure of their competency, and if the regulatory authority subsequently designates them to perform specific tasks.

Policy-related objectives:

» Establish a formal mechanism for inter-ministerial coordination on testing needs and market surveillance requirements, ensuring a gender-inclusive approach;

» Review and update the testing mandate for each ministry to avoid duplication by ensuring that roles are defined and prioritised;

» Avoid potential conflicts of interest and promote trust and transparency by ensuring appropriate separation between laboratories responsible for regulatory functions and those with other responsibilities;

» Promote the establishment and use of public and private laboratories, for the acceptance of test results, especially between countries;

» Ensure the quality of testing of public laboratories by establishing the minimum standards requirements for priority area and scopes, such as accreditation and Good Laboratory Practice (GLP);

» Ensure participation of competent private laboratories in regulatory conformity assessment activities in a fair, impartial and competitive way—ensuring a gender-inclusive approach.

6.2.4 INTERNATIONAL STANDARDS AND REQUIREMENTS

Adopting international standards—based on a country's strategic priorities and demonstrated needs—is encouraged. The local laboratory capacity and capability needed to ensure conformity with such requirements is integral to this. Technical specialists—with insights into the laboratory and other conformity assessment specific issues for a particular area of standardization—should be intimately involved in the process. The risks of not considering local capacity and capability are clear. An international standard, developed and agreed elsewhere, may not be effectively realised or have the intended impact because the requisite testing capabilities are unavailable locally.

Policy-related objectives:

» Ensure relevant institutions for coordinating the development, dissemination and promotion of standardization activities are in place;

» Promote access to, and adoption/adaption of, international standards;

» Mainstream a gender-inclusive approach to standardization and regulations;

» Ensure provision and access to relevant national and international standards;

» Promote harmonization, facilitate international recognition and avoid duplication of efforts, while ensuring relevant international standards prevail wherever available;

» Encourage national institutions to participate in the development of international standards, as well as developing national standards where necessary; and

» Build and maintain capacity and capability among internal and external stakeholders to ensure conformity with relevant standards.

6.2.5 METROLOGY AND CALIBRATION

Establishing a trusted metrological capability is a crucial building block of the Laboratory Infrastructure system. It is common for a government to identify and designate an organization to be the National Metrology Institute (NMI). The next key steps are to:

» Legally appoint the NMI as the national reference laboratory for traceable measurement within the country; and

» Link the NMI internationally with the Calibration and Measurement Capability (CMC) mutual recognition system (CIPM MRA) administrated by the Bureau Internationale de Poids et Mésures (BIPM).

The designated NMI is then responsible for several further steps to:

» Realise international metrology definitions at the national level, by establishing national measurement standards, the best measurement capability of which is recognised by the international metrology infrastructure; and

» Establish, maintain and continuously improve a national calibration service. The service is tasked with disseminating traceability from the national measurement standards to authorities and society, so all measurements emanating from the country are internationally acceptable.

Many regulations relating to trade, health, safety, and environmental protection set measurement-based requirements as well as requirements for the measuring instruments used for such purposes. "Legal metrology" is the term used to comprise all the activities for which legal requirements are prescribed on measurement. It thus includes prescribed units of measurement, requirements on the use of measuring instruments or systems and methods of measurement, and activities performed by or on behalf of governmental authorities, in order to ensure an appropriate level of confidence in measurement results in the national regulatory environment. This aspect of legal metrology applies not only to trading parties, but also to the protection of individuals and society as a whole (e.g. law enforcement, health and safety measurements). Public authorities need to rely on measurement results, especially when there are conflicting interests in measurement results, thus necessitating the intervention of an impartial referee. Typical activities in this field include:

» Type approval of measuring instruments used in regulated fields, such as scales, fuel pumps, utility meters, speed guns, exhaust gas analysers, certain medical instruments, etc.;

» Initial and ongoing verification and inspection;

» Control of the quantity in pre-packaged goods; and

» Application of sanctions in cases of non-compliance with legislation.

The responsibilities associated with administering legal metrology regulations, as well as type approval, verification and inspection procedures, are normally undertaken by a designated organisation within an economy. It is important that such activities are based on internationally agreed models, such as the International Recommendations published by the International Organization of Legal Metrology (OIML).

Type approval activities can also make use of the OIML Certification System (OIML-CS) to ensure alignment with international best practice and make the best use of resources and expertise nationally or regionally available.[20] This system can help domestic measuring instrument manufacturers gain better access to international markets, as well as ensuring imported measuring instruments used in the national legal metrology system meet international standards.

The appointed NMI or other public and private calibration laboratories can also provide industrial calibration services to end-users in industry and commerce, as long as their calibration equipment is traceably calibrated to the national measurement standards kept by the NMI, or those of another country's NMI with known and recognised measurement capability. Such calibration laboratories should be accredited for the relevant scopes of calibration, and their accreditation body should be covered by the ILAC MRA or by Regional Arrangements recognised by ILAC.

[24] For further information see the OIML / UNIDO publication: Certification of Measuring Instruments.

Policy-related objectives:

» Provide and ensure access to relevant services from an NMI or other designated entity to public and private laboratories;

» Retain government responsibility for providing services the private sector does not or will not cover, thus preventing the government duplicating existing services;

» Ensure a government-established legislative framework for the NMI and legal metrology; and

» Accredit calibration laboratories providing traceability directly to industry and commerce for the relevant scopes of calibration they provide.

6.2.6 ACCREDITATION

Accreditation is another fundamental building block for the independent demonstration of the competence of a laboratory and certified reference material and proficiency testing service providers. The government should establish a National Accreditation Focal Point within the appropriate ministry where there is no national accreditation body. This focal point can facilitate the accreditation of calibration, testing and medical laboratories, certified reference material and proficiency testing providers through the ILAC MRA member accreditation bodies. The government should also remain sensitive to the principle of inclusiveness, so they have a comprehensive picture of the situation for consumers and on the market. The government should also support Regional Economic Community activity that seeks to address the national needs for internationally recognised accreditation through the regional structures of ILAC.

Policy-related objectives:

» Provide an independent and trusted mechanism for laboratories to demonstrate their competence; and

» Facilitate trade and investment through international recognition of laboratory capability against a defined scope of activity.

7. DEVELOPING AND IMPLEMENTING AN LP

7.1 DEVELOPING A STRUCTURED APPROACH TO AN LP

The LP provides the necessary guidance for obtaining and maintaining international recognition for the identified capabilities and capacity needs of the laboratories forming part of the LI. A structured and systematic approach to the strengthening and development of the Laboratory Infrastructure allows for more optimal development. When drafting an LP, all the factors that may influence the policy's successful implementation should also be considered. It is therefore advisable to develop simultaneously an LP implementation plan that takes into consideration the financial viability of the LP, its priorities and resource implications. It should also address the need for sustainable maintenance. Implementing an LP requires time and concerted effort by a group of committed and dedicated individuals. These efforts enable a more proactive, and cost-effective approach to the development of appropriate, efficient and cost-effective LI.

Table 2 outlines the process for the development of an LP. It is adapted from a similar process used in the development of a Quality Policy, given the interdependent relationship between these two policies.[24]

[24] See Quality Policy, A Practical Tool. UNIDO, Vienna, Austria, 2018.

TABLE 2:

KEY STAGES	DETAILED STEPS	OBJECTIVE	GUIDING PRINCIPLES
1. Do the groundwork		*Ensure ownership and coordination within government and with the private sector.*	
	1.1 Establish clear leadership and buy-in	Ensure leadership and commitment from the highest level and overcome potential resistance from other key players.	» Coherence » Integrity » Inclusiveness
	1.2 Form a Steering Committee (SC) and the Working Group (WG)	Establish responsibilities for coordination and ensure strategic and operational oversight to meet timelines. Be clear about how the SC will oversee and assist the WG. Focus in particular on the principle of inclusiveness when choosing the members for SC and WG.	» Coherence » Integrity » Inclusiveness » Sustainability

KEY STAGES	DETAILED STEPS	OBJECTIVE	GUIDING PRINCIPLES
2. Strategic Planning		*Determine needs, define priorities and allocate resources*	
	2.1 Analyse the national context and identify laboratory-related issues	Ensure that the LP will sustainably address the strategic needs.	» Inclusiveness » Optimization » Sustainability
	2.2 Identify key stakeholders	Decide which stakeholders need to be consulted during the consensus-building process.	» Coherence » Inclusiveness » Sustainability
	2.3 Preliminary stakeholder engagement	Obtain initial inputs to allow for preliminary drafting of the LP.	» Inclusiveness » Optimization » Sustainability
	2.4 Analyse and differentiate options considering existing infrastructure, feasibility and sustainability	Learn from others, benchmark, and decide on the most cost-effective basis for a sustainable LI.	» Coherence » Optimization » Sustainability
3. Prepare the draft LP and build consensus		*Provide for transparency, and consensus-building and assure coherence*	
	3.1 WG technical sub-committees used as needed	Ensure that the LP addresses the laboratory-related needs of key sectors.	» Inclusiveness » Optimization » Sustainability
	3.2 Prepare the first draft of the LP	Provides a starting point for discussion.	» Inclusiveness
	3.3 Wider engagement with stakeholders	Allow for inputs from a larger group of stakeholders.	» Coherence » Inclusiveness » Optimization
	3.4 Incorporate feedback	Improve the draft LP and ensure appropriate incorporation of stakeholder feedback.	» Coherence » Optimization » Sustainability
	3.5 Circulate for public consultation	Ensure wider buy-in for the LP and allow for public comment through covering all key stakeholders throughout the economy.	» Coherence » Inclusiveness » Optimization » Sustainability
	3.6 Incorporate comments and prepare 'final' version of the LP	Further improvement of the draft LP and prepare for final validation and implementation.	» Coherence » Integrity » Inclusiveness » Optimization » Sustainability

KEY STAGES	DETAILED STEPS	OBJECTIVE	GUIDING PRINCIPLES
4. Obtain approval		*Incorporate as part of national policy*	
	4.1 Final review and validation	Ensure that there is no "sustained opposition" that could affect implementation.	» Integrity » Inclusiveness » Sustainability
	4.2 Obtain formal government approval	Have the LP formally adopted by Government.	» Optimization » Sustainability
5. Deploy the LP		Ensure effective and sustainable implementation	
	5.1 Publish the LP	Make the LP available to all citizens.	» Coherence » Integrity » Inclusiveness » Optimization » Sustainability
	5.2 Prepare implementation strategy, communicate and promote the LP	Plan for implementation, ensure effective implementation and promote awareness.	» Coherence » Inclusiveness » Optimization » Sustainability
	5.3 Monitor, review and improve the LP	Adapt to changing circumstances[26] and national priorities.	» Optimization » Sustainability

[26] The OECD notes that consultations done well can be time consuming and resource intensive. They highlight the need, given budgetary constraints, that they be conducted in a manner that elicits the necessary information at least cost.

7.2 LEGAL, GOVERNANCE AND STRUCTURAL ISSUES

The adopted legal and regulatory framework has a defining impact on a country's business environment. It also impacts on the Laboratory Infrastructure, and public laboratories in particular. These are often bound by legislation that prescribes their authority, governance, finances, and scope of operations. As part of facilitating the implementation of the LP, the government should review existing laboratory-related legislative and regulatory frameworks as a priority. It should also ensure it complies with their international and regional trade or other obligations.

The legal framework should promote entrepreneurship, with a particular aim of supporting women entrepreneurs and MSMEs. It should also take the existing infrastructure and its continued effectiveness, efficiency and sustainability into consideration. This is needed to ensure the resulting environment is conducive to delivering the type of laboratory services required to support national and REC development strategies, and the UN Sustainable Development Goals (SDGs). As such, a holistic and integrated approach is needed. This can help ensure no oversights, overlaps, duplication or conflicts of interest among the various laboratories and their parent institutions that constitute the Laboratory Infrastructure of the country concerned.

7.3 KEY STAKEHOLDERS AND THEIR ROLES

7.3.1 GOVERNMENT

The government, through its various institutions, has a vital role in the implementation of the LP; one of enabling, coordinating and educating. The government must outline the vision and objectives of the policy and manage the activities of the parties involved. It must also establish and maintain the public-funded elements of the LI. In doing so, it should act in the best interests of the country and ensure LP-related activities are conducted with transparency, in coordination and cooperation with the various actors.

To create a conducive environment for the establishment of a fit-for-purpose LI, the government should review the current and planned public sector laboratory service offering. The review should identify gaps and assess their ability to confirm domestic and international requirements and obligations by adopting best practices for laboratories.

To minimise market failure, the government should review the legislation that defines the responsibilities of public-funded laboratories. Legislation should encourage fair competition, so consumers have the greatest range of laboratory services at appropriate prices. This includes the need to ensure the private sector also has the opportunity to provide laboratory-related services.

Although the process of developing an LP should be politically neutral, changes in government policies or relevant ministers can still pose a significant risk. As such, it is vital to ensure broad political consensus on the benefits of an LP, from incumbent ministers to members of opposition parties. Other risks that need to be identified and addressed include the involvement of many ministries and inter-agency conflicts between elements of the LI, such as standardization, accreditation and metrology institutions. The government may also play an important role in the establishment of the National Laboratory Association.

7.3.2 PRIVATE SECTOR

The private sector also has a critical role in the development and implementation of the LP. To achieve the maximum benefit from the LP, the private sector—in cooperation with others—should actively seek to:

- Provide laboratories and continue to invest in their ongoing development to benefit from the improved market opportunities that result from the implementation of the LP;
- Participate in financing activities that support and promote the further development and expansion of laboratory capacity and capability;
- Develop human resources for the laboratories they manage, training the people needed for delivering the data and test results required to maintain and improve the quality of their products and services;
- Participate, as laboratory representatives, in the structures and technical committees dealing with metrology, standardization, accreditation or other laboratory-related activities; and
- Identify, as users of laboratory services, what is required to ensure the quality of their goods and services, including where and whether these are currently available.

7.3.3 NGOS AND CIVIL SOCIETY

The active involvement of NGOs and civil society are crucial for the successful implementation of the LP. Organizations or institutions that can play a key role include associations for the promotion of quality and excellence, consumer organizations, chambers of industry, trade and commerce, and the media. The value of NGO and civil society contributions should

never be underestimated. These contributions can include:

» Arranging and participating in awareness campaigns for consumers in general, and women in particular, to ensure consumer rights are properly understood;

» Promoting and participating in laboratory-related education and training activities;

» Helping to disseminate laboratory-related information;

» Implementing activities that promote the improvement of quality and the environment, based on trusted measurements; and

» Contributing to the preparation and improvement of the LP.

7.3.4 INTERNATIONAL QI/LI-RELATED ORGANIZATIONS

Strong international relationships, including those fostered through international QI organizations, can help the laboratory community understand and adapt to global trends. As such, it is crucial to create conditions that promote active and meaningful participation in the work of international organizations related to the various technical functions and activities of laboratories and their service providers. Responding to the challenges of globalization, trade and sustainable development, fourteen international organizations agreed to enhance their cooperation in promoting the understanding, value and acceptance of QI and providing guidance and support for its effective implementation and integration worldwide as part of the International Network on Quality Infrastructure (INetQI).[27] These organizations are the:

» **BIPM** - Bureau International des Poids et Mesures.

» **IAF** - International Accreditation Forum.

» **IEC** - International Electrotechnical Commission.

» **IIOC** - Independent International Organisation for Certification.

» **ILAC** - International Laboratory Accreditation Cooperation.

» **IQNET** - International Certification Network.

» **ISO** - International Standards Organization.

» **ITC** - International Trade Centre.

» **ITU** - International Telecommunication Union.

» **OIML** - International Organization of Legal Metrology.

» **UNECE** - United Nations Economic Cooperation for Europe.

» **UNIDO** - United Nations Industrial Development Organization.

» **WBG** - World Bank Group.

» **WTO** - World Trade Organization.

Many of the INetQI members also actively support activities associated with developing, implementing and sustaining an appropriate LI. As mentioned elsewhere in this document,[28] other international organisations such as the IPPC, OIE and WHO also provide internationally recognised standards and important guidance that inform and direct the activities of laboratories.

7.3.5 INTERNATIONAL DEVELOPMENT PARTNERS

Many international development and donor agencies are active in building or strengthening laboratory capacity in developing countries. All partner or recipient organizations of these international development agencies should seek to ensure that laboratory development and capacity building programmes:

» Support the development and implementation of the LP;

» Coordinate support of these partners in the execution of priority laboratory-related programmes;

» Support the transfer of relevant calibration and testing technology to the country;

» Support the transfer of knowledge, skills and information which allows for the development of adequate LI, with a particular focus on gender inclusion; and

» Provide the training and development opportunities laboratory scientists and technicians need to successfully implement the LP, with a focus on the participation of women.

7.4 FINANCING

The effective implementation of the LP requires the availability of both public and private financial resources. Financing the development, upgrade and restructuring of existing public sector laboratories is

[27] See https://www.inetqi.net

[28] See paragraphs 2,2,2, regarding IPPC and OIE and 4.3.2 regarding WHO.

normally the responsibility of government. In particular, the government should retain full responsibility for funding the following:

» The establishment and maintenance of national primary measurement standards which are a public good;

» Those legal metrology services that cannot be funded through the fees and levies paid by the users of measuring equipment falling within the scope of legal metrology legislation;

» The establishment and maintenance of lower level calibration and testing capacity in support of the LP, with the proviso that these services should be commercialised as soon as it is financially viable to do so, so as not to compete with the private sector on an unequal basis. Strategically important testing capacity that could never be successfully commercialised should continue to receive the appropriate operational funding until it is no longer a strategic necessity; and

» The establishment of proper market surveillance operations to ensure compliance with technical regulations. The funding for the testing of products falling within the scope of technical regulations should remain the responsibility of the suppliers of regulated goods and services.

While the government is responsible for creating a facilitating business environment—one that encourages appropriate private investment within the LI—the financing of private sector laboratories remains the responsibility of the private sector. The private sector should also be encouraged to be actively involved in technical committees and other laboratory-related meetings at the national, Regional Economic Community and international levels.

Some laboratory services are relatively simple to run, with costs easy to cover. The private sector should have no difficulty investing and providing such services. However, some laboratory services need more complex infrastructure, making them more expensive to deliver. The public sector may have no alternative but to continue to fund and provide these services in such cases, especially where they support national priorities. Yet, even in such a scenario, laboratories still need to employ best management practices and ensure continued value for money. Appropriate business modelling and associated operational practices should, therefore, be encouraged.

Any pressure on publicly funded institutions to provide laboratory services below their true cost risks compromising their long-term financial sustainability. It also negates any advantages they have gained through adopting sustainable laboratory management practices. National priority sectors that need such strategic laboratory test and measurement support should be funded in other, more transparent, ways. MSMEs, for example, could be refunded for some of the costs associated with using laboratory services on presentation of a test report or calibration certificate.

Another challenge public institutions face is when government departments request testing from other public institutions without payment. This can jeopardize the funding that these institutions receive from their line ministry. To prevent this challenge, government departments and their agencies should allocate a suitable budget for the laboratory services they require, and reimburse these institutions accordingly. This is also an important consideration for any future strategies by the government to liberalize laboratory activities and allow private sector organizations to also—or solely—provide these services.

7.5 EDUCATION, TRAINING AND CAREER PATHS

Government, academic institutions and laboratory associations representing all laboratories within an economy (both public and private) or specific sectors (e.g. health, agriculture, manufacturing) should be encouraged to establish appropriate programmes at different educational levels. These should aim to strengthen or develop the specialised knowledge and expertise needed to implement the LP. Such interventions should include specialised adult training programmes. These training interventions should also consider gender inclusiveness with a particular effort to encourage the involvement of women in the LI. Laboratories should also be encouraged to take measures to develop and implement training, development and registration programmes as part of developing career plans for their staff.

7.6 INFORMATION AND KNOWLEDGE SHARING

The development and implementation of a fit-for-purpose information network—involving all the various institutions that operate laboratories—is crucial for the ongoing success of the LP. Laboratories are in a unique position to collect data that could be useful for many applications. In many instances such data is currently used almost exclusively to service the immediate needs of a particular customer. With the necessary encouragement, laboratories, and where appropriate their accreditation bodies, could process data systematically to generate strategic intelligence. Data used in this way could assist in identifying new development trends, and better-informed strategic planning and policymaking.

Establishing innovative tools, such as knowledge hubs, is beneficial for the sharing and retention of specialist

knowledge. The development and maintenance of such a network should appropriately consider data management, confidentiality, impartiality, data reliability, storage, and other such considerations related to the sharing of information.

Such an information network should also include the national TBT Enquiry Point, the appointed SPS Enquiry Point, and the SPS National Notification Authority. If one exists, a National Laboratory Association could play an important role in information and knowledge sharing between its member laboratory constituency. For a truly effective network, as many laboratory-knowledgeable participants from all other relevant stakeholders should be included as possible. It is also vital to increase awareness among consumers and create a culture of quality and sustainability.

A large volume of information on the development of laboratories—Laboratory Infrastructure in particular and Quality Infrastructure, in general—is already available. UNIDO's Digitalization, Technology and Innovation (DTI) Knowledge Hub is an interactive online platform, which serves to create, share and exchange knowledge around trade, investment and innovation. The DTI Knowledge Hub provides the latest news, upcoming events, a range of interactive web tools, knowledge sharing and publications. It also includes a training platform. More information and links for access—about this and other organizations that have developed laboratory-related information—are contained in Annex D.

8. CONCLUSION

The UNIDO approach to LI development is systemic and holistic, from building awareness to helping initiate, develop and strengthen a fit-for-purpose LI that runs efficiently and is cost-effective. This approach emphasizes the need for strong collaboration with all stakeholders and is driven by national and regional priorities including private sector needs. The laboratory-specific information builds on an existing suite of three documents on the QI umbrella that has already been published by UNIDO:

- **Quality Policy – Guiding Principles**
- **Quality Policy – Technical Guide**
- **Quality Policy – A Practical Tool**

Together with partners from the public and private sector, academia, national and international organizations in charge of standards-setting and global practices on metrology, standards and conformity assessment, including laboratories, UNIDO promotes good practices, capacity building and training, and fosters global cooperation in measurement and compliance development along value chains.

The need for a Laboratory Policy that meets the specific situation of each country, taking regional and international economic partners into consideration has been highlighted. The information contained in this guide therefore also outlines the aspects that need to be considered in developing and successfully implementing an LP. It aims to give Laboratory Policy developers the practical knowledge they need for such a task. The guide is also intended to help decision-makers understand the need for an LP and guide them using known practices. It provides suggestions on how to develop a conducive environment for the Laboratory Infrastructure, and one that addresses the different development aims of countries.

Three tiers of activity are covered. Issues in each need addressing to develop and implement a Laboratory Policy successfully, namely at the:

- Macro-level (policy level): the guide identifies the guiding principles for the formulation of an LP;
- 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;
- 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.

The development and implementation of an LP presents a unique opportunity to build the LI required to assist economies in achieving the intentions and benefits associated with the 2030 Agenda for Sustainable Development and associated SDGs. Ultimately, the success of an LP and Laboratory Infrastructure will depend on the strength of the dialogue and cooperation between everyone concerned, including policymakers, stakeholders and organizations within the Laboratory Infrastructure. The information provided in this guide should assist them in developing a pragmatic and implementable LP that achieves its intended outcomes in the short term, while also ensuring longer-term sustainability.

ANNEXES

ANNEX A: GLOSSARY

There are many expressions used within the quality, technical regulation and laboratory domain with very specific meanings. These terms are defined below to prevent possible misunderstandings of the contents during the development and subsequent implementation of an LP. The terms and definitions that follow are based on current best practice and understanding.

TERM	DEFINITION	SOURCE
Accreditation	Third-party attestation related to a conformity assessment body, conveying formal demonstration of its competence, impartiality and consistent operation in performing specific conformity assessment activities.	ISO/IEC 17000:2020, 7.7
Calibration	Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.	International vocabulary of metrology – Basic and general concepts and associated terms (VIM), JCGM 200:2012, 2.39
Certified Reference Material	Reference material characterised by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.	ISO Guide 30:2015, Reference materials – Selected terms and definitions
Codex Alimentarius	The CODEX Alimentarius is a joint FAO/WHO Programme setting international food standards, guidelines and codes of practice for the safety, quality and fairness of international food trade.	OECD - The Contribution of International Organisations to a Rule-Based International System
Conformity Assessment	Evidence that specified requirements are fulfilled.	ISO/IEC 17000:2020, 4.1
Good Laboratory Practice	Good Laboratory Practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. The principles have been created in the context of harmonising testing procedures for the Mutual Acceptance of Data (MAD).	OECD Principles on Good Laboratory Practice (as revised in 1997), 2.1.1
Inspection	Examination of an object of conformity assessment and determination of its conformity with detailed requirements or, on the basis of professional judgement, with general requirements.	ISO/IEC 17000: 2020, 4.3

Laboratory Infrastructure	See Annex B.	
Proficiency Testing	The evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.	ISO/IEC 17043:2010,3.7
Quality Infrastructure	See Annex B.	
Quality Policy	See Annex B.	
Reference Material	Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.	ISO Guide 30:2015, Reference materials — Selected terms and definitions
Stakeholder	Person or organization that can affect, be affected by, or perceive itself to be affected by the quality policy. Also referred to as an interested party.	
Standard	A document—established by consensus and approved by a recognised body—that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. Note: According to ISO/IEC Guide 2: 2004, a standard may be Mandatory. Under the WTO TBT Agreement, a standard is a voluntary document, while a document of mandatory compliance is a technical regulation.	ISO/IEC Guide 2: 2004, 3.2
Laboratory Infrastructure	See Annex B.	
Laboratory Policy	See Annex B.	
Measurement standard	Realization of the definition of a given quantity, with stated quantity value and associated measurement uncertainty, used as a reference.	International vocabulary of metrology – Basic and general concepts and associated terms (VIM), 3rd Edition, JCGM 200:2012, 5.1
Technical Regulation	The document that lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory, and which can also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.	
Testing	Determination of one or more characteristics of an object of conformity assessment, according to a procedure.	ISO/IEC 17000:2020, 6.2

ANNEX B:
EXPANDED DEFINITIONS OF KEY TERMINOLOGY

Quality Policy (QP): A QP is a basic government instrument. It is the approach adopted—usually at the national or REC level—to develop and implement an effective QI.[29] It is the glue that links and underpins other national policies in areas such as trade, industry, environment, SMEs, science, research and innovation, and investment. Moreover, it specifies the objectives of the QI, by putting the foundations and appropriate infrastructure needed to assist local enterprise, including MSMEs, to access local, REC and global markets. It should seek to achieve this, while also maintaining human, animal and plant health and safety and ensuring environmental protection. The availability of a QP enables and strengthens a country's ability to comply with REC and international commitments and appropriately align and focus the activities of the associated QI with national priorities and established best practice.

Quality Infrastructure (QI): It is important at the outset to distinguish and understand the difference between 'quality of physical infrastructure' and the national 'quality infrastructure', or QI.

» **Physical infrastructure** – Refers to the fundamental facilities and systems serving a country, city, or other area, including the services and facilities necessary for its economy to function. It is composed of public and private physical improvements such as roads, bridges, tunnels, water supply, sewers, electrical grids, and telecommunications. A well-functioning infrastructure is a cornerstone of a modern society.

» **Quality infrastructure** – QI is the system comprising the organizations—both public and private—together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes.[30] QI is required for the effective operation of domestic markets, and its international recognition is important to enable access to foreign markets. It is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing. It relies on metrology, standardization, accreditation, conformity assessment and market surveillance in regulated areas.

Laboratory Policy (LP): To guide and strengthen the laboratory component in QI conformity assessment, an LP is an approach adopted to coordinate further development towards a more cohesive, aligned and effective LI. The LP ensures that calibration and test data, reports and certificates are produced most effectively and efficiently and meet the prioritised needs of government and local enterprises, including MSMEs, in accessing domestic and international markets while also continuing to ensure human, animal and plant health and safety and the protection of the environment. The availability of an LP also enables and strengthens a nations' ability to appropriately align and focus the activities of the associated Laboratory Infrastructure with established best practices.

Laboratory Infrastructure (LI): Laboratory Infrastructure comprises public and private laboratories together with the scientific principles, practices and supportive laboratory quality control systems—such as Proficiency Testing, Certified and other Reference Materials—that are required to quantify, underpin and enhance quality competitiveness, innovation, productivity, safety, health and environmental soundness of goods, services and processes.

[29] Quality Policy – Guiding Principles. UNIDO/International Network on Quality Infrastructure, Vienna, Austria. 2018.
[30] Definition adopted in June 2017 by INetQI (then DCMAS Network: BIPM, IAF, IEC, ILAC, ISO, ITC, ITU, OIML, UNECE and UNIDO) and the World Bank

ANNEX C:
EXAMPLES OF INTERNATIONAL STANDARDS AND REQUIREMENTS FOR LABORATORIES

1. ISO/IEC 17025

Where the technical competence and quality of testing of calibration laboratories and their measurements are in doubt, it can represent an inherent barrier to free trade. This has been a long-standing issue; concerns in this regard led to the first International Laboratory Accreditation Conference (ILAC) in 1977.[31] ILAC provided inputs on the needs and contents of laboratory standards to the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), given their internationally accepted roles as international standards development organizations. ISO and IEC subsequently developed and published a joint document, designated as ISO/IEC Guide 25, General Requirements for the Competence of Testing Laboratories in 1982.

The latest version of ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories was published in 2017.[32] This latest revision also introduces the concept of risk-based thinking for the management of laboratories, to "enable some reduction in prescriptive requirements and their replacement by performance-based requirements". It also provides management with "greater flexibility… in the requirements for processes, procedures, documented information and organizational responsibilities".[33] The technical criteria remain almost identical to those appearing in previous versions.

Laboratories are encouraged to use ISO/IEC 17025 to implement a quality system aimed at improving their ability to produce valid results consistently. A prerequisite for a laboratory to become accredited is to have a documented quality management system as the basis for accreditation from an internationally recognised accreditation body (AB).

Those involved in developing and implementing a Laboratory Management System (LMS) need to understand the requirements of the standard based on their own laboratory perspective. This is particularly important if the laboratory is small and not part of a larger ISO 9001 certified organization. "The key issue is not the amount or quality of paperwork, but the accuracy, repeatability, traceability, the use of acceptable methods, technical competence, and quality of the data upon which critical decisions are made."[34]

2. ISO 17043

The need for ongoing confidence in laboratory performance is not only essential for laboratories and their customers but also for other interested parties, such as regulators, laboratory accreditation bodies and other organizations that specify requirements for laboratories. There is a growing need for proficiency testing for other conformity assessment activities, such as inspection or product certification. Most of the requirements in this International Standard apply to those evolving areas, especially regarding

management, planning and design, personnel, assuring quality, confidentiality, and other aspects, as appropriate. This International Standard provides a consistent basis for all interested parties to determine the competence of organizations that provide proficiency testing.

3. ISO 15189

The ISO 15189 standard, Medical laboratories – Requirements for quality and competence, was first published in 2003, revised in 2007 and again in 2012. Medical laboratories can use ISO 15189:2012 in developing their quality management systems and assessing their own competence. It can also be used for confirming or recognising the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies. By 2015, about 60 countries had made ISO 15189 part of their mandatory medical laboratory accreditation requirements.[35]

ISO 15189 is divided into management requirements and technical requirements. Part 4 focuses on the quality management system structure, function, and effective management of laboratory operations, its quality system, guiding policies, and processes. Part 5 focuses on technical competency and related procedures and processes. ISO 15189 is intended to

[31] ILAC subsequently changed its name to become the International Laboratory Accreditation Cooperation.
[32] ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, ISO, Geneva.
[33] Ibid
[34] Quotation based on similar comments made by Larry Gradin in General Measurement Device and Calibration Topics, https://elsmar.com.
[35] Schneider, F. et al. Ann Lab Med. 2017 Sep; 37(5): 365–370.

apply to all divisions of a medical laboratory, regardless of the services it provides or the way it is organized. The standard is as relevant in a full-service medical laboratory as it is in a laboratory providing services exclusively for either clinical or anatomic pathology. [36]

4. ISO 15190

This international standard specifies requirements to establish and maintain a safe working environment in a medical laboratory. As with all such safety guidelines, there are requirements to ensure that there is a named person ultimately responsible and that all employees take personal responsibility for their own safety at work and the safety of others who may be affected by it. While this international standard is not intended to provide guidance on accreditation, it may be used for such purposes by a government, professional, or other authoritative body.

5. ISO 15195

This international standard specifies requirements for competence to carry out reference measurement procedures in laboratory medicine, using the requirements of ISO/IEC 17025 as a normative reference and listing additional requirements for calibration laboratories to perform their tasks adequately.

6. The OECD Good Laboratory Practice (OECD GLP)

The OECD Principles of Good Laboratory Practice (GLP) ensure the generation of high-quality and reliable test data related to the safety of industrial chemical substances and preparations. [37] The principles have been created in the context of harmonising testing procedures for the Mutual Acceptance of Data (MAD). The MAD system helps to avoid conflicting or duplicative national requirements, provides a common basis for cooperation among national authorities and avoids creating non-tariff barriers to trade.

OECD countries and full adherents have agreed that a safety test carried out under the OECD Test Guidelines and Principles of Good Laboratory Practice in one OECD country must be accepted by other OECD countries for assessment purposes. This is the concept of “tested once, accepted for assessment everywhere” that recognises that while the receiving government must accept the study, how it interprets study results is its own prerogative. This saves the chemicals industry the expense of duplicate testing for products that are marketed in more than one country.

[36] Ibid
[37] See https://www.oecd.org/chemicalsafety/testing/good-laboratory-practiceglp.htm

ANNEX D:
FURTHER INFORMATION ON LABORATORY AND QUALITY INFRASTRUCTURE

1. UNIDO Digitalization, Technology and Innovation Knowledge Hub

UNIDO has developed a number of complementary tools to help fulfil the demand for quality services in developing countries. These tools help quality infrastructure practitioners and policymakers develop robust, holistic, and demand-driven quality infrastructure systems.

In addition, the Digitalization, Technology and Innovation (DTI) Training Academy provides interactive training on topics in the field of trade, investment and innovation, such as Quality Infrastructure and Trade, Quality Policy, E-commerce, Industry 4.0, and Impact Investment.

Some of the guidance UNIDO has developed includes:

» **Quality Policy Guidance:** Developed together with partners in the International Network on Quality Infrastructure (INetQI), and built on the experience of designing some 26 national and regional policies for developing countries and countries in transition.

» **Building Trust – the Conformity Assessment Toolbox:** Developed jointly with ISO; this comprehensive and user-friendly handbook covers all aspects of conformity assessment and its role in international trade.

» **ISO/IEC 17025:2017 Guidance:** This practical guide helps with the first-time implementation and transition to the new version of the ISO/IEC 17025:2017 for testing and calibration bodies. It enables laboratories to demonstrate they operate competently and generate valid results, helping promote confidence in their work both nationally and around the world.

» **Establishing Accreditation Bodies Guidance:** Developed jointly with the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC), this guide helps with setting up Accreditation Bodies in Developing Countries.

» **ISO 9001 Quality Management Systems Guidance**: UNIDO's Good Practices: Experience in the Market Surveillance of ISO 9001 Quality Management Systems publication presents lessons learned and good practices in applying Market Surveillance methodology to monitor the effectiveness of ISO 9001 certification in manufacturing enterprises and evaluate the performance of respective certification and accreditation bodies

Other interactive tools include:

» **Rejection Analysis Tool:** Border rejections can illustrate some of the compliance challenges of certain products and countries. UNIDO's unique Rejection Analysis Tool provides information on reasons for border rejections in major import markets, including the EU, USA, Australia, Canada and Japan. This allows exporting nations to identify and address compliance bottlenecks of specific product groups.

» **The Laboratory Network (LabNet):** This web-based portal brings together conformity assessment service providers and enterprises looking to prove that their products are fit-for-purpose.

For more information on the training academy, the publications and tools are available on the Digitalization, Technology and Innovation (DTI) Knowledge Hub: **hub.unido.org**

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