



ZAMBIA

Quality Infrastructure Assessment Report of Zambia

February 2022

On behalf of



Federal Ministry
for Economic Cooperation
and Development

On behalf of the Federal Government of Germany, the Physikalisch-Technische Bundesanstalt promotes the improvement of the framework conditions for economic, social and environmentally friendly action and thus supports the development of quality infrastructure.

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The Rapid Diagnostic Tool was jointly developed by the World Bank Group and PTB.

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Executive Summary

This report provides an assessment and analysis of the national quality infrastructure of Zambia. An inclusive, fit-for-purpose and implementable NQI is a necessity for all countries, and given the growing strategic importance of standards, technical regulations and conformity assessment systems, is considered essential for supporting trade objectives. To address the ongoing international dynamics of global trade, there is a need for trade policies that meet the challenges of the post-Uruguay Round trading environment under the WTO/TBT Agreement and other arrangements. These challenges include issues that result from varying and non-robust NQIs and thus affect trade and the ensuing effective participation in regional and global value chains. Moreover, these deficits impair the implementation of bilateral and multilateral trade agreements, which rely heavily on harmonized standards, reliable and correct measurements, and conformity assessment regimes and systems deemed competent by recognized accreditation systems.

Methods of analysis for this assessment included a review of the literature and virtual interviews of stakeholders. The list of stakeholders interviewed is found in Appendix 9.1. The interviews were conducted using a tool, the Rapid Diagnostic Tool, developed by the World Bank and PTB, which enables a much faster but less detailed assessment of a country's QI. It covers tailor-made questions on accreditation, metrology and standardization,

which are the building blocks of an NQI together with the technical regulatory framework and the conformity assessment aspects of inspection, testing and certification. These tailor-made questions have scores attached to their answers and the results of the interviews are generated from Excel spreadsheets and depicted in tables and graphs.

The results of the data analysed show that the NQI of Zambia is not yet fully developed, not robust, and in need of improvement. Nonetheless, positive steps have been taken, including the adoption of the National Quality Policy (NQP) of 2010, to streamline the QI institutions along the lines of international best practice. This was done through the enactment of different pieces of legislation that established the ZMA and the ZCSA. Both institutions' mandates were hived off from the ZABS. Industrial/scientific and legal metrology are covered by ZMA, which serves as the country's national metrology institute and is the custodian of national standards, currently for mass, length, volume, electricity, force and thermometry. Recommendations for the declaration of compulsory standards to the MCTI and the enforcement of their implementation through inspection services fall under the mandate of ZCSA. Under its latest mandating act, ZABS is now responsible for standards development, testing and certification, and it is the country's National Enquiry Point for the WTO/TBT Agreement.



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Legislation establishing an accreditation body has not yet been passed by Parliament. A National Accreditation Focal Point has been established within the MCTI to coordinate accreditation matters and serve as a link to the SADC Accreditation Service (SADCAS), which currently provides accreditation services in the country. Some conformity assessment services, mainly testing, are also provided by a number of medical laboratories and private sector entities serving the mining industry. These medical laboratories, which are accredited by SADCAS to the ISO/IEC 15189:2012 standard, are at the Nchanga North General Hospital, Ndola Teaching Hospital Pathology Laboratory, the Chest Diseases and Arthur Davison Children's Hospital Laboratories as well as the Tropical Diseases Research Centre Laboratory. The private sector laboratories are Ranking Engineering Consultants, Indeni Petroleum Refinery Company Limited, and the SGS Inspection Services Minerals Laboratory accredited to ISO/IEC 17025:2017.

A Department of Technical Regulation has been established within the MCTI to coordinate the technical regulation framework as part of the NQI and serve as the country's Notification Authority to the WTO. However, the department's limited activities are currently being carried out by staff in another MCTI department (the Department of Industry) since the Department of Technical Regulation has as yet not deployed any staff. There are several regulators within Government ministries and departments as well as parastatal organizations whose mandates include the development of technical regulations and provision of inspection services in different sectors, such as energy, food, information communication technology, road transport, telecommunications, and water and sanitation, but this work is done with no formal relationship with, or coordination by, the Department of Technical Regulation.

The report's findings and conclusions indicate that the NQI of Zambia in its current position and form requires improvement and further development. The major areas of weakness include:

- Failure to include all relevant institutions and stakeholders from both the public and private sectors in the NQP, which is primarily focused only on the public sector. The lack of sustainable funding models for the established institutions is also evident from the stakeholder interviews.
- The partial non-implementation of provisions set forth in the legislation for some QI institutions that was enacted after the adoption of the NQP. This primarily pertains to the Zambia Metrology Agency. A board of directors to govern this institution has never been appointed, and the provision of some metrology services demanded by industry (e.g., for flow and ionization radiation) is lacking, as is the promulgation of regulations for the introduction of certain legal metrology services for speed limit enforcement and health aspects.
- The lack of effective coordination of the technical regulation framework, including notifications of new and reviewed technical regulations to the WTO.
- Lack of a robust communication strategy providing role clarity among the QI and technical regulation institutions as well as awareness and promotion of a quality culture among the general public.
- Implementation of further legislative provisions for some QI Institutions that have not yet been implemented. These include solving a governance issue by appointing a board of directors for the Zambia Metrology Agency, extending the fields of metrology to include ionization radiation and flow, developing the required regulations to implement the remaining legal metrology aspects, and creating a mechanism for designating other standards development organizations for specific scopes of activities under the ZABS Act. However, the implementation of further provisions must always be done in consideration of the need and priority of ensuring that the QI should be demand-driven in line with socio-economic needs.
- Development and implementation of a strategy to effectively coordinate the NQI and the associated technical regulation framework, its related institutions, and the clarification of the critical roles played by the Department of Technical Regulation and the Business Review Regulatory Agency.
- Development and implementation of a robust communication strategy, including the promotion of a quality culture in the general public as part of the implementation of the NQP.

These require further assessment and remedial action by the Government of Zambia.

Recommendations discussed include:

- A comprehensive review of the NQP, which was adopted in 2010, to ensure the inclusion of all relevant stakeholders in both the public and private sectors. There will be a need to fund the implementation of the reviewed NQP. This review process can be guided by the provisions of the African Quality Policy adopted by the African Union in September 2021 and be aligned to it accordingly.

The report also indicates that the conducted assessment and analysis have limitations centred around the non-availability of interviewees for scheduled appointments. The ongoing Covid-19 pandemic played a significant role in causing the indisposition of some relevant personnel, hence stretching the assignment over an extended period.



Introduction

The Physikalisch-Technische Bundesanstalt (PTB) is implementing a long-term strategy called *Quality for Africa* within the scope of a pan-African project designated the *Upgrading of Quality Infrastructure in Africa* in several African countries, including Zambia.

The project's overall objective is to support the Pan-African Quality Infrastructure (PAQI) initiative and institutions in assessing national quality infrastructure systems. These assessments will in turn inform policy makers and other interested parties, allowing them to identify development potential and further enhance national quality infrastructure systems so that the NQIs can work in support of sound and effective participation in regional and inter-African trade. Any resultant upgrade of NQI systems in the countries concerned following a quick, systematic assessment and evaluation of the status quo would also support and contribute to the countries' participation in global trade.

Assessment is done by employing the Rapid Quality Infrastructure Diagnostic Toolkit jointly developed by the World Bank and PTB. The Rapid Diagnostic Toolkit is designed to provide rapid feedback to indicate the status of a country's NQI, to suggest whether a more comprehensive assessment of the country's QI is required, and to identify gaps that must be addressed in order to further develop the country's QI.



1. Brief Trade and Economic Overview for Zambia

1.1. Trade and Economic Environment

1.1.1. Background

Zambia is a politically stable multi-party democracy and is endowed with abundant natural resources. The country holds general elections every five years; the last one in August 2021 ushered in a new government.

1.1.2. Zambia's GDP Growth and Sector Contributions (2018–2020)

The key sectors of the economy are agriculture, tourism, manufacturing, mining and electricity generation. While the country registered fifteen years of significant socio-economic progress and achieved a lower middle-income status in 2014 (according to the World Bank analytical classification), economic performance has stalled in recent years. Between 2015 and 2019 GDP growth slowed to 3.1 % per annum. This slow growth was attributed to maintenance problems in the mining sector, falling copper prices, a decline in agricultural output and hydro-electric power generation due to insufficient rains, and a policy space insufficiently adjusted to mitigate the external shocks.

The Covid-19 pandemic also slowed economic activity and growth, which was estimated at 1.2 % in 2020, marking the country's first recession since 1999. The impact of the pandemic has been felt in the tourism, retail and wholesale sectors.

1.1.3. Trade Liberalization

Investment in Zambia (domestic and foreign) is regulated and implemented by the Zambia Development Agency under the Zambia Development Agency Act of 2012, which has opened most activities to foreign investors. According to the World Bank Doing Business Report of 2020, Zambia is ranked 85th among 190 economies. This ranking is an improvement from being ranked 87th in the previous reporting period. While foreign direct investment flows grew from 2009 to 2014 (from USD 700 million to USD 2.5 billion), they were largely directed at only one sector, mining, indicating low levels of economic diversification. The various factors that are hampering the country's diversification efforts revolve around the prohibitive costs of doing business, including unreliable energy, access to financing, high interest rates and more recently, macroeconomic uncertainties (frequent policy changes in mining taxation and foreign exchange rate volatility).

Several reforms have been implemented to improve the country's business environment, attract FDI and enable economic diversification. These include the establish-

Year	Agriculture	Industry	Services
2017	4.02 %	37.3 %	52.09 %
2018	3.34 %	34.49 %	54.24 %
2019	2.86 %	34.94 %	54.6 %
2020	2.73 %	42.74 %	48.32 %

Table 1: GDP Share by Economic Sector (2017–2020) (<https://www.statista.com/statistics/457737/Share-of-economic-sectors-in-the-gdp-in-zambia>)

ment in 2015 of the Business Regulatory Review Agency, which works to ensure that only necessary licenses are introduced in order to make doing business easier and to increase the accountability of regulatory authorities.¹

1.1.4. Trade Balances

In 2020, Zambia’s trade surplus was estimated at USD 2.49 billion, up from trade deficits estimated at USD -0.13 and -0.43 billion in 2019 and 2018, respectively, according to figures calculated by Statista from WTO data. The country’s imports are more diversified than its exports, with the main imports being machinery, transport equipment, oil and automotive products. The main export by far is copper.²

1.1.5. Export Portfolio

The country’s major export, copper, accounts for about 70 % of Africa’s production and in 2020 accounted for 74 % of the country’s total exports. Other exports include sugar (1.5 %), tobacco (1.5 %), salt, sulphur and other minerals (2.0 %).

The main export partner is Switzerland with a share of 44 % of total exports in 2020. Others include China (19 %), Singapore (12 %), Congo-Kinshasa (12 %) and South Africa (2.6 %).³

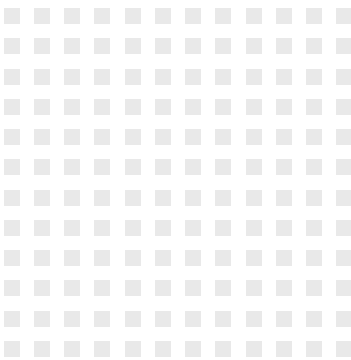
Switzerland	44 %
China	19 %
Singapore	12 %
Congo-Kinshasa	12 %
South Africa	2.6 %

Table 2: Zambia’s Main Export Partners

1.2. The Role of a National Quality Infrastructure

A national quality infrastructure is a valuable tool that can be used to improve competitiveness and facilitate a country’s meaningful participation in regional and international trade. Countries can become more competitive by rationalizing and abolishing overly restrictive technical regulations, harmonizing standards with regional and international trading partners, concluding mutual recognition agreements with trading partners on conformity assessment procedures and results, and improving the ease of doing business.

Additionally, a functioning NQI can deliver the expected socio-economic outcomes espoused in national visions and development plans as well as in other relevant national policies, strategies and programmes. Every level of an NQI must be inclusive (available, accessible, affordable and acceptable) if a society, including its vulnerable groups, is to benefit from it.⁴



1 WTO Trade Policy Review WT/TPR/S/340. Zambia
2 <https://www.statista.com>
3 United Nations COMTRADE Database
4 <https://www.gihub.org/articles/quality-infrastructure-should-be-inclusive>

2. Objective and Methodology

2.1. Objective

The objective of this assessment is to gauge the status of the national quality infrastructure in Zambia by using the Rapid Diagnostic Tool developed by PTB and the World Bank as part of the QI-Reform Toolkit. The results will be used to draft recommendations and to support the development of the national quality infrastructure system.

2.2. Methodology

In undertaking the tasks required under the scope of this project, the assessment was conducted by applying several approaches that combined desk research and interviews with relevant stakeholders. Several data sources were reviewed and used to collect, distil and analyse the information needed for drawing conclusions, issuing recommendations and authoring the report. Each NQI unit was assessed based on the four pillars implemented in the PTB/WBG Rapid Diagnostic Tool:

- Legal and institutional framework
- Administration and infrastructure
- Service delivery and technical competency
- External relations and recognition

2.2.1. Desk Research

Desk research was done through the collection of secondary information, which included the consultation and review of strategic national, regional and continental protocols, trade agreements, policy documents, frameworks, initiatives and programmes. Among these were the Zambia Vision 2030, Zambia National Development Plan 7 (2017–2021), Smart Zambia Transformation Agenda 2064, and the Zambia National Quality Policy 2010. Acts of Parliament establishing the Zambia Bureau of Standards, Zambia Compulsory Standards Agency, Zambia Metrology Agency, SADC Protocol on Trade, COMESA–EAC–SADC



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Tripartite Agreement, AfCFTA Agreement, the World Trade Organization Technical Barriers to Trade Agreement as well as other pertinent websites were also reviewed.

2.2.2. Stakeholder Interviews

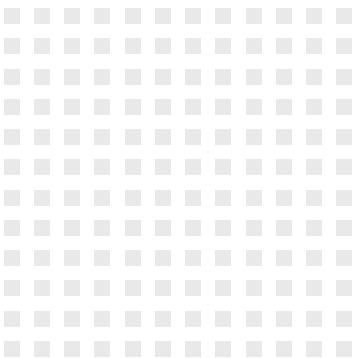
A list of stakeholders that included the main quality infrastructure institutions was provided by the Zambia Ministry of Commerce, Trade and Industry. The names of those interviewed are given in Annex 9.1. Primary data was then largely obtained through virtual interview meetings followed up by email correspondence and telephone calls with the relevant personnel from the said institutions. These discussions were guided by the questions found in the Rapid Diagnostic Tool.

The questions in the Excel sheets covered the four pillars of a QI cited in section 2.2. above and included a few which were of an informational nature. Most were scored on a scale of 0 to 4 points, depending on the extent to which the stated benchmark was met, with 4 points indicating full compliance. The scores for each pillar are compounded and expressed in a radar diagram that serves as an aid in deciding whether a comprehensive assessment of the NQI should be conducted.

2.2.3. Limitations

The main limitation to the study was the non-availability of interviewees for the scheduled appointments and/or the limited time available, which necessitated email follow-ups. These email follow-ups might also have impaired the potential for spontaneity that would otherwise exist in face-to-face interviews. Additionally, responses to email correspondence were not necessarily prompt and sometimes required many reminders. This then caused the study to stretch out over a lengthy period covering several months. It is acknowledged that during the Covid-19 pandemic many organizations made arrangements that included staff working from home, and this at times presented internet connectivity challenges. Some relevant personnel were also affected by absenteeism and hospitalization due to the pandemic.

But the conducted interview meetings along with the email follow-ups did in certain cases enable the study and analysis to take place, and these have in turn formed the basis for the conclusions (section 6) and recommendations (section 7) made in this report.



3. Overview of Zambia's QI

3.1. General Organizational Context

The need for investment in Zambia's NQI has been expressed in the country's Vision 2030 as well as in the National Development Plan 7 (2017–2021), the National Export Strategy, the Smart Zambia Transformation Agenda 2064, and other national initiatives. Such investment is required, among other things, to enable the implementation of major projects across several sectors in order to meet private and public needs and further the socio-economic and industrial development of the country.⁵

Prior to the development of the country's National Quality Policy (NQP) of 2010, the NQI was composed of the Zambia Bureau of Standards (ZABS), which was established in 1982 by an act of Parliament. ZABS evolved over the years into a multi-disciplinary organization responsible for standards development, enforcement of compulsory standards, testing, metrology and certification services. This was done with the aim of providing protection to consumers and the economy and thus contributing to the enhancement of trade both locally and globally.

Many developing countries have followed this integrated model in which national standards bodies provide both voluntary and regulatory standardization and conformity assessment services. However, some have moved away from this model, opting instead to adopt best international practices.

These best practices, which must be considered, embrace the need for countries to accommodate both the public and private sector in the provision of the essential QI services of metrology, standards, calibration, testing, inspection, certification and accreditation. It is further necessary that these services be internationally recognized, meaning that:

- the calibration and measurement capabilities of metrology institutes should be traceable and should be included in the key comparison database managed by the BIPM;
- legal metrology service providers' regulations must be aligned to the relevant OIML Guidelines;
- standards development organizations should actively participate in and contribute to the work of relevant technical committees of regional, continental and international standards setting bodies;
- inspection, testing and certification service providers should be accredited.

Several Ministries in Zambia also have regulatory mandates and oversee the development and/or implementation of regulations through specific agencies across different sectors. These regulators include the Energy Regulation Board, Food and Drugs Control Laboratory, National Water Supply and Sanitation Council, Road Transport and Safety Agency, Tropical Disease Control Research Centre, Zambia Environmental Management Agency, Zambia Information and Communication Technology Authority, and Zambia Medicines Regulatory Authority. The regulatory authorities' approach to the development and implementation of regulations does not necessarily comply with WTO/TBT Agreement requirements (such as the requirement to provide notification of new and reviewed regulations for such bodies), and this can create unnecessary barriers to trade. The recently established Business Review and Regulatory Agency will go a long way in instituting the good regulatory practice of conducting risk assessments prior to developing and/or reviewing regulations.

It is indeed important for countries to consider adopting international best practices when designing their NQIs. However, it is also important to note that evolution from the integrated models used to date (wherein one institution is mandated to develop standards and technical regulations, enforce them, and provide metrology and conformity assessment services) should be pursued over time and aligned to the country's socio-economic needs, industrial development level and growth trajectory. And, of key importance, it must be sustainable. Therefore,

⁵ <https://www.mndp.gov.zm>

while governments should put in place and finance the essential services of standards development, metrology and accreditation, market dynamics (supply and demand) and a commercial orientation should be the determining factors with respect to the provision of certain conformity assessment services. It is important to note that for many developing countries like Zambia, governments had to initially set up and support the provision of all QI services. This was usually done within one institution due to the limited resources available and given the country's industrial development level and/or the weakness of the private sector, and hence the low demand for such services.

3.1.1. Legal and Institutional Framework

a) Legal Framework

Zambia's NQI landscape comprises public institutions and state-owned agencies. There are some private entities, including laboratories belonging to and/or serving the mining sector. Public institutions and agencies are established by acts of Parliament, which detail the mandates and operations of the different institutions/agencies.

Zambia is a member of the Common Market for Eastern and Southern Africa (COMESA) and of the Southern African Development Community (SADC), and it is a state party to the African Continental Free Trade Area (AfCFTA) Agreement. Therefore, the relevant QI legal and other provisions in the treaties establishing COMESA and SADC, as well as the objectives of the AfCFTA Agreement, apply to Zambia as a member and state party, respectively.

Article 112 of the COMESA treaty recognizes the importance of standardization and quality assurance in the promotion of consumer protection and trade, among other objectives. It further advocates the evolution and application of a common standardization and quality assurance policy for the production and trading of goods within the common market. The operationalization of the treaty's Article 112 is done through the COMESA Standards, Metrology, Conformity Assessment and Accreditation Policy, under which a COMESA Committee on Standards, Metrology and Conformity Assessment (SMCAA) has been established, of which Zambia, through its main QI institutions, is a member.

Implementation of the SADC Treaty's provision for recognition of the importance and effect on trade of Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT) are realized through the implementation of the SADC Protocol on Trade. Articles 16 and 17 of the SADC Protocol on Trade regarding SPS and TBT, respectively, as well as Annexes VIII and IX provide details of the operationalization of member states' cooperation in SPS and TBT matters.

In the same vein, Annexes 6 and 7 of the AfCFTA Agreement on TBT and SPS matters respectively detail the mode of cooperation between state parties to the AfCFTA Agreement. The adoption of the AfCFTA Agreement in 2018 and its implementation from January 2021 provide opportunities for state parties to produce goods that will not only be competitive and enhance participation in regional value chains, but also tap into global value chains. Hence, information and knowledge of Zambia's QI and any necessary upgrading can effectively help the country to take advantage of the opportunities available under the trading environment of the AfCFTA Agreement to enhance its socio-economic development.

The other institutional legal framework relevant for QI is the National Quality Policy (NQP) of 2010. Its main objective is to ensure that goods and services produced and traded in Zambia meet the requirements and expectations of local and export markets' consumers and regulators. The policy is meant to provide guidance to all QI stakeholders in both the public and private sectors so that they can perform their distinct roles effectively. The NQP's intention is to usher in a supportive QI that can provide the standardization, metrology and conformity assessment services needed to facilitate the implementation of the country's policies and programmes, including the Private Sector Development Reform Programme of 2004, the Commerce, Trade and Industry Policy, and the Micro, Small and Medium Enterprises Policy approved in 2009, all of which are designed to facilitate product competitiveness, growth and industrial development in the country.

The NQP also aims to achieve international recognition of the QI services. The establishment of the NQP called for the review and restructuring of Zambia's technical regulation regime and the existing quality infrastructure. This resulted in the enactment of different pieces of legislation that established the new institutions discussed in the following section.

b) Institutional Framework

The Government of Zambia's recognition of the importance of an internationally recognized and supportive quality infrastructure and technical regulation framework as one of the major drivers for the country's competitiveness necessitated the development of a National Quality Policy.

The adoption of the National Quality Policy of 2010 resulted in a revamping of Zambia's QI and regulatory framework that involved the restructuring, comprehensive review and consolidation of relevant legislation. This in turn resulted in the legal establishment, mandating and designation of the following main QI institutions:

- The Zambia Metrology Agency
- The Zambia Bureau of Standards
- The Zambia Compulsory Standards Agency
- The Department of Technical Regulations
- The Zambia Accreditation Service/Body
(National Accreditation Focal Point)

Institutional profiles

The Zambia Metrology Agency (ZMA) established under the Metrology Act No. 6 of 2017 is in charge of metrological activities (scientific/industrial and legal). ZMA has the sole mandate to maintain Zambia's national measurement standards and to establish legally enforceable metrology requirements for measuring equipment.

The Zambia Bureau of Standards (ZABS) established under the new Standards Act No. 4 of 2017 is mandated to provide standards development and some testing and certification services for both management systems and products. It is also charged with the provision of the framework required to develop national standards and other normative documents and has the sole mandate to publish at the national level.

ZABS has evolved over the years since first being established by Act 20 of 1982, which was repealed and replaced in 1994 by CAP 416 of the Laws of Zambia. Under this 1994 law, ZABS was responsible for standards development, enforcement of compulsory standards, testing, certification and metrology services. The enforcement of compulsory standards has since been transferred to the Zambia Compulsory Standards Agency (ZCSA) and the provision of metrology services to ZMA.

The Zambia Compulsory Standards Agency (ZCSA) established under the Compulsory Specifications Act No. 3 of 2017 is mandated to enforce compulsory specifications. National standards are developed by ZABS and some standards, or parts of standards, are recommended by ZCSA to the Minister of Commerce, Trade and Industry for declaration as compulsory, with compliance then enforced by ZCSA.

The Department of Technical Regulation, a department under the Ministry of Commerce, Trade and Industry, was established to coordinate all technical regulations across all Government ministries and other agencies and to manage the country's WTO/TBT Notification Point. This role is in the interim currently performed by the Department of Industry, which is within the same ministry, as permanent staff members have yet to be recruited.

Accreditation: Accreditation services for conformity assessment bodies (CABs) in Zambia are currently provided by foreign national accreditation bodies and by the SADC Accreditation Service (SADCAS). The National Accreditation Focal Point based in the Ministry of Commerce, Trade and Industry serves as liaison between SADCAS and the CABs. The law establishing the Zambia Accreditation Service has not yet been passed by Parliament, though a bill to that effect was approved at cabinet level in 2019.

3.1.2. Capacity

As discussed in 3.1.1. b) above, the QI of Zambia was reviewed after the adoption of the National Quality Policy 2010, with the legal establishment of several institutions taking place in 2017. The following table indicates the staffing levels and associated timelines of the main QI institutions:

Institution	Year of establishment	Year operations began	Current estimated total number of staff
Zambia Metrology Agency	2017	2018	47
Zambia Bureau of Standards	New Act (2017)	2018	68
Zambia Compulsory Standards Agency	2017	2018	18

Table 3: Timelines and Staffing

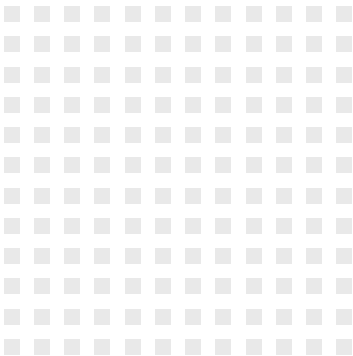
3.1.3. International Recognition

The ZMA has been an associate member of the BIPM for about eight years and is a signatory to the CGPM as well as an active member of AFRIMETS and SADC MET. It participates in the relevant technical committees and in key intercomparisons of the respective organizations. The organization has listed 11 CMCs (temperature) in the BIPM KCDB and is planning to list 20 by the end of its current strategic plan, which ends in 2021. It also participates in the International Conference of the OIML.

The ZABS is a corresponding member of ISO, an Affiliate Plus member of the IEC, a member of AFSEC and ARSO, the Regional Coordinator of SADCSTAN and a member of the SMCAA.

3.1.4. Institutional Coordination

The Ministry of Commerce, Trade and Industry coordinates and finances, through government grants for recurrent expenditure, the work of all of the QI statutory bodies it oversees. The institutions (ZMA, ZABS and ZCSA) and the National Accreditation Focal Point can invite each other to participate in the relevant technical committees and other programmes, though procedures here are not formalized. However, from the interviews conducted, some regulators in other ministries were not aware of the existence and/or role of the Department of Technical Regulation and whether the regulations they develop or review require notification to the WTO.



4. Findings

4.1. Accreditation

The legislation to establish the Zambia Accreditation Agency has not yet been passed by Parliament. The chart and the radar diagram seen below reveal that some work has been done towards the establishment of a national accreditation body and has resulted in a draft bill under the *Legal and institutional framework* pillar. It is, however, opportune that the plan to establish the agency be considered for review during the comprehensive review of the NQP so that the economy's need for the agency can be re-assessed in terms of sustainability, given that accreditation services are now provided in the country by SADCAS.

	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
Accreditation strategy	0.0			
Legal entity	0.3			
Autonomy	0.0			
Legal standing of accreditation	0.0			
Governance	0.0			
Financial sustainability	0.0			
Chief executive officer		0.0		
Organizational structure		0.0		
Management and personnel		0.0		
Premises		0.0		
Equipment		0.0		
Lead assessors			0.0	
Assessors and technical experts			0.0	
Specialist technical committees			0.0	
Quality system documentation			0.0	
Assessment process			0.0	
Approvals process			0.0	
Accreditation and follow-up			0.0	
Training system				0.0
Liaison with regional organizations				0.0
Liaison with international organizations				0.0
International recognition				0.0
Coordination within the QI system				0.0

Figure 1: Accreditation

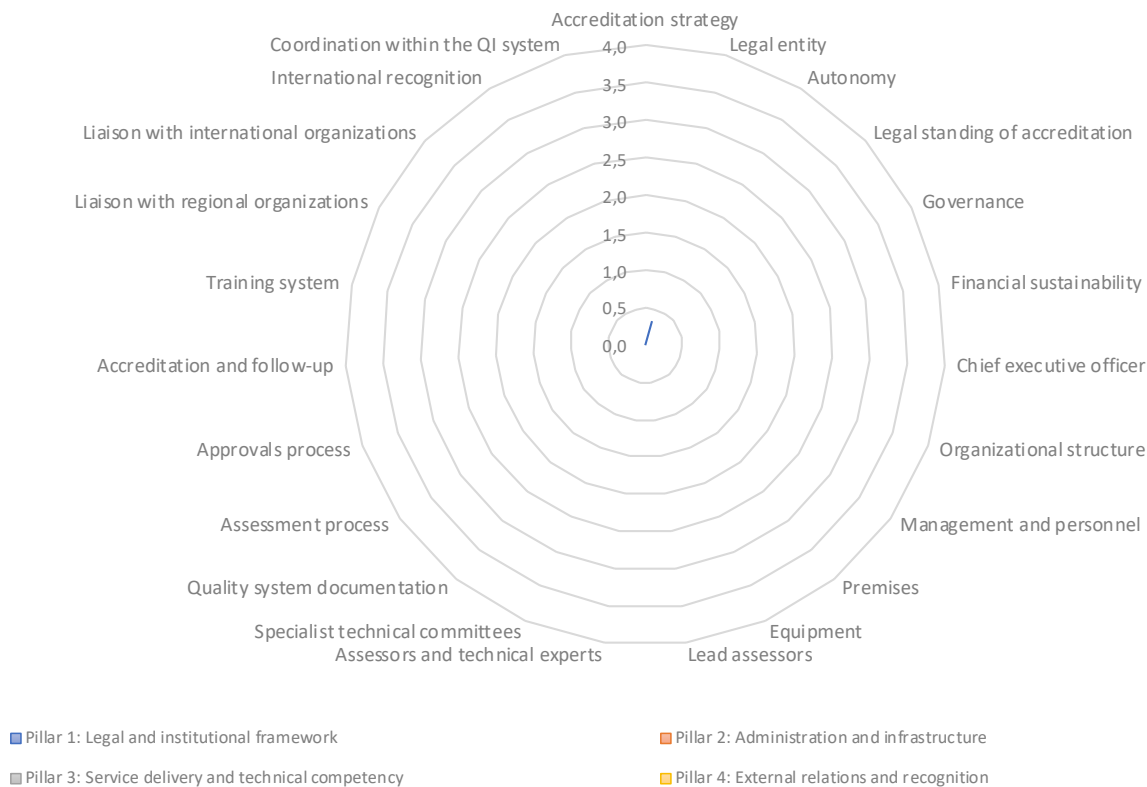
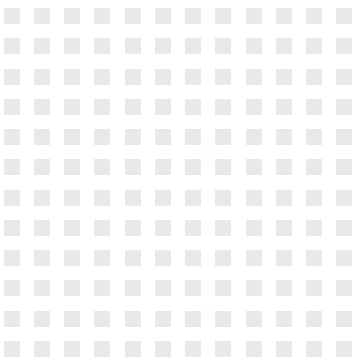


Diagram 1: Accreditation

4.1.1. National Accreditation Focal Point

The National Accreditation Focal Point (NAFP), whose role is to coordinate the services provided by SADCAS, is staffed by one person. Currently, 20 CABs (mainly laboratories) are accredited by SADCAS, and capacity building of lead and technical assessors has been conducted under the auspices of SADCAS and a number of development partners. The NAFP maintains a database of the country's CABs, their accreditation status, technical assessors and technical experts. Most of the accredited laboratories are accredited to ISO 15189:2012 Medical Laboratories – Requirements for quality and competence and ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories. The NAFP also coordinates the organization of proficiency testing schemes for water under SADC MET and for medical laboratories under a World Health Organization project. There is good cooperation between the NAFP, the National Laboratory Association and the Quality Management Association, all of whom hold joint events from time to time.



4.2. Metrology

The metrology services provided by the ZMA are overseen by an executive director and undertaken through two directorates, one for industrial metrology and one for legal metrology, each headed by a director. Since starting operations in 2018, the organization has not had a board of directors appointed, even though such a board is provided for in its founding act. This represents a weakness in governance as shown in the radar diagram below.

4.2.1. Industrial/Scientific Metrology

This department is currently a custodian of national standards for mass, length, volume, electricity, force and thermometry. Some areas have been identified for review since operations started in 2018, as certain metrology services required by the economy are still lacking, such

as flow and ionization radiation, and these require funding (equipment and trained personnel). The department represents the country and is an active member of SADC-MET and AFRIMETS. It participates in some regional interlaboratory comparisons with other metrology institutes in the SADC region, e.g., the Botswana Bureau of Standards (BOBS), the Kenya Bureau of Standards (KEBS), the National Metrology Institute of South Africa (NMISA) and the Namibia Standards Institution (NSI), as well as in some multilateral intercomparisons involving BOBS, NSI, TBS and ZMA. The department is an associate member of the BIPM and a signatory to the CGPM. This is advantageous and contributes positively to the country's metrology system in terms of technical competency, including the listing of 11 CMCs for temperature in the BIPM KCDB, which results in a reasonable score for *External relations and recognition* as depicted in the radar diagram below. Staff training and the acquisition of associated equipment need to be strengthened in order to get more CMCs listed and, among other things, to further develop the QI system.

	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
Metrology strategy	2.7			
Legal entity	2.3			
Autonomy	0.0			
Legal standing of national measurement standards	2.7			
Financial sustainability	0.7			
Governance	2.0			
Chief executive officer		1.0		
Organizational structure		3.2		
Management and personnel		2.5		
Premises		2.0		
Equipment		2.0		
Quality system documentation		4.0		
Metrologists			2.7	
Interlaboratory and key comparisons			3.5	
Calibration and measurement capability (CMC)			2.3	
Calibration service			0.3	
Training system				3.3
Liaison with regional organizations				2.5
Liaison with international organizations				2.7
Coordination within the QI				0.7
Designated institutes (DIs)				0.0
Stakeholder engagement				0.5

Figure 2: Scientific Metrology

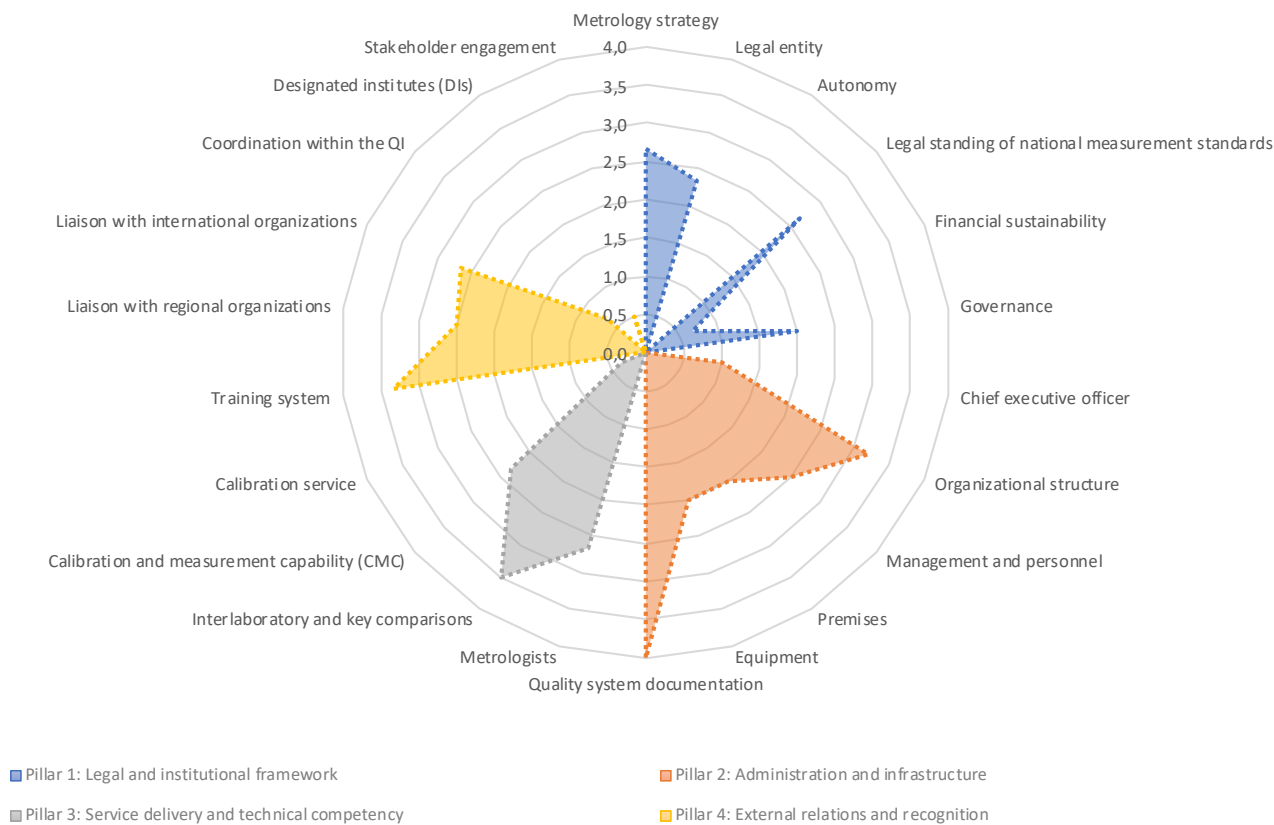


Diagram 2: Scientific Metrology

4.2.2. Legal Metrology

Since the department became operational under Act No. 6 of 2017, only the commercial transactions part of the act has been activated in some areas of law enforcement, safety, health, and environmental management. The department is in the process of developing regulations to support the implementation of other parts of the act. This will necessarily involve the acquisition of equipment for electricity and water meters as well as for law enforcement (speed enforcement cameras), things that will require funding and sustainability as shown in the radar diagram below. The commercial transactions implemented include the inspection of imported pre-packaged goods (pre- and post-market) as well as those for industrial manufacturing.

	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
Legal metrology strategy	3.8			
Legal entity	2.7			
Governance	2.7			
Financial sustainability	1.5			
Director		3.5		
Organizational structure		2.7		
Management and personnel		2.3		
Equipment		0.7		
Quality management system		3.0		
Premises		2.0		
Legal metrology technical staff			4.0	
Calibration and verification services			4.0	
Market surveillance			1.3	
Training system			3.3	
Type approval of measuring instruments			4.0	
Liaison with regional organizations				4.0
Liaison with international organizations				2.7
Coordination within the QI				2.7
Designated organizations				0.0
Consultative forum				1.7

Figure 3: Legal metrology

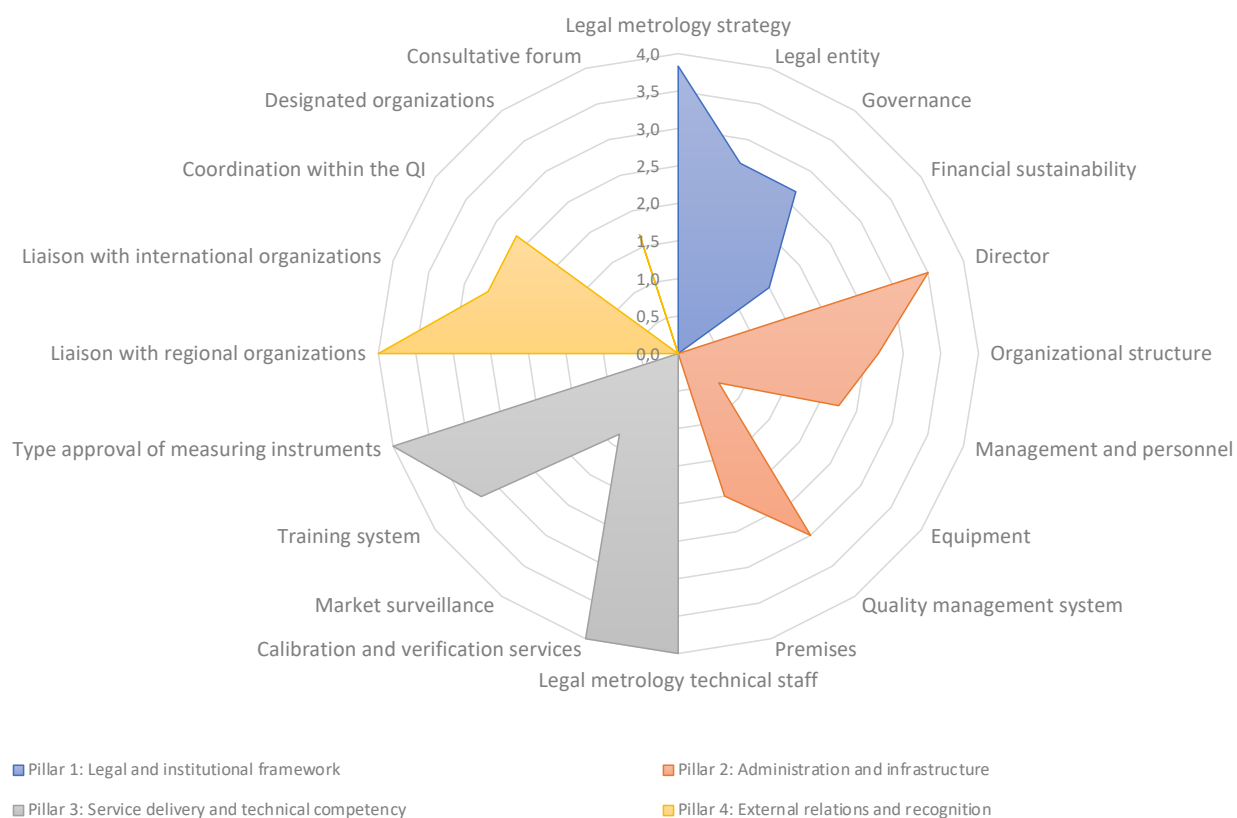


Diagram 3: Legal metrology

4.3. Standardization

The Standards Act No. 4 of 2017 was operationalized in 2018 after the adoption of the National Quality Policy of 2010. This act established ZABS as the sole body responsible for publishing national standards. While the act has a provision for the recognition of standards development organizations (SDOs) for specified scopes of activities, to date, no mechanism for implementing this provision has been developed.

4.3.1. Zambia Bureau of Standards

ZABS operates within the Ministry of Commerce, Industry and Trade (MCTI) and has no regulatory functions as summarized above. ZABS has been appointed as the WTO/TBT National Enquiry Point. It disseminates standards-related information and also sells standards. The institution offers training services in quality management systems and standards, with these services tailored to specific standards and to SMME needs. It is governed by a seven-member Board of Directors drawn from major stakeholders from government and the private sector. The annual budget of the organization is mainly composed of allocations by Parliament through MCTI and primarily dedicated to the organization's operations. Most capital expenditure requirements are covered by and rely on development funds provided through projects with development partners, a situation which is not sustainable.

	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
Standards strategy	4.0			
Legal entity	4.0			
Autonomy index	4.0			
Legal standing of national standards	2.7			
Governance	3.7			
Financial sustainability	3.2			
Chief executive officer		2.5		
Organizational structure		4.0		
Management and personnel		3.8		
Premises		2.3		
Equipment		3.3		
Standard for a standard			4.0	
Technical committees			3.8	
New project approval and work program			3.7	
Committee process			3.0	
Relevance of standards			1.3	
Coherence of standards			2.7	
Public comment			3.3	
National standards			0.7	
National adoptions			4.0	
Standards information			1.6	
WTO TBT Inquiry Point				4.0
Training system				3.3
Liaison with international organizations				1.5
Liaison with regional organizations				3.7
Coordination within the QI				2.0
Standards development organizations				0.0
Stakeholder engagement				0.0

Figure 4: Standards

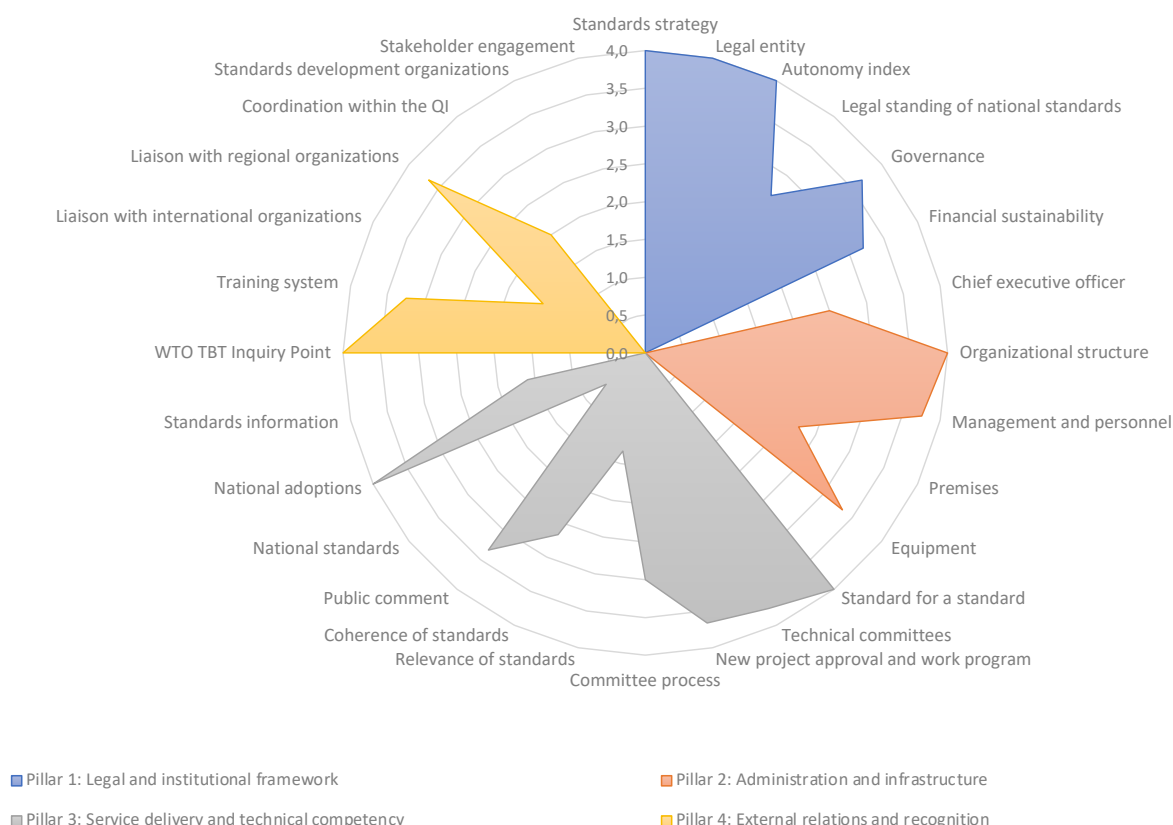


Diagram 4: Standards

4.4. Conformity Assessment

ZABS also carries out conformity assessment services (testing and certification) which are voluntary and charged for. Proceeds from testing and certification services are deposited to the Government treasury. This model is disadvantageous as the funds generated by the institution are not necessarily reinvested in it, but rather spread among other Government entities. This negatively affects the financial sustainability of the institution (as shown in the radar diagram) and points to the need to strengthen this aspect.

4.4.1. Testing

Testing services provided by ZABS include the chemical and microbiological testing of food and construction materials, with 35 of the 51 tests offered at the time of the interview with the institution accredited to ISO/IEC 17025:2017 by SADCAS. The available equipment covers about 70% of current needs, and it is envisaged to acquire new equipment, as shown in the radar diagram above, for construction and solar-related testing if/when funds are available.

4.4.2. Certification

ZABS' management systems and product certification schemes are yet to be accredited to ISO/IEC 17021-1:2015-Part 1 Conformity assessment – Requirements for bodies providing auditing and certification of management systems, and ISO/IEC 17065:2012 Conformity assessment – Requirements for bodies certifying products, processes and services, respectively. Documentation reviews for both schemes have been conducted by SADCAS and a combined assessment is being envisaged, which is a positive development. ZABS has a partnership with the Citizen Empowerment Agency wherein SMMEs are funded by this agency so that they can join the ZABS programme for Aquaculture.



	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
System certification strategy	0.0			
Designated system certification bodies	0.0			
Certification bodies for the export markets	0.0			
System certification schemes to upgrade SMEs	0.0			
Training and registration of auditors and lead auditors	0.0			
Legal entity	4.0			
Governance	0.0			
Financial sustainability	0.0			
Top management		2.5		
Organizational structure		0.0		
Management and personnel		2.0		
Premises		0.0		
Equipment		0.0		
System certification scopes			1.3	
Quality management system documentation			2.0	
Certification process			0.0	
Surveillance process			2.7	
Accreditation			0.0	
Recognition at national level				0.5
Recognition at international level				0.0
Coordination within the QI				0.0

Figure 5: System certification

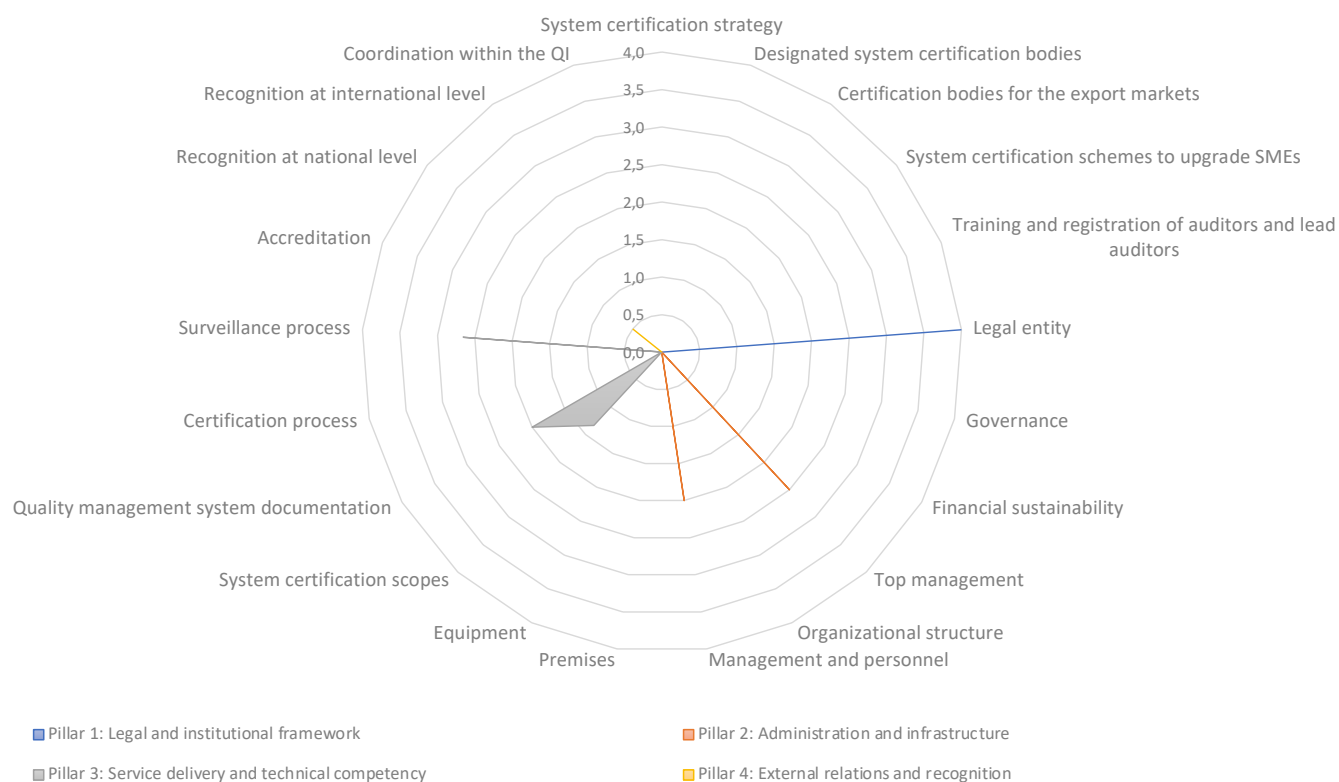


Diagram 5: System certification

	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
Product certification strategy	2.7			
National certification body for the home and regional markets	1.0			
Designated product certification bodies	0.0			
Product certification schemes to upgrade SMEs	0.0			
Legal entity	2.0			
Governance	0.0			
Financial sustainability	0.0			
Top management		1.0		
Organizational structure		0.0		
Management and personnel		2.0		
Premises		0.0		
Equipment		0.0		
Product certification scopes			1.0	
Quality management system documentation			0.0	
Accreditation			0.0	
Certification process			0.4	
Recognition at national level				0.0
Coordination within the QI				0.0

Figure 6: Product certification



Diagram 6: Product certification

4.4.3. Inspection

Inspection services relating to legal metrology are offered under the purview of the ZMA, while those for compulsory standards are overseen by the ZCSA, as elaborated, respectively, in sections 4.2.2 above and 4.5.1 below. Several regulators discussed in section 4.5.2 below also conduct various inspections under their mandates.

4.5. Technical Regulation Framework

As discussed in section 3.1.1b) above, the Department of Technical Regulation in the MCTI was set up to coordinate all technical regulators in the country and to serve as the WTO Notification Point. However, no officers have yet been recruited for the department and its role is in the interim being performed by the Department of Industry in the same ministry. It is apparent that much still needs to be done in the technical regulatory space, given that some of the regulators interviewed (save for those within MCTI) were not aware of the existence and/or

role of the Department of Technical Regulation and/or of obligations to notify it of new drafts or changes in regulations that relate to the WTO/TBT or SPS Agreements.

4.5.1. Zambia Compulsory Standards Agency

As discussed in 3.1.1 b) above, the recommendation and enforcement of compulsory standards or parts thereof is the responsibility of ZCSA as per Act No.3 of 2017. There were 70 compulsory standards at the time this report was authored. ZCSA implements ISO/IEC 17020:2012 – Requirements for the operation of several types of bodies performing inspection, in its inspection work for locally manufactured and imported goods covered by compulsory standards, although the services are not yet accredited. However, an application for accreditation of the services has been submitted to SADCAS, which is a positive step as reflected by the strength in the *Service delivery and technical competency* area of the radar diagram below. The relationship and coordination with the Department of Technical Regulation requires improvement.

	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
Technical regulation framework Technical regulation coordination office Regulatory authorities	0.3 1.0 1.0			
Director Organizational structure Management and personnel Premises Equipment Quality system		4.0 2.3 4.0 1.7 1.7 2.5		
Developing technical regulations Premarket approvals Market surveillance Sanctions Training system			0.0 4.0 3.0 4.0 3.5	
Information systems Liaison with regional organizations Liaison with international organizations				2.5 3.0 0.0

Figure 7: Technical regulations

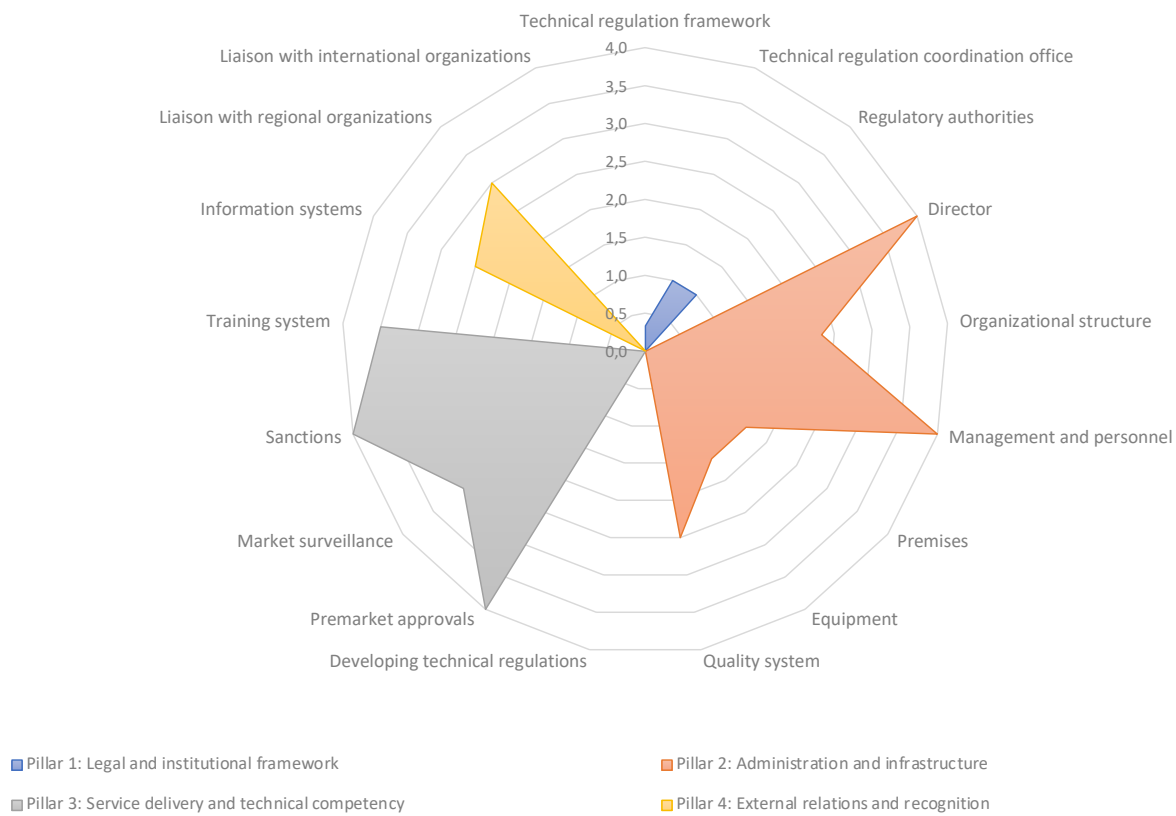


Diagram 7: Technical regulations



4.5.2. Other Regulators

Eight regulators responsible for the development and/or enforcement of regulations in certain sectors of the economy were also interviewed as discussed in i) to viii) below.

i. Energy Regulation Board

The Energy Regulation Board (ERB) operates under the Energy Regulation Act Cap 436 of the Laws of Zambia. The ERB has a Directorate of Technical Regulations through which it develops and conducts inspections of facilities that implement regulations pertaining to electricity, fossil fuels, fuel marking and renewable energy. As depicted in the radar diagram below, the ERB has a robust administration and infrastructure system.

The development of new regulations and the revision of existing ones are subject to a rigorous stakeholder consultation process and performed based on national standards, if available. It was not evident from the interview whether these regulations are notified to the WTO, pointing, as previously discussed, to the weak coordination of the regulation framework. The ERB has working standards for equipment which it uses in its inspections,

and these standards are calibrated to national measurement standards at the required frequencies. Its inspection services are not yet accredited.

Relevant products are inspected at ports of entry and at local warehouses prior to distribution to the market. There is good cooperation between the ERB and other government agencies that maintain a presence at the ports of entry, such as ZCSA, to ensure that all products subject to inspection have valid required certificates. Internal market surveillance includes quarterly sampling and testing of fuel at bulk fuel depots. Through its Fuel Marking Unit, the ERB also undertakes testing of the petroleum supply chain to check for any dilution or contamination to deter the adulteration of petroleum products. The ERB is a member of the Regional Electricity Regulators Association of Southern Africa (RERA) and actively participates in the harmonization of standards pertaining to the transportation of dangerous goods by road under the auspices of SADCTRLC and SADCSTAN. This work has a positive effect on the QI system.

	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
Technical regulation framework	0.0			
Technical regulation coordination office	0.0			
Regulatory authorities	0.0			
Director		4.0		
Organizational structure		4.0		
Management and personnel		4.0		
Premises		4.0		
Equipment		4.0		
Quality system		0.0		
Developing technical regulations			0.0	
Premarket approvals			3.3	
Market surveillance			4.0	
Sanctions			3.7	
Training system			3.0	
Information systems				2.0
Liaison with regional organizations				2.5
Liaison with international organizations				0.0

Figure 8: Technical regulations

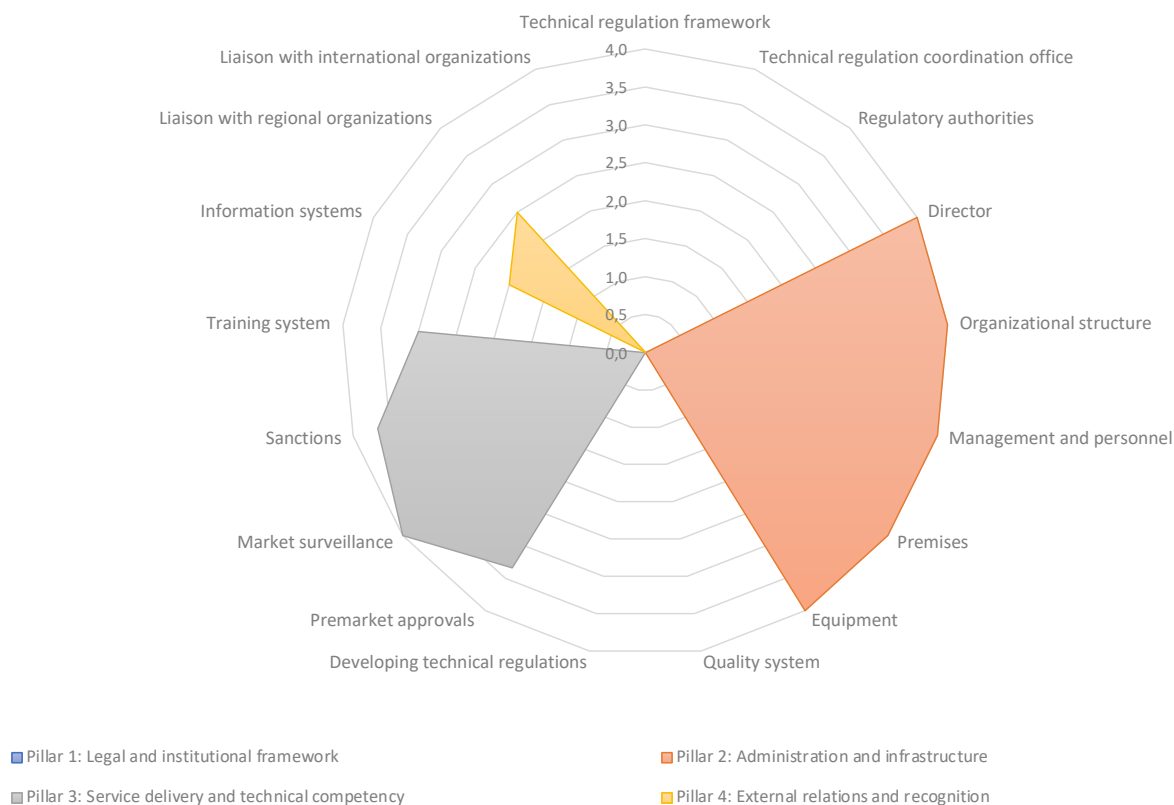


Diagram 8: Technical regulations

ii. Food and Drug Control Laboratory

The Food and Drug Control Laboratory previously operated under a 1972 act of Parliament to provide for public health through the sale and use of safe foods and cosmetics. In 2019, the act was repealed and replaced with the Food Safety Act No. 7 of 2019, which provides for the protection of the public against health hazards and fraud in the manufacture, sale and use of food.

The laboratory, which is attached to the Ministry of Health, provides general food and water testing services for other Government departments and agencies, the private sector and individuals through its units for Food Microbiology, Food Chemistry, Water Chemistry, and Toxicology (drug screening).

Its service provision is guided by the current Health Sector Strategic Plan (2017–2021), and it will also implement the 2022–2026 Strategic Plan. Government grants cover 50% of its operational needs, while 20% is covered by revenue generated from services for private sector clients. These figures indicate a shortfall that impairs the laboratory’s financial sustainability.

The laboratory is implementing the ISO/IEC 17025:2017 standard and none of its services are accredited. However, it participates in proficiency testing (PT) schemes in the EAC with the Kenya Bureau of Standards (KEBS) and with the Botswana Bureau of Standards (BOBS) in the SADC. Participation in PT schemes helps laboratories to compare their performance and the accuracy and quality of their test results with peers in a particular testing area.

This provides some assurance to clients and is taken into consideration during assessments by accreditation bodies, which is an advantage. While it is not formally designated to provide services in other regulated areas, the laboratory does provide services on an as-needed basis to the pharmaceuticals sector. It is a corporate member of the Zambia National Laboratory Association and actively participates in the relevant technical committees of ZABS. It further sees a need to also reach out to ZCSA and to participate in its relevant technical committees as well.



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	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
Testing services strategy	0.0			
Designated test laboratories	0.0			
Test laboratories for export market	0.0			
Test laboratories for the health sector	0.0			
Legal entity	4.0			
Governance	0.0			
Testing services scope	0.0			
Financial sustainability	2.0			
Top management		4.0		
Organizational structure		4.0		
Management and personnel		3.3		
Premises		1.8		
Equipment		2.3		
Quality management system documentation			3.0	
Proficiency testing			2.0	
Preassessment for accreditation			0.0	
Initial assessment for accreditation			0.0	
Accreditation			0.0	
Recognition at national level				0.0
Recognition at international level				0.0
Coordination within the QI				2.0

Figure 9: Testing

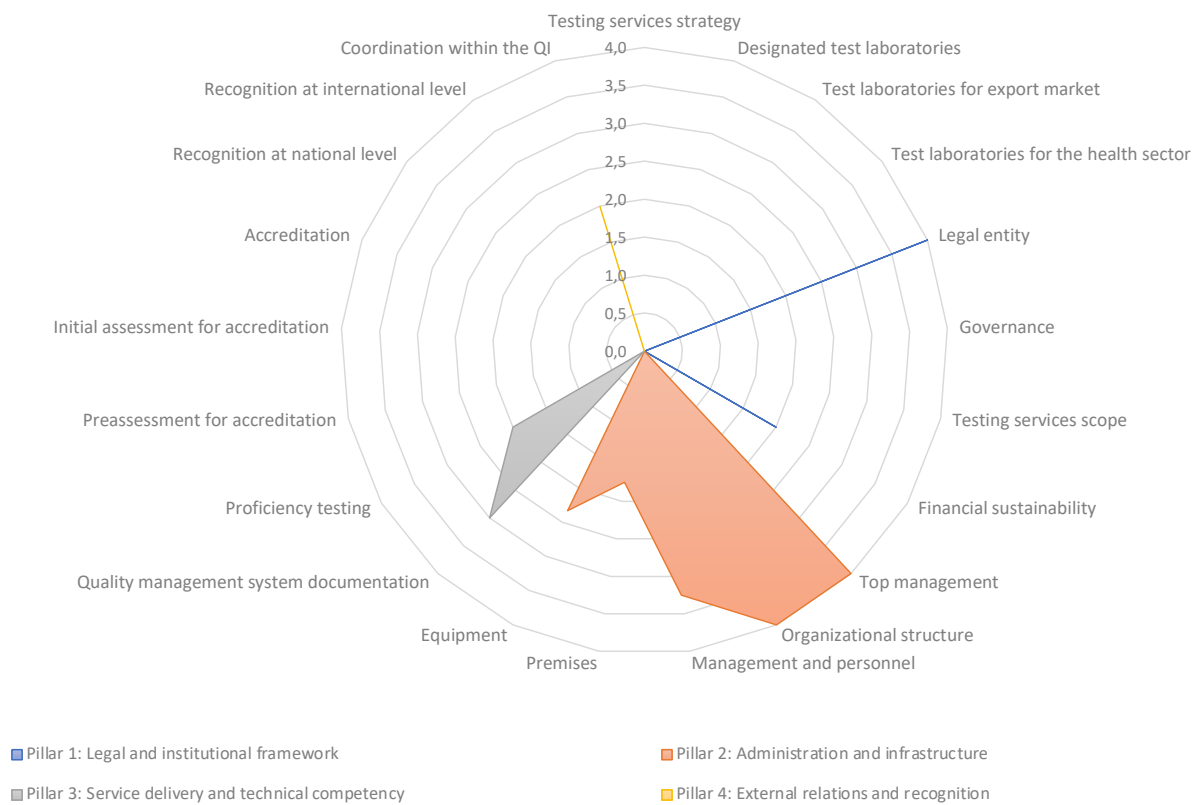


Diagram 9: Testing

iii. National Water Supply and Sanitation Council

The National Water and Sanitation Council (NWASCO) was established by the Water Supply and Sanitation Act No. 28 of 1997 as the regulator of water and sanitation services. Its mandate covers overseeing policy direction, providing advice to government and local authorities on water supply and sanitation matters, issuing licenses, formulating guidelines, and enforcing water and sanitation standards. The council’s largest department is the Inspectorate, which includes part-time inspectors to complement the full-time inspection staff. It does not have a dedicated laboratory. Its establishing act is currently under review and no timeline was given for the review’s completion.



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	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
Technical regulation framework	0.0			
Technical regulation coordination office	0.0			
Regulatory authorities	0.0			
Director		0.0		
Organizational structure		0.0		
Management and personnel		0.0		
Premises		1.7		
Equipment		2.0		
Quality system		0.0		
Developing technical regulations			0.0	
Premarket approvals			0.0	
Market surveillance			0.0	
Sanctions			2.0	
Training system			3.5	
Information systems				0.0
Liaison with regional organizations				0.0
Liaison with international organizations				0.0

Figure 10: Technical regulations

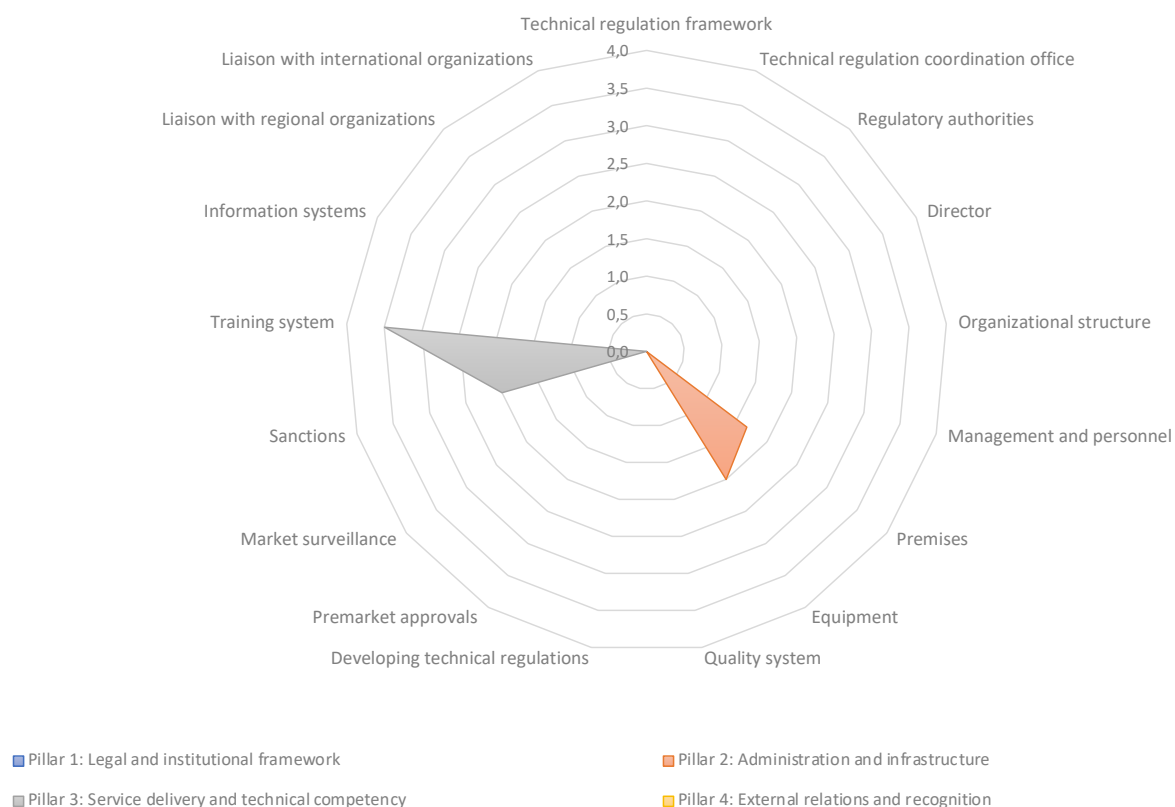


Diagram 10: Technical regulations

iv. Nchanga North General Hospital

The Nchanga North General Hospital is a public hospital categorized as a Level 2 hospital and governed by the Ministry of Health. It has a medical laboratory accredited by SADCAS to ISO 15189:2012 for several test methods and it runs a high-cost unit that provides services on a commercial basis, which is an advantage for its operations and depicted strengths in the pillars of *Administration and infrastructure* and *Service delivery and technical competency*, as shown in the radar diagram below.

The hospital is a coordinator for interlaboratory comparison schemes for hospitals in the country. It is a member of the National Laboratory Association as well as a member of the Biomedical Society of Zambia.

	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
Testing services strategy	0.0			
Designated test laboratories	0.0			
Test laboratories for export market	0.0			
Test laboratories for the health sector	0.0			
Legal entity	0.0			
Governance	0.0			
Testing services scope	0.0			
Financial sustainability	1.0			
Top management		4.0		
Organizational structure		4.0		
Management and personnel		2.5		
Premises		2.0		
Equipment		4.0		
Quality management system documentation			4.0	
Proficiency testing			3.5	
Preassessment for accreditation			2.0	
Initial assessment for accreditation			2.0	
Accreditation			2.7	
Recognition at national level				2.0
Recognition at international level				2.0
Coordination within the QI				2.5

Figure 11: Testing

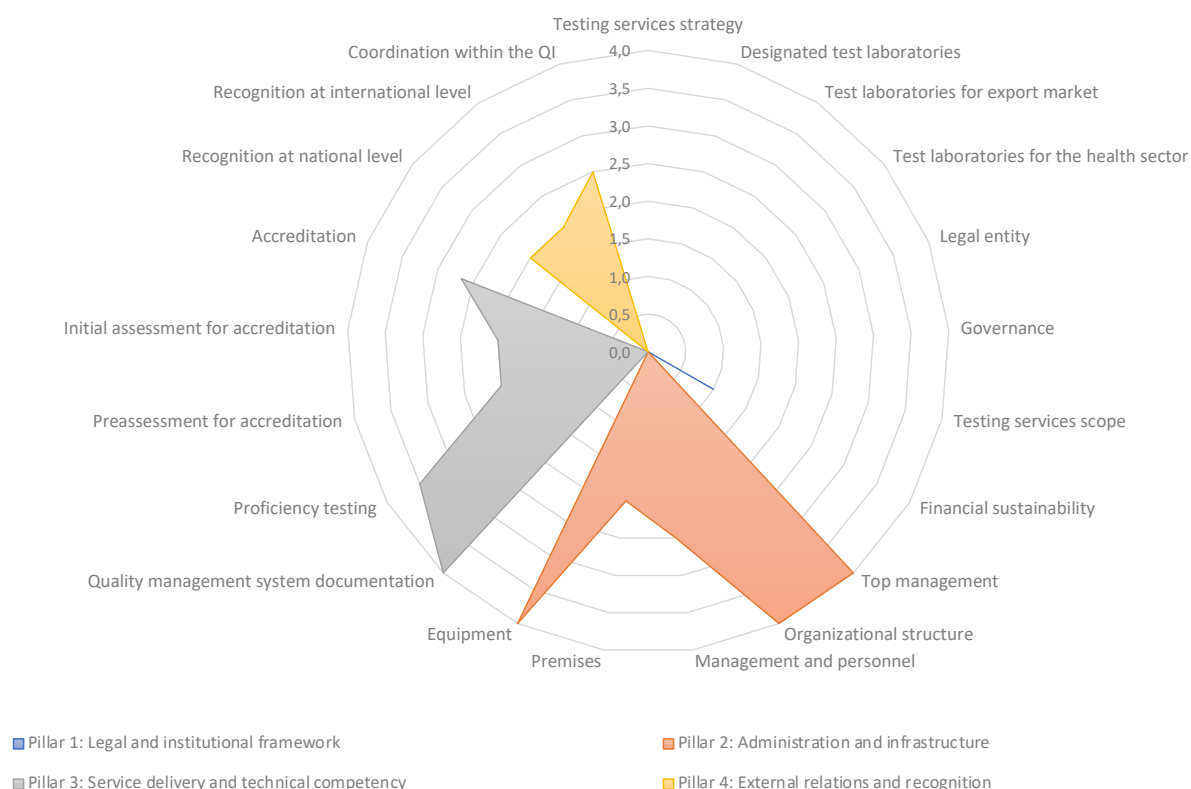


Diagram 11: Testing

v. Tropical Diseases Research Centre

The Tropical Diseases Research Centre is part of Zambia's testing laboratories sector under the research portfolio of the Ministry of Health. It is a key health research institution established through a 1981 act of Parliament, which is currently under review. It is governed by a board of directors and provides its services to both the public and private sectors. The centre has been designated by the Ministry of Health for Covid, HIV, malaria and TB testing, and four of its laboratories are accredited by SADCAS to ISO 15189:2012. It is financed partly through government grants and charges fees for some of its services (e.g., training and some testing), which assists its operations and is hence an advantage that is reflected as strengths in the radar diagram below and which should be maintained. The centre and some individual members of staff are members of the Zambia National Laboratory Association, and it collaborates widely with other institutions both inside and outside the country.



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	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
Testing services strategy	0.0			
Designated test laboratories	0.0			
Test laboratories for export market	0.0			
Test laboratories for the health sector	0.0			
Legal entity	4.0			
Governance	4.0			
Testing services scope	4.0			
Financial sustainability	3.7			
Top management		3.0		
Organizational structure		4.0		
Management and personnel		3.3		
Premises		2.3		
Equipment		3.3		
Quality management system documentation			4.0	
Proficiency testing			3.5	
Preassessment for accreditation			0.0	
Initial assessment for accreditation			0.0	
Accreditation			3.0	
Recognition at national level				3.0
Recognition at international level				1.0
Coordination within the QI				2.5

Figure 12: Testing

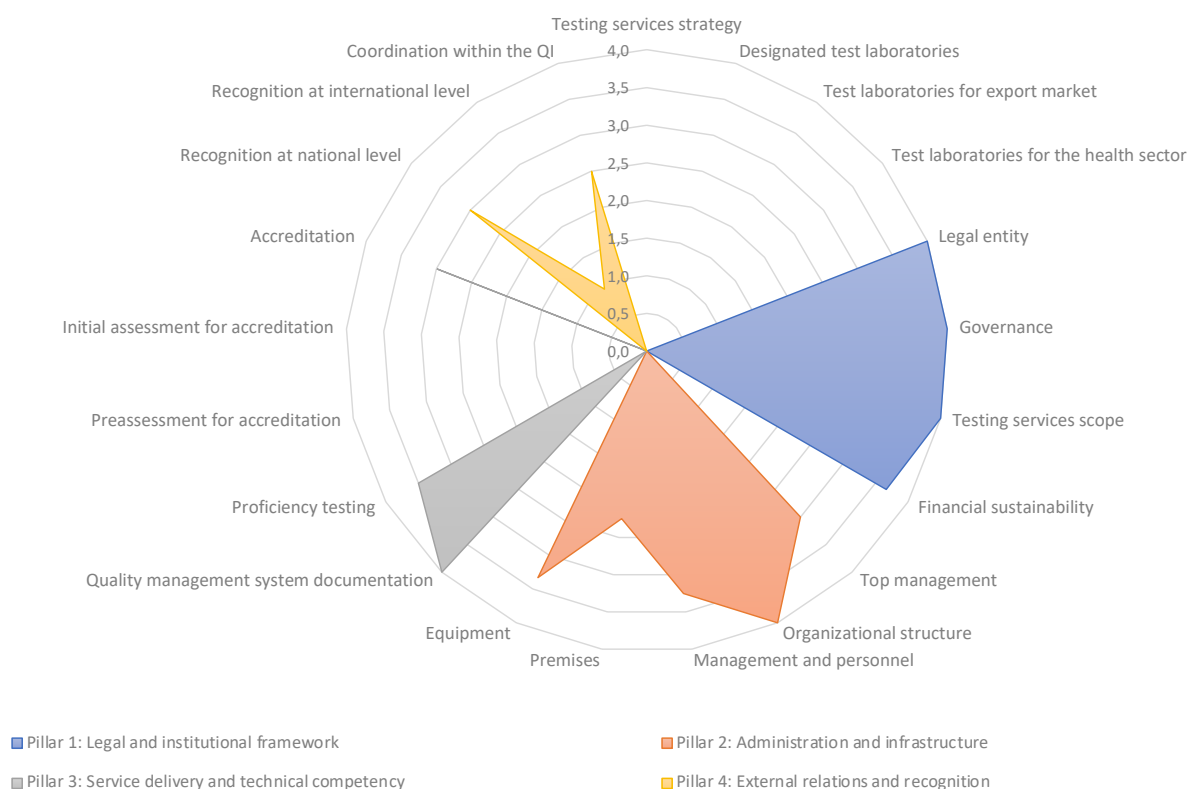


Diagram 12: Testing

vi. Zambia Environmental Management Agency

The Zambia Environmental Management Agency was established through the Environmental Act No.12 of 2011. Its mandate is to regulate matters in the areas of environmental management (sustainability assessment, education and awareness), and pollution control and prevention (air, water, emissions). The scope of regulations implemented by the agency are those requiring licensing based on national, regional and international standards as appropriate. When regulations are drafted, extensive stakeholder consultations are carried out in accordance with the guidelines of the Business Regulatory Agency. The Zambia Environmental Management Agency conducts inspection services and issues the relevant licenses/permits for imports/discharge. It operates from two regional offices in the north and south of the country. It is currently in the process of establishing a laboratory to serve in implementing its mandate; no timeline was given for completion.



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	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
Inspection services strategy	0.0			
Designated inspection bodies	0.0			
National inspection bodies for the regional markets	0.0			
Legal entity	4.0			
Impartiality and independence	2.5			
Financial sustainability	0.7			
Top management		4.0		
Organizational structure		2.7		
Management and personnel		2.8		
Premises		1.3		
Equipment		3.3		
Inspection scheme(s) scopes			2.7	
Quality management system			1.0	
Accreditation			1.0	
Inspection process			3.0	
Selection and training of inspectors			2.0	
Recognition at national level				2.0
Coordination within the QI				0.5

Figure 13: Inspection

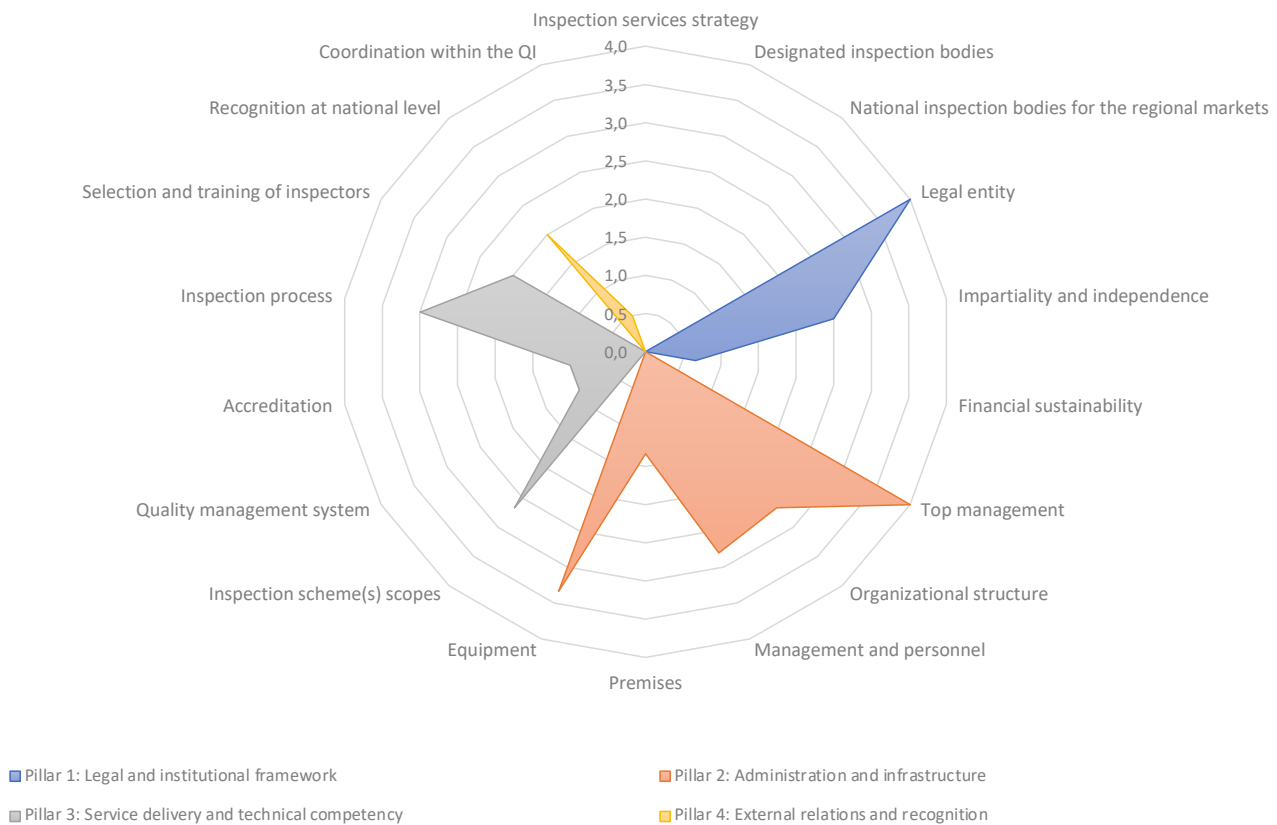


Diagram 13: Inspection

vii. Zambia Information and Communication Technology Authority

The Zambia Information and Communication Technology Authority was established through the Information and Communications Technology Act No.15 of 2019, which established the authority as a regulator for the development and implementation of technical regulations and for the issuing of licenses in the information and communication technology sector. This work also serves to support consumer protection and ensures universal access to bridge the digital divide. The authority has a memorandum of understanding with ZABS, participates in the relevant ZABS technical committees and has a partnership with the customs administration on type approval matters.



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	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
Technical regulation framework	0.3			
Technical regulation coordination office	0.0			
Regulatory authorities	3.0			
Director		4.0		
Organizational structure		3.0		
Management and personnel		3.5		
Premises		2.7		
Equipment		1.3		
Quality system		0.0		
Developing technical regulations			0.0	
Premarket approvals			3.3	
Market surveillance			3.5	
Sanctions			2.7	
Training system			3.5	
Information systems				1.5
Liaison with regional organizations				3.0
Liaison with international organizations				1.1

Figure 14: Technical regulations

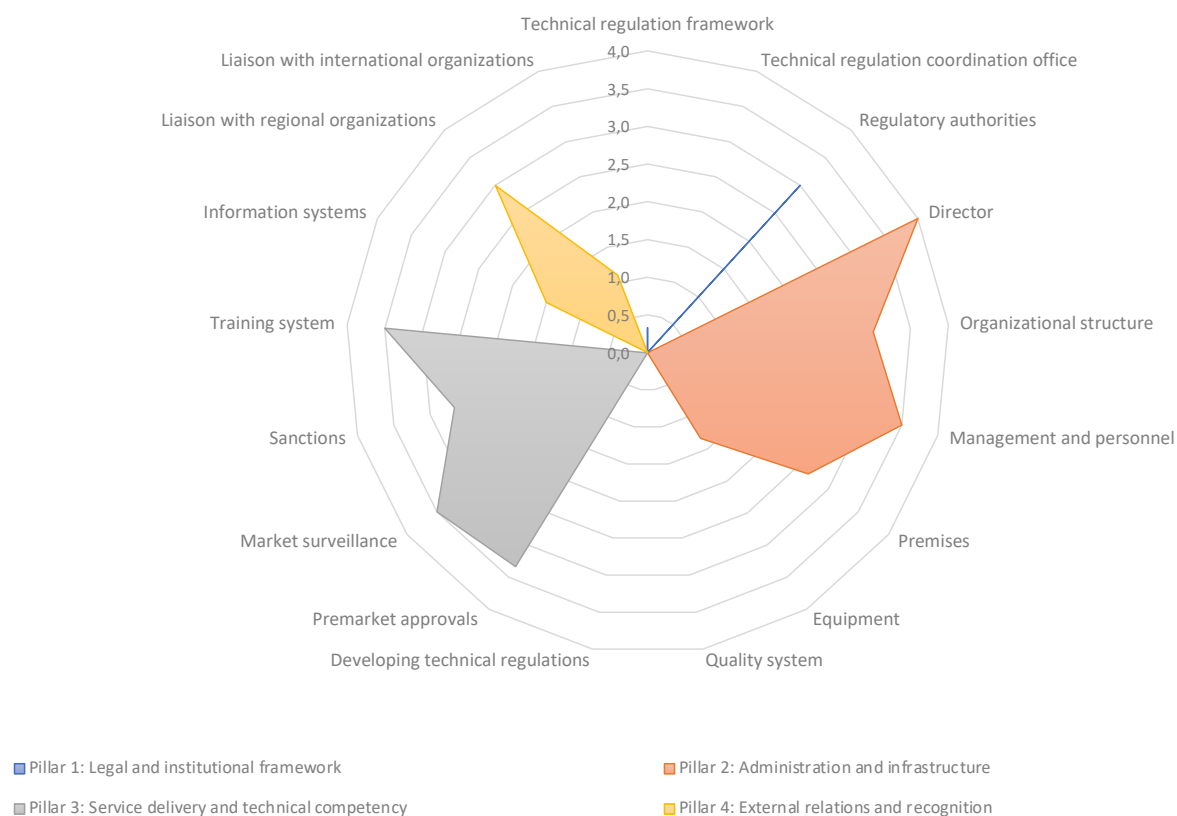


Diagram 14: Technical regulations

viii. Zambia Medicines Regulatory Authority

The Zambia Medicines Regulatory Authority was established by the Medicines and Allied Substances Act No. 3 of 2013. Its mandate is to protect human health through the control of the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances. It is a semi-autonomous organization governed by a board appointed by the Minister of Health. Its operations are run by the three directorates of Laboratory Services, Corporate Services and Medicines Control. The regulator bases its work on national and World Health Organization standards and guidelines. It participates in the relevant ZABS technical committees and uses the ZMA's calibration services to calibrate its laboratory equipment. All of these activities benefit the QI system and strengthen the institutions with respect to *Service delivery and technical competency*, as shown in the radar diagram below.



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	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical competency	Pillar 4: External relations and recognition
Technical regulation framework	1.3			
Technical regulation coordination office	2.5			
Regulatory authorities	1.3			
Director		4.0		
Organizational structure		3.0		
Management and personnel		3.5		
Premises		3.3		
Equipment		4.0		
Quality system		2.5		
Developing technical regulations			0.0	
Premarket approvals			4.0	
Market surveillance			3.0	
Sanctions			4.0	
Training system			3.0	
Information systems				3.0
Liaison with regional organizations				2.5
Liaison with international organizations				0.0

Figure 15: Technical regulations

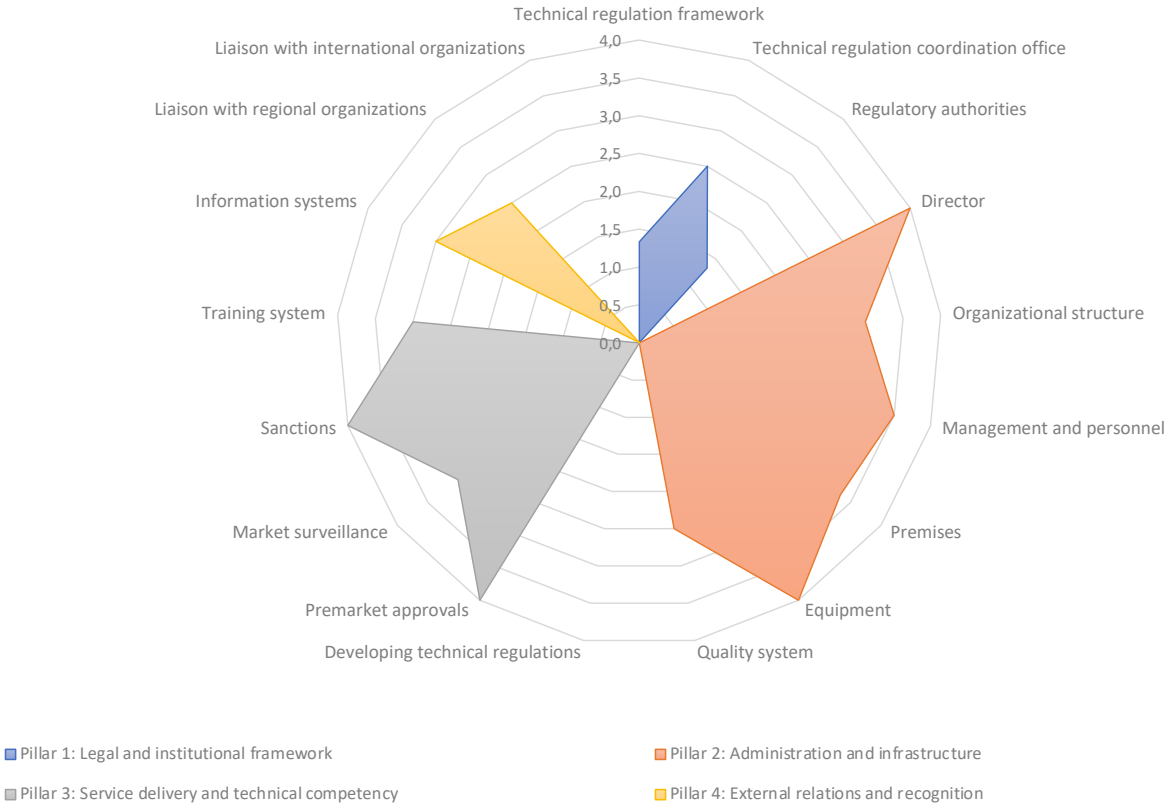
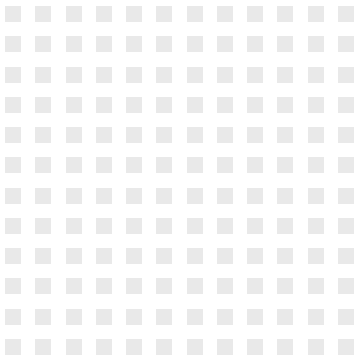


Diagram 15: Technical regulations



5. QI Stakeholders

Other relevant and important QI stakeholders include the Business Regulatory Review Agency (BRRA), which was established through Act No.3 of 2014, and the Competition and Consumer Protection Commission (CCPC), established through Act No.24 of 2010. In addition, there is the National Laboratory Association of Zambia, the Quality Management Association and the Zambia Consumers Association, as well as CABs in the private sector. Of these, however, it was only possible to secure an interview with the National Laboratory Association of Zambia.

5.1. Zambia National Laboratory Association

The Zambia National Laboratory Association (ZNLA) is an important part of the country's QI. It was registered with the Registrar of Societies as a legal entity in 2012 and has several categories of membership. Its objectives include fostering information exchange amongst its members, training and capacity building, and advocacy on matters of interest to improve the quality of its members' conformity assessment work. It is a member of the SADC Regional Laboratory Association.

6. Conclusions

The National Quality Policy of 2010 sets a good foundation for a well-organized NQI governed by new legislation for the main QI institutions. Aligned to international good practices, this legislation was passed in 2017 and its implementation began in 2018.

What has lagged, however, is a robust implementation strategy backed up by adequate resourcing of the established institutions in terms of personnel and infrastructure (mainly equipment). Consequently, some provisions in the enacted legislation have not yet been implemented. These include a governance issue concerning the appointment of a board of directors for the Zambia Metrology Agency, extending the fields of metrology to include ionization radiation and flow, development of the required regulations to implement the remaining legal metrology aspects, and the development of a mechanism to designate other standards development organizations for specific scopes of activity under the ZABS Act. However, the implementation of further provisions must always be done in consideration of the need and priority of ensuring that the QI should be demand-driven in line with socio-economic needs.

The current policy also fails to clearly articulate the role(s) of CABs in the private sector.

The procedures for coordinating between the QI institutions and the technical regulation framework, including the particular roles and responsibilities of the Department of Technical Regulation and its relationship with regulators other than those in the Ministry of Commerce, Industry and Trade, as well as its relationship with the Business Regulatory Review Agency, is not clear to stakeholders, as was indicated during the interviews, especially those conducted with certain regulators.

The lack of a robust communication strategy that provides role clarity among the QI and technical regulation institutions while fostering awareness of and promoting a public culture of quality is evidenced by the fact that most of the stakeholders interviewed did not have strong stakeholder engagement programmes.

7. Recommendations

7.1. National Quality Policy

Issue: Implementation of the National Quality Policy has been ongoing for about ten years now, and a review period of ten years, or on an as-needed basis, was established in the National Quality Policy of 2010. The lessons learned during this implementation period have highlighted both positive and negative experiences.

Recommendation: *It is time for the Government of the Republic of Zambia, spearheaded by the Ministry of Commerce, Trade and Industry, to review the policy. This review should be done in consultation with the relevant stakeholders in both the public and private sectors to infuse and update the policy by including clearly defined roles for the QI institutions that take account of national, regional and international developments in the QI arena, and by aligning the policy to the country's trade agreements and other policy objectives. It is also opportune for the review to be guided by the African Quality Policy adopted by the African Union in September 2021. Further, the review should be supported with a robust and comprehensive implementation strategy, which should include aspects of publicity, awareness creation, SMME support, and the development and promotion of a quality culture among the general public. This should be resourced and financed accordingly (human resources, infrastructure, etc.) as financial sustainability is a cross-cutting challenge that was emphasized during the stakeholder interviews.*

7.2. QI Legislation

Issue: Several pieces of legislation were put in place in 2017 as a result of the implementation of the National Quality Policy of 2010. These established a number of main QI institutions by splitting and hiving off the enforcement of compulsory standards and metrology functions from ZABS. The institutions established include:

- ZCSA through Act No. 3 of 2017
- ZMA through Act No. 6 of 2017

Legislation to establish the Zambia Accreditation Agency is at the bill stage and CAP 416 of the laws of Zambia was repealed and replaced by the Standards Act No.4 of 2017, which legislated the new functions of standards development, testing and certification for ZABS. The Department of Technical Regulation was also set up in the Ministry of Commerce, Trade and Industry. Implementation of the new laws began in 2018, but not all provisions in all legislation have yet been operationalized and implemented (e.g., ZMA still does not have a governing board of directors and is not yet providing some metrology services required in the economy, including ionization radiation and flow and some legal metrology topics such as speed limit enforcement). The Department of Technical Regulation has also not yet been resourced with its own staff for instituting effective coordination of the technical regulation framework. Further, the Zambia Bureau of Standards has not yet developed a mechanism for the recognition of other standards development organizations for specific scopes of activity.

Recommendation: *The pieces of legislation enacted in 2017 and implemented since 2018 should be fully implemented, and any reviews deemed necessary to align them to international best practice should be introduced gradually. The introduction of reviews should be based on lessons learned during implementation since 2018 and take account of national socio-economic development and programme demands, as well as of QI developments seen at both the regional and international levels.*

7.3. Coordination of QI Institutions

Issue: The QI elements are interrelated and require seamless coordination, guarding against any duplication of roles and responsibilities between the various QI institutions and bodies while meeting the country's obligations under the WTO and other trade agreements. From the interviews conducted, some regulators were not aware of the existence and/or coordinating role of the Department of Technical Regulation and its relationship with the Business Regulatory Review Agency (BRRA). The BRRA's objectives include ensuring that regulatory bodies discharge their functions effectively, efficiently and in a coordinated manner.

Recommendation: *The established NQI coordinating department should therefore be strengthened to become effective and adequately resourced. The roles and responsibilities of both the Department of Technical Regulation and the BRRA should be clearly defined, communicated and articulated to the QI institutions, the regulatory bodies, the private sector and the public at large.*

7.4. Communication

Issue: The lack of a robust communication strategy that provides role clarity among the QI and technical regulation institutions while fostering a general awareness of the importance of a public culture of quality and the associated capacity building, including in the SMME sector.

Recommendation: *The development and implementation of a robust communication strategy, including the promotion of a public culture of quality as part of the implementation of the NQP.*



8. References

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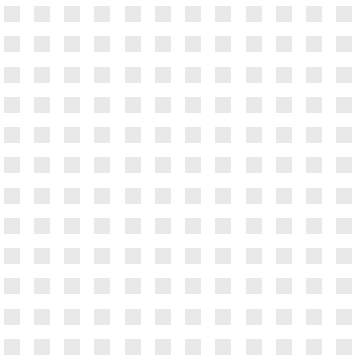
Zambia Vision 2030



9. Annexes

9.1. List of Interviewed Stakeholders

2021-03-23	Zambia Bureau of Standards
2021-03-23	Zambia Metrology Agency (Scientific/Industrial Metrology)
2021-03-24	Department of Technical Regulation
2021-03-24	Energy Regulation Board
2021-03-24	Department of Technical Regulation
2021-03-24	Nchanga North General Hospital
2021-03-25	Tropical Disease Research Centre
2021-03-25	Food and Drug Control Laboratory
2021-03-26	Zambia Environmental Management Agency
2021-03-26	Zambia Information and Communication Technology Authority
2021-03-29	Zambia Medicines Regulatory Authority
2021-03-29	Zambia National Laboratory Association
2021-03-31	Zambia Compulsory Standards Agency
2021-04-06	Zambia Accreditation Service (NAFP)
2021-04-26	National Water and Sanitation Council
2021-05-13	Zambia Metrology Agency (Legal Metrology)



Abbreviations

AfCFTA	African Continental Free Trade Area
AFRIMETS	African Metrology System
AFSEC	African Electrotechnical Standardization Commission
ARSO	African Organization for Standardization
BIPM	Bureau International des Poids et Mesures
BOBS	Botswana Bureau of Standards
BRRA	Business Regulatory Review Agency
CABs	Conformity assessment bodies
CCPC	Competition and Consumer Protection Commission
CMCs	Calibration and measurement capabilities
COMESA	Common Market for Eastern and Southern Africa
ERB	Energy Regulation Board
EU	European Union
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
KCDB	Key Comparison Database
KEBS	Kenya Bureau of Standards
MCTI	Ministry of Commerce, Trade and Industry
NAFP	National Accreditation Focal Point
NMISA	National Metrology Institute of South Africa
NQI	National quality infrastructure
NQP	National quality policy
NSI	Namibia Standards Institute
NWASCO	National Water and Sanitation Council
OIML	Organization Internationale de Metrologie Legale
PAQI	Pan-African Quality Infrastructure
PTB	Physikalisch-Technische Bundesanstalt
QI	Quality infrastructure
RDT	Rapid Diagnostic Toolkit
RERA	Regulators Association of Southern Africa
SADC	Southern African Development Community
SADCAS	SADC Accreditation Service
SADCMEL	SADC Cooperation in Legal Metrology
SADCMET	SADC Cooperation in Measurement Traceability
SADCSTAN	SADC Cooperation in Standardization
SADCTRLC	SADC Technical Regulation Liaison Committee
SDOs	Standards development organizations
SMCAA	Standards Metrology and Conformity Assessment (COMESA Committee)
SMMEs	Small, medium and micro enterprises
ZABS	Zambia Bureau of Standards
ZCSA	Zambia Compulsory Standards Agency
ZMA	Zambia Metrology Agency

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