UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

GUIDE

LABORATORY POLICY

DRAFT FOR CONSULTATION
JULY 2020

GUIDE

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July 2020

You are invited to submit comments to the consultation paper by **31 August 2020** at the latest. Comments shall be submitted to UNIDO by email to: k.monaco@unido.org

Please note that in order to ensure a fair and transparent consultation process only responses received within the deadline will be taken into account.

Executive Summary

Globalisation has transformed how we trade. While trade in manufactured goods has continued to rise, so has the trade in services, semi-finished parts and raw materials. Although legal and policy frameworks can differ from country to country, important steps like harmonised specifications, clear technical requirements, reliable measurement, trusted testing procedures and accurate data can further unlock the benefits of export-led growth.

Technology is also transforming how we trade. The Fourth Industrial Revolution (4IR) is bringing physical and biological systems into the digital realm. From artificial intelligence to mobile supercomputing, we are in a new digital age. These huge trends have massive implications for how countries plan their future development. They must now consider the latest changes in trade and technology together with existing factors, like demography, domestic needs, export and import facilitation and participation in global value chains.

This new digital age presents particular challenges for developing countries, not least in the field of laboratory policy. For laboratories in developing countries, providing the measurements and testing needed to serve domestic and international markets can be difficult, regardless of whether you are dealing with manufactured goods or agricultural products. Where clients in foreign markets don't accept results from local laboratories, exporters often have to arrange for repeat measurement or testing in every market they serve. Not only is this costly, but it can easily render them uncompetitive. This is why the development and strengthening of laboratory infrastructure can be so important. While systems and processes adopted by other economies may provide some valuable lessons, it is essential that each economy takes ownership and addresses its own measurement and testing needs.

This laboratory policy guide helps countries develop and implement their own laboratory policy (LP), so they can establish a fit-for-purpose, efficient and effective laboratory capability, based on UNIDO's successful track-record of laboratory capacity building. The guide covers three areas that need to be addressed to develop and implement an LP successfully: the macro-level, the meso-level and the micro-level. At the macro-level, the guide identifies the guiding principles for the formulation of an LP. At the meso-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. At the micro-level, the guide identifies and considers common issues that have surfaced during support for the development and strengthening of laboratories in the past.

This guide will help policymakers develop an LP that meets the specific situation of each country, taking its regional and international economic partners into full consideration. 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. Bringing the right people together with the right policy guidance offers an opportunity to transform an Laboratory Infrastructure, giving it the robust technical underpinning needed to capitalise on the benefits and opportunities of globalisation and the 4IR, while realising the United Nations (UN) sustainable development goals (SDGs).

Abbreviations and Acronyms

AB	Accreditation Body
BIPM	Bureau Internationale de Poids et Mésures
CA	Conformity Assessment (i.e. testing, inspection and certification)
CIPM	International Committee for Weights and Measures
CIPM MRA	CIPM Mutual Recognition Arrangement
CMC	Calibration and Measurement Capability
CRM	Certified Refence Material
EAC	East African Community
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
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
NSB	National Standards Body
OECD	Organization for Economic Cooperation and Development
OIML	International Organization of Legal Metrology
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

1. Introduction

1.1 The role of Laboratory Infrastructure

Quality Infrastructure (QI) is the combination of initiatives, institutions, organizations, activities and people that help ensure products and services meet the requirements of customers. Laboratories are a key component of this. They are necessary for proving the compliance of products and services with regulations and market requirements. The data laboratories provide is essential for transparent and trustworthy decision making; it enables decision-making for inspection and certification activities, while ensuring products and services meet the triple bottom line of quality, safety and sustainability.

This demonstrates why developing or strengthening a Laboratory Infrastructure can be so critical. However, there is always a balance to be struck: between the cost of investment and the expected benefits. In many developing countries—where resources are sometimes limited—this can mean hard choices. For example, should you prioritise the quality, safety and sustainability of products and services? Or, should you focus your resources on building physical infrastructure like roads, bridges and hospitals? Yet these choices are not always as binary as they might seem at first. Capital-intensive infrastructure projects can run aground due to quality issues, adding costs or even posing a threat to life.

This shows why a robust needs analysis—one that considers a country's strategic development and policy objectives in parallel with its laboratory capacity requirements—is so important. As a part of this, understanding which laboratory services are available in your country—and their level of accessibility—is essential before taking further investment decisions. It is also important to understand both initial and ongoing cost implications, versus the identified needs and benefits. Taken together, this information allows for a fuller picture when evaluating any further investment in laboratory capability.

Strategies that aspire to meet future market needs must also contend with two further challenges. First, how to adapt to take full advantage of the technology of the Fourth Industrial Revolution (4IR). Second, how to demonstrably meet the Sustainable Development Goals (SDGs) as part of the 2030 Agenda for Sustainable Development to which they have signed up. Indeed, the need for a sustainable Laboratory Infrastructure is implied in the 2030 Agenda:

> *"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".*

It is clear that strategies that consider and leverage the advantages of both the 4IR and the SDGs will ultimately accrue greater benefits.

1.2 Laboratory Infrastructure & the Fourth Industrial Revolution (4IR)

Today, we are at the early stages of the 4IR, which brings physical and biological systems into the digital realm. Technologies driving the 4IR 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).

These technologies are transforming every part of our lives; testing and calibration is no exception. Machine learning, smart sensors, drones and virtual reality have all been deployed with success. They offer developing countries more possibilities as well as greater flexibility, for a Laboratory Infrastructure that is more efficient, effective and sustainable.

1.3 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 Sustainable Development Goals. 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 contributes to three of the SDG pillars: People, Prosperity and Planet.

1.3.1 People

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

- **Food security and sustainable agriculture:** Laboratory Infrastructure 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 food and agricultural products, which are often a key export for many developing countries.
- **Good health and wellbeing:** Quality healthcare is underpinned by the measurements used in the diagnosis of health conditions. Appropriate measurements can ensure therapies are delivered safely and effectively. Guidelines and regulations on their own are meaningless. The measurements to verify compliance need to be accurate, traceable to agreed reference standards, and use competently calibrated instruments.
- **Gender:** As countries expand and strengthen Laboratory Infrastructure, including the use of technical assistance, the inclusion of women should be considered at all levels, serving as best practice for other QI-related projects. Considering gender issues as part of Laboratory Infrastructure can also have far-reaching positive benefits.
- **Reduced inequality:** Increased trade and participation in the global value chains can be an essential contributing factor in reducing disparities between economies. With increased business activity often comes increased opportunities in the workforce. For products and services to be attractive in the global marketplace and contribute to increased economic activity on the local market, they must be of proven quality and produced safely and sustainably. If not, the damage to reputation may not be confined solely to the manufacture or supplier but also the country of origin. The Laboratory Infrastructure provides crucial data to support the determination of the quality, safety and sustainability of products and services.
- **Affordable and clean energy:** The availability of the necessary calibration and testing laboratory capability helps governments and organizations' 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.
- **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 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.

1.3.2 Prosperity

Laboratory Infrastructure also makes significant contributions to the second SDG pillar: 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, 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.

1.3.3 Planet

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

- **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 verification of compliance.
- **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.

An 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;
- Trade competitiveness in global markets;
- Efficient use of natural and human resources;
- Food-safety;
- Health;
- Environmental protection; and the
- Mitigation of, and adaptation to, climate change.

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.

1.4 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 well as cost-effective. As such, it is widely recognised as an essential requirement 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.

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.
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.

1.5 The scope of this guide

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

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

This guide intends to help decision-makers understand the need for an LP and guide them using known practices. It also gives suggestions on how to develop a conducive environment for the Laboratory Infrastructure, and one that addresses the different development aims of 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:

1. **Macro-level (policy level):** Identifying critical principles for the formulation of a fit-for-purpose LP;
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 the development phase of a Laboratory Infrastructure.

2. Background

2.1 Regulations

2.1.1 Intergovernmental level

The World Trade Organization (WTO) deals with the global rules of trade between nations. Its primary function is to ensure that trade flows as smoothly, predictably and freely as possible. Three key WTO agreements emphasise the crucial role technical regulations, standards and conformity assessment procedures—such as testing, inspection and certification—play in preventing unnecessary obstacles to trade:

- **Technical Barriers to Trade Agreement (TBT):** Sets the rules for how technical regulations are prepared, adopted and applied. Besides standards—which are voluntary by definition in the TBT Agreement—standards also play an essential role. The TBT agreement requires WTO members to use relevant international standards, guides or recommendations for their conformity assessment procedures, when negotiating mutual recognition of conformity assessment results. This also applies to conformity assessment bodies (CABs), such as laboratories.
- **Sanitary and Phytosanitary Measures Agreement (SPS):** Encourages governments to establish national SPS measures that are consistent with international standards. The SPS Agreement states that when SPS measures are based on international standards, they do not constitute unnecessary trade obstacles.
- **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 and customs compliance issues.

Organizations within an Laboratory Infrastructure have a key role to play in addressing the requirements of all three agreements. Regulations often specify requirements that can only be proven by the provision of acceptable test results, and thus from an institution acceptable to regulatory authorities. Where laboratory services have been liberalised, a supplier can normally choose from accredited laboratories in the public or private sector. This greater choice means users of laboratory services can decide which they use based on preferred criteria, such as cost or speed of results.

2.1.2 Regional and national level

While safety and sustainability requirements can be set at a national level, there may also be a regional or international dimension; this will depend on a country's trade partners and the trade agreements to which they have signed up. Regulations may also include the conformity assessment process manufacturers or service providers need to use to show compliance with regulations.

At a national level, the goals, institutions, roles and responsibilities for an Laboratory Infrastructure —and QI in general—are defined in legislation. National legal frameworks should seek to develop a robust, competitive and sustainable laboratory services sector. Two factors can support this aim. First, encouraging the private sector to invest in and develop laboratory services. Second, ensuring government laboratories charge fees that cover the costs of their services.

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 the competence of laboratories and their laboratory management system is **ISO/IEC 17025**, published by the **International Organization for Standardization (ISO)** and the **International Electrotechnical Commission (IEC)**.

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; and
- **ISO 15190** – for safety requirements.

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

- **ASTM International** (formerly known as the American Society for Testing and Materials); and the
- **Institute of Electrical and Electronics Engineers Standards Association (IEEE SA).**

There are many other industry or sector-specific standards organizations. Crucially, not all of these are considered as 'international standards' according to the WTO TBT Agreement.

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 is the **OECD Principles for Good Laboratory Practice (GLP)**, 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 production, plant and animal health, and are recognised as providers of international standards 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 relating to foods, food production and food safety.
- **International Plant Protection Convention (IPPC):** Established by FAO member states, the IPPC develops international standards for phytosanitary measures (ISPMs) for safeguarding plant resources. These address issues, such as import regulations and pest risk analyses.

- **World Organization for Animal Health (OIE):** Develops international standards to support and promote animal disease control, including the safety of the global trade in animals and animal products.

2.3 Metrology

Common units of measurement, accurate and reliable measuring instruments and techniques are all fundamental components of science and technology. As such, they are indispensable for a broad range of human activities.

Metrology provides reliable measurements as a basis for 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. 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.

Metrology is a key component of any LP. 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 trusted and repeatable.

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. International organizations, such as the International Bureau of Weights and Measures (BIPM), provide the basis for a single, coherent system of measurements throughout the world, traceable to the International System of Units (SI).

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".*

As such, it links a result of any particular measurement to the reference of the best possible measurement, and eventually to the internationally accepted measurement references. 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 test data 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 test results and supportive measurements are still accurate and trustworthy.

Where metrological traceability to the SI units is not technically possible, appropriate references—such as certified reference materials, reference methods or consensus standards—can also be used to demonstrate metrological traceability (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.

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."*[1]

Accreditation is also being increasingly employed by national authorities to ensure the competence of conformity assessment bodies. Laboratories are included, by definition, as conformity assessment providers.

Accreditation 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.

The role of an Accreditation Body (AB) is to assess and attest the technical competence of a laboratory and 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). These criteria are normally supported by technical requirements specific to a scientific discipline. In many developing countries, national ABs may not exist, or are still to have their activities recognised internationally. Many developing countries' laboratories, therefore, seek out ABs 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 and proficiency testing results of the accredited laboratories of its members. The ability of these accredited laboratories to include the logo of their chosen AB, together with the ILAC MRA logo which they are licensed to use, helps provide increased confidence in the laboratory, while promoting acceptance of the results they provide. As of December 2019, the ILAC Arrangement covered 101 accreditation bodies from 101 economies.

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

3. Why an LP is needed

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. Good governance requires public resources to be used responsibly. Investments in infrastructure and other resources should not only 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 QI 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 it contributes to, 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 LP arises.

3.1 What an LP can offer

First, 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 Laboratory Infrastructure. It can recognise and build on the existing laboratory-related infrastructure, and set objectives for how it can be changed, adapted and upgraded. It is no longer sufficient to simply try to follow what other economies have done; indeed, this probably was never the best approach. While learning from the mistakes of others can provide valuable insights, attempts at complete emulation rarely deliver the intended benefits. Economies in general, and developing economies in particular, need to take ownership of their own needs and seek appropriate solutions.

Second, 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.

Third, in addition to the trade dimension, an LP directed Laboratory Infrastructure can support and help ensure the health and safety of the citizens and the protection of the planet.

3.2 Understanding the need for an LP

International acceptability of laboratory results depends on demonstrable and continuous compliance 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 in this regard, which indicate the need for an LP.

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

Second, some government departments can tend to 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. This tendency also often negatively impacts the financial support received from the laboratory service provider's line ministry 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 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.

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. However, this responsibility 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.

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 Laboratory Infrastructure.

Given the investment associated with maintaining an Laboratory Infrastructure, an LP can help focus available resources which can assist in delivering the many test results needed, cost-effectively and efficiently. Without such a focus, the ability of the Laboratory Infrastructure to underpin the health of the people, protect the environment, guarantee the rights of the consumers, support competitiveness of national producers, and access international markets could easily be compromised.

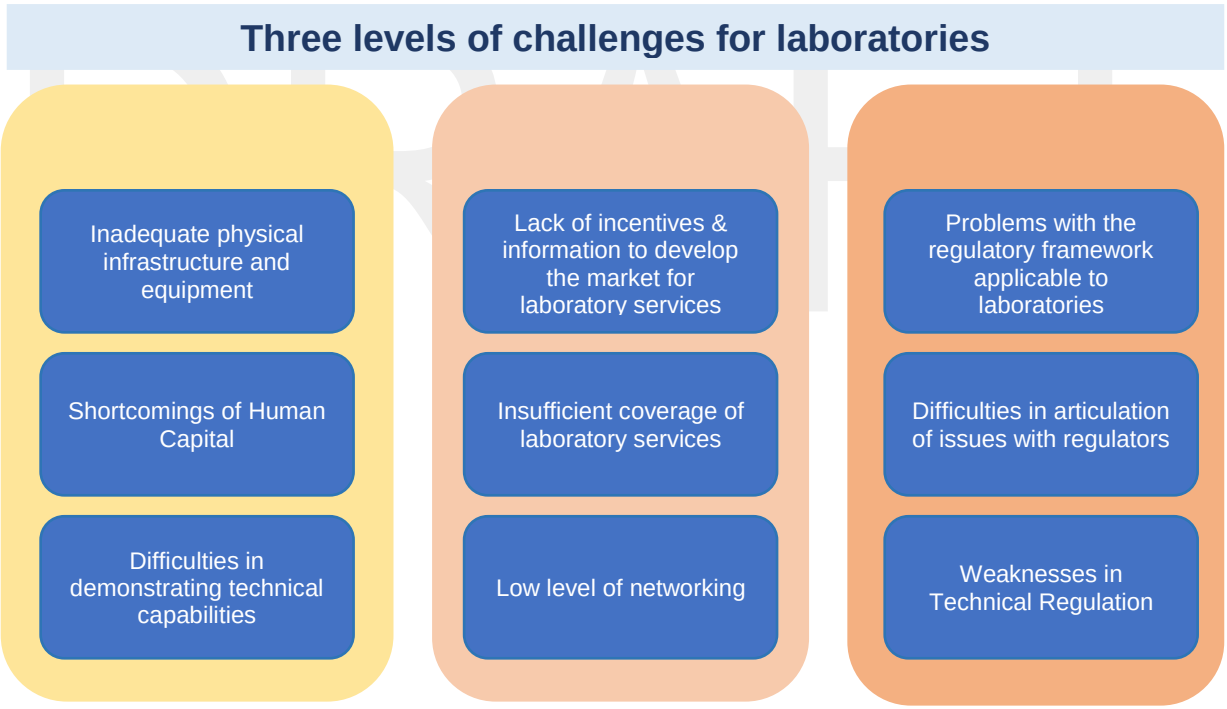
4. Challenges and benefits for laboratories

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 major constraints that cut across countries and regions. These can include:

- 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 underlying challenges and 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 repeatable results, often due to unstable power;
- Expensive quality assurance and regular inter-laboratory comparisons; 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.

Figure 1 illustrates the three levels of challenges for laboratories:

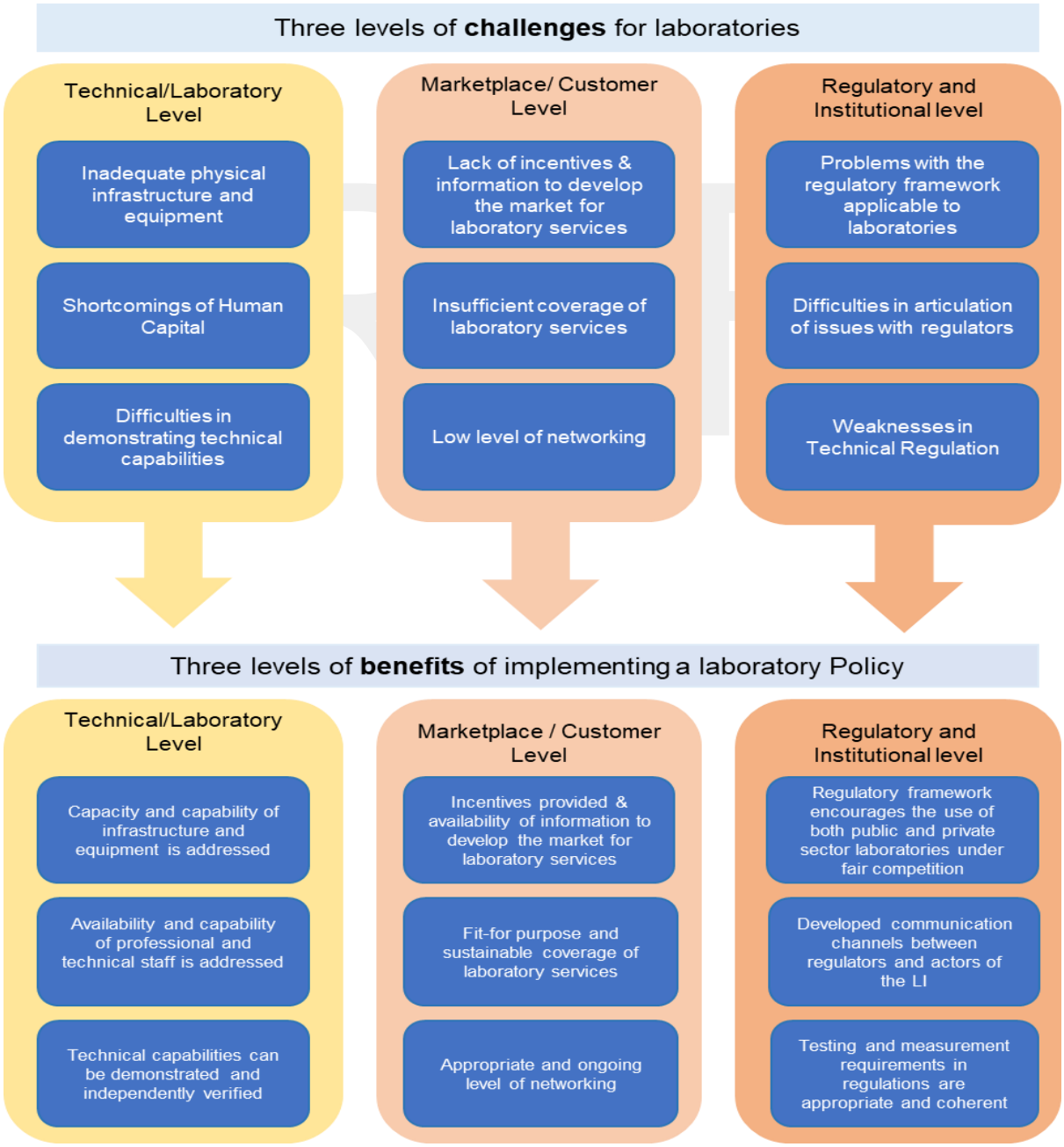


4.2 Benefits of developing an LP

Some of the many benefits of developing and implementing an LP can be similarly categorised to the grouping of challenges identified in Figure 1. 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 Laboratory Infrastructure, as a result of national interventions.

Figure 2 illustrates the three levels of challenges and the benefits of implementing an LP



4.3 Developing a sustainable Laboratory Infrastructure

An 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 initial development of laboratory capacity is often driven by a number of factors. These can include the needs of government, multinationals, development agencies, and the public and private sector. In many cases, the availability of sufficient and ongoing funding—regardless of where if comes from—is also a key factor. Under these circumstances, the development of laboratory capacity does not always appropriately consider factors such as the availability of other laboratory capacity, or the overall demand regarding national and sectoral priorities. This situation can be made worse where there is a lack of suitable information on the supply and demand of existing laboratory capacity and services, and the geographical concentration of supply. In many cases, this leads to unnecessary duplication, fragmentation or inter-agency competition. This can result in scarce scientific and technical resources being 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, 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 these cases, governments may need to either invest in providing such capability, or incentivise the private sector to make such investments.

Each economy should take the lead in determining its goals for development and associated needs, including those related to infrastructure. Many countries do not have a national AB. Laboratories in those countries usually need to address their accreditation needs through an AB elsewhere. In many cases, such internationally recognised AB services can only be sourced from more developed countries. This has the key disadvantage of needing foreign currency to pay for them, which can make it an expensive exercise. 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 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".*[2]

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 needs of a Regional Economic Community (REC).

4.3.3 Micro-level

UNIDO's experience in assessing the needs of laboratories and providing appropriate technical assistant has helped identify a range of challenges at the micro-level. These challenges can be grouped into three distinct areas: the quality of 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 the 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;
- Failing to adopt a more business-like approach in servicing their customer needs;
- 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;
- Lacking suitable safety methods and associated infrastructure including maintenance processes to manage hazardous materials such as chemicals, biological materials, and inflammable equipment;
- Having only limited quality control procedures;
- Having no—or only some—validated methods;
- Failing to calibrate equipment as regularly as required; and
- Failing to perform necessary verification checks.

[2] Development of National Health Laboratory and Plan, WHO, 2011. Pgg. viii

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. Many countries already have laboratory associations. In some cases, these associations may benefit from further strengthening and a clearer understanding of their role.

The SADC Regional Laboratory Association (SRLA)[3]

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. Since then, 13 out of 16 SADC member states have formally established independent laboratory associations to support their laboratory activities. For members 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 1702.

[3] 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. It should also consider the advantages of new technology offered through the 4IR. An initial needs analysis should provide the foundation for subsequent work. As a minimum, it should 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 stakeholders across several groups, including:

- Laboratory Infrastructure or QI organization ownership – public, private or associations;
- Customer needs – products or services;
- Gender – man or women;
- Customer size – from large conglomerates to MSMEs;
- Representatives of the wider community – NGOs and educational institutions.

The provision of public sector funded laboratory capacity is usually 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 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.

An LP allows for the future development of the associated Laboratory Infrastructure to ensure it is strategically aligned, fit-for-purpose and sustainable. The LP 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.[4] Given that an LP is a subcomponent of a QP, the LP guiding principles are designed to align with QP principles. The LP guiding principles below have therefore been adapted and expanded to focus on Laboratory Infrastructure issues specifically. The principles are:

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

1. Coherence;
2. Integrity;
3. Inclusiveness;
4. Optimization; and
5. Sustainability.

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

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 an LP 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 inter-laboratory, inter-ministerial and inter-sectoral level—is crucial, especially when resources are scarce and overworked. There is also a need for appropriate coherence with other policies 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 encourages 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 compliance-related activities easier to navigate, resulting in less effort and cost on the part of laboratory users;
- Encouraging the use of calibration data and test results to address multiple compliance-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.

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

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 Laboratory Infrastructure.

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 in the implementation and subsequent monitoring of the LP. The initial process of developing an LP should identify all relevant stakeholders. These should include:

- Stakeholders directly impacted by the LP – such as the Laboratory Infrastructure and other QI component organizations and their customers;
- 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 or associations;
- Customer needs – products or services;
- Gender – man or women;
- 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 Laboratory Infrastructure, 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 Laboratory Infrastructure, 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 Laboratory Infrastructure, such as smart sensors, drones, machine learning and real-time data analysis;
- Feedback on what is needed to ensure that laboratory-related services offered continue to meet the needs of intended users and consumers.

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. First, you can target investments to address strategically determined and demonstrable needs identified through the needs analysis. Second, you can identify synergies which can, in turn, be used to achieve your future economic goals more cost-effectively. Third, you can embrace the use of private enterprise testing, measurement and calibration where it can deliver a more efficient and effective laboratory service.

Optimized laboratory resources can help with cost-effective access to local, neighbouring country and other international markets with goods and services of the requisite quality. It can 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, too much focus has been placed on developing generic and basic capabilities within laboratories. This was based on the belief it would provide an initial platform to subsequently also address other, more specialised, and often ever-expanding testing and calibration needs. But experience has shown this often results in capability that is inappropriate and underutilised, if used at all. All too often, there are significant discrepancies between actual demand versus the available supply of laboratory services.

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 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 Laboratory Infrastructure;

- 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 pro-actively identifying the further strengthening activities required to satisfy new and emerging Laboratory Infrastructure requirements.

5.5 Sustainability

The concept of optimization refers to the capability, adaptability and survival of the Laboratory Infrastructure in the longer-term. 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.

SDG 12 calls 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 that of today. This will require a substantial reduction in the ecological footprint of economic activities. An associated and emerging global trend is the moving away from linear economic models—which are rapidly reaching their limits—towards the so-called 'circular economy'. This will undoubtedly impact laboratory functions and activities too. The LP should guide and support the attainment of these transformations, and many others.

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 funding and the relatively low absorption capacity of national institutions and their staff. The LP must enable the government to clearly articulate its commitment to creating and maintaining an environment that encourages innovative solutions in addressing Laboratory Infrastructure -related needs. This includes the need to provide the necessary assurance and associated stability to establish and maintain international trust in the laboratory activities covered under national and REC mandates.

Another critical issue is that women are commonly underrepresented in the STEM subjects: Science, Technology, Engineering and Mathematics. Their 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 development process. To do so, gender roles and assumptions and stereotypes about women's capabilities and capacities may also need addressing.

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

- **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.
- **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 Laboratory Infrastructure;
- 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. Key elements 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 and enhance trust;
- The economic feasibility at both macro- and micro-levels;
- The needs and roles of all types of laboratories – including testing, pathology, research and calibration.

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 Laboratory Infrastructure:** Demonstrates the intention to enhance the required test and measurement capability and capacity of a country. It also shows the ambition to establish an Laboratory Infrastructure where both public and private sector actors 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 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. 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 compliance 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:

- Stimulate the demand for the provision of private sector calibration and testing services;
- Promote a culture of quality among private sector laboratories;
- Promote or facilitate the establishment of public-private partnerships (PPPs) for the provision of test and measurement capabilities required for regulatory functions;
- Promote the use of new technology such as IT-infrastructure, machine learning, smart sensors, remote assessments of products and services;
- Streamline the requirement for establishing private sector laboratories, through initiatives such as fiscal incentives, tax reductions on revenue and exemptions of import duties for laboratory equipment;
- Facilitate the import and export of Certified Reference Materials (CRMs) and the chemicals used for quality control purposes within a laboratory;
- Support and facilitate capacity building in management and technical practices and 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 (Risk assessment and 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 important to ask a series of questions of your staff:

- *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 pay due attention to safety?*

In a test laboratory, there are a number of risks to safe operation to address as part of developing and implementing an LP. These include:

- Use of cultures and how to grow microorganisms;
- Use of safety cabinets and filters to maintain a safe working environment in a laboratory;
- 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.

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 sector—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 designates them.

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;
- 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 your country's strategic priorities and demonstrated needs—is encouraged. The local laboratory capacity and capability needed to ensure compliance 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;
- Take 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;
- Build and maintain capacity and capability among internal and external stakeholders to ensure compliance 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;
- 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.

Legal metrology involves the legislated use of metrology to ensure fair weights and measures are applied in both national and import-export trade. Typical activities in this field include:

- Type approval of measuring instruments used in trade, such as scales and fuel pumps;
- Initial and ongoing verification and inspection; and
- Application of sanctions in cases of non-compliance with legislation.

Legal metrology regulations, as well as type approval, verification and inspection procedures, should be 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.[5] 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 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.

[5] 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 an external 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, if not already addressed through initiatives such as a National Quality Policy (NPQ). 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 REC activity that seeks to address the national needs for internationally recognised accreditation through the REC 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 Laboratory Infrastructure. A structured and systematic approach to the strengthening and development of the Laboratory Infrastructure allows for more optimal development. It should also address the need for sustainable maintenance. Implementing an LP enables increased coherence in the further development of an appropriate, efficient and cost-effective Laboratory Infrastructure.

Table 2 (below) 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.[6]

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
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

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

Key stages	Detailed steps	Objective	Guiding Principles
	2.2 Identify key stakeholders	Decide which stakeholders need to be consulted during the consensus-building process.	○ Coherence ○ Inclusiveness ○ Sustainability
	2.3 Conduct preliminary stakeholder consultation	Obtain inputs to allow for preliminary drafting of the LP.	○ Inclusiveness ○ Optimization ○ Sustainability
	2.4 Analyse & differentiate options considering feasibility and sustainability	Learn from others, benchmark, and decide on the most cost-effective basis for sustainable Laboratory Infrastructure.	○ 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	Make sure that the LP addresses the laboratory-related needs of all pertinent sectors.	○ Inclusiveness ○ Optimization ○ Sustainability
	3.2 Prepare the first draft of the LP	Provides a starting point for discussion.	○ Inclusiveness
	3.3 Initial consultations with stakeholders	Allow for inputs from relevant stakeholders.	○ Coherence ○ Inclusiveness ○ Optimization
	3.4 Incorporate feedback	Improve draft LP and ensure appropriate incorporation of stakeholder feedback.	○ Coherence ○ Optimization ○ Sustainability
	3.5 Circulate for public consultation	Ensure wider buy-in for NQP and allow for public comment through covering key stakeholders throughout the country.	○ Coherence ○ Inclusiveness ○ Optimization ○ Sustainability ○
	3.6 Incorporate comments and prepare ‘final’ version of the NQP	Further improvement of draft NQP and prepare for final validation and implementation.	○ Coherence ○ Integrity ○ Inclusiveness ○ Optimization ○ Sustainability
4. Obtain approval		***Incorporate as part of national policy***	○

Key stages	Detailed steps	Objective	Guiding Principles
	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 and national priorities.	○ Optimization ○ Sustainability

7.2 Legal, governance and structural issues

A legal and regulatory framework can have a defining impact on a country's business environment. It also impacts on Laboratory Infrastructure institutions, and public institutions in particular, which are bound by legislation which governs their objectives, authority, governance, finances, processes and 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 Laboratory Infrastructure. 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 Laboratory Infrastructure, 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 independent, 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.

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, to:

- Arrange and participate in awareness campaigns for consumers in general, and women in particular, to ensure consumer rights are properly understood;
- Promote and participate in laboratory-related education and training activities;
- Help disseminate laboratory-related information;
- Implement activities that promote the improvement of quality and the environment, based on trusted measurements;
- Contribute to the preparation and improvement of the LP.

7.3.4 International organizations

Strong international relationships, including those fostered through international 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 international organizations related to the various technical functions and activities of laboratories and their service providers.

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 allow for the development of adequate Laboratory Infrastructure, with a particular focus on gender inclusion;
- 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 laboratories should sit within the public sector. In particular, the government should retain full responsibility for funding the following:

- The establishment and maintenance of national measurement standards;
- 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 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. The 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 private investment within the Laboratory Infrastructure —the financing of private sector laboratories remains the responsibility of the private sector. The private sector should also be involved in technical committees and other laboratory-related meetings at the national, REC 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 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 and private academic institutions should 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. Establishing innovative tools, such as knowledge hubs, is beneficial for the sharing and retention of specialist knowledge. Such an information network should also include the national TBT Enquiry Point, the appointed SPS Enquiry Point, and the SPS National Notification Authority. 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 Trade, Investment and Innovation Knowledge Hub (TII Knowledge Hub) is an interactive online platform, which serves to create, share and exchange knowledge around trade, investment and innovation. The TII 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

This guide has outlined many of the aspects that need to be considered to develop and implement an LP successfully. It aims to give practitioners the practical knowledge they need. Perhaps equally important, however, is the other aspect of this guide. It seeks to equip them with the broader context—including the risks and opportunities involved—needed to develop an LP that achieves the intended outcomes in the short-term, while ensuring it is genuinely successful in the long-term.

As we have seen, the context is fast-changing; evermore intricate technical products and sophisticated service offerings make for some novel challenges. Climate change, long-running trade disputes, technological disruption resulting from the 4IR, and global pandemics all add to this increasingly complex picture of a rapidly changing world. There is clearly a need to find a better way of doing things.

This is why developing and implementing a fit-for-purpose LP is so important. Because in this new world of rapidly growing international trade, countries compete less based on the availability of natural resources, geographical advantages, or the lower cost of labour, and more on the factors related to their ability to access and compete in new markets.

For developing countries, in particular, this represents a real opportunity. Armed with the crucial knowledge of how to develop and implement an LP, they can participate much earlier in global value chains, with all the resultant benefits for their economic development. More than that, it presents a unique chance to play a crucial part in realising the SDGs, and progress the 2030 Agenda for Sustainable Development in the long-term interests of people, prosperity and planet.

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 to carry out specific conformity assessment tasks.	ISO/IEC 17000:2004, 5.6
Calibration	Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material and the corresponding values realised by standards.	International Vocabulary of Metrology (VIM).
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
Conformity Assessment	Evidence that specified requirements relating to a product, process, system, person or body are fulfilled.	ISO/IEC 17000:2004, 2.1, modified
Good Laboratory Practice	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. The principles have been created in the context of harmonising testing procedures for the Mutual Acceptance of Data (MAD).	ISO/IEC 17000:2004, 4.3
Inspection	Examination of product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements.	
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
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.	
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.	
Technical Regulation	The document which 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 17000:2004, 4.2

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.[7] 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.[8] 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 certificate 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 LI with established best practices.

Laboratory Infrastructure (LI): LI 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.

[7] Quality Policy – Guiding Principles. UNIDO / International Network on Quality Infrastructure, Vienna, Austria. 2018.
[8] 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.[9] 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.[10] 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".*[11] 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".*[12]

2. 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.[13]

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 apply

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

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.[14]

3. 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.

4. 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.[15] 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 which are marketed in more than one country.

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

Annex D: Further information on laboratory and quality infrastructure

1. UNIDO Trade, Investment 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 Trade, Investment and Innovation Training Academy provide 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 UNIDO Knowledge Hub: www.hub.unido.org

United Nations Industrial Development Organization, UNIDO
Department of Digitalization, Technology and Innovation, DTI

You are invited to submit comments to the consultation paper by **31 August 2020** at the latest. Comments shall be submitted to UNIDO by email to: k.monaco@unido.org