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ASSESSMENT OF **MALAYSIA'S** NATIONAL QUALITY INFRASTRUCTURE

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ACRONYMS AND ABBREVIATIONS

4IR	Fourth Industrial Revolution
AB	Accreditation Body
ACCSQ	ASEAN Consultative Committee on Standards and Quality
ACCSQ-WG3	ASEAN Consultative Committee on Standards and Quality – Working Group on Legal Metrology
AMS	ASEAN member states
APAC	Asia Pacific Accreditation Cooperation
APEC	Asia-Pacific Economic Cooperation
APLAC	Asia Pacific Laboratory Accreditation Cooperation
APLMF	Asia-Pacific Legal Metrology Forum
APMP	Asia Pacific Metrology Programme
ARISE	ASEAN Regional Integration Support by the European Union
ASEAN	Association of Southeast Asian Nations
AUV	Acoustics, Ultrasound, Vibration
BIPM	International Bureau of Weights and Measures
CAB	Conformity Assessment Body
CB	Certification Body
CC	Consultative Committee
CEO	Chief Executive Officer
CGPM	General Conference of Weights and Measures
CIPM	International Committee of Weights and Measures
CMA	Communications and Multimedia Act
CMC	Calibration and Measurement Capability
COVID-19	Coronavirus Disease 2019
CRM	Certified Reference Material

CT	Consultancy Team
DE	Development Expenses
DI	Designated Institute
DMSB	De Metrology Sdn. Bhd.
DRN	Digital Regulatory Notification
E&E	Electrical and Electronics
ECI	Economic Complexity Index
EM	Electricity and Magnetism
EMS	Environmental Management System
EN	European Standards (from the German name Europäische Norm)
EU	European Union
FSQD	Food Safety and Quality Division
FSQP	Food Safety and Quality Programme
GDP	Gross Domestic Product
GLP	Good Laboratory Practice
GPQI	Global Project Quality Infrastructure
GQII	Global Quality Infrastructure Index
GRP	Good Regulatory Practice
GSP	Good Standardisation Practice
HACCP	Hazard Analysis and Critical Control Point
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
INetQI	International Network on Quality Infrastructure
IQM	Institute of Quality Malaysia

IR	Ionizing Radiation
ISMS	Information Security Management Systems
ISO	International Organisation for Standardisation
ITC	International Trade Centre
JICA	Japan International Cooperation Agency
JSM	Department of Standards Malaysia
KCDB	BIPM Key Comparison Database
KPI	Key Performance Indicators
L	Length
LKTN	National Kenaf and Tobacco Board
M	Mass and Related Quantities
MCM	Metrology Corporation Malaysia Sdn. Bhd.
MCMC	Malaysian Communications and Multimedia Commission
MCO	Movement Control Order
MDTCA	Ministry of Domestic Trade and Consumer Affairs
MIBAS	Malaysia Inspection Bodies Accreditation Scheme
MITI	Ministry of Investment, Trade and Industry
MOH	Ministry of Health
MOSTI	Ministry of Science, Technology and Innovation
MP12	Twelfth Malaysia Plan
MPAC	Masterplan on ASEAN Connectivity
MPB	Malaysia Productivity Blueprint
MPB	Malaysian Pepper Board
MPC	Malaysia Productivity Corporation
MPK	<i>Majlis Pengukuran Kebangsaan</i> (National Measurement Council)

MRA	Mutual Recognition Arrangement
MRB	Malaysian Rubber Board
MSAC	Malaysian Standards and Accreditation Council
MSME	Micro, Small and Medium Enterprise
MSTQ	Metrology, Standards, Testing and Quality
MTIB	Malaysian Timber Industry Board
MTSFB	Malaysia Technical Standards Forum Bhd
MyIPO	Intellectual Property Corporation of Malaysia
NAB	National Accreditation Body
NAC	National Accreditation Committee
NCSLI	National Conference of Standards Laboratories International
NEM	New Economic Model
NEP	New Economic Policy
NIC	Newly Industrialised Country
NISIR	National Institute for Scientific and Industrial Research
NMI	National Metrology Institute
NMIM	National Metrology Institute of Malaysia
NML	National Metrology Laboratory
NMSL	National Measurement Standards Laboratory
NPDIR	National Policy for Development and Implementation of Regulations
NPGRP	National Policy for Good Regulatory Practice
NQI	National Quality Infrastructure
NQP	National Quality Policy
NSB	National Standards Body
NSC	National Standards Council

ODA	Official Development Assistance
OECD	Organisation for Economic Co-operation and Development
OIML	International Organisation of Legal Metrology
OSH MS	Occupational Safety and Health Management Systems
PAC-MLA	Pacific Accreditation Cooperation Multilateral Accreditation Arrangement
PASC	Pacific Area Standards Congress
PCB	Product Certification Body
PEMUDAH	Special Task Force to Facilitate Business
PMAM	Persatuan Makmal Akreditasi Malaysia
PR	Photometry and Radiometry
PSC	Project Steering Committee
PT	Project Team
PT	Proficiency Testing
PTB	Physikalisch-Technische Bundesanstalt (German National Metrology Institute)
QI	Quality Infrastructure
QIS	Quality Infrastructure System
QM	Chemistry and Biology
QMS	Quality Management System
R&D&C&I	Research and Development, and Commercialisation and Innovation
RDT	Rapid Diagnostic Tool
RIA	Regulatory Impact Analysis
RIS	Regulatory Impact Statements
RMO	Regional Metrology Organisation
RMP	Royal Malaysia Police
RQI	Regional Quality Infrastructure

RQI	Regional Quality Infrastructure
RQP	Regional Quality Policy
RURB	Reducing unnecessary regulatory burdens
SAMM	Skim Akreditasi Makmal Malaysia
SC	Steering Committee
SDG	Sustainable Development Goal
SDO	Standards Development Organisation
SI	International System of Units
SIM	Standards Institute of Malaysia
SIRIM	Standards and Industrial Research Institute of Malaysia
SME	Small and Medium Enterprises
SMIIC	Standards and Metrology Institute for Islamic Countries
SOP	Standard Operating Procedure
SPS	Sanitary and Phytosanitary Measures
SQAM	Standards, Quality Assurance, Accreditation and Metrology
SQASI	SIRIM QAS International Sdn. Bhd.
STEM	Science, Technology, Engineering, and Mathematics
STRACAP	Standards, Technical Regulations, and Conformity Assessment Procedures
T	Thermometry
TAT	Turn Around Time
TBT	Technical Barriers to Trade
TC	Technical Committee
TF	Time and Frequency
TIC	Testing, Inspection and Certification
TMB	Technical Management Board

TOR	Terms of Reference
ToT	Training of Trainers
TSR	Technical Standards Regulations
UNIDO	United Nations Industrial Development Organisation
UPC	Unified Public Consultation
VIM	International Vocabulary on Metrology
WHO	World Health Organisation
WKB	Shared Prosperity Vision
WTO	World Trade Organisation

EXECUTIVE SUMMARY

The International Network on Quality Infrastructure, recently defined Quality Infrastructure (QI) as: *“the system comprising the organisations (public and private), policies, relevant legal and regulatory frameworks and practices required to support and improve the quality, safety and environmental performance of goods, services and processes. It is a critical element in promoting and sustaining economic development and environmental and social well-being.*

It is based on metrology, standardisation, accreditation, conformity assessment and market surveillance (in regulated areas).” (INetQI, 2022)

Malaysia began building the foundation of its Quality Infrastructure System (QIS) in 1964, shortly after its independence in 1957. Since then, QI in Malaysia has organically developed as demand grew, without following a formally defined Quality Policy (QP) or being systematically studied to determine its effectiveness or the deficiencies that need attention. Given the vital role QI plays in international trade and development, reviewing Malaysia’s QIS and taking the necessary steps to close gaps is urgently required, primarily since the country aims to reach high-income status by 2024 (World Bank, 2021b).

Against this backdrop, one of the objectives of the ARISE Plus Malaysia project is to further develop Malaysia’s QIS. The European Union (EU) funded the project, while the International Trade Centre (ITC) implemented it in collaboration with the Ministry of International Trade and Industry (MITI). The project aims to align Malaysia’s QIS with ASEAN and EU standards. One of the activities under this project objective is the development of a draft National Quality Policy (NQP). To this end, the ITC has appointed a team of consultants to support Malaysia in realising this objective.

This report is the outcome of the first phase of the consultancy, which assesses Malaysia’s QIS and sets the stage for developing the draft NQP. The assessment uses qualitative and quantitative methods in collaboration with three committees – the Project Team, the Technical Committee, and the Steering Committee – each with an additional layer of authority. The consultants began with desk research by sourcing and studying all available documents on Malaysia’s QIS, regulatory framework, and economy, including legislations, annual reports, and strategic plans. This was supplemented with questions submitted to

relevant stakeholders for feedback and interviews where necessary. In addition, the consultants used the Rapid Diagnostic Tool (RDT), developed by the World Bank and the Physikalisch-Technische Bundesanstalt (PTB), to interview QI service providers systematically. This gave the consultants a bird's-eye view of the supply side of Malaysia's QIS. To understand the demand side of the QIS, the consultants conducted a qualitative enterprise survey with 420 firms across all economic sectors in Malaysia.

The findings revealed that Malaysia's QIS is reasonably advanced for an economy of its size, despite its unco-ordinated development. In 2020, Malaysia ranked 40th out of 184 countries in the Global Quality Infrastructure Index (GQII), with an overall score of 86.3%. Concerning standards, the country ranked 21st out of 184 countries. Department of Standards Malaysia (Jabatan Standard Malaysia or JSM) serves as the country's National Standards Body (NSB) and, as of April 2022, has developed approximately 4,844 standards covering 26 sectors, 46.39 % of which have been aligned with international standards (Department of Standards Malaysia, 2022d). The Malaysia Standards (MS) development process follows Good Standardisation Practice (GSP) principles, which are essential for the efficient and effective operation of NSBs (Kellermann, 2019c).

Malaysia, through JSM, is represented and actively participates in several regional and international standardisation organisations. The results of the standards section of RDT showed that Malaysia performed well in most areas. The main shortcomings were related to the legislation, which is not up to date; regulators not consistently referring to MS when regulating; the organisation and co-ordination of technical committees, the World Trade Organisation (WTO) Technical Barriers to Trade (TBT) Enquiry Point, and Standards Development Organisations (SDO); and the accessibility of standards. Nevertheless, JSM has been working towards tackling these issues, some of which are addressed in its Business Plan and Strategic Plan for the period 2022 to 2025 and improving standardisation in Malaysia.

Malaysia is moderately advanced concerning technical regulations. There are 31 ministries and other government entities responsible for technical regulations. The RDT results showed that even though the country has a National Policy for Good Regulatory Practice (NPGRP), only 60% of the regulators confirm its availability and applicability. Additionally, most regulators comply with the NPGRP requirement to conduct a Regulatory Impact Assessment (RIA) when

developing or revising regulations. However, not all regulators publish draft regulations within a reasonable time or notify new technical regulations to other WTO members between the 60-day to six-month timespan between publication and entry into force.

Furthermore, organisational structure and allocation of premises vary among the regulators. In most cases, while the premises allow for suitable working conditions, storage space for inspection equipment and product sample is often missing. Moreover, according to prevailing International Organisation for Standardisation (ISO) standards, quality systems are hardly implemented and assessed or accredited. In addition, market surveillance systems based on risk assessment and the principle of proportionality are established by a few regulators only. In summary, more effort is required to improve certain areas of technical regulations in Malaysia.

Malaysia's metrological competence is commendable. According to the latest GQII data, the country ranked 37th out of 184 countries in metrology in 2020 (GQII, 2021). The NMIM serves as the National Metrology Institute (NMI) and is responsible for implementing Malaysia's metrology legislation, managing the legal units of the International System of Units (SI), sustaining the National Measurement System, and ensuring that the national infrastructure measurement system aligns with global standards and complies with the WTO TBT Agreement. The NMIM has already successfully developed six of the seven SI base units, missing only the mole (SI base unit of amount of substance), which is still in progress to create new primary methods. In addition, the NMIM and the Designated Institutes (DIs) across the country meet about 60% of the needs of Malaysian companies. Malaysia is represented, through the NMIM, in the major regional and international metrology organisations. Nevertheless, there is room for improvement in governance, financial stability and increasing competence concerning Certified Reference Materials (CRMs) and Calibration and Measurement Capabilities (CMCs).

The Ministry of Domestic Trade and Consumer Affairs (MDTCA) is responsible for legal metrology in Malaysia. Overall, legal metrology is relatively advanced. Malaysia is well-represented in regional and international legal metrology organisations and aligns its legal metrology strategy with their recommendations. Additionally, the legislation is up to date; and MDTCA has a high level of financial stability, adequately trained staff members and

appropriate premises. Nevertheless, there are areas for improvement, such as capacity building in market surveillance, particularly pre-packaging. More effort is needed to develop training courses for legal metrologists covering all relevant new instruments and technologies. Furthermore, greater co-ordination is required between MDTCA and NMIM to upgrade Malaysia's membership in the International Organisation of Legal Metrology (OIML).

JSM also serves as the country's National Accreditation Body (NAB). According to the latest GQII data, Malaysia ranked 50th out of 184 countries in accreditation in 2020. While accreditation is relatively well-developed in the country, some areas need attention. JSM is a signatory of the Mutual Recognition Arrangement of the International Accreditation Forum (IAF MLA), which allows their accreditations to be internationally recognised. Additionally, JSM covers most of the internationally recognised accreditation scopes and has accredited numerous certification bodies, laboratories, inspection bodies and conformity assessment bodies. However, the Standards of Malaysia Act 1996 was last updated in 2012 and requires a review. Additionally, greater co-ordination is needed between JSM, the NMIM and other relevant QI institutions to ensure no gaps or overlaps in service delivery or activities.

For conformity assessment (inspection, testing, product certification and system certification), Malaysia's performance ranges from moderate to good, according to the RDT assessment. There are about a thousand accredited Conformity Assessment Bodies (CABs) in Malaysia. In most cases, the CABs are financially stable and have adequate equipment and suitable premises. However, some attention is required regarding the accreditation of certification bodies. Because accreditation is voluntary, not all CBs delivering certification services are accredited by JSM or a foreign accreditation body. There are some deficiencies in the external relations and recognition of CABs. CABs are not all co-ordinated through associations in these areas, and technical regulation co-ordination offices only operate in a few technical domains, such as communication. Only accredited laboratories have an official platform to discuss and collaborate on various programme in enhancing testing services in Malaysia.

Quality promotion is another main component of a robust QIS. In Malaysia, awareness and information on QI are still in the infancy stage, with no overarching framework for disseminating a quality culture in Malaysia. There is minimum access to QI-related information on the leading QI organisations' websites and social media platforms. In addition, there are no leads or links on these websites and social media platforms for users seeking information on QI in Malaysia. Furthermore, the individual activities to inform companies and consumers about QI are fragmented.

Concerning the demand side of QI in Malaysia, the enterprise survey mainly revealed positive results. About 98% of enterprises refer to standards, showing that standards are prevalent in the Malaysian economy, especially for certification purposes. Additionally, an outstanding share, around 66.66% of enterprises get their products or systems certified. Furthermore, most enterprises (83%) assess conformity assessment services as relevant for developing their core business. Moreover, over 70% of users rate the availability and quality of conformity assessment services as excellent or good, and another quarter as still acceptable.

Nevertheless, some shortcomings were revealed in this area. Around 80% of surveyed companies face quality or quality assurance issues, of which compliance with technical regulations and voluntary standards are most prominent. Approximately 33.3% of companies would prefer to have further testing, certification, or calibration services available. Furthermore, 13% of enterprises were unaware of the requirement to comply with technical regulations before entering the domestic market, and 19% lacked information on market surveillance for their products or services.

The assessment results of Malaysia's QIS culminated in the development of blanket recommendations for the further advancement of QI in the country. The main recommendations include drafting a National Quality Policy for the country, revising relevant QI legislation, capacity building within the QI institutions on QI-related issues, increased co-ordination among the leading QI institutions and supporting both the territorial expansion and the expansion of QI services. In addition, developing an overall QI communication and quality promotion plan is also highly recommended to disseminate information about QI to all societal groups. Furthermore, more sensitisation sessions should be organised for policymakers on the Good Regulatory Practices in Malaysia and systematic QI service gap

assessments for key sectors of the economy should be undertaken. The recommendations are presented in this report in a generic and concise manner. Their purpose here is merely to answer the question, “What to do?” In the second phase of the project, these recommendations will be further elaborated to give a clearly defined response to the question “How to do it?” These recommendations will be detailed in the implementation plan, which will accompany the NQP.

I. INTRODUCTION

The ASEAN Regional Integration Support by the European Union (ARISE) Plus Malaysia supports inclusive and sustainable trade growth and poverty reduction in Malaysia while contributing to economic integration in the ASEAN region. The project is being implemented by the International Trade Centre (ITC) in collaboration with the Ministry of International Trade and Industry (MITI).

ARISE Plus Malaysia's second specific objective is to align the country's Quality Infrastructure (QI) system (including standardisation, accreditation, conformity assessment, and metrology) with ASEAN and EU standards and practices. Meeting this objective entails 1) developing a National Quality Policy (NQP) for Malaysia, 2) harmonising Malaysia's standards and technical regulations, and 3) strengthening the country's conformity assessment services to better demonstrate the compliance of its products and services with international standards.

ITC has appointed a consultancy team to work towards meeting the first target under this objective. To this end, the first activity is to assess Malaysia's National Quality Infrastructure (NQI) to support the development of an NQP, which is the objective of this report. This report provides a comprehensive analysis of Malaysia's NQI – it highlights the current situation with respect to the demand and supply of QI services, underscores the strengths and identifies gaps in the QI system and makes recommendations to strengthen Malaysia's NQI.

An NQP is a basic government instrument, adopted at the national level, that oversees the development and maintenance of an efficient and effective QI system. The final deliverable of this consultancy will be a document containing important foundational elements for developing a draft NQP. These elements include a common vision for Malaysia's NQI in five years and key actions and strategies to realise this vision.

Before developing a draft NQP, it is essential first to map and assess the current capabilities of Malaysia's NQI. The NQI is the system comprising the organisations (public and private), policies, relevant legal and regulatory frameworks, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services, and processes.

It relies on metrology, standardisation, accreditation, conformity assessment, and market surveillance.

An assessment of the NQI will highlight the key areas for improvement that will be addressed in a draft NQP, in addition to those gathered during consultations and exchanges with stakeholders and QI institutions, and service providers.

Robust government policy guidance is required to align the country's QI system with that of its main trading partners. This stimulates trade by improving the ability of goods producers and service providers in Malaysia to compete in global markets and participate in international value chains, which in turn promotes and sustains economic development, as well as environmental and social wellbeing.

It is therefore essential to raise awareness among policymakers, regulators, and the wider business community on the importance of quality infrastructure as an integral part of an enabling environment for effective participation in international trade. These efforts will help reinforce national and regional connectivity, in line with both the Masterplan on ASEAN Connectivity (MPAC) 2025, and the 2018 EU Strategy on Connecting Europe and Asia.

This initiative is important as the final project beneficiaries will be government agencies; regulators; business communities; and industries, including multinational corporations (MNCs) and micro, small, and medium-sized enterprises (MSMEs), such as producers, processors, collectors, traders, exporters, as well as women workers throughout and along the value chains of products. Additionally, it will play a crucial role in improving governance and policy, boosting productivity growth, and expanding export markets, which are all in line with the focus of the Twelfth Malaysia Plan 2021-2025, all aimed at rejuvenating the economy to restore the momentum of growth (*12MP*, 2021).

A. Why is a National Quality Infrastructure important?

The NQI contributes substantially to sustainable development through building prosperity and meeting the needs of people, while protecting the planet. The establishment of a robust NQI system, with all the necessary components (standardisation, metrology, accreditation,

conformity assessment, particularly testing, certification, inspection services, and market surveillance), stimulate industrial development, productivity, trade competitiveness and innovation. It increases market efficiency by offering quality assurance services and helping to eliminate restrictive regulations. NQI equips companies with the necessary knowledge and tools to meet international standards, which facilitates their access to foreign markets. Hence, in the case of Malaysia, upgrading the NQI will lead to more opportunities to export and diversify Malaysian products, attract investments, become embedded in global value chains, and earn foreign currency.

Furthermore, NQI plays an essential role in ensuring safety and protecting the health of the population and the environment. It helps consumers make informed decisions through increased transparency and encourages companies as well as the government to integrate sustainable practices within their procurement processes. This can help lower Malaysia's ecological footprint and support the country in reaching its targets under the Sustainable Development Goals (SDGs) and the enhanced environmental, social and governance (ESG) standards.

B. Why do we need to assess the NQI?

This report assesses Malaysia's NQI from a bird's view perspective. While various components of NQI have already been established in Malaysia, there is a lack of comprehensive knowledge about the NQI system. All the components of NQI must act synergistically with each other to maximise the benefits for the country. There is no ready-made or "one size fits all" QI system that will effectively meet the needs of every country. Therefore, an assessment of the current situation is needed to highlight the gaps in Malaysia's NQI and provide guidance for making improvements.

This exercise will shed light on how aware the business population is about the importance of QI; to what extent it is currently being used by stakeholders in Malaysia; and moving forward, other areas in which it can be further utilised. A comprehensive analysis of QI in Malaysia will facilitate international benchmarking which provides insights into Malaysia's performance and practices in comparison with the performance of other countries and international best

practices. In addition, an NQI assessment is a necessary preliminary work to identify the needs and feasibility of developing an NQP.

C. How can Malaysia leverage the NQI assessment?

An NQI assessment is essential for improving the QI system in Malaysia. Above all, it guides the development of a NQP for the country. It provides direction for the improvement of the individual components of the country's QI system, as well as the system as a whole. It sheds light on how the QI institutions that already operate in Malaysia can be further developed, and which components are missing and need to be established. QI institutions play an integral role in facilitating trade competitiveness.

Furthermore, Malaysia can leverage the NQI assessment to highlight its position in global rankings, for example, in the Global Quality Infrastructure Index (GQII). This will enable the country to compare itself with other countries to determine whether its QI system is appropriate for its level of development and whether further investment is necessary. This becomes beneficial in national budget allocations and in attracting investment and donor attention. Additionally, with the publication of the Twelfth Malaysia Plan (MP12) and the New Investment Aspirations (NIAs), an NQI assessment will be useful in adjusting the current scope of services to help meet new targets and handle new challenges as the country moves towards higher development. Malaysia can also use the NQI assessment as one of the tools in measuring its achievement of the SDGs and ESG standards. In relation to this, the NQI assessment can be used in the transition towards more sustainable production and consumption patterns. However, accomplishing these goals before the 2030 deadline requires a paradigm shift in terms of economic activity, social practice, and human behaviour.

D. What is a National Quality Policy?

A quality policy at the national level is a relatively new field of governance. A national quality policy serves to develop and maintain an efficient and effective QI.

The QI comprises a system of public and private organisations, the relevant legal and regulatory framework, and the practices and policies required to support and improve the

quality, safety, and environmental performance of the country's goods, services, and processes.

QI is necessary for the effective functioning of domestic markets, and its international recognition is essential to enable access to foreign markets. Moreover, it is a critical element in promoting and sustaining economic development, productivity and competitiveness, as well as environmental and social well-being.

Malaysia's quality infrastructure components consist of standardisation and accreditation (represented mainly by JSM), metrology (represented primarily by the National Metrology Institute of Malaysia), conformity assessment (represented by numerous public and private bodies, e.g., Department of Chemistry & SIRIM QAS Sdn. Bhd.), and market surveillance.

E. Why does Malaysia need an NQP?

An NQP is critical for establishing and overseeing the development, maintenance and harmonisation of NQI in Malaysia. Given that there are no ready-made NQI models that suit the needs of all countries, an NQP that considers the reality of Malaysia is essential when setting objectives for the development of the country's NQI.

Furthermore, the development of an NQP provides the opportunity to increase awareness of the importance of QI and nurture a quality culture in Malaysia since it is developed with the participation and input of a broad spectrum of stakeholders, including ministries, agencies, regulatory bodies, trade and industry associations, chambers of commerce, consumer associations, and providers and users of QI services.

Quality and standards cut across sectors; therefore, the NQP should not exist in a vacuum. Instead, it should be promulgated within the context of industrial development, export and trade promotion, productivity, and other similar government policies and strategies.

Additionally, an NQP is necessary to guide the development of standards and technical regulations in Malaysia. This will prevent the inconsistent use of standards and technical

regulations, which have the potential to become unnecessary Technical Barriers to Trade and impede the trade of goods and services between Malaysia and its trading partners.

The preamble on how quality policies and regulations relate to productivity is hinged on the fact that productivity needs to be significantly considered when talking about quality policies.

Quality policies and regulations are inclusive, responsive, and agile to the economic situation and industry's needs. Quality business policies and regulations form a competitive and supportive business ecosystem, leading firms, the industry, and the economy in totality to be productive and competitive.

Data from the Worldwide Governance Indicators (WGI) by the World Bank presented a dependency between regulatory quality and productivity growth. WGI Regulatory Quality reflects the perception of a government's ability to formulate and implement sound policies and regulations that enable and promote private sector development. WGI Regulatory Quality Ranking indicates the percentile rank value among all countries, in which 0 indicates the lowest to 100 at the highest rank value.

The chart shows the correlation between WGI ranking in Regulatory Quality and productivity growth. Highly productive countries such as Singapore, Switzerland, and the USA were ranked higher in regulatory quality.

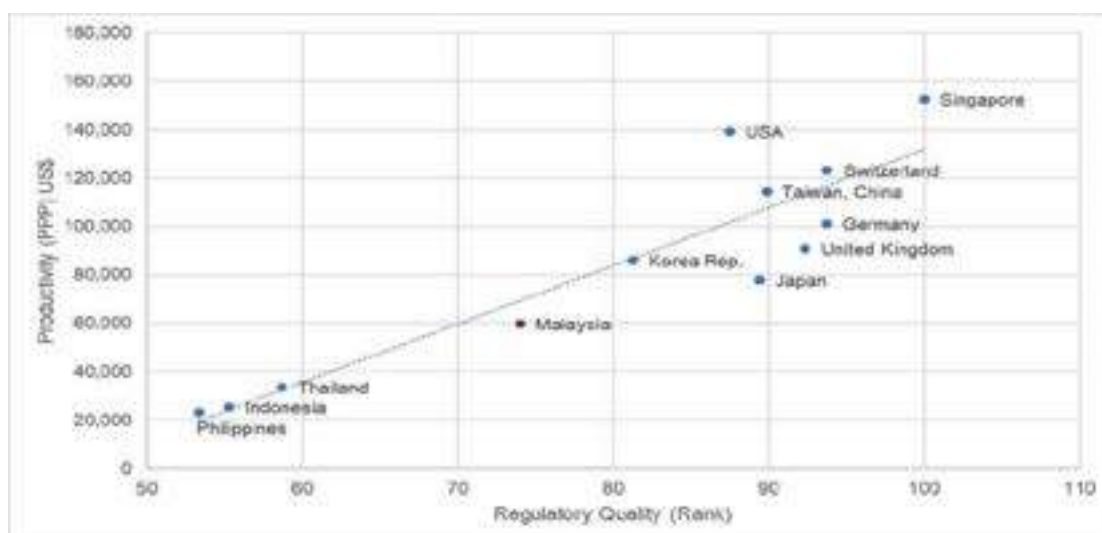


Figure 1: Regulatory quality (rank value) correlates with productivity growth (PPP,US\$), selected countries, 2021

Source: The Worldwide Governance Indicators (2021 Update) by the World Bank and IMD World Competitiveness Yearbook 2021

Productivity, in turn, affects a country's global competitiveness. The top-performing economies in global competitiveness registered higher productivity growth. As productivity grows, the country's competitiveness increases. The close association between productivity and competitiveness calls for Malaysia to improve its productivity performance to enhance competitiveness. Improving productivity means robust and quality growth.

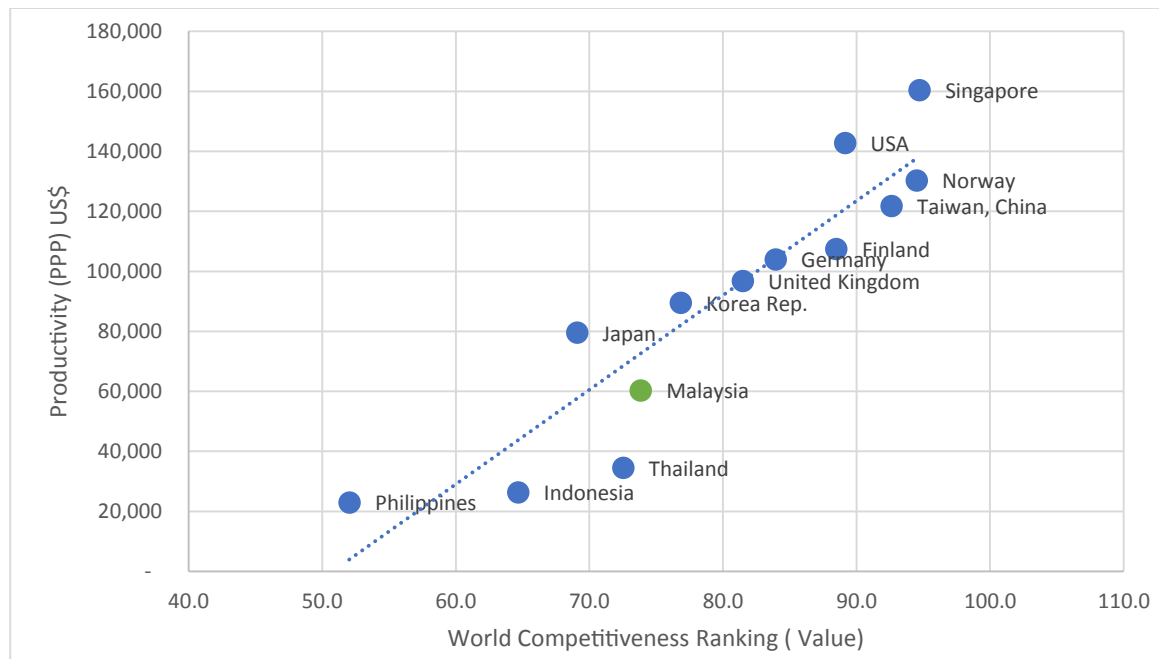


Figure 2: Selected countries' global competitiveness ranking (value) and productivity growth (PPP), 2021

Source: IMD World Competitiveness Yearbook 2021

F. Who leads the NQP development in Malaysia?

The Malaysian QI system has been evolving over many decades and has reached a certain degree of maturity and international recognition today. As such, the responsibility for the various components of QI (accreditation, conformity assessment, metrology, standardisation, technical regulations and market surveillance) is shared among several institutions, organisations, and agencies, which fall under the auspices of different ministries in Malaysia.

A specific ministry should take the lead role with respect to overseeing the development of the NQP and NQI in Malaysia. Undoubtedly, overseeing the development and implementation of the NQP is an overarching task which transcends the purview of a single ministry. Hence, the Ministry selected to lead this process needs to closely co-ordinate with other competent ministries for developing regulations (with relevance to product and service quality) and market surveillance in different policy areas.

G. What is the scope of the NQI assessment and NQP design?

The project will focus on assessing the NQI and drafting an NQP for Malaysia in the ARISE Plus Malaysia Trade-related Technical Assistance project. Therefore, the NQP resulting from this project will have an industry, trade and competitiveness focus.

The newly drafted NQP is expected to lay the foundation for a solid government policy to guide the required alignment of the Malaysia QI system with its main trading partners in ASEAN and beyond. The NQP will lead to more efficient and effective QI, stimulate trade and improve the capability of Malaysian manufacturers and producers of goods and services to tap into business opportunities, compete in global markets and participate in international value chains.

II. METHODOLOGY

A. Who conducted the QI Assessment?

The development of this QI assessment was a collaborative, iterative process that began in September 2021. The impetus for assessing Malaysia's NQI came from JSM's administration who saw the need to take stock of the overall system. The last analysis of Malaysia's QI, the Standards, Quality Assurance, Accreditation and Metrology review (SQAM review), took place in 2013. Since then, Malaysia's QI system has evolved while the international trade and development environment has changed.

The implementing agency responsible for ARISE Plus Malaysia, the International Trade Centre (ITC), responded positively to this request and engaged a team of international and national consultants to facilitate the new NQI assessment. Accordingly, the ITC officers and the external consultants formed the Consultancy Team (CT).

The central body of the consultancy is the project team (PT) led by JSM. Representatives from MITI, the NMIM, SIRIM Berhad, MPC and the CT are also involved. The CT meets weekly, while the PT typically meets on a bimonthly basis to discuss the project, its progress, and the way forward. In the preparation of this assessment report, the PT supported the consultants in conducting surveys and interviews with representatives of the organisations and users of the QI system. In addition, the consultants regularly reported on their analysis results and received feedback from the expert organisations represented in the PT.

Additionally, a technical outlook on the QI Assessment is provided by the Technical Committee (TC). Its members are senior officials of QI bodies in Malaysia, other relevant ministries, and representatives of the private sector and academia. It is chaired by the Director General of JSM. The central task of the TC is to deliberate and validate the NQI Assessment before it is presented to the Steering Committee (SC).

An international good practice is to use the recommendations of an NQI assessment to develop a national quality policy. The decision to develop a national quality policy will be determined after the adoption of the NQI assessment by the SC.

B. How has the NQI system been assessed?

In the QI assessment, the consultancy team reviewed and systematised current information (*desk research*) and collected qualitative and quantitative data specifically for this study (*field research*).

In analysing the QI environment, the consultants conducted extensive Internet research on international trade and global development issues. They paid particular attention to studies on global trade and regional integration in the ASEAN region. The authors also evaluated national development strategies. In interpreting the information, the discussions at the PT meetings were constructive in making sense of the findings.

To better assess the level of QI development, the consultants compared Malaysia's data with other countries with more developed QI infrastructure. These were Australia, Germany, Mexico and Indonesia. Qualitative information, as well as data from the GQII ranking, were used for the comparison. The GQII is a database of comparable QI data for 184 countries worldwide (GQII, 2021).

For the study of the QI and its components, the consultants could draw on rich information from institutional websites, annual reports and other documents. JSM made several unpublished studies and internal documents and reports available to the team.

This information base was expanded through field research. Most of the field research was conducted remotely via online meetings with the stakeholders involved in Malaysia's QIS. At the same time, members of the PT organised presential meetings to further elaborate on the information gathered and increase the participation of relevant stakeholders. In March 2022, PT organised a presential workshop with regulators in East Malaysia to gain more insight into the status of the QIS in these States. In July 2022, PT organised a hybrid workshop to review a draft version of the NQI Assessment Report with TC members and get their feedback on how it could be revised.

The consultants used the Rapid Diagnostic Tool developed by the World Bank and the Physikalisch-Technische Bundesanstalt (PTB) to interview providers regarding QI service

providers systematically. In addition to JSM (standards and accreditation) and the NMIM (metrology), a representative number of conformity assessment bodies and various ministries responsible for technical regulations were surveyed. At the same time, the survey also served to sensitise stakeholders about the whole QI system.

A QI system is effective when its services are oriented towards the actual user demand. Accordingly, for the first time, the consultancy team conducted a representative user survey with Malaysian companies on their knowledge, use and assessment of the QI. An Internet questionnaire operationalised the survey. The questionnaire reached the companies via QI service providers, private sector associations and social networks. To better understand the survey results, the consultancy team asked key stakeholders additional questions in semi-structured interviews.

This form of data collection is not only beneficial for the QI assessment, it could also be performed on a regular basis as part of monitoring the development of the QI system. In this respect, the qualitative and quantitative data presented in this study can also be understood as a baseline of indicators for measuring the development of the QI system.

C. What will follow the QI Assessment?

The ITC consultancy is designed to assess the Malaysian NQI system. This document aims to describe the current state of NQI development and identify needs for improvement and expansion. The NQI assessment (Phase 1) will serve as a basis for the formulation of a draft National Quality Policy text (Phase 2), including a proposal for an implementation plan. The consultants thus provide the Malaysian government with a draft text as the basis for developing a Quality Policy for Malaysia.

Should the Government of Malaysia decide to have a National Quality Policy (NQP), a dedicated phase (Phase 3) of consultation, agreement, and revision of the NQP text would become necessary. For this, the government could agree on additional expert support. An illustration of the process can be seen in Figure 3.

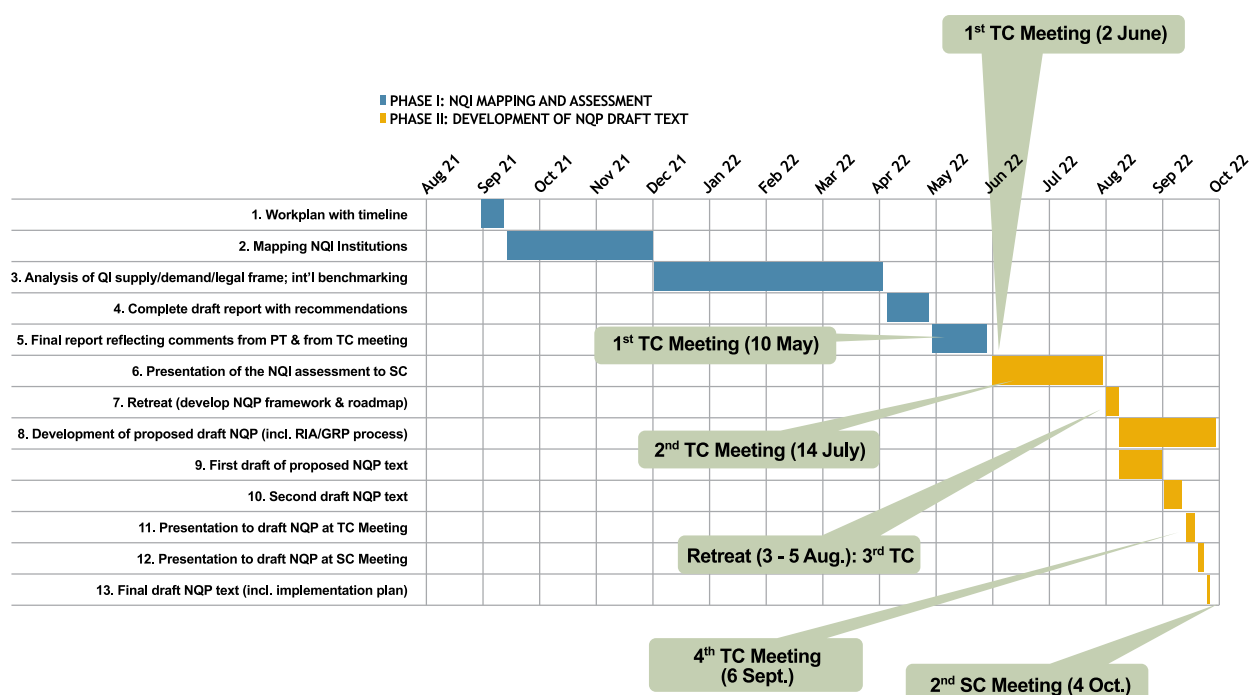


Figure 3: Project timeline

A physical retreat of the TC and CT is planned for 3-5 August 2022. This event will take place at a location near Kuala Lumpur. The objectives of the retreat are as follows:

- To understand the development of a quality policy for Malaysia and to clarify political leadership and governance structure.
- To agree on the strategic action lines (based on NQI recommendations, see chapter VI) of a national quality policy.
- Outline a possible implementation plan.

A 3rd TC meeting is suggested for the end of August to review the draft NQP text. Written feedback on the revised NQP text is collected and considered for a review, before the draft NQP text is discussed in a SC meeting at the end of September.

III. SOCIOECONOMIC AND POLITICAL CONTEXT

A. Malaysia's transformation in light of the SDGs and MP12

Malaysia gained its independence in 1957 and formed the Federation of Malaysia in 1963, originally consisting of Malaya, Singapore, Sarawak, and Sabah. In 1965, Singapore was obliged to leave the Federation, which left Malaya with 11 states now known as the Peninsular Malaysia, and Sarawak and Sabah now known as East Malaysia (Drabble, 2004). Malaysia has embarked on a journey of rapid industrialisation to become a fully developed industrial society in line with its Vision 2020 aspirations (Embong, 1996). Malaysia is viewed as one of the most successful non-western countries in achieving a relatively smooth transition to modern economic growth over the past century (Drabble, 2004). The country is consistently ranked amongst the most competitive economies in Asia. The Government is committed to achieving developed-nation status against the demanding environment and challenges of enhancing competitiveness, achieving sustainable development, and inclusive growth. Malaysia is one of the most open economies in the world with a trade to GDP ratio averaging over 130% since 2010 (World Bank, 2021b).

Since 1970, the nation's leading sector in development has been focusing on export-oriented manufacturing industries, i.e., textiles, electrical and electronic goods, rubber products etc. Malaysia has been a major supplier of tin, rubber, palm oil, timber, oil, liquified natural gas, etc. to the industrialised countries. By 1990, it had met the standards for the Newly-Industrialised Country (NIC) status with 30% of exports consisting of manufactured goods (Drabble, 2004). Malaysia has enjoyed one of the best economic growth records in Asia in previous decades. The country has achieved stable real GDP growth of 6.2% per annum since 1970, successfully transforming from being an economy dependent on agriculture and commodity to manufacturing in the mid-1980s and modern services in the 1990s. Malaysia now plays host to robust manufacturing and service sectors making it a leading exporter of electrical appliances, parts, and components (World Bank, 2021b).

Malaysia's sustainable development started with the introduction of the New Economic Policy (NEP), 1971-1990, to eradicate poverty and restructure the societal imbalance. During the

subsequent five years, Malaysia continued to place emphasis on sustainable development encompassing sustainable economic growth, growth with equitable distribution to all sections of society, access to basic infrastructure and utilities, access to education and healthcare services and mainstreamed environmental conservation via the Malaysia Plan (*National Voluntary Review to the HLPF*, 2017).

Since 1986, policy emphasis shifted back from social equity to wealth creation. Pro-market, outward-oriented policy measures were adopted. The Industrial Master Plan 1 (IMP1, 1986-1995) laid the foundation for the manufacturing industry and promoted the processing of natural resources instead of exporting them in raw form. The Industrial Master Plan 2 (IMP2, 1996-2005) tried to broaden manufacturing capability through cluster-based industrial development and manufacturing strategies. The Industrial Master Plan 3 (IMP3, 2006-2020) further broadened the scope by including services and featuring functional targets, such as SMEs, human resource development, technology, logistics and marketing.¹

In 1991, the Vision 2020 was introduced to make Malaysia a fully developed country. Vision 2020 formed the basis of the National Development Policy, 1991-2000 (NDP) encompassing economic, political, social, spiritual, psychological, and cultural dimensions to create a more united and just society through balanced development by the year 2020. In 2009, Malaysia introduced the New Economic Model (NEM) which aimed at further enhancing the nation's commitment to pursuing sustainable development. The NEM was based on three pillars i.e., high income, inclusivity and sustainability. These three pillars were the mirrors of the three United Nation's Sustainable Development Goals (SDGs), namely the economy, social and environment.

The national development priorities are clearly mentioned in the Twelfth Malaysia Plan, 2021-2025; A Prosperous, Inclusive, Sustainable Malaysia (MP12) (2021) where the objective is to achieve a prosperous, inclusive and sustainable Malaysia. This objective is in line with the

¹ <https://www.grips.ac.jp/forum/pdf06/VDFFreport/4malaysia.pdf>

Vietnam Development Forum, 2006, Industrial Policy Formulation in Thailand, Malaysia and Japan, <https://www.grips.ac.jp/vietnam/VDFTokyo/Doc/TMJreportEN.pdf>

Shared Prosperity Vision 2030 (WKB 2030) and the 2030 Agenda of the Sustainable Development. The initiatives to achieve these objectives are clearly spelled out in the MP12 representing Malaysia's commitment into implementing SDG 17: Partnerships for the Goals. Additionally, MP12 highlights the policies, programmes, and projects in accordance with meeting SDG 17. In addition, MP12 incorporates strategies and initiatives that safeguard national security and sovereignty, which are vital for sustainable socioeconomic development.

Under the National Investment Aspirations (NIA) framework, MITI has identified five key sectors (electrical and electronics, pharmaceutical, digital economy, aerospace and chemicals) that can attract more foreign investors to invest either in research and development or manufacturing facilities using new technologies. These five sectors focus on high-impact and technological investments and should generate quality and high-skilled employment opportunities for locals and strengthen the country's competitiveness.²

Challenges and opportunities

The new millennium has brought about challenges for the nation in terms of globalisation, liberalisation, and swift expansion of information and communication technology. Amidst the various efforts implemented to raise the income and uplift the wellbeing of the population during MP11 (2015), the nation's economy grew at an average annual rate of 2.7%. This was mainly driven by the manufacturing and services sectors. Even though there was socioeconomic progress in the nation, Malaysia had yet to achieve a fully developed economy. Hence, the WKB 2030, the successor of Vision 2020, aims to enhance Malaysia's economy by attaining development for all, addressing wealth and income disparities as well as making Malaysia a united, prosperous and dignified nation. It is committed to achieving sustainable economic growth accompanied by fair, equitable and inclusive economic distribution across all income groups, ethnicities, regions and supply chains to raise the household purchasing power of households commensurately with the growth of the economy.

² <https://www.miti.gov.my/NIA/nia.html>.

B. Economic snapshot and key sectors of the economy

Malaysia's economy takes the fourth position in terms of size in Southeast Asia and 38th position globally in 2018 (Bada, 2018). According to the Department of Statistics, Malaysia's economy is led by the services, manufacturing, agriculture, mining and quarrying, and construction industries. This is illustrated in Figure 4.

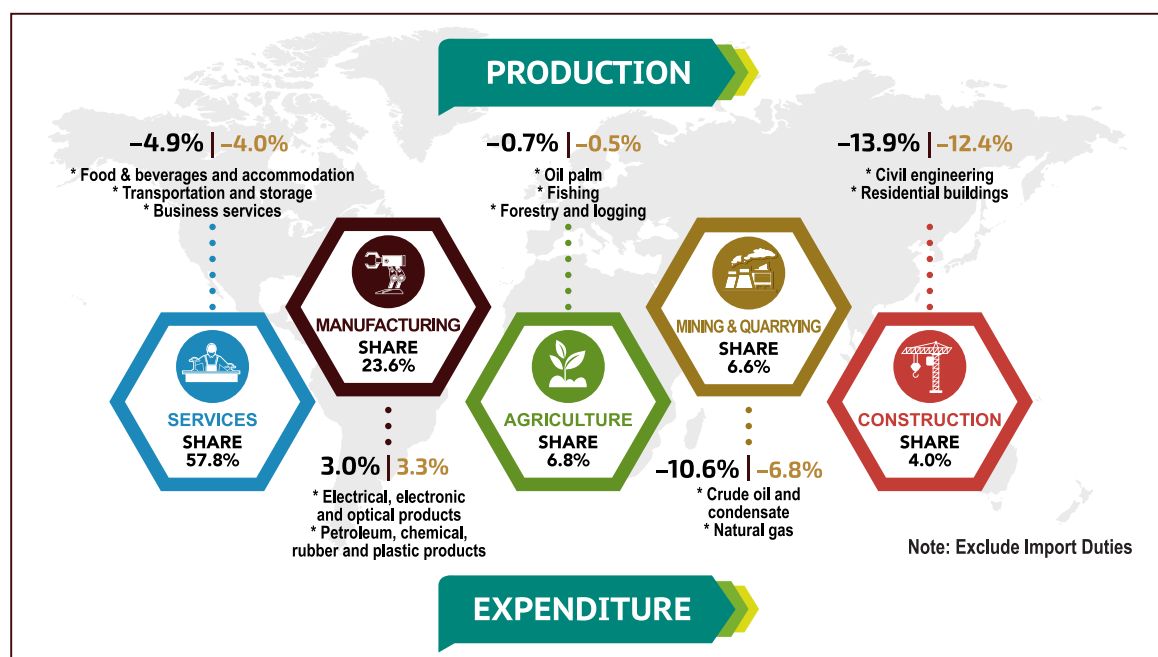


Figure 4: Malaysia's economic activities

Source: Department of Statistics Malaysia (2021)

Moving forward in the MP12, the Government is committed to delivering game-changing and radical initiatives to ensure that the objectives of prosperity, inclusivity and sustainability are achieved. Emphasis will be on resetting the economy, strengthening security, wellbeing and inclusivity as well as advancing sustainability. The MP12 has identified additional industries to focus on to achieve high impact industries to boost the economic growth. Other industries identified include electrical and electronics, global services, halal, creative industry, aerospace, biomass, smart farming, and tourism. These eight industries have been identified as strategic and high impact industries with an intention that its activities will catalyse the nation's economic growth. The MP12 also aims to enable Micro, Small and Medium Enterprises (MSME) entrepreneurs to transform, compete and penetrate global markets by

assisting them to create a conducive and holistic ecosystem. The plan investigates the importance of embracing the circular economy by encouraging the public and private sectors to adopt and integrate the SDGs and Environmental, Social and Governance (ESG) principles in their decision making.

During MP11, measures were undertaken to pursue green growth by strengthening governance, conserving natural resources, addressing climate change and reducing disaster risks. Nonetheless, challenges remain in terms of unsustainable consumption and production practices, loss of biodiversity and lack of a supportive enabling environment. The MP12 will advance green growth by implementing a clean, green and resilient development agenda through a whole-of-nation approach. The key strategies will include increasing resilience against climate change and disasters, embracing the circular economy, mainstreaming SDGs and ESG principles in investment decisions, sharing responsibilities in moving towards a low-carbon nation, implementing evidence-based and risk-informed strategies, and ensuring equitable benefit sharing and steering behavioural changes. Effective execution of policies and strategies under the clean, green and resilient development agenda, supported by mindset and behavioural changes, will contribute to sustainable growth and better planetary health as well as the achievement of the 2030 Agenda.

Efforts to accelerate productivity will continue under the MP12, which will contribute to higher labour productivity growth. Focus will be given to gearing up for the Fourth Industrial Revolution (4IR), providing an enabling environment for the digital economy, intensifying research and development, and commercialisation and innovation (R&D and C&I) as well as developing the required talent. The Malaysia Productivity Blueprint represents a bold step in raising labour productivity to achieve the set targets. The blueprint has been designed and developed to accelerate productivity improvement strategies, initiatives and programmes at the national, sectoral and enterprise levels. It provides guided implementation to expedite productivity improvements as envisaged in the starting of the 11MP through five strategic thrusts and will continue as a living documents spearheading productivity. These thrusts are to ensure holistic and systematic change rather than fragmented efforts. In striving for higher productivity growth, Malaysia must prepare for uncertain external factors as shifts in

economic policies could affect a diverse range of outcomes for the Malaysian economy and local labour market conditions. Such externalities can be mitigated by stronger collaboration among the stakeholders through establishing various productivity nexus (Economic Planning Unit, Prime Minister's Department, n.d.).

C. International trade

Since its independence in 1957, Malaysia has successfully diversified its economy to keep up with changes in the global economy. The country transitioned from an economy initially dominated by agriculture and commodities to one with robust manufacturing and services sectors. This resulted in Malaysia having the 35th largest economy in the world in terms of GDP in 2019 (OECD, 2020) with a total of US\$364.7 billion (World Bank, 2021a). In the same year, Malaysia ranked 21st (out of 225) in total product exports and 25th (out of 225) in total product imports (OECD, 2020). Concerning services, the country ranked 11th (out of 69) in exports and 10th (out of 69) in imports (OECD, 2020). Malaysia is currently classified as an upper-middle-income country (The President and Fellows of Harvard College, 2021). Since 2010 its economy has experienced positive growth, with an average of 5.4%, putting Malaysia on track to reaching high-income status by 2024 (World Bank, 2021b).

In 2019, Malaysia's product exports totalled US\$273 billion and its services exports totalled US\$37.6 billion (OECD, 2020). The country's top product exports were integrated circuits, refined petroleum, petroleum gas, semiconductor devices and palm oil (OECD, 2020). A snapshot of the country's exports can be seen in Figure 5 and Malaysia's global market share by sector from 1996 to 2018 is presented in Figure 6.

Over the past decade the country has managed to steadily increase its market share in electronics, which explains why its export growth over the past five years has been predominantly driven by electronics. In addition, in 2019 Malaysia was the largest exporter in the world of rubber apparel, other vegetable oils, copper powder, asphalt mixtures and platinum clad metals (OECD, 2020). The main services exported by Malaysia included personal travel, other business services, transportation, computer and information services, and

business travel (OEC, 2020). Malaysia's main export partners included Singapore, China, the United States, Hong Kong and Japan (OEC, 2020).

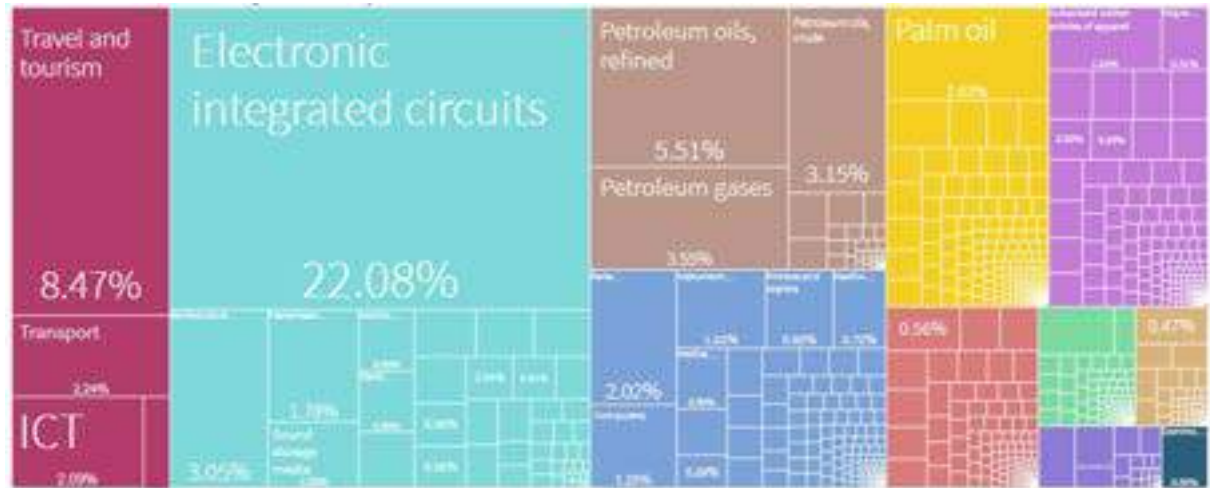


Figure 5: Malaysia's exports in 2019
Source: The President and Fellows of Harvard College (2021)

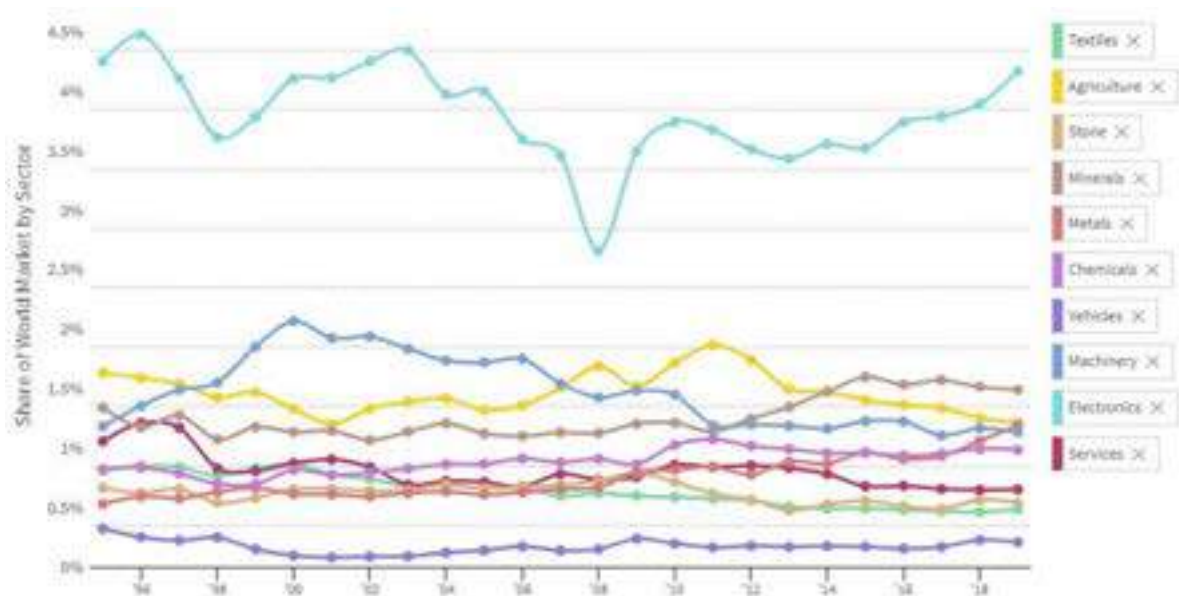


Figure 6: Malaysia's global market share by sector from 1996 to 2018
Source: The President and Fellows of Harvard College (2021)

In 2019 Malaysia imported US\$207 billion in products and US\$42.9 billion in services (OEC, 2020). The country's top product imports were integrated circuits, refined petroleum, crude petroleum, broadcasting equipment and coal briquettes (OEC, 2020). Malaysia was the world's largest importer of tin ores, scrap plastic and tin bars in 2019. With respect to services,

Malaysia mainly imported transportation, personal travel, other business services, computer and information services and insurance services. A snapshot of the country's imports can be seen in Figure 7. Malaysia's main import partners included Singapore, China, the United States, and Japan (OEC, 2020).

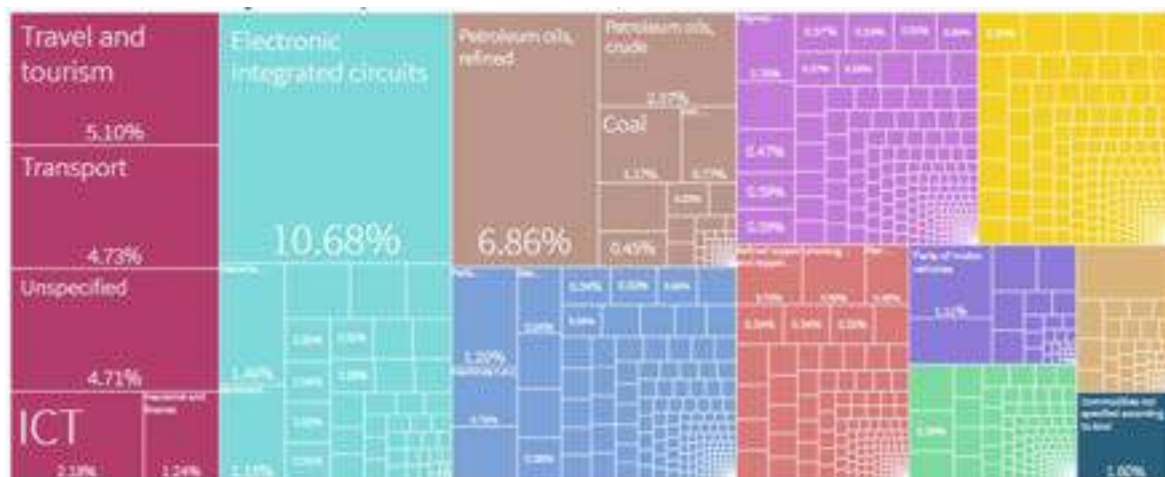


Figure 7: Malaysia's imports in 2019
Source: The President and Fellows of Harvard College (2021)

Malaysia's level of complexity is very high given its income level. Countries with more complex exports than expected for their income level have been found to grow faster (The President and Fellows of Harvard College, 2021). In 2019, Malaysia was the 24th (out of 133) most complex country according to the Economic Complexity Index (ECI) ranking (The President and Fellows of Harvard College, 2021). Countries can improve their ECI ranking by increasing the number and complexity of their exports.

Over the past decade, Malaysia's economy has become progressively more complex, improving nine positions in the ECI ranking (The President and Fellows of Harvard College, 2021). From 2004 to 2019, Malaysia successfully introduced thirty new products to its export list. Some of them include unwrought aluminium, ferroalloys, machines, synthetic rubber, and petroleum coke, among others. In 2019, these new products contributed US\$10.1 billion to its GDP (The President and Fellows of Harvard College, 2021). Malaysia's largest export products, electronics, and minerals, are both high and low in complexity respectively. Figure 8 shows

the complexity of Malaysia's exports and Figure 9 shows how Malaysia compares to the benchmark countries selected for this assessment with respect to economic complexity.

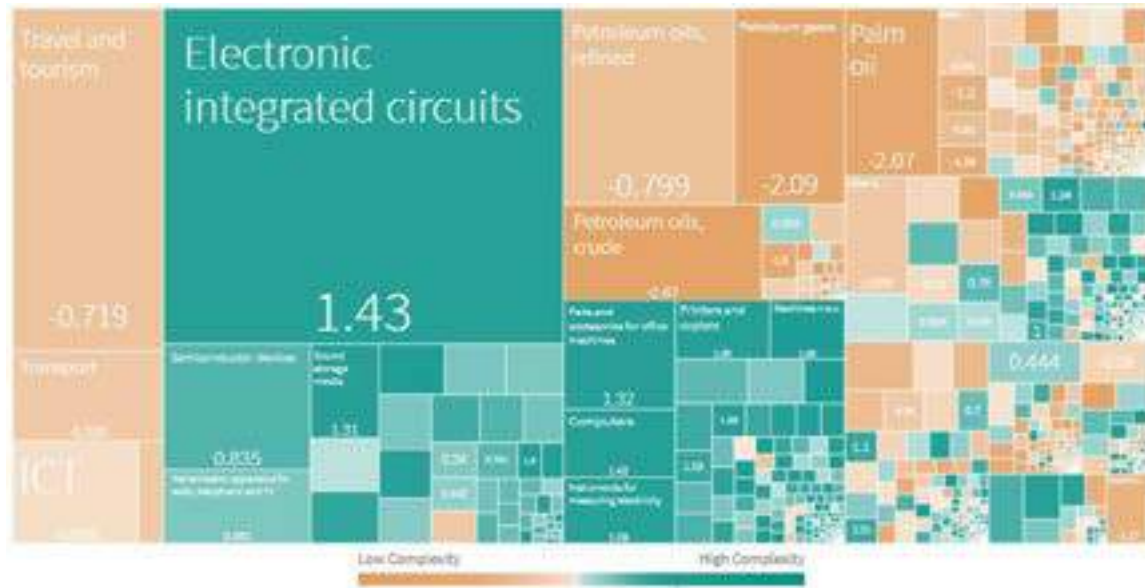


Figure 8: Economic complexity of Malaysia's exports
Source: The President and Fellows of Harvard College (2021)

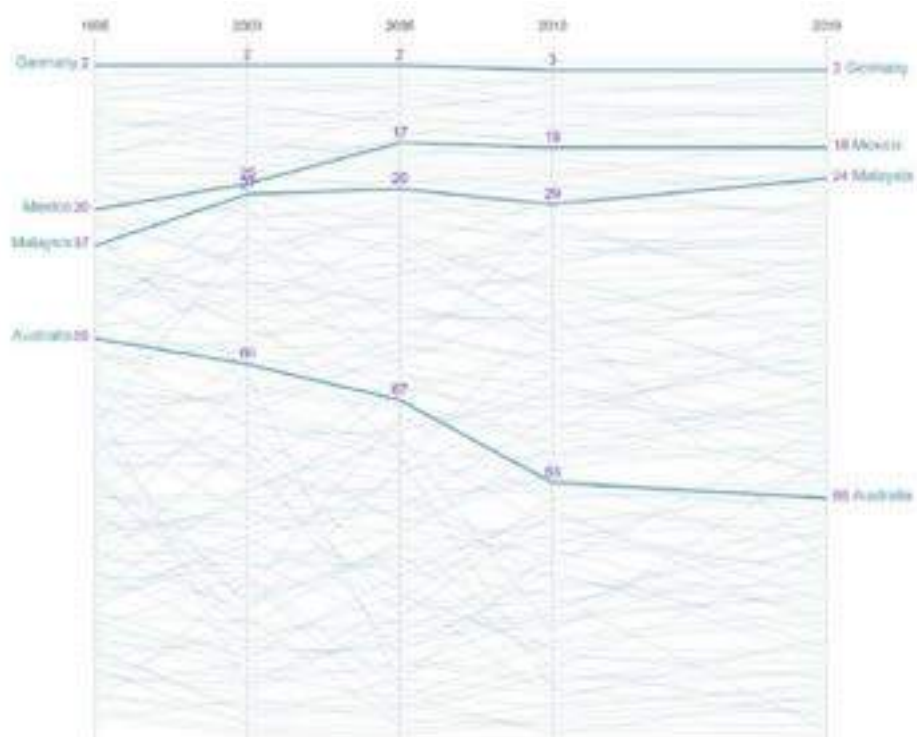


Figure 9: Malaysia's economic complexity 2019 compared to benchmark countries
Source: The President and Fellows of Harvard College (2021)

Given the number and complexity of Malaysia's exports, the country has many opportunities to further diversify its economy by moving into nearby or related products or products that need similar knowledge to build on existing capabilities (The President and Fellows of Harvard College, 2021). Based on the connectedness of Malaysia's know-how, some sectors with high potential for diversification include organic chemicals and apparatuses (optical, medical, etc.). Figure 10 shows a list of the top ten products Malaysia has the potential to start producing based on its existing knowledge and experience.

PRODUCT NAME	"NEARBY" DISTANCE	OPPORTUNITY GAIN	PRODUCT COMPLEXITY	GLOBAL SIZE (USD)	GLOBAL GROWTH 5 YR
Inorganic compounds, liquid or compressed air (2851 HS4)	◆◆◆◆◆	◆◆◆◆◆	◆◆◆◆◆	\$2.56B	↑ 271.3%
Glass, cast or rolled (7003 HS4)	◆◆◆◆◆	◆◆◆◆◆	◆◆◆◆◆	\$3.53B	↑ 90.9%
Apparatus and equipment for photographic laboratories, n.e.c. (9010 HS4)	◆◆◆◆◆	◆◆◆◆◆	◆◆◆◆◆	\$42.2B	↑ 67.4%
Photographic film, developed (3705 HS4)	◆◆◆◆◆	◆◆◆◆◆	◆◆◆◆◆	\$1.72B	↑ 56.2%
Microscopes, other than optical (9012 HS4)	◆◆◆◆◆	◆◆◆◆◆	◆◆◆◆◆	\$2.91B	↑ 55.1%
Other articles of glass (7020 HS4)	◆◆◆◆◆	◆◆◆◆◆	◆◆◆◆◆	\$3.73B	↑ 28.4%
Instruments for physical or chemical analysis (9027 HS4)	◆◆◆◆◆	◆◆◆◆◆	◆◆◆◆◆	\$45.4B	↑ 23.4%
Halogenated derivatives of hydrocarbons (2903 HS4)	◆◆◆◆◆	◆◆◆◆◆	◆◆◆◆◆	\$10.7B	↑ 17.3%
Spark-ignition reciprocating internal combustion piston engines (9407 HS4)	◆◆◆◆◆	◆◆◆◆◆	◆◆◆◆◆	\$52.1B	↑ 14.4%
Thermometers, hydrometers etc. (9025 HS4)	◆◆◆◆◆	◆◆◆◆◆	◆◆◆◆◆	\$5.61B	↑ 14.2%

Figure 10: Sectors with high potential for new diversification in Malaysia
Source: The President and Fellows of Harvard College (2021)

D. Post-pandemic economic recovery

The Coronavirus disease (COVID-19) in Malaysia is part of an ongoing global crisis. The COVID-19 pandemic, which began in 2019, is a disease caused by the severe acute respiratory syndrome. Malaysia recorded its first COVID-19 wave in January 2020 and continued to rise

to its peak in August 2021. The number of COVID-19 cases have decreased in Malaysia with the current new daily cases as of 31 December 2021 recorded below 3,000 cases and the total active cases at about 40,000. The Ministry of Health, Malaysia had reported that the total number of cases in the nation has reached 2.76 million with over 31,000 deaths.

Responding to the surge of cases in March 2020, the Malaysian government imposed a nationwide phase one lockdown known as the Movement Control Order (MCO). The lockdown was imposed on social and economic sectors. During the MCO, only certain businesses and sectors were allowed to operate with limited capacity. This temporary nationwide closure of business and travel resulted in a major hit to the country's economy. Malaysia's economy was badly impacted in 2020 due to the COVID-19 containment measures which resulted in a slowdown in economic activities (Department of Standards Malaysia, 2020). The nation's full year economic performance fell by 5.6% in 2020, which recorded the worst annual performance since the 7.4% decline in 1998 during the Asian Financial Crisis (Sipalan, 2021). A decline of 4.5% was observed in the third quarter of 2021 (Bank Negara Malaysia, 2021). However, the domestic economy is expected to be on track to expand by 3-4% growth with the increase in the economic activities as the COVID-19 containment measures are progressively relaxed (Bank Negara Malaysia, 2021).

In view of the economic downturn, the Malaysian government has incorporated various economic stimulus packages (PRIHATIN, PEMERKASA). The first theme of the MP12 is 'Resetting the Economy' to restore the growth momentum of all the sectors whilst accelerating the development of high potential industries. Sectors, such as services, manufacturing, agriculture, mining, and construction, will be rejuvenated by encouraging these sectors to move up the value chain by adopting 4IR technologies, digitalisation, and the green economy. This strategy in the MP12 looks at improving the quality, productivity and competitiveness of these sectors.

Productivity is the single most important factor in a country's long-term growth. High-productivity nations are able to quickly adapt to changes in macroeconomic challenges, as well as fundamental shifts brought on by technological advancement. In addition, the MP12 focuses on catalysing strategic and high-impact industries to boost economic growth by

enhancing the electrical and electronics, global services, aerospace, creative, tourism, halal and biomass industries, as well as smart farming activities as the new sources of growth.

IV. NATIONAL QUALITY INFRASTRUCTURE

A. Overview

Since its independence in 1957, the Quality Infrastructure System (QIS) in Malaysia has developed organically over time as needs arose without following a formally defined Quality Policy (QP). As the economy diversified from being predominantly based on agriculture and commodities to having robust manufacturing and services sectors, QI services became essential for Malaysian companies seeking to enter and compete in international markets. Subsequently Malaysia began its QI journey in 1964, making it a fairly young country in the field, compared to more developed countries, like Germany and Australia. However, the effectiveness of the NQI system in Malaysia has not been systematically studied since 2013, which makes it difficult to determine where gaps currently exist and what should be done moving forward. Given the important role QI plays in international trade and development, reviewing Malaysia's QIS and taking the necessary steps to close whatever gaps may exist is urgently needed, especially if the country is aiming to reach high-income status by 2024 (World Bank, 2021b).

There have been many achievements in the development of Malaysia's QIS since 1964. A summary of some of these milestones is presented in Table 1. In 1966, the Standards Institute of Malaysia (SIM) was established, and in 1972 the National Institute for Scientific and Industrial Research (NISIR) was founded (SIRIM, 2022). In 1975 SIM and NISIR merged to form the Standards and Industrial Research Institute of Malaysia (SIRIM) (SIRIM, 2022). SIRIM Laboratory Accreditation Scheme, Skim Akreditasi Makmal Malaysia (SAMM) and the Malaysia Accreditation Council were established in 1987, 1990, 1994, respectively. (SIRIM, 2022). The year 1996 was very eventful for Malaysia's QIS as the Standards of Malaysia Act 1996 was passed in Parliament, JSM)- officially started its operations, and JSM accredited its first certification body (CB) for Quality Management Systems (QMS) – SIRIM Berhad (Department of Standards Malaysia, 2006). In 2000, the National Metrology Laboratory in SIRIM (NML-SIRIM) was established, and in 2002 JSM accredited its first CB for Environmental Management Systems (EMS) – Moody International Certification (M) Sdn Bhd (Department of

Standards Malaysia, 2006). In 2003 JSM launched the accreditation programme for Product Certification Bodies (PCBs).

The year 2004 was another significant year for Malaysia's QIS as the Government re-affirmed the status of JSM as the national accreditation body for all conformity assessment activities. In addition, a national standard (MS 1500:2004 – Halal Food – Production, Preparation, Handling and Storage – General Guidelines) for halal food was approved, and JSM accredited its first CB for the Product Certification Body Programme – SIRIM QAS International Sdn Bhd (Department of Standards Malaysia, 2006). Furthermore, the SAMM Scheme extended its scope to include Medical Testing, where the Medical Testing accreditation programme was launched.

In 2005, JSM started its new accreditation programme for Occupational Safety and Health Management Systems (OSH MS), and the accreditation field for Veterinary Testing was launched (Department of Standards Malaysia, 2006). Additionally, JSM issued its first accreditation certificate on Medical Testing – Sunway Medical Centre; and JSM accredited its first CB for OSH MS – SIRIM QAS International Sdn. Bhd. Furthermore, JSM started its new accreditation programme for Hazard Analysis and Critical Control Point (HACCP), resulting in HACCP-based food safety systems and Information Security Management Systems (ISMS).

In 2006, JSM was rebranded as Standards Malaysia. In 2007, the National Measurement System Act 2007 was passed in Parliament, and in 2015 NML-SIRIM repositioned and renamed as the National Metrology Institute of Malaysia (NMIM) (NMIM, 2020b). Finally in 2018, the responsibility for JSM and SIRIM was transferred to the Ministry of International Trade and Industry (MITI) after previously being under the purview of the Ministry of Science, Technology and Innovation (MOSTI) (Ministry of International Trade and Industry, 2019a)

Table 1 : Summary of major milestones in Malaysia's QIS development

Year	Milestone
1964	The government of Malaysia directed a study on the establishment of a national standards organisation
1966	Establishment of the Standard Institute of Malaysia (SIM)
1970	Malaysia adopted the metric system
1971	Establishment of the New Economy Policy

Year	Milestone
1972	Establishment of the National Institute for Scientific and Industrial Research (NISIR)
1974	The National Action Council decided that SIM be merged with the National Institute for Scientific and Industrial Research (NISIR) to form the Standards and Industrial Research Institute of Malaysia (SIRIM)
1975	Establishment of Standards and Industrial Research Institute of Malaysia (SIRIM)
1978	Metrology Unit established in SIRIM
1987	Establishment of the SIRIM Laboratory Accreditation Scheme
1990	Establishment of the Skim Akreditasi Makmal Malaysia (SAMM) programme
1994	Establishment of the Malaysia Accreditation Council
1996	Passing of the Standards of Malaysia Act 1996 in Parliament
1996	Corporatisation of SIRIM and establishment of the Department of Standards Malaysia (JSM)
1996	JSM accredited its first CB for QMS - SIRIM Berhad
2000	Establishment of NML-SIRIM, National Metrology Laboratory in SIRIM
2002	The Cabinet approved measures to improve national standardisation initiatives
2002	JSM accredited its first CB for EMS – Moody International Certification (M) Sdn. Bhd.
2003	JSM launched accreditation programme for PCBs
2004	The Government re-affirmed the status of JSM as the national accreditation body for all conformity assessment activities
2004	JSM accredited its first CB for the PCB programme – SIRIM QAS International Sdn Bhd
2004	National standard - MS 1500:2004 – for halal food was approved which marked a major milestone in Halal certification programme for food
2004	Launching of the Medical Testing Accreditation Programme under SAMM
2005	JSM started its new accreditation programme for Occupational Safety and Health Management Systems (OSH MS)
2005	The Laboratory Accreditation Field for Veterinary Testing was launched
2005	JSM issued its first accreditation certificate on Medical Testing – Sunway Medical Centre
2005	JSM accredited its first CB for OSH MS – SIRIM QAS International Sdn Bhd
2005	JSM started its new accreditation programme for HACCP-based food safety systems and ISMS

Year	Milestone
2006	Re-branding of DSM to Standards Malaysia
2006	JSM started its new accreditation scheme for Malaysia Inspection Bodies Accreditation Scheme (MIBAS)
2007	Establishment of the National Measurement System Act 2007
2008	JSM appointed as Compliance Monitoring Authority (CMA) for the Organisation for Economic Co-operation and Development (OECD) Good Laboratory Practice (GLP)
2012	Amendment of Standards of Malaysia Act 1996 (Act 549)
2013	JSM started its new accreditation scheme for MyPTP
2013	JSM received full adherent to Mutual Acceptance Data under OECD GLP
2015	NML-SIRIM repositioned and renamed as NMIM
2018	Responsibility for JSM and SIRIM transferred to MITI
2019	JSM became a full-fledged Standard Development Agency

Source: Own elaboration using information from Department of Standards Malaysia (2006), MITI (2019a), NMIM (2020b), and SIRIM (2022)

In addition to the domestic developments that have taken place in Malaysia's QIS trajectory, the country has been working towards fostering relationships with regional and international QI bodies. In 1998, Malaysia signed the Pacific Accreditation Co-operation Multilateral Accreditation Arrangement (PAC-MLA) for QMS and in 1999, the country signed the International Accreditation Forum MLA (IAF-MLA) for QMS (Department of Standards Malaysia, 2006). In 2002, JSM became a signatory to the Asia Pacific Laboratory Accreditation Co-operation Mutual Recognition Arrangement (APLAC-MRA) for the testing scope; and one year later JSM signed the International Laboratory Accreditation Co-operation MRA (ILAC-MRA) for testing, the APLAC-MRA for calibration and the ILAC-MRA for calibration (Department of Standards Malaysia, 2006). In 2013, JSM received full adherent to Mutual Acceptance Data under OECD GLP.

Furthermore, Malaysia, through JSM, holds memberships to both ISO, IEC and Standards and Metrology Institute for Islamic Countries (SMIIC). Malaysia, through the NMIM, is a corresponding member of the International Organisation of Legal Metrology (OIML) (OIML, 2021); and a full member of the International Bureau of Weights and Measures (BIPM) (BIPM, 2022).

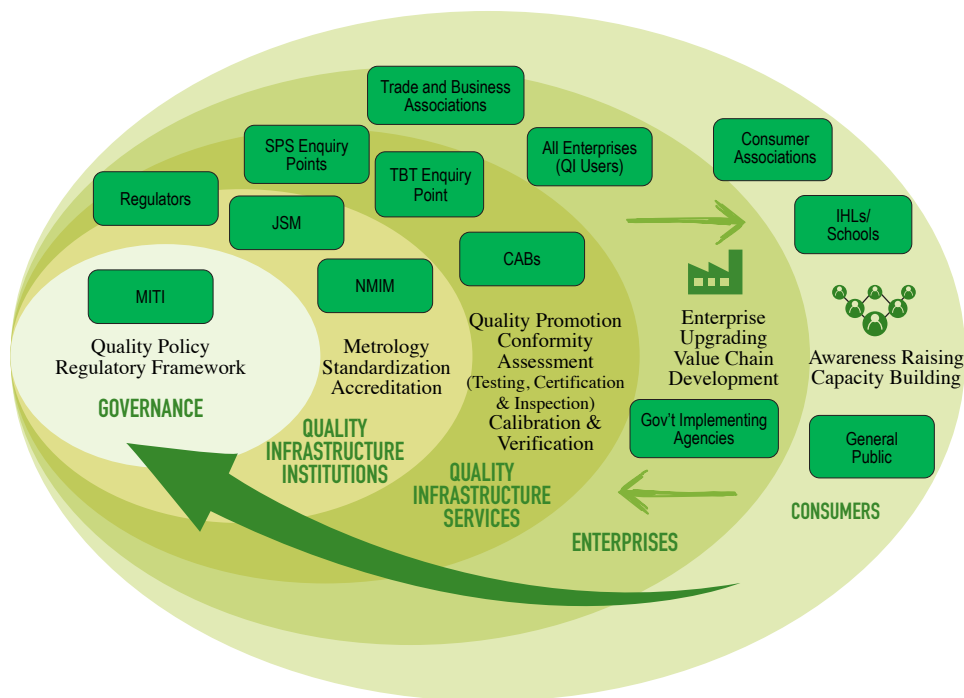


Figure 11: Key elements and stakeholders in Malaysia's Quality Infrastructure System
Source: Adapted from UNIDO (2016b)

An efficient and effective QIS requires co-operation and collaboration among different elements and organisations to facilitate trade; and promote consumer welfare, environmental safety, and sustainable development. Figure 11 and Figure 12 illustrate the current QIS in Malaysia. They highlight the central institutions of Malaysia's NQI system and their spheres of influence and relationships.

As presented in Figure 12, the National Standards Body (NSB) and National Accreditation Body (NAB) under the ambit of JSM provide standardisation and accreditation services, while the NMIM provides metrology services in Malaysia. According to the National Quality Policy Development Guide issued by UNIDO (2016b), ideally, at the national level, the standards body, the accreditation body and the metrology institute should be independent of each other. However, this is not economically feasible for some countries; therefore, some combinations of QI institutions at the national level are accepted (UNIDO, 2016b). It should be noted that while one possible combination is the NSB and the NAB being housed under one organisation (as in Malaysia), this is not common and requires a fairly advanced

conformity assessment service infrastructure in both the public and private sectors (UNIDO, 2016b). This is because the NSB in this case would not be able to provide any conformity assessment services since it would present a serious conflict of interest (UNIDO, 2016b).

The central lime green area shows the main QI services under standardisation, accreditation, and metrology.. JSM is responsible for standardisation and accreditation, and the NMIM for scientific and industrial metrology. The NMIM is part of SIRIM, which is active in various areas of the system. JSM, SIRIM and NMIM are all under the supervision of MITI.

The right-hand side of the chart, highlighted in peach, shows the mandatory area of the QI system. This includes legal metrology, overseen by the MDTCA, and technical regulation, which is the responsibility of many ministries and agencies of the Malaysian government. Market surveillance is also under these competent authorities.

The upper part of the chart shows the regional and international organisations arranged by the QI component. The Malaysian QI institutions participate in achieving international harmonisation and recognition of standards, accreditation, measurement and conformity assessment.

The lower part of the graph shows the QI users, the businesses and other organisations and consumers. The companies use the conformity assessment services to meet the technical rules and standards requirements, and systemically manage the quality of their products and services, to increase business operation efficiency which ultimately enhances productivity at the enterprise level. Through QI services, consumers should receive safe and high-quality products that enhance their quality of life.

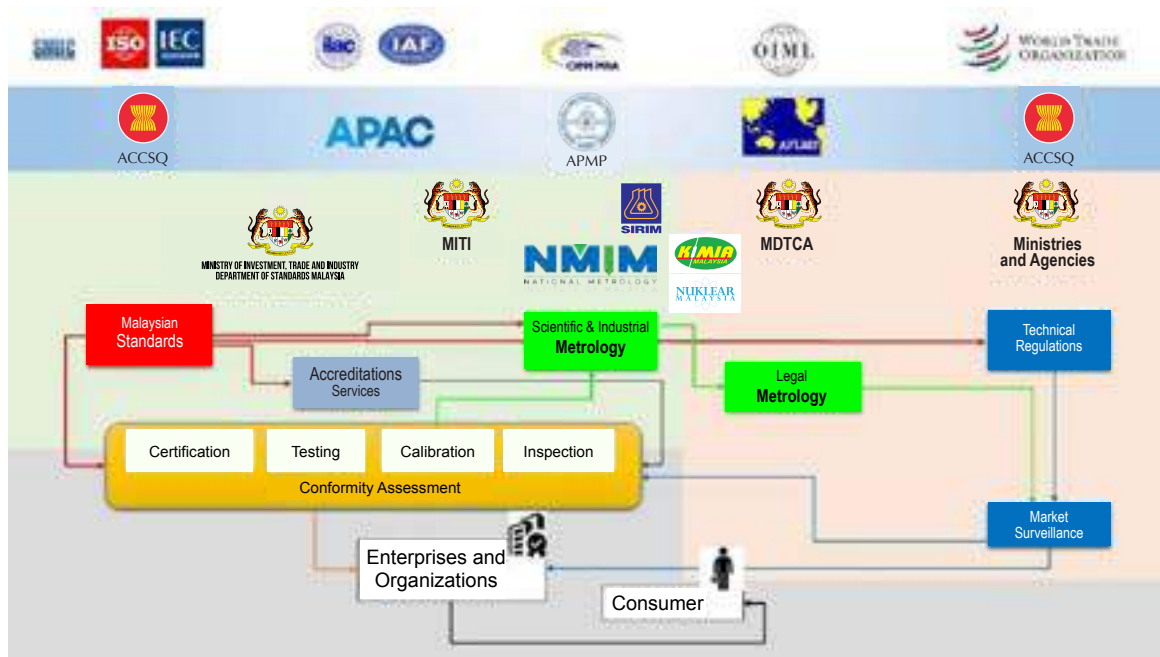


Figure 12: Malaysia's Quality Infrastructure System

According to the latest GQII data, Malaysia ranked 40th out of 184 countries in 2020 (GQII, 2021). The country ranked 33rd, 39th and 46th (out of 184) in metrology, standards and accreditation, respectively (GQII, 2021). The GQII country profile for Malaysia is presented in Figure 13. Nevertheless, despite the important steps that the country has taken to advance its QIS over the years, the term “Quality Infrastructure” seems to be quite new in Malaysia in this context. In the Asia-Pacific Economic Co-operation (APEC), the term “quality infrastructure” is used to refer to the quality of hard infrastructure like buildings and roads. Regardless of the lack of awareness about the use of “quality infrastructure” in this context, it is necessary to conduct a thorough assessment of the QIS to determine if it meets Malaysia’s needs as an upper middle-income country and determine what more needs to be done to further improve the state of QI in the country.

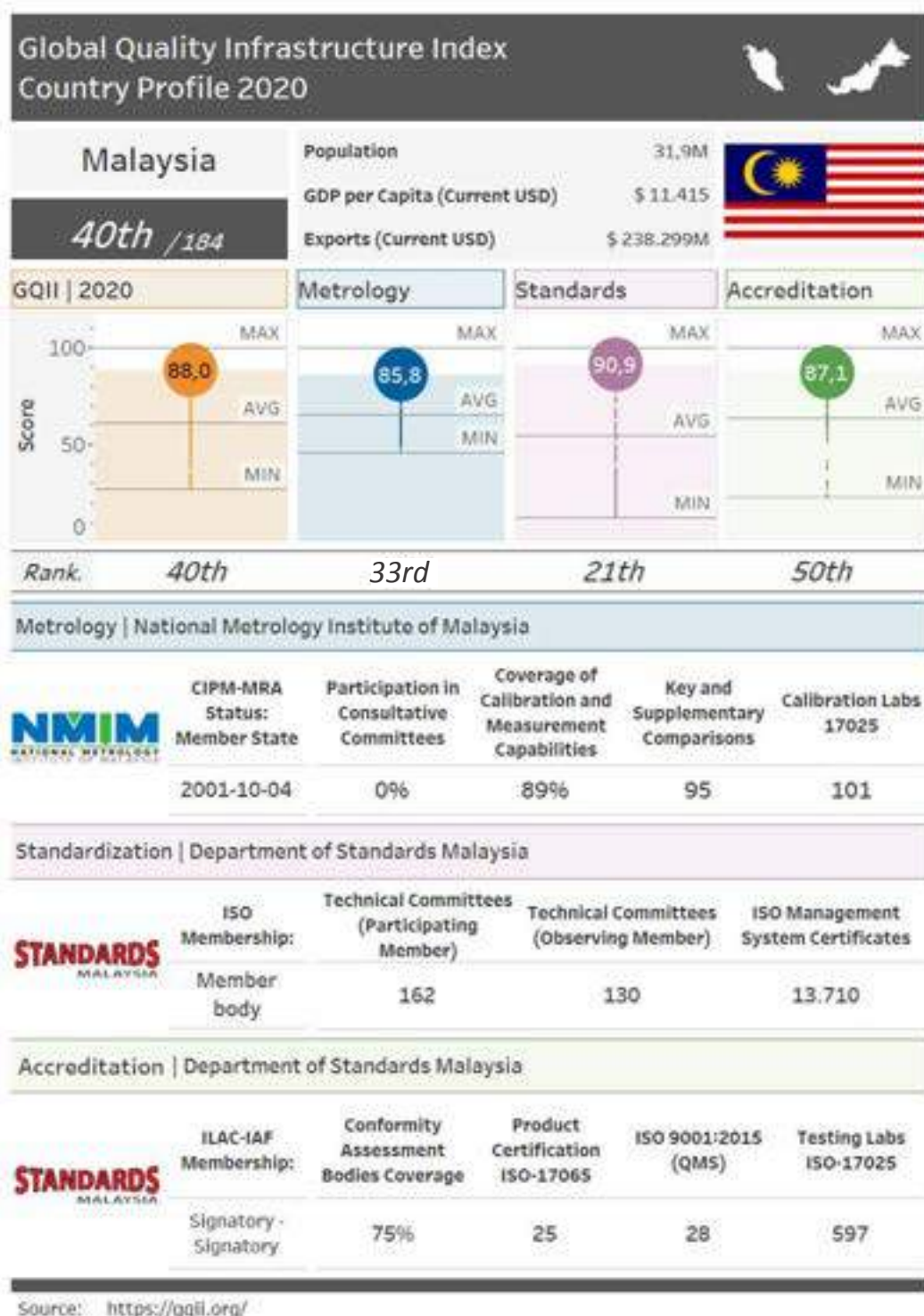


Figure 13: GQII country profile for Malaysia
Source: GQII (2021)

B. Framework and institutional setting

1. Legal framework

The term "quality infrastructure"

As previously mentioned, the usage of the terms "QI" and "quality infrastructure" is not very prevalent in Malaysia. Until now JSM and the NMIM³ have only made selective use of the terms "National Quality Infrastructure" and "NQI". More commonly used in the ASEAN context is the term "STRACAP", which refers to standards, technical regulations, conformity assessment procedures (ACCSQ, 2016).

The terminology of QI agreed on by the International Network on Quality Infrastructure (INetQI) in 2017 replaces previously used terms and acronyms, like Metrology, Standards, Testing and Quality (MSTQ) and Standards, Quality Assurance, Accreditation and Metrology (SQAM).⁴

Following the INetQI definition, the consultant team (CT) understands quality infrastructure as:

"the system comprising the organisations (public and private), policies, relevant legal and regulatory frameworks and practices required to support and improve the quality, safety and environmental performance of goods, services and processes. It is a critical element in promoting and sustaining economic development and environmental and social well-being.

It is based on metrology, standardisation, accreditation, conformity assessment and market surveillance (in regulated areas)." (INetQI, 2022)

Due to the novelty of the term in Malaysia, its definition is required whenever stakeholders are informed about QI and get involved in the NQI assessment. Therefore, a key area of focus

³ See, e.g., NQP graphic on <https://www.nmim.gov.my/index.php/about-nmim/national-quality-infrastructure> (retrieved 06/04/22)

⁴ The acronym was used for the previous review of Malaysia's NQI (Innovation Associate Consulting 2013).

for QI promotion and a future national quality policy is educating policymakers, businesses, and consumers about quality infrastructure, its functions, and benefits.

Constitution

Malaysia follows international practice and has established the essential QI organisations in the areas of standardisation, metrology and accreditation as public organisations as stipulated by law:

The starting point is the Federal Constitution (Perlembagaan Persekutuan Malaysia), which came into force when the country became independent in 1957 (Federal Constitution, 1957). The version with the Amendments through 2007 includes a list of legislative powers (see [NINTH SCHEDULE: Legislative Lists \[Articles 74, 77\]](#))⁵. In the area of trade, commerce and industry, the Constitution assigned the competencies for the following legislation, among others:

- Establishment of standards of weights and measures.
- Establishment of standards of quality of goods manufactured in or exported from the Federation.

Currently, MITI is responsible for weights, measures, and standards. However, responsibility for weights and measures, particularly the legal aspect, is shared with the MDTCA.

The following Acts specify the designation of these competencies:

Weights and Measures Act 1972 [Act 71]

The Weights and Measures Act 1972 was introduced to harmonise Malaysia's national legal metrology units to the International System of Units (SI) and promote fair trade. It is under the purview of MDTCA. The Act provides for establishing national measurement standards of physical quantities based on the SI and lays down the statutory basis for regulating weights

⁵ https://www.jac.gov.my/spk/images/stories/10_akta/perlembagaan_persekutuan/federal_constitution.pdf

and measures and instruments for weighing and measuring (Innovation Associates Consulting, 2013). In addition, it makes provisions for the appointment of the Custodian of Weights and Measures and its duties and powers (Act 71, 2006). Furthermore, it prescribes the mechanism for enforcement and inspection of weights and measures and systematic verification of measuring equipment used in trade (Act 71, 2006).

National Measurement System Act 2007 [Act 675]

The National Measurement System Act 2007 forms the legal basis for the National Measurement Standards Laboratory and its functions. In addition, it prescribes uniform units of measurement based on the International System of Units (IS); establishes measurement standards and measurement traceability; and co-ordinates Malaysia's national measurement system (Innovation Associates Consulting, 2013). Furthermore, the National Measurement System Act 2007 provides for the establishment of a National Measurement Council. It confers powers to the Minister to appoint the National Measurement Standards Laboratory (NMSL), the competent organisation within Malaysia, to carry out certain functions that the NMSL does not have the capacity to (Act 675, 2007). In 2008, NML-SIRIM, later renamed as the NMIM, was appointed as the NMSL. Additionally, the Malaysian Nuclear Agency and the Department of Chemistry Malaysia have been designated as custodians of national measurement for their respective areas.

The Act is under the purview of MITI and applies to all measurement systems in the country used for legal purposes. Even though it provides the legislation for measurement, it does not grant enforcement powers. Therefore, it does not supersede existing legislation related to weights and measures or the relevant ministries (Innovation Associates Consulting, 2013). This is one reason for the continued implementation of Act 71. Furthermore, Act 71 and Act 675 have different objectives and functions. Act 71 ensures weights, sizes and measures used for trading purposes adhere to the SI; and regulates weights and measures and instruments for weighing and measuring in trade. Act 675 provides for uniform units of measurement standards, measurement traceability and co-ordination of Malaysia's national measurement system. Additionally, Act 675 acts as an umbrella Act for all measurement legislations in

Malaysia and enables individuals and organisations to have the capacity to make accurate and traceable measurements.

Nevertheless, both Act 71 and Act 675 are similar in terms of metrological traceability demands, i.e., the measurement process must be defined and controlled to ensure trustworthy measurement results. The approach to the measurement process is the same for all disciplines: definition of the measurand, selection of the most suitable measurement method, and determination of the influencing parameters. These factors all influence the results and produce a level of uncertainty compatible with requirements. However, the results of the metrological operation are used for different purposes. For example, in legal metrology, they are used to achieve regulatory conformity and to guarantee the conformity of the instrument with this regulatory requirement so that it can continue to be legally used.

Trade Descriptions Act 2011 [Act 730]

The Trade Descriptions Act 2011 is also under the purview of the MDTCA. It confers power to the MDTCA to conduct market surveillance and take legal action against individuals or enterprises that engage in unfair trade-related activities. The Act's primary purpose is to promote good trade practices through the prohibition of false trade descriptions and false or misleading statements, conduct and practices for the supply of goods and services; and to prescribe penalties for contraventions (Act 730, 2011).

Standards of Malaysia Act 1996 [Act 549]

The Standards of Malaysia Act 1996 provides the statutory basis for standardisation and accreditation. It repealed the Standards and Industrial Research Institute of Malaysia (Incorporation) Act 1975 [Act 157], which assigned responsibility for standardisation to SIRIM (CommonLII, n.d.). Under Act 549, this responsibility was transferred to JSM. Additionally, Act 549 designated JSM as the NSB and NAB.

Act 549 provides for the appointment of a Director-General by the Minister responsible for standardisation and accreditation (currently the Senior Minister of MITI) (Act 549, 1996). It established the Malaysian Standards and Accreditation Council (MSAC) to play an advisory

role. The Senior Minister of MITI appoints members to the MSAC. Furthermore, as the NSB, it empowers JSM to appoint Standards Development Organisations (SDOs) - external organisations to develop standards. Additionally, it empowers JSM, as the NAB, to accredit conformity assessment bodies (CABs), maintain a register of accredited bodies and their certification marks, represent Malaysia in regional and international activities related to accreditation and appoint organisations to provide accreditation assessment services, among others (Act 549, 1996).

Despite the many provisions included in Act 549, there are several limitations. A key limitation is conferring the final authority for standards and accreditation to the Minister in charge (Act 549, 1996). This is inconsistent with good international practices since standards should be developed according to the needs of society and should therefore reflect a consensus of stakeholders (Innovation Associates Consulting, 2013). Additionally, the MSAC is restricted to its advisory role. The Director of NSB and the NAB take direction from the Minister in charge, without input from the MSAC (Innovation Associates Consulting, 2013). This restricts the autonomy of JSM to fully reflect the interest of stakeholders.

Furthermore, the autonomy of JSM is restricted because its administration is subject to government rules. The recruitment of staff members and their compensation takes place through the government mechanisms in place, which may have implications on the speed of recruitment and the ability to recruit personnel with specific qualifications (Act 549, 1996). Finally, funding for JSM's activities must be requested annually from the ministry in charge (Act 549, 1996). This is not conducive to developing self-funding models for accreditation services and reduces JSM's flexibility to quickly change its rates for services provided, as necessary.

Noteworthy is that most of the legislative instruments related to QI in Malaysia are almost a decade or older and need revision. At the time of writing, the revision process was in progress only for Act 549. The amendment of all Acts and regulations in Malaysia must comply with Good Regulatory Practice, as stipulated in the National Policy for Good Regulatory Practice (NPGRP). Once this is completed, they will be tabled to the House of Parliament for approval. While it is possible to develop an overarching national quality Act instead of revising each QI-

related Act individually, due to the GRP and legislative processes this will entail, it will require a significant amount of time and the involvement and approval of many key stakeholders. Furthermore, additional time would be needed for the proposed umbrella Bill to be passed in Parliament to solidify its place as an Act.

NMIM was gazetted as National Measurement Standard Laboratory in the announcement of the National Measurement Standard Laboratory setting [P.U. (B) 45/2008] which was broadcasted in the Federal Government Gazette on 30 January 2008. Through the Orders of the Federal Government Ministers (No.3) on 9 July 2020, National Measurement Committee had been assigned under MITI.

2. *Regulatory framework*

Technical regulations

The WTO Agreement on Technical Barriers to Trade (TBT Agreement) defines a technical regulation as follows: *“A document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method”*.⁶

The Standards of Malaysia Act⁷ 1996 defines a “technical regulation” as any written law that provides for technical requirements, either directly or by referring to or incorporating the content of a standard, technical specification or code of practice.

Under the Constitution, different ministries are the competent authorities for specific areas of technical regulation. Each regulating authority has a respective act that enacts its

⁶ WTO TBT Agreement, Annex 1: Terms and their definitions for the purpose of the Agreement

⁷ The document can be accessed at: <chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/viewer.html?pdfurl=http%3A%2F%2F58.82.155.201%2FAEC%2Fpdf%2Fflaws%2F2sa%2F2my%2F3.SA-MY-03.pdf&clen=509720&chunk=true>

establishment, functions, and operation. In the past, the Malaysian Government has introduced a National Policy for Development and Implementation of Regulations (NPDIR) to co-ordinate all regulation, including technical regulations. This policy follows the OECD recommendations on Regulatory Policy and Governance (OECD, 2012a) and international best practice. In July 2021, the National Policy on Good Regulatory Practice (NPGRP) was published, replacing the NPDIR. This policy requires all federal ministries and agencies to adopt and implement good regulatory practices (GRP) including undertaking regulatory impact analysis (RIA) when developing a new or amending an existing regulation, before it goes to the Cabinet, or another decision maker as stipulated in the NPGRP.

The Malaysia Productivity Corporation (MPC) co-ordinates the NPGRP and a network of representatives from all government agencies⁸. The MPC is also the Secretariat for the Special Task Force to Facilitate Business (PEMUDAH) and the bridge for NPGRP implementation and stakeholders outside the Government. Established in 2007, PEMUDAH aims to reduce government bureaucracy in business and functions as a platform for consultation between business and government.

A mandatory standard database available on JSM's website provides users a list of mandatory Malaysian Standards being referred for regulatory purposes. Market surveillance is conducted by each respective regulatory authority as defined by its respective acts and regulations. For market surveillance activities, an obligation to use CABs is not stated explicitly. However, most regulatory authorities use accredited CABs, which may be accredited public technical agencies or private organisations.

JSM does not have a regulatory role, as adoption and compliance with standard and accreditation are voluntary. As any other stakeholder, JSM gives inputs relevant to its core functions in the development of a particular technical regulation. Also, JSM participates in the engagement sessions conducted by the regulatory authorities and advise on matters related to standards, accreditation and conformity assessment.

⁸ <https://www.mpc.gov.my/npgrp/>

Good Regulatory Practice (GRP)

GRP definition

Good Regulatory Practices are internationally recognised processes, systems, tools and methods for improving the quality of regulations. GRP aims at making sure that regulations are fit for their purpose and will deliver what they are set out to achieve in terms of policy objectives.

ASEAN Guidelines on Good Regulatory Practices

In the ASEAN context, the significance of GRP is underlined in the ASEAN Policy Guideline on Standards and Conformance, endorsed in 2005. The original ASEAN Good Regulatory Practice (GRP) Guide was developed by the ASEAN Consultative Committee for Standards and Quality (ACCSQ) in 2009. In 2018, the ACCSQ reviewed the document and renamed it ASEAN Guidelines on Good Regulatory Practices. The ASEAN GRP Guidelines were endorsed in 2019 by the ASEAN member states (AMS) and intend to assist AMS in designing and implementing adequate regulatory approaches toward the preparation and application of technical regulations. The Guidelines should be used in conjunction with the ASEAN Policy Guideline on Standards and Conformance.

Malaysia (represented by JSM) was involved in the development of the ASEAN GRP Principles. The input given then originated from the GRP guidelines developed by MPC. Hence, the ASEAN GRP Guidelines are very much aligned with Malaysia's domestic practices. As of now, most activities for ASEAN GRP are conducted under the purview of ACCSQ, in which JSM is the representative from Malaysia. For any activities related to ASEAN GRP, JSM involves MPC as the custodian of the national GRP.

The ASEAN member states have agreed on a set of core principles of GRP for ASEAN as follows:

1. clarity in policy rationale, objectives, and institutional frameworks;
2. produce benefits that justify costs and be least distortive to the markets;
3. be consistent, transparent, and practical;
4. support regional regulatory co-operation;

5. promote stakeholder engagement and participation; and
6. be subject to regular review for continued relevance, efficiency, and effectiveness.

To avoid unnecessary trade barriers, the GRP is additionally observing principles defined in the WTO TBT Agreement: non-discrimination, transparency, and the use of relevant international standards wherever appropriate.

In the ASEAN GRP Guidelines, the GRP process elements are categorised as follows:

1. establishing the potential need for government intervention (defining the problem);
2. assessing the options;
3. preparing and reviewing technical regulations;
4. notification and information;
5. consultation; and
6. enforcing technical regulation.

In the process of preparing and reviewing technical regulations (step 3 above), the AMS should observe the GRP principles (see above) and meet the relevant WTO TBT obligations.

Besides, specific requirements should be complied with, namely:

1. based on international or national standards harmonised to international standards;
2. refer to only those parts of a standard that represent minimum requirements to fulfil the desired objectives;
3. be the least trade restrictive to achieve the desired objectives;
4. be performance based rather than prescriptive; and
5. equal treatment of products of national origin and products imported from AMS.

If referring to standards is considered an appropriate option for regulatory objective achievement, the respective regulator should optimise interaction with the NSB and participate in the development process of the relevant standards. Malaysian regulators usually optimise the interaction with JSM through the setup of a committee (policy or technical) in carrying out any initiative pertaining to implementation of regulations.

There is also technical engagement on standards development and the relevant accreditation scheme to support the required conformity assessment services. Relevant regulators are always involved in standards development significant to their functions. It is part of the SOP in Malaysian Standards (MS) development to have a balanced group of all key stakeholders involved. At the end of 2021, technical regulations referred to 554 MS. The frequency of such references is depending on the key stakeholder's decisions.

Strengthening GRP in Malaysia

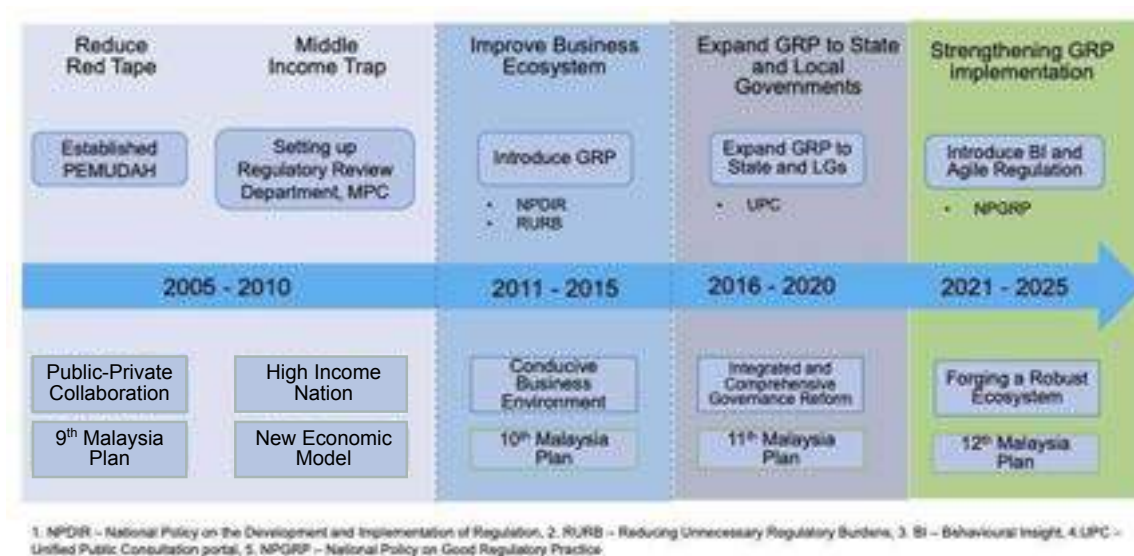


Figure 14: Malaysia's Good Regulatory Practice journey
Source: MPC (2021)

Malaysia has established an evidence-based rule-making methodology to strengthen GRP by increasingly using regulatory management tools, such as regulatory impact assessment (RIA), ex-post evaluation, stakeholder engagement and behavioural insight. Malaysia's regulatory reform process is visualised in Figure 14.

In 2019, MPC started reviewing the NPDIR document and the guidance handbook to improve regulatory management and its implementation at all government levels. With World Bank support, a Unified Public Consultation (UPC) Portal has been set up, which is a web-based tool to support and improve public participation in rulemaking. With APEC support, the public consultation strategy has been improved. Various ministries and agencies, including JSM, have

been using UPC as one of the methods to conduct public comment for MS development (see Figure 15).

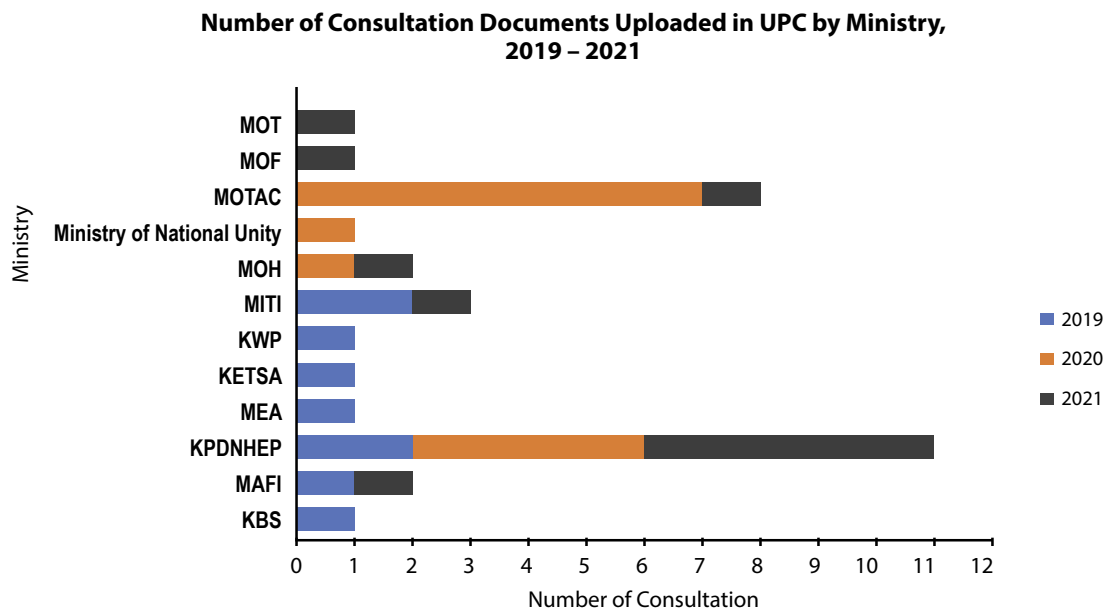


Figure 15: Number of consultation documents uploaded in UPC by Ministry (2019-2021)

The changes made after MPC's review of the regulatory management and its implementation in 2021 led to the introduction of the NPGRP, launched in 2021. The NPGRP newly contains:

- New scope encompasses economy, social aspects and environment;
- Three-tiered assessment (DRN, Initial regulatory impact statements - RIS and Final RIS);
- Existing regulations must be subjected to a regulatory review once every five years;
- Post-implementation Review (PIR) is required when a regulation has been introduced, removed or changed without RIS. PIR must be completed within two years after implementation of the regulation. Binding policies that require quick action, for example a disease outbreak, are exempted from RIA. In such cases, a PIR is conducted; and
- Including Behavioural Insights (BI) as non-regulatory option for regulators to consider aside from regulations. BI are being used to enhance the effectiveness of government interventions. The aim is to observe and change the behaviours of stakeholders to

design policies that would incentivise people to meet policy goals without forcing them through regulations.

In the meantime, Malaysia has established all three crucial GRP categories: (1) internal government co-ordination of rulemaking; (2) RIA by NPDIR and (3) public consultation mechanism.

Strengthening RIA through sufficient public consultation

In 2013, the NPDIR (see above) was introduced with a *Best Practice Regulatory Handbook*, which requires all federal ministries and agencies to undertake GRP and RIA in developing new regulations and amending existing ones. A National Development and Planning Committee acts as a gatekeeping authority to endorse RIS prepared by the regulators.

The RIA elements listed in the NPDIR are as follows:

1. defining a clear problem statement;
2. stating clear objectives to solve the problem;
3. providing a range of options;
4. assessing each option to weigh the cost and benefit;
5. engaging sufficient public consultation with affected parties, including regulators;
6. identifying recommended options and a conclusion; and
7. describing a comprehensive implementation strategy on the preferred options.

A study from 2019 stated that these elements are not always adopted, mainly due to implementers' lack of competency and other shortcomings (Latif, M. 2019). The study also identifies "large variations and inconsistencies in the application of RIA, and GRP principles are not religiously followed".

RIA case examples of a trade-relevant technical regulation are:

- Strategic Trade (Compounding of Offences) Regulations 2019 (completed).

- Amendment of Section 16, Animal Act 1953 by Department of Veterinary Services (On-going)⁹.

Vertical ex-post evaluation

A vertical ex-post evaluation assesses the impacts of regulations within a ministry or agency. The review of business licences is often initiated by business associations. In some ministries vertical ex-post evaluation had become an annual routine to identify inefficiency in public delivery. From 2010 onwards, the 10th Malaysia Plan (10MP) required a review of all business licences regularly. The 11th Malaysia Plan (2016–2020) focused on logistics and trade facilitation. The MP11 was complemented by the Malaysia Productivity Blueprint, in which Thrust No. 13 deals with the review of non-tariff measures to accelerate the movement of goods and raw materials to increase production for export.

The stock of regulations in Malaysia includes about 1,000 primary regulations and another 2,000 subsidiary regulations. Therefore, reviewing regulations on a five-year basis is both time and resource intensive. Under the GRP there is a specific requirement for all ministries to prepare a regulatory plan entailing which regulations under their purview they intend to review. While this procedure works in theory, in practice the plans are not always fully executed or updated. The MPC, in addition to its other roles, functions as a monitor that supervises how often ministries review their regulations and notifies them if certain regulations have not been reviewed for a long time.

Horizontal (sectoral) ex-post evaluation

Sectoral ex-post evaluation is a comprehensive horizontal review of existing regulations to create a conducive business environment. The ex-post approach is guided by the respective value chains and information generated by businesses. Details of this approach depend on the complexity of the value chain and the agreement between MPC and the stakeholders. The

⁹ <https://upc.mpc.gov.my/csp/sys/bi/%25cspapp.bi.work.nc.custom.regulation.cls?regId=472>

evaluation study usually provides recommendations addressing issues and concerns of regulators and enterprises.

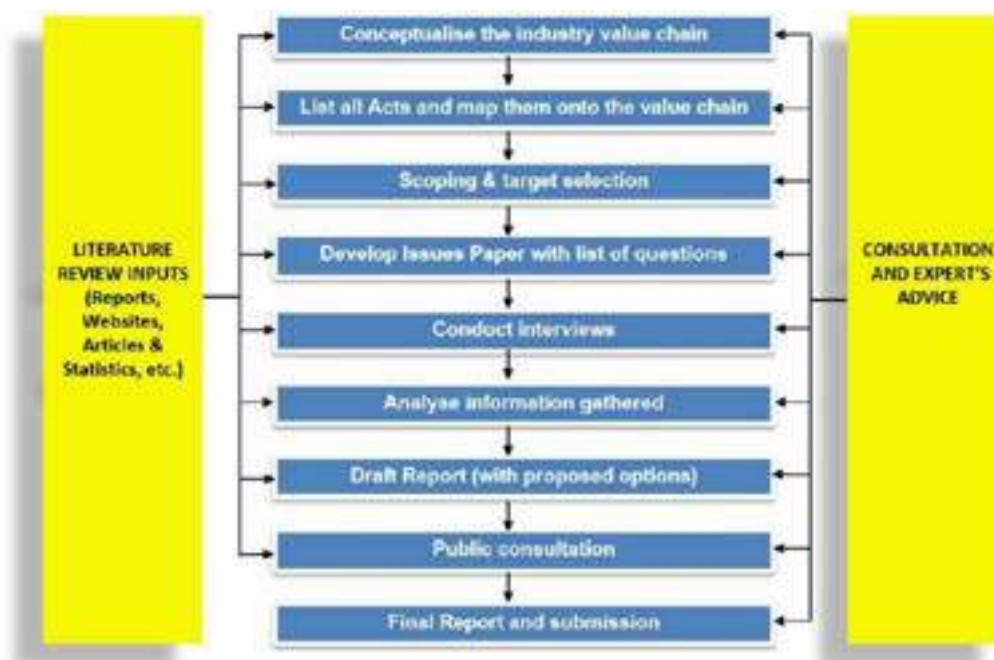


Figure 16: RURB process in Malaysia

Source: MPC 2022

In addition, Australia's Productivity Commission has helped MPC to develop a methodology for reducing unnecessary regulatory burdens (RURB) across the sectoral value chain. Burdens are unnecessary when they are based on poor or obsolete regulations or on the poor implementation of regulations (see Box). RURB helps regulated businesses identify regulatory burdens, suggest solutions, and then present them to regulators in a credible way (see Figure 16).

Box 1: Australia's Approach to Reducing Regulatory Burden

Australia is a federation consisting of six states. The States have plenary legislative power. This means that they essentially have absolute power to legislate on any subject, with no limitations. Each State has its own constitutions, parliaments, governments, and laws. Consequently, regulations differ among States. While this was not initially problematic, over the past decades, as the geographic reach of economic activity expanded beyond the States

and the Federation as a whole, regulatory layering and mismatches became cumbersome (Banks, 2006). As a result, since at least the 1980s, Australian governments have been making concerted efforts to reduce the regulatory burden. Over the years a variety of regulatory agendas, mechanisms and measurements to reduce regulatory burden have been developed, which have been interpreted and implemented differently across jurisdictions (Allen et al., 2021).

Australia's latest approach to reducing the regulatory burden is the incumbent Government's Deregulation Agenda. The Deregulation Agenda is a key component of the Government's plan to improve Australia's regulatory setting so that it fosters productivity and competitiveness; and supports well-functioning markets, business investment, job creation and growth (Australian Government, n.d.).

3. Oversight of NQI institutional setting

For many years MOSTI was responsible for the oversight and leadership of Malaysia's QIS, with support from the MDTCA for legal metrology. However, in 2018 MOSTI's responsibilities concerning QI were transferred to MITI. Therefore, MITI has only had a short period to fully settle into its new role and co-ordinate the new functions associated with it. These new functions, as listed on MITI's website, include *"[providing] credible [standardisation], accreditation and conformity assessment services to enhance societal and environmental well-being as well as facilitate trade and economic growth."* (Ministry of International Trade and Industry, 2019b).

Table 2: QI-related highlights in MITI's timeline

Year	Milestone
April 1956	The Ministry of Commerce and Industry was established and situated in the Government Office, Jalan Raja.
February 1972	The Ministry was renamed the Ministry of Trade and Industry
October 1990	The Ministry was separated into two Ministries: MITI; and MDTCA.
2012	MITI has successfully maintained the MS ISO 9001:2008 certification awarded by SIRIM QAS International
January 2015	The "Halal Malaysia" logo was registered as a sign of certification under the Trademark Act 1976. JAKIM is the owner of the halal logo.
July 2018	JSM and SIRIM Berhad was gazetted as an agency under MITI
July 2019	The Majlis Pengukuran Kebangsaan (MPK) was gazetted as the advisory council under MITI

Source: MITI (n.d.)

As a result of this transfer, the central QI organisations – JSM, NMIM and SIRIM – now fall under the auspices of MITI. These organisations currently report to and are allocated their budgets through MITI. Some of the main QI-related milestones in MITI’s trajectory are highlighted in Table 2.

The following figure shows MITI's organisational structure and the assigned agencies.

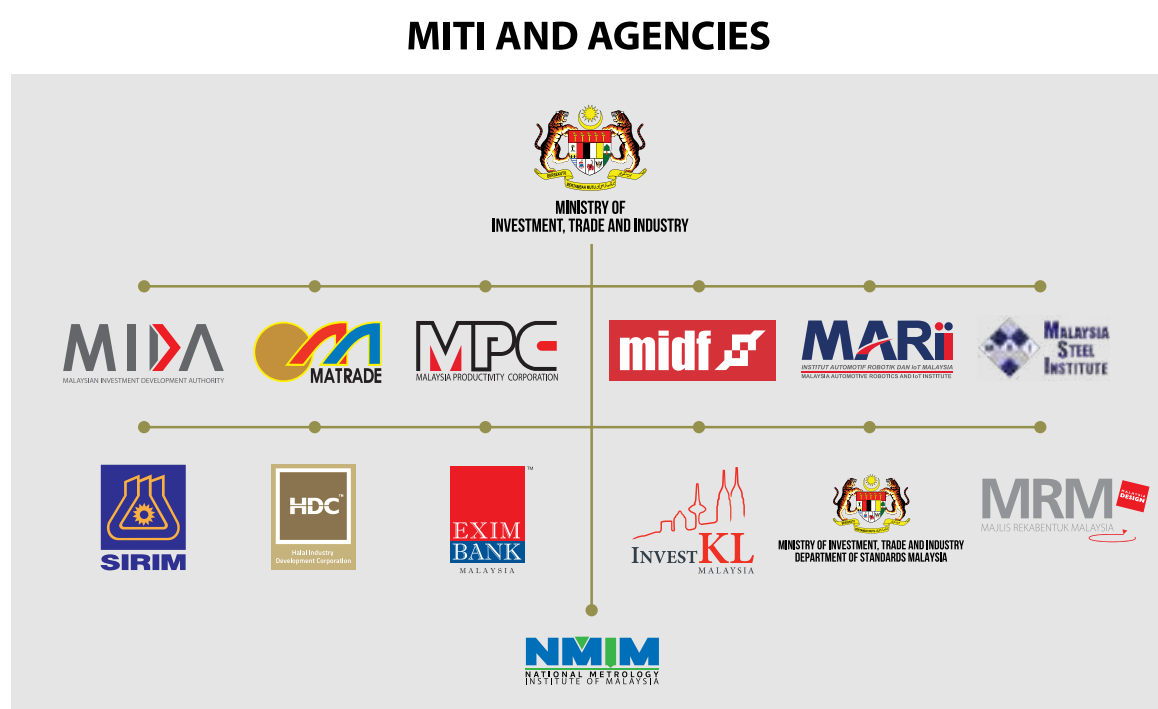


Figure 17: MITI's organisational structure
Source: MITI (2021)

QI-related agencies under MITI

The Department of Standards Malaysia (JSM)

JSM is the National Accreditation Body and National Standardisation Body of Malaysia. As such, it strives to provide credible standardisation and accreditation services to facilitate international trade and develop industry competitiveness (Department of Standards Malaysia, 2022a). It does this through the execution of the following QI-related functions:

- Promulgate and promote national standards;
- Maintain credibility, integrity and competency of the national standardisation and accreditation systems;
- Safeguard the interest of Malaysia at a regional and international level in the fields of standardisation and accreditation; and
- Further international co-operation in relation to standards and accreditation (Department of Standards Malaysia, 2022a).

Malaysian Standards and Accreditation Council (MSAC)¹⁰

The MSAC is responsible for ensuring the continuous implementation of activities required to accomplish duties and functions related to standardisation, accreditation, and other relevant matters. The responsibilities of the Council are to advise and submit recommendations for consideration and approval of the Minister relating to standardisation and accreditation based on Section 13 (3) Act 549. The Council may establish the rules for their activities.

SIRIM Berhad

SIRIM is a premier quality, industrial research and technology organisation in Malaysia, wholly owned by the Ministry of Finance Incorporated (SIRIM Berhad, 2022). SIRIM has over forty years of experience and expertise. Its main roles and responsibilities include research and technology development, and national champion of quality (SIRIM Berhad, 2022).

As the national champion of quality, SIRIM, through its subsidiary company SIRIM QAS International, is Malaysia's leading testing, inspection and certification services provider, accredited by numerous bodies, including JSM and the United Kingdom Accreditation Service (UKAS) among others (SIRIM Berhad, 2022). In addition, SIRIM plays an active role in the development of local industry standards and supports national growth in the human capital of local industries through technology and certification training programmes. SIRIM also assists organisations with the implementation of excellent business culture by associating

¹⁰ <https://www.jsm.gov.my/malaysian-standards-and-accreditation-council-msac-2#.YpERfS8Rr0o>

quality, technology and best practices (SIRIM Berhad, 2022). SIRIM continues to play an essential role in enabling Malaysian products and services to achieve international recognition in quality through its unique advantages in industry standards and quality (SIRIM Berhad, 2022).

SIRIM QAS International Sdn. Bhd.

SIRIM QAS International is a wholly owned subsidiary of the SIRIM Group established in March 1997 (SIRIM QAS International, 2022). Today it is Malaysia's leading testing, inspection and certification body (SIRIM QAS International, 2022). Furthermore, as an International Certification Network (IQNet) partner, SIRIM QAS International's management system certificates are globally recognised (SIRIM QAS International, 2022). Additionally, SIRIM QAS International is accredited by JSM and UKAS.

SIRIM STS - Malaysia's WTO/TBT Enquiry and Notification Point

Malaysia's WTO/TBT Enquiry and Notification Point falls under the auspices of SIRIM STS, which is a subsidiary of SIRIM. SIRIM STS is responsible for developing SIRIM Industry Standards, and providing consultancy and training on standards, technical regulations and conformity assessments (SIRIM STS, 2022a). This also includes consultancy to ensure compliance of product with the relevant standards and regulations, standards and quality infrastructure and economic impact studies (SIRIM STS, 2022a).

In addition, SIRIM STS operates the function of the WTO/TBT Enquiry and Notification Point on behalf of SIRIM Berhad, which has been designated by the government to be Malaysia's National WTO/TBT Enquiry and Notification Point (SIRIM STS, 2022a). As the Malaysia's WTO/TBT Enquiry and Notification Point, SIRIM STS:

- Handles inquiries from businesses and stakeholders on technical regulations/standards/conformity assessment procedures of WTO members;
- Enables businesses and interested organisations to review and comment on notifications of other WTO members that can affect their trade interests. This is done by facilitating the access of TBT Notifications, which are disseminated to the national

stakeholders via a free, web-based e-mail registration service known as E ping Alert System, e-Ping;

- Assists Malaysian regulators with drafting and submitting notifications on proposed technical regulations to the WTO to ensure Malaysia meets its obligations under the WTO/TBT Agreement; and
- Provides support and updates to the National TBT Committee on matters related to the implementation of the WTO/TBT Agreement and operation of the WTO/TBT Enquiry and Notification Point (SIRIM STS, 2022b).

National Metrology Institute of Malaysia

NMIM is a Strategic Business Unit under SIRIM. It functions as a statutory body and was gazetted as the National Measurement Standard Laboratory (NMSL) under [P.U.(B) 45/2008], which was published on 30 January 2008 and took effect from 24 August 2015.

NMIM plays an essential role in disseminating the traceability of measurement to all of Malaysia based on the International System of Units (SI) (NMIM, 2020a). NMIM is responsible for ensuring that the national metrology infrastructure meets and complies with global measurement standards (NMIM, 2020a). Furthermore, NMIM has been mandated to realise and maintain the National Measurement Standards and Certified Reference Materials under the National Measurement System Act 2007 (Act 675) (NMIM, 2020a). Additionally, under the Weights and Measures Act 1972 (Act 71), NML-SIRIM, now renamed and repositioned as NMIM, was mandated as the Custodian of the Weights and Measures and as an advisor to the Minister on matters relating to measurement (NMIM, 2020a). The important functions of NMIM increased in significance after Malaysia signed the WTO TBT Agreement, which emphasises the importance of a harmonised national infrastructure measurement system (NMIM, 2020a).

NMIM works closely with JSM to ensure traceability to the accredited testing and calibration laboratories and also provides Proficiency Testing and Measurement Audit programmes (NMIM, 2020a). To ensure the credibility of the National Measurement System of Malaysia at the international level, NMIM has participated in many international comparisons, such as key

comparison, supplementary comparison and proficiency testing program (NMIM, 2020a). Furthermore, NMIM actively participates in the activities of the Asia Pacific Metrology Programme (APMP) and the Asia Pacific Legal Metrology Forum (APLMF) (NMIM, 2020a). NMIM is also a signatory to the CIPM-MRA on behalf of Malaysia, which allows National Measurement Standards, which are developed in Malaysia, as well as certificates of measurement/calibration issued locally to be globally recognised (NMIM, 2020a). International memberships of NML-SIRIM include the General Conference of Weights and Measures (CGPM)/Metre Convention, the International Organisation of Legal Metrology (OIML), the ASEAN Consultative Committee on Standards and Quality (ACCSQ), the ASEAN Consultative Committee on Standards and Quality on Legal Metrology (ACCSQ-WG3) and the National Conference of Standards Laboratories International (NCSLI) (NMIM, 2020a).

Majlis Pengukuran Kebangsaan (MPK) (National Measurement Council)

MPK was established and assigned its functions under Part IV of the National Measurement System Act 2007 (Act 675) (NMIM, 2020c). Its main function is to advise on all matters related to the objectives of national policy for the measurement system activities (NMIM, 2020c). In addition, MPK is responsible for submitting proposals to increase international confidence in measurement activities in Malaysia; supporting Malaysia's international obligations on measurement; facilitating Government policy in national and international trade; among other functions (NMIM, 2020c). NMIM is the Secretariat of MPK.

Malaysia Productivity Corporation

The Malaysia Productivity Corporation (MPC), formerly known as the National Productivity Corporation, was established in 1962 (MPC, n.d.). In 1966, the organisation became an autonomous body with the passing of the National Productivity Council (Incorporation) Act No. 408. This Act was later amended as the National Productivity Council (Incorporation) (Amendment) Act A305 1975, as the role of the organisation expanded (MPC, n.d.). Subsequently further amendments were made and the National Productivity Centre (Incorporation) (Amendment) Act A801 1991 came into effect, which changed the National Productivity Council to the National Productivity Corporation. In 2008, the National

Productivity Corporation (NPC) was officially renamed as the Malaysia Productivity Corporation (MPC) when the Minister of International Trade and Industry (MITI) signed the document enforcing the National Productivity Corporation Act (Incorporated) (Amended) 2008 (MPC, n.d.). Further amendments were made as a result of the organisation's growing list of responsibilities and today the Act is known as the Malaysia Productivity Corporation Act (Incorporated) 1966 (MPC, n.d.). By the provisions under Section 7 of the Act, MPC fulfils the following QI-related functions and responsibilities:

- To establish an information and reference centre for productivity indices for the country and management systems and case studies;
- To generate local expertise in the field of productivity, quality, management and entrepreneurship;
- To advise on and co-ordinate the implementation of programmes and activities related to productivity and quality;
- To assess and certify supervisory and management training programmes, entrepreneurship programmes and productivity and quality management programmes conducted by the private sector for the public;
- To conduct training or other programmes relating to productivity, quality, management and entrepreneurship;
- To provide consultancy services relating to productivity, quality, management and entrepreneurship; and
- To collect, produce and publish information on productivity, quality, management and entrepreneurship and other related matters.

MPC has been given the mandate under the Malaysia Productivity Blueprint (MPB) to propel Malaysia to become an advanced economy and an inclusive nation. MPB outlines the following five key strategic thrusts to raise productivity and address the challenge: Building Workforce of the Future, Driving Digitalisation and Innovation, Making Industry Accountable for Productivity, Forging a Robust Ecosystem and Securing a Strong Implementation Recognition. In addition, the Sector Productivity Nexus plays a key role in supporting

enterprises on the ground, while simultaneously improving the quality of the products and services.

In addition, MPC has the following QI-related objectives:

- Providing value-added information on productivity, quality, competitiveness and best practices through research activities and databases; and
- Conducting review on regulation and promoting Good Regulatory Practice to create a more competitive business environment.

C. Status by components

1. Standards

The Standards of Malaysia Act of 1996 defines a standard as:

a document approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory; and which may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method (Act 549, 1996).

This definition is consistent with the terminology used by the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC) and the specification in the WTO TBT Agreement, which elaborates that standards are voluntary – not compulsory or mandatory (Kellermann, 2019c).

In today's increasingly globalised and technologically advanced world, standards play a multifaceted role. They are essential for facilitating international trade and promoting economic efficiency and innovation. In addition, they contribute to the protection of consumers and the environment, the reduction of waste, the sustainable use of resources, and the development of a circular economy. Furthermore, they play a key role in ensuring health and safety. Additionally, standards should form the basis of technical regulations, which are compulsory or mandatory (Kellermann, 2019c).

Standards drive industries to produce high value-added products and services without compromising quality aspect which will bring Malaysia's productivity growth to pre-pandemic levels, targeted at 3.6% in 2022 (Malaysia Productivity Corporation, 2022)

While it is evident that the qualitative impact of standards is significant, it is complex to quantify their economic impact. Nevertheless, several studies have been conducted over the years to determine the economic benefits of standardisation. Case studies conducted by the ISO and its members since 2010 in over 20 countries have found that using standards helped companies streamline their internal operations, innovate and scale up operations, and create or enter new markets (ISO, 2014). A study by the German Institute for Standardisation in 2011 found that standards had a significant and positive association with economic output (Standards Australia, n.d.). Additionally, a study by Standards Australia on the impact of standards on the Australian economy found a positive relationship between standards and GDP – a 1% increase in the production of standards was associated with a 0.17% increase in GDP, which amounted to about \$2.78 billion in 2009 (Standards Australia, n.d.). More recently, a study conducted by JSM on the impact of standards on key value chain activities and GDP across several sectors showed that standards had a positive macroeconomic impact and acted as a driver of economic growth (Berger, 2020). Therefore, standardisation is essential for countries seeking economic growth.

Malaysia ventured into standardisation in the 1960s with the establishment of the Standards Institute of Malaysia (SIM) in 1966, as its economy started moving away from agriculture and commodities to manufacturing and services. As the country's needs for standardisation services increased, the more its National Standards Body (NSB) evolved. Today JSM serves as the NSB of Malaysia, and despite its relatively young age, it has made significant strides to ensure that standardisation in Malaysia is on par with the rest of the world. According to the latest GQII data, in 2020 Malaysia ranked 21st out of 184 countries in standards (GQII, 2021). As of April 2022, JSM has developed approximately 4,844 standards, 46.39 % of which have been aligned with international standards (Department of Standards Malaysia, 2022d). These

standards cover the 26 key sectors¹¹ of the economy and take national sectoral policies into account (Department of Standards Malaysia, 2022d). Furthermore, the standards support implementing the country's national development strategy – MP12.

The Malaysian Standards (MS) development process is closely aligned with Good Standardisation Practice (GSP) principles, which were developed by the Committee on Technical Barriers to Trade, and then augmented by the ISO. These principles include transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, development dimension, stakeholder engagement, due process, and national adoption or implementation of international or regional standards (Kellermann, 2019c). The MS development process is listed on JSM's website and illustrated in Figure 18. Upon receiving a request for a new MS, the National Standards Committee (NSC) approves it once a consensus is reached. Then, the JSM evaluates funding and prioritisation (Department of Standards Malaysia, 2022c). Standards are prioritised according to the number of users and whether they will be mandatory or certifiable (G. Bosmans, personal communication, 2022).

¹¹ Agriculture; Chemicals and Materials; Consumer Interests; Buildings, Construction and Civil Engineering; Power Generation, Transmission and Distribution of Energy; Mechanical Engineering; Information Technology, Communications and Multimedia; Petroleum and Gas; Halal Standards; Plastics and Plastic Products; Packaging and Logistics; Transport; Fire Safety; Rubber and Rubber Products; Metallic Materials and Semi-Finished Products; Textiles and Apparels; Medical Devices and Facilities for Healthcare; Electrical and Electronics Equipment and Accessories; Tourism, Exhibition and Hospitality Services; Food and Food Products; Timber, Timber Products and Timber Structure; Occupational Safety and Health; Oil Palm and its Products; Quality and Organisational Management; Environmental Management.



Figure 18: MS development process

Source: JSM (2022c)

A Technical Committee (TC)/Working Group (WG) drafts the MS and then submits it for public comment and proofreading. The draft is then reviewed by the NSC and approved if accepted by a majority of two thirds (Department of Standards Malaysia, 2022c). The draft is then verified by JSM before being submitted to the Minister for approval. Once it is approved, it is published on the MySQL portal at <https://mysql.jsm.gov.my/> (Department of Standards Malaysia, 2022c). The timeline for developing an indigenous MS is between 12 and 18 months, while the timeline for adopting a MS based on international standards is between four and nine months (Department of Standards Malaysia, 2022c). Complying with the principles of GSP is essential since they allow NSBs to operate efficiently and effectively (Kellermann, 2019c). Furthermore, since standards form the basis of technical regulations, compliance with these principles can prevent the development of unnecessary trade barriers.

Malaysia is part of the regional and international standardisation organisations. Malaysia is a full member of ISO, enabling the country to influence ISO standards development and strategy by participating and voting in ISO technical and policy meetings (ISO, n.d.). Additionally, full members can sell and adopt ISO International Standards nationally (ISO, n.d.). Malaysia takes advantage of its membership by either participating or being an observer in several ISO Technical Committees (TC). A summary of Malaysia's ISO TC participation is presented in Table 3.

Table 3 : Summary of Malaysia's participation in TCs of international standard organisations

JSM	Number	Technical Committees
Chairman	5	<ol style="list-style-type: none"> 1. ISO/TC 45 Rubber and rubber products 2. ISO/TC 45/SC 4 Products (other than hoses) 3. ISO/TC 157, Non-systemic contraceptives and STI barrier prophylactic 4. SMIIC/TC 10 – Halal Supply Chain 5. SMIIC/TC 16 Halal Pharmaceutical Issues
Secretariat	5	<ol style="list-style-type: none"> 1. ISO/TC 45 Rubber and rubber products 2. ISO/TC 45/SC 4 Products (other than hoses) 3. ISO/TC 157, Non-systemic contraceptives and STI barrier prophylactics 4. SMIIC/TC 10 – Halal Supply Chain 5. SMIIC/TC 16 Halal Pharmaceutical Issues
Convenor	11	<ol style="list-style-type: none"> 1. ISO/TC 45/SC 3/WG4 -Natural Rubber 2. ISO/TC 45/SC 3/WG5 - Gloves and other latex products 3. ISO/TC 61/SC 2/WG 2 - Hardness and surface properties 4. ISO/TC 61/SC 9/WG 6 – Polyolefins 5. SO/TC 207/SC 2/AHG 1 – Environment Auditing 6. ISO/TC 207/SC 7/TG 3 - Engagement and Communication 7. ISO/TC 210/WG7- Good engineering maintenance management 8. ISO/TC 218/WG 4 – Test Methods 9. ISO/TC 241/WG 5 - ISO 39002 - Good practices for commuting safety Systems 10. IEC/TC 115/WG 4 Guidelines on Asset Management of HVDC Installations
Participating member	180	<p>List of TCs are available at : https://www.iso.org/member/1911.html?view=participation&t=PT</p>

JSM	Number	Technical Committees
Observing Member	126	List of TCs are available at : https://www.iso.org/member/1911.html?view=participation&t=OT
PDC participation	3	<ol style="list-style-type: none"> 1. ISO/ CASCO Committee on conformity assessment 2. ISO/ COPOLCO Committee on consumer policy 3. ISO/DEVCO Committee on developing country matters

Source: ISO (n.d.)

JSM sits on the ISO Council for the 9th term (2022-2024), the highest policy committee in the ISO which enables the country to participate in the development of international standards policies that have an impact on trade, and by extension protect its interest in the areas of standards (Department of Standards Malaysia, 2022b). JSM also represents Malaysia in the ISO Technical Management Board (TMB) for the 6th term (2021-2023), with delegated authority for decision-making, for the general management of the technical committee structure (including establishment, co-ordination, and dissolution of ISO's technical bodies), the supervision of their activities, and the development and maintenance of the rules for the work of the ISO technical committees.

Additionally, Malaysia is a full member of the IEC – the country participates in [40 TC/SCs](#)¹² (Subcommittee) and is an observer member in [57 TC/SCs](#)¹³ (IEC, 2022). As a member of the Standards and Metrology Institute for Islamic Countries (SMIIC), JSM represents Malaysia on the Board of Directors (SMIIC BOD) (2022-2024) and is also a member to the SMIIC Standard Management Council (SMIIC SMC) (2022-2024) and Management of SMIIC Accreditation Council (SMIIC AC) (2022-2024).

Malaysia also actively participates in three regional organisations concerned with standardisation activities – the Asia Pacific Economic Co-operation Sub-Committee on

¹² https://www.iec.ch/ords/f?p=103:33:509937924224474:::FSP_ORG_ID,FSP_LANG_ID:1042,25

¹³ https://www.iec.ch/ords/f?p=103:33:509937924224474:::FSP_ORG_ID,FSP_LANG_ID:1042,25

Standards and Conformance (APEC-SCSC), the Pacific Area Standards Congress (PASC) and the ASEAN Consultative Committee for Standard & Quality (ACCSQ) (Department of Standards Malaysia, 2022b). Also noteworthy is JSM's liaisons with the NSBs of several countries, including the United Kingdom, Australia, Japan, Korea, Vietnam, Canada, Sri Lanka, the United States of America, China, Thailand, Singapore, Saudi Arabia, New Zealand, Germany, India and Indonesia (Department of Standards Malaysia, 2022b). Additionally, Malaysia is connected to several associations that develop standards for specific sectors, including SAE International, the American Petroleum Institute (API), the American Society of Mechanical Engineers (ASME), ASTM International, the National Fire Protection Association (NFPA), and UL Standards (Department of Standards Malaysia, 2022b).

In addition to developing standards, JSM has been taking advantage of various technical assistance projects to build the capacity of its personnel to carry out their roles and responsibilities. For instance, under the umbrella of ARISE Plus Malaysia, in 2021, 56 JSM management and staff members participated in a series of online training sessions on the ISO methodology for developing National Standards Strategies (G. Bosmans, personal communication, 2022). Additionally, JSM's management and staff undertook a stakeholder analysis exercise which resulted in the preparation of a six-month "Plan for a Plan", which set out the necessary steps to develop a National Standards Strategy (NSS) for 2022-2024 (G. Bosmans, personal communication, 2022). Further training was then provided on developing communication strategies to support the development of an NSS and raising awareness of the importance of standards and the economic benefits of standards to stakeholders (G. Bosmans, personal communication, 2022). However, due to limited resources within JSM, the development of the NSS was postponed for the foreseeable future.

The World Bank's Rapid Diagnostic Tool (RDT) was used to assess the level of maturity of Malaysia's NSB. A summary of the findings is presented in Figure 19.

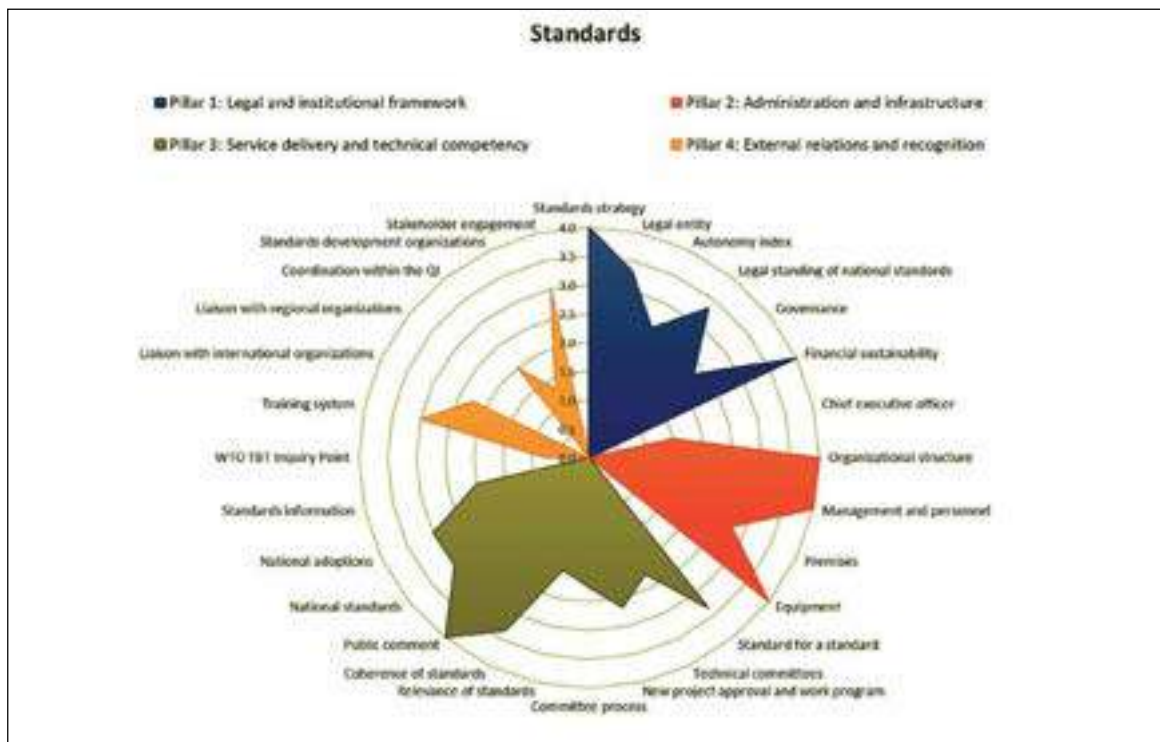


Figure 19: Rapid Assessment – Standards

Source: Elaboration by consultants using the Rapid Diagnostic Tool (World Bank & PTB, n.d.) based on input from JSM

The analysis was categorised into four pillars and 28 building blocks. As can be seen in Figure 19, even though there is room for improvement, the country's scores were relatively high for Pillar 1: Legal and institutional framework, Pillar 2: Administration and infrastructure, Pillar 3: Service delivery and technical competency and Pillar 4: External relations and recognitions. With respect to Pillar 1, while JSM performed well in the legal entity building block, which relates to the establishment of JSM as the legal entity responsible for standards development and publication activities, the legislation - Standards of Malaysia Act 1996 (Act 549) – is not up to date. Act 549 was last revised in 2012. Additionally, it was revealed under Pillar 2 of the assessment that regulators are not legally obliged to refer to national standards when regulating. This affects the application of GRP and thus the effectiveness of the national regulatory system.

Under Pillar 3, it was noted that some processes of standardisation are reactive and not very formalised. For instance, participation in technical committees for standards development is not widely advertised and therefore not all societal groups are represented. Moreover, when

the RDT was conducted in February 2022 some shortfalls existed in the co-ordination and organisation of these technical committees. For example, a formal work programme has not been developed to manage committee activities. Furthermore, the minutes of technical committee meetings, highlighting the decisions and outcomes discussed, are circulated to committee members only before the next meeting and not within a week after the meeting, according to international good practices. Additionally, the Standard Operating Procedure (SOP) is only for JSM's internal use. Finally, there are still some limitations concerning accessing standards. For instance, standards can be purchased physically and online, paid using cash, online banking and telegraphic transfer only, and the data collected on standards sales is not analysed and used for future planning.

Malaysia's scores for Pillar 4: External Relations and Recognition were significantly lower than for the other pillars. This pillar evaluates the NSB's presence in regional and international standards development. NSB needs to represent the country's interests and serve as a channel for up-to-date information for local industry and the government on future technological and market developments (Kellermann, 2019a). The lower score for this pillar was mainly attributed to some shortcomings of the WTO TBT Enquiry and Notification Point, Malaysia's liaisons with regional standardisation organisations, and the recognition and co-ordination of standards development organisations (SDOs) by JSM. The assessment revealed that some of the WTO TBT Enquiry and Notification Point's responsibilities were not being effectively fulfilled. For example, the WTO TBT Enquiry and Notification Point is unable to provide country-related information on the standards used in the development of all the technical regulations in the country, the conformity assessment regimes for standards and technical regulations, and international and regional co-operation agreement regarding conformity assessment. Furthermore, the WTO TBT Enquiry and Notification Point does not analyse WTO TBT notifications on a regular basis and is consequently unable to provide "early warning" information to relevant stakeholders. There is also a lack of communication and co-ordination between the bodies responsible for WTO TBT issues in Malaysia – the TBT Enquiry and Notification Point and the National Mirror Committee (NMC). NMC is responsible for mirroring WTO TBT meetings and discussing TBT issues related to Malaysia. However, NMC only meets biannually and there is a low participation rate in some meetings because they coincide with

Malaysian holidays. Additionally, there is often insufficient time between WTO meetings and NMC meetings to discuss TBT matters that affect Malaysia in adequate detail and the issue of staff rotations without proper onboarding which causes delays as new members take time to get up to speed with their roles and responsibilities.

Despite JSM's website indicating that the country participates actively in regional and international organisations concerned with standardisation activities, the assessment revealed that JSM is not actively participating in these organisations, or the standards-setting activities organised by them. Furthermore, the results show that in terms of regional standards, European Standards (EN) are occasionally adopted when required.

Currently, there is no support for standards development organisations (SDOs) to develop standards in Malaysia (G. Bosmans, personal communication, 2022). As such, there are no strategies in place to evaluate standards developed by SDOs and co-ordinate their work programmes with that of JSM or the country's regional and international obligations. As a result, the country's score under the SDO building block is low. While this is in alignment with JSM's decision to be a full-fledged SDO, a common practice in many of the leading countries in QI is to designate SDOs and allow them to develop standards following formal procedures that have been established and implemented by NSB. This practice is especially useful for niche sectors that require specific standards that JSM may not have competencies in, for instance the aerospace and finance sectors.

Nevertheless, JSM is continuously working towards improving standardisation in Malaysia. JSM is currently working towards the targets set in its Business Plan and Strategic Plan for the period 2022 to 2025. Some of the key areas of focus will be JSM's role as the reference point for TBT matters, capacity building, training and engagement with key stakeholders to enhance industry competency in standards and conformance, and promoting standards and conformance (Department of Standards Malaysia, n.d.-b). For 2022 in particular, some of the key deliverables include launching the new JSM website; developing 350 MS and 50 International Standards under ISO/IEC/SMIIC; developing and promoting two high-impact MS to support enforcement activities by the relevant regulatory bodies in Malaysia (MS 2530

series and MS on waste paper); and launching the Malaysian Standards Online platform (MySOL) (Department of Standards Malaysia, n.d.-a).

SIRIM industry standards

In addition to the national standard body, JSM, SIRIM Berhad develops its complementary industry standards. These standards should cater to their specific needs. Industry standards define the minimum requirements needed to uphold quality in organisations.

SIRIM industry standards also provide an alternative way to industries in situations where a national consensus is not required, mainly when the needed standard is intended to cater to an organisation's specific requirements or a particular sector of industry.¹⁴

SIRIM Berhad differentiates three types of its industrial standards:

SIRIM standards: A standard developed or funded using SIRIM's fund or external funding. Consensus is developed by representing all sectors that are interested in the use of the standard.

Association standards: A standard developed with consensus among the many companies within an association or professional society, e.g., a trade association comprised of many different petroleum companies.

Organisation standards: A standard developed with consensus from the organisation's management.

There are currently 49 SIRIM industrial standards. The range extends from Guidelines for the cleanliness of mosque and surau toilets (SIRIM 1: 2014) to Natural cosmetic products - Requirements (SIRIM 48:2022).

¹⁴ Another example is SIRIM STS Sdn. Bhd., a subsidiary of SIRIM Berhad, which has been appointed as co-ordinator for the development of Malaysia Railways Industrial Standard. As the secretariat for the rail industry standards, SIRIM STS is tasked with developing a series of industry standards on trackwork components; e.g. concrete sleepers, ballast, rail pads, base plates, clips, etc. Additional information can be found at: <https://www.sirim.my/Pages/SIRIM-Press-Release/Malaysia-Railways-Industrial-Standard.aspx>

Apart from co-ordinating the development and sales of local and industry standards, SIRIM Berhad also adopts international standards such as ISO, Japanese Industrial Standards (JIS), German Institute for Standardisation (DIN), American Society of Mechanical Engineers (ASME), American Society for Testing and Materials (ASTM), Aerospace Standards (AS), National Fire Protection Association (NFPA), Automotive Industry Action Group (AIAG), etc., to suit local needs and conditions.

In addition, SIRIM Berhad operates its virtual standards shop, which sells international and foreign standards from other countries.

2. Technical regulations

Background

Countries can enact primary or secondary legislation to regulate different aspects of business and life in society. Concerning the regulation of products, the WTO TBT Agreement indicates that no country should be prevented from taking measures necessary to ensure the quality of its exports; for the protection of human, animal, or plant life or health of the environment; or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade.

A definition of technical regulations according to WTO and Malaysia's Standard Act is provided in Chapter IV.B.1 above.

Malaysia's regulators

The number of regulatory bodies in Malaysia differs in different sources and assessments. Table 4 shows a long list of Malaysian regulators composed using various sources.

Table 4 : List of regulators in Malaysia

1. Food Safety and Quality Division, Ministry of Health Malaysia (MOH)*	2. Fire & Rescue Department of Malaysia (BOMBA)*
3. Department of Occupational Safety and Health Malaysia (DOSH)	4. Department of Quarantine & Inspection Services (MAQIS)
5. Medical Device Authority (MDA)*	6. Local Government Department (JKT)*
7. National Pharmaceutical Regulatory Agency (NPRA)*	8. Department of Occupational Safety and Health (DOSH)
9. Ministry of Domestic Trade and Consumer Affairs (MDTCA)	10. National Water Services Commission (SPAN)*
11. Ministry of Agriculture and Food Industry (MAFI)	12. Federal Agricultural Marketing Authority (FAMA)*
13. Energy Commission (ST)	14. Malaysian Communications and Multimedia Commission (MCMC)*
15. Ministry of Transport Malaysia (MOT)*	16. Malaysian Construction Industry Development Board (CIDB)
17. Department of the Environment (DOE)	18. Road Transport Department Malaysia (JPJ)
19. National Solid Waste Management Department (JPSPN)	20. Malaysian Cocoa Board (LKM)
21. Royal Malaysian Customs Department	22. Malaysian Palm Oil Board (MPOB)*
23. Public Works Department (JKR)	24. Plan Malaysia
25. Jabatan Kemajuan Islam Malaysia (JAKIM)	26. Malaysia Nuclear Agency
27. Construction Industry Development Board (CIDB)*	28. Malaysian Timber Industry Board (MTIB)
29. Malaysian Pepper Board (MPB)	30. National Kenaf and Tobacco Board (LKTN)
31. Malaysian Rubber Board (MRB)	

Note: The regulators marked with an asterisk participated in the RDT assessment.

Above regulatory authorities define technical specifications to ensure citizens are protected from unsafe products and practices, the environment is not harmed, and consumers are treated fairly. A typical method to incorporate standards (or parts of them) into the legal

framework is defined in the principal Acts of Parliament on issuing regulations. Standards are referenced or included in technical regulations to detail technical specifications. JSM has published a guide¹⁵ to help regulatory authorities in this regard. This guide is based on a similar guide published by the ISO and draws from the experience of other countries (Australia, Canada, US) (Innovation Associates Consulting, 2013).

Assessment of technical regulations in West Malaysia

Using the World Bank's Rapid Diagnostic Tool (RDT), the ITC consultancy team assessed the level of maturity of Malaysia's technical regulatory regime. The assessment was divided into four pillars and 23 building blocks. The results revealed that the country is moderately advanced in several areas of technical regulation, while more efforts are required for a few building blocks.

According to the RDT, the technical regulation assessment is summarised in Figure 20.

¹⁵ SIRIM Berhad (2010). Guidelines for Regulatory Bodies on Reference to Standards in Technical Regulation, May 2010.

Technical Regulations

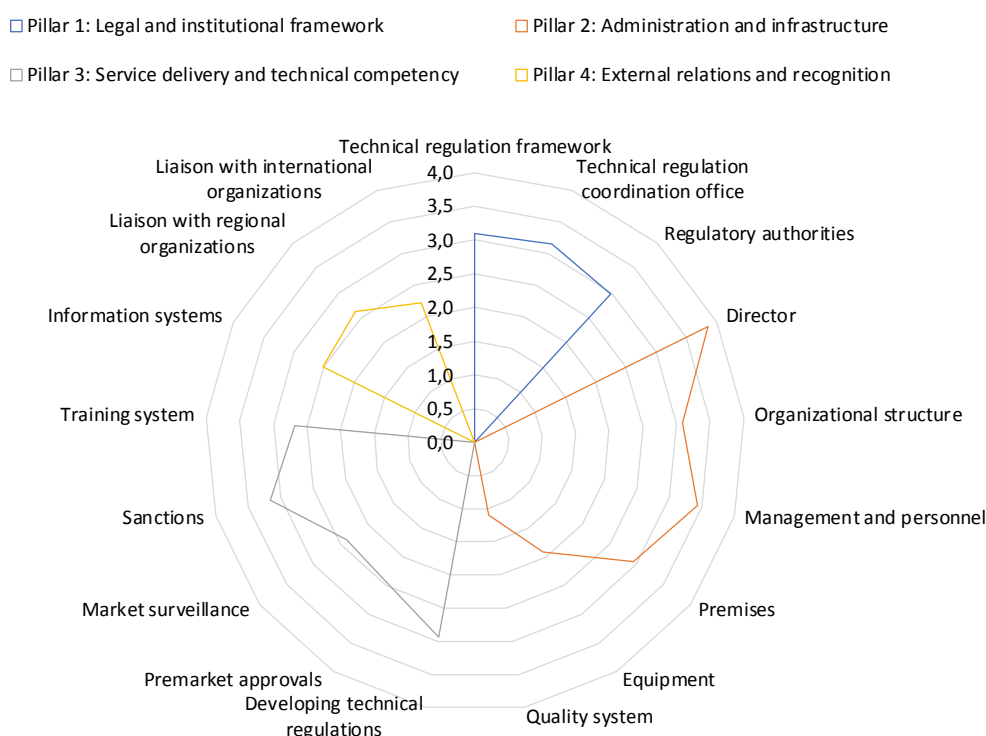


Figure 20: Rapid Assessment – Technical Regulations

Source: Elaboration by consultants using Rapid Diagnostic Tool (World Bank & PTB, n.d.).

Malaysia performed modestly in several building blocks concerning Pillar 1: Legal and institutional framework. Although the recently published general technical regulation framework NPGRP (Malaysia Productivity Corporation, 2021) is available, not all regulators seem to be informed. Only about 60 % confirm such a framework's availability and general applicability. Some regulators consider their agency's principal legal act to be this general framework for formulating regulations. The same share of respondents agrees to know about a technical regulation co-ordination office, even though there is insecurity about where precisely this office is located. Some suspect it to be in MITI or JSM, others in the purview of

their line ministries. Again about 60 % of respondents think that all regulatory authorities are widely known¹⁶ and their responsibilities clearly defined to avoid overlap.

In Pillar 2: Administration and infrastructure, the building blocks of Director and Management and Personnel performed well. In most cases, a responsible individual fills the role of director without undue interference from the outside. Between 80% and 100% of managerial and technical posts are filled with clearly defined skill sets, responsibilities, and key performance indicators (KPIs). However, organisational structure and premises are very differently developed among the regulators. While some report having established divisions regarding product categories and service requirements, such as pre-market approval or market surveillance, others have done so only partially. Only some of them have established a presence close to the marketplace. In most cases, the premises allow for suitable working conditions, but storage space for inspection equipment and product sample is often missing. However, quality systems according to prevailing ISO standards are hardly implemented and assessed or accredited.

Pillar 3: Service delivery and technical competency show moderate performance. The building block 'Developing technical regulations' shows that most regulators apply RIA before developing and implementing a technical regulation. Most technical regulations are based on international or national standards. However, not all regulators publish draft regulations for a reasonable time or notify the WTO between 60 days or six months in advance of their implementation. Some even doubt that they are obliged to do so. The two other critical services of regulators, pre-market approval, and market surveillance are performing relatively poorly with some regulators in Malaysia. Only some carry out risk assessments and early inspection of high-risk products. Market surveillance systems based on risk assessment and the principle of proportionality are established by a few regulators only. In the case of violating regulations, the sanction policy seems to be better developed, though. Training systems for

¹⁶ <https://www.malaysia.gov.my/portal/agencydir>

inspectors are in place but show some gaps and room for enhancement with some of the regulators.

Pillar 4: External relations and recognition are least developed in Malaysia. While some regulators recognise the existence of an IT-based information system that connects regulatory authorities, others do not. Also, the prompt publication of new technical regulations in government channels is not confirmed by all regulators. In terms of liaison with regional organisations, such as in ASEAN, not all regulators are informed about the forums or mechanisms in place. Further, many regulators lack knowledge of how far Malaysia as a WTO member, complies with notification requirements.

These results confirm the outcome of an interview with the TBT Enquiry and Notification Point. It was stated that some regulators are not aware of their responsibilities concerning notifying technical regulations. Consequently, the TBT Enquiry and Notification Point under SIRIM Berhad has sent letters to specific regulators informing them about notifying the WTO about technical regulations. One challenge is a lack of knowledge transfer and training when there are changes in the staff. Typically, regulators send the technical measure they want to notify the TBT Enquiry and Notification Point. The TBT Enquiry and Notification Point offers guidance for drafting the notification. The TBT Enquiry and Notification Point uploads the notifications through the WTO system. Both SIRIM Berhad and the National Mirror Committee (NMC) organise information sessions with regulators. These sessions cover specific trade concerns (STCs) raised by the WTO, making an MS compulsory, capacity building, GRP, technical regulations, functions of the national TBT Enquiry and Notification authority, etc.

Assessment of technical regulations in East Malaysia

To learn about current practices and perceptions of regulators in East Malaysia , representatives of JSM and the ITC consulting team travelled to Sabah and Sarawak in March 2022 to facilitate RDT sessions in each of the two states. In Sabah state, four regulators participated in the RDT survey on technical regulations; and in Sarawak state, eleven regulators participated. Some of the regulators in East Malaysia are of the view that the regulatory system is different than the one in Peninsular Malaysia. This is primarily related to

its process flows which are more relevant to the state government than the Federal government. Most of the regulators are not aware of WTO notification requirements and believe they are not directly relevant to their agencies. Most regulators agreed that there is a gap in the information flow in relation to NQI in East Malaysia compared to Peninsular Malaysia.

The combined results of the two East Malaysian states are shown in Figure 21.

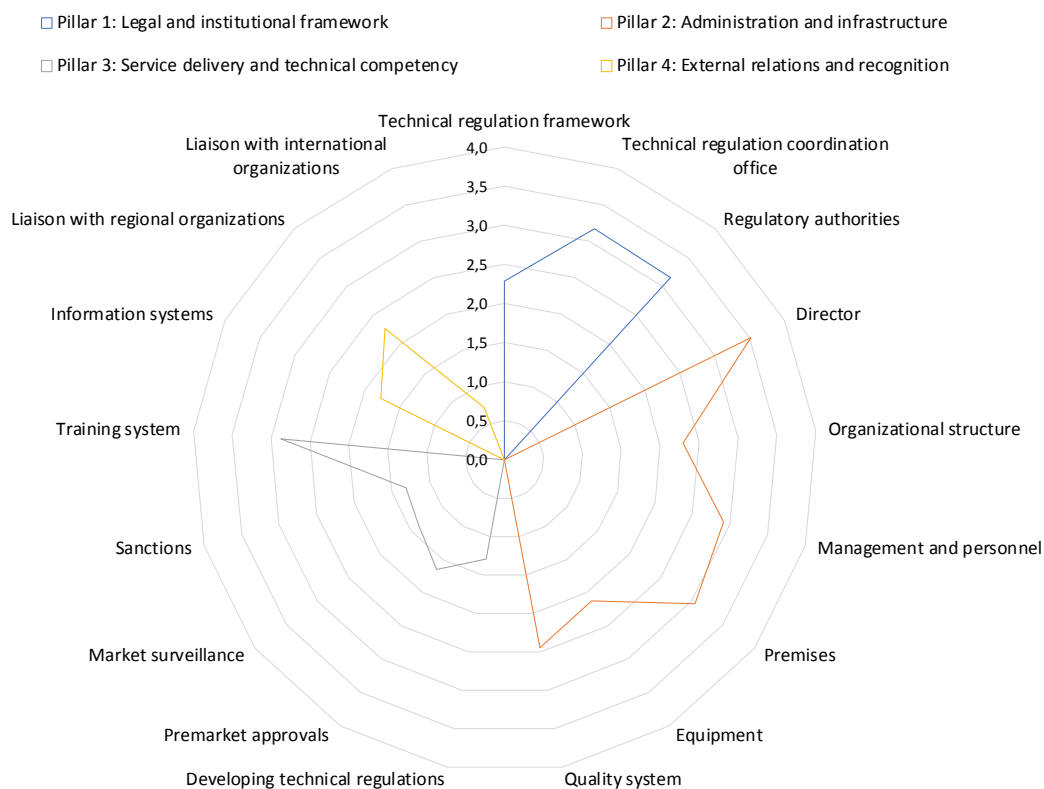


Figure 21: Rapid Assessment – Technical Regulations in East Malaysia

Source: Elaboration by consultants using Rapid Diagnostic Tool (World Bank & PTB, n.d.).

While the assessment of Pillar 2 “Administration & Infrastructure” is comparable to the national level (see Figure 20), differences of the East Malaysia assessment become obvious in Pillars 3 and 4 and the building block “technical regulation framework” in Pillar 1.

Regulators in East Malaysia are often unclear about the “technical regulation framework” they need to consider when drafting and launching regulations. The NPGRP (2021) is often unknown or known but not yet used. Some regulators instead quote their technical or subject-

specific legal frameworks, such as the Plant Quarantine Act, the Ordinance related to Electricity and Gas or the Environment Protection Enactment 2002, to give just a few examples.

The three levels of government in Malaysia – federal, state and local – need to be stressed here. Each level has different powers. The MPC disseminates information about GRP to the federal government because the federal government is obligated to comply with GRP. States have their own GRPs to comply with. For instance, the State of Sabah has issued the State Policy on Good Regulatory Practice dated 23 August 2021, which is informed by the national-level NPGRP, launched two months earlier in June 2021. The MPC has taken the initiative to go to different states and encourage them to use the GRP and provide assistance to states upon request.

In East Malaysia, Pillar 3 “service delivery and technical competence” is weak in almost all indicators apart from training systems, which fares medium well. Apart from training systems, service delivery in the context of technical regulations refers to developing technical regulations, pre-market approval, market surveillance and sanctions.

In terms of Pillar 4 “external relations and recognition”, there is a moderate liaison with regional organisations and forums in the ASEAN context, but not with international organisations or at least this is unknown to regulators at the state level.

3. Metrology

Terminology

Metrology is "the science of measurement and its application" (BIMP (2012), as cited in Kellermann (2019c)). It includes (1) the definition of internationally accepted units of measurement; (2) the realisation of the units of measurement by scientific methods in measurement standards; and (3) traceability, linking measurements made in practice to measurement standards (Kellermann, 2019c). Metrology is generally classified into three categories:

1. Scientific metrology relates to the establishment of units of measurement, the development of new measurement methods, the realisation of measurement standards, the transfer of traceability from these standards to users in society, and the establishment and maintenance of national measurement requirements (Kellermann, 2019c).
2. Industrial metrology relates to applying measurements to manufacturing and other processes and their use in society, considering the suitability of measurement instruments, their calibration, and quality control (Kellermann, 2019c).
3. Legal metrology relates to activities that result from regulatory requirements regarding measurement units, instruments and methods (Kellermann, 2019c).

Metrology is a fundamental aspect of QI and permeates almost every human endeavour in the modern world, vital for trade, production processes, health care and science. It has significant economic implications and can increase productivity in organisations. Precise measurements and quick feedback from measurement to control are associated with a positive impact on efficiency, quality, and productivity (Kellermann, 2019c). Additionally, metrology stimulates innovation. It offers an objective way to demonstrate to consumers that innovation is superior to the products already in the market, which helps prevent market failure for new products (Kellermann, 2019c). Furthermore, it can demonstrate the purity and quality of products, which reduces asymmetric information between buyers and sellers and transaction costs (Kellermann, 2019c).

Metrology, therefore, plays an invaluable role in promoting fair trade. In addition, metrology is used by almost all groups of society. For example, it is used by health care providers who depend on precise measurements for diagnosing medical conditions and administering medication; consumers who rely on accurate measurements of product characteristics to guarantee quality, purity, and safety; environment conservationists who depend on precise measurements; and educators in assessing student aptitude and performance, etc.

National Metrology Institute of Malaysia (NMIM)

Even though Malaysia's National Metrology Institute (NMI) – the National Metrology Institute of Malaysia (NMIM) – was only officially established in 2015, the country has been advancing its metrology capabilities since the 1970s (NMIM, 2020b).

NMIM is responsible for implementing Malaysia's metrology legislation, managing the legal units of the International System of Units (SI), building capacity in calibration laboratories in the country, and sustaining the National Measurement System. NMIM also ensures that the national infrastructure measurement system aligns with global standards and complies with the WTO TBT Agreement.

Today, Malaysia's metrological competence is internationally recognised. However, according to the latest Global Quality Infrastructure Data (GQII) data, in 2020, Malaysia ranked 37th out of 184 countries in metrology (GQII, 2021).

The metrological competencies can be divided into nine areas:

1. Acoustics, Ultrasound, Vibration (AUV)
2. Electricity and Magnetism (EM)
3. Length (L)
4. Mass and Related Quantities (M)
5. Photometry and Radiometry (PR)
6. Chemistry and Biology (QM)
7. Ionising Radiation (RI)
8. Thermometry (T)
9. Time and Frequency (TF)

Since 2001, Malaysia has participated in international benchmarking under the CIPM MRA. NMIM is a signatory of the CIPM MRA. The following have been made designated institutes: Malaysian Nuclear Agency (since 2007); and the Department of Chemistry Malaysia (DOC/KIMIA, since 2017).

In 2021, Malaysia had 123 Calibration and Measurement Capabilities (CMCs) registered in eight of the nine metrology domains in the CIPM Key Comparison Database (see Table 5). However, only in chemistry and biology (QM) does the country not yet have any CMCs.

Table 5 : Malaysia's measurement capabilities

Area	AUV	EM	L	M	PR	T	TF	QM	RI	Total
CMCs	21	32	7	15	8	21	4	0	15	123

Source: KCDB 2021/ GQII2021

The traceability of the industrial measurements to the international measurement system is carried out via public and private calibration bodies. JSM's accreditation body has accredited a total of 109 calibration laboratories.¹⁷ Together, the calibration laboratories provide services in all nine metrology areas. In addition, there are calibration laboratories whose technical competence is recognised by foreign accreditation bodies.

Currently, the CMCs of NMIM and the Designated Institutes (DIs) across the country meet about 60% of the needs of Malaysian companies. This is limited to the metrology fields mentioned above. There are still gaps concerning CMCs to support the emerging technology and oil and gas sectors. It is therefore necessary to develop more CMCs in mechanical measurement, medical metrology, nanotechnology, low temperature measurements and other parameters in the electrical and electronics (E&E) sector.

Additionally, there is a significant gap between supply and demand with respect to CMCs in chemical metrology. NMIM acknowledges the need to build its capacity in developing certified reference materials (CRMs) to support new CMCs for Malaysia. DOC/KIMIA only began to develop CRMs in 2001 and most of the focus has been on CRMs to support gas emission devices and forensic alcohol to support the Royal Malaysia Police. However, the demand for CRMs in the manufacturing sector, particularly among producers of food and beverages and

¹⁷ See <https://www.jsm.gov.my/accredited-organisation-directories> Data retrieved on 01/04/22).

chemical-based products, has been steadily increasing as companies need to guarantee quality assurance and show compliance with international standards. Since only a small number of CRMs are produced in Malaysia, companies must rely on international suppliers, which has serious implications on their production cost, turnaround time (TAT), and competitiveness. Furthermore, there is a need for high precision analytical instruments, infrastructure for characterisation and preparation of matrix reference material, and infrastructure for analysis and preparation of natural gas reference material. In general, there is a need for more chemical metrology infrastructure, experts and facilities to meet the demands of companies that produce chemicals and chemical products, food and beverages, oil and gas, nanoproducts and advanced materials.

NMIM has been working towards building its CMC capacity and engaging more actively with industries to meet their needs. NMIM has already submitted its development expenses (DE) request to MITI for the period 2021 to 2025 in accordance with MP12. The DE request covers plans to develop 27 CMCs in various sectors, including E&E (6 CMCs), Temperature (6 CMCs), Chemical Metrology (5 CMCs), Mechanical parameters (6 CMCs) and Oil and Gas (3 CMCs). Furthermore, NMIM intends to expand the scope of Malaysia's metrological competencies to include AC resistance, high and medium temperature, piston prover, differential pressure, pesticide analysis, heavy metal analysis, remote time and frequency measurement system time via GPS and the Internet, and calibration of gauge block by interferometry and the comparison method.

With respect to scientific metrology, development took place at a more rapid pace compared to chemical metrology, especially in physical measurements. This was because NMIM received more support and funding, including trained experts in various fields, during the early stages of development from 1970 to 1980. During this time NMIM collaborated with the Japan International Co-operation Agency (JICA), which gave them access to programmes and special aid from Japan, to develop their scientific metrology capabilities. However, after 1990 NMIM's development in scientific metrology slowed as government funding for both development and operations decreased. This affected the development of primary standards at NMIM.

Sufficient funding from the government is essential for ensuring that the staff of NMIM receive the knowledge and training they require in the different areas of metrology.

The continued advancement of scientific metrology in Malaysia is fundamental. It is also essential for more experts with a strong metrology foundation to join the staff of NMIM. NMIM has been making concerted efforts to keep up with developments at the international level. The institute has conducted research on the 2019 redefinition of the SI base units to improve its capacity to develop the primary standard at NMIM. Furthermore, NMIM is co-ordinating with the Human Resources Group¹⁸ to increase the number of personnel with doctorates in relevant fields. Additionally, NMIM intends to increase its research activities and to improve its networking with other NMIs.

NMIM has already successfully developed six of the seven SI base units. Currently missing is only the mole (SI base unit of amount of substance), which is still in progress for the development of new primary methods. The development of scientific metrology for chemicals takes a slightly different approach compared to physical metrology. There are more primary methods and dedicated techniques for each field or parameter in chemical composition and bioanalysis. To achieve or establish the primary method for each parameter, NMIM has designed a comprehensive work plan, which includes experts, special skills and the procurement of dedicated equipment for the specific chemical parameters. Additionally, NMIM has documented strategies and memorandums of understanding (MoUs) with various universities to actively participate in research related to scientific metrology, including attending any international forum related to scientific metrology.

The World Bank's Rapid Diagnostic Tool was used to assess the level of maturity of Malaysia's NMI. Figure 22 summarises the findings.

¹⁸ The Malaysian Institute of Human Resource Management (MIHRM) was established in 1976. It was Malaysia's first professional body promoting the practice of Human Resource Management. As the leading and independent body for Human Resource Management in Malaysia, MIHRM has trained thousands of competent HR professionals and practitioners in both the private and public sectors. More information can be found at: <https://mihrm.com/about/overview/>.

The assessment was categorised into four pillars with 22 building blocks. This can be seen in Figure 22. Even though there were some shortcomings, NMIM performed exceptionally well in Pillar 1: Legal and institutional framework and Pillar 2: Administration and infrastructure.

Pillar 1: Legal and institutional framework

The high scores in Pillar 1 were attributed to the country's metrology strategy and its implementation plan. In addition, the legitimacy of NMIM has been embedded in legislation – the National Measurement System Act 2007 (Act 675) and the Weights and Measures Act 1972 (Act 71) – so that it can be held legally responsible for national measurement standards and the national metrology system.

Furthermore, NMIM operates autonomously and can effectively manage its affairs without undue interference or restrictions from external sources. Nevertheless, there is room for improvement in terms of governance and financial stability. The assessment revealed that private sector representation in the NMIM's council is minimal, and that the director is not appointed through the council. Furthermore, NMIM does not have adequate financial resources to meet approximately 30% of its needs.

Pillar 2: Administration and infrastructure

Concerning Pillar 2, the high scores were attributed to NMIM's leadership, management and personnel, organisational structure, and quality management system. NMIM has a full-time senior director with clear responsibilities who also sits on the council and whose performance is evaluated systematically by the council. Furthermore, most managerial and technical posts are filled by duly skilled and qualified individuals who have clearly defined tasks. Additionally, despite being under SIRIM and the Majlis Pengukuran Kebangsaan (MPK), NMIM is an identifiable and separate entity responsible for all the functions of Malaysia's NMI.

NMIM offers services in the main fields of metrology and has clearly defined responsibilities within its organisational structure to maintain and build its capacity. In addition, NMIM's quality management system complies with ISO/IEC 17025:2017 (general requirements for the competence, impartiality and consistent operation of laboratories). Nonetheless, there is

some room for improvement in establishing national measurement standards and reference standards to meet the country's needs. Additionally, there are some shortfalls concerning the physical requirements of laboratories.

Pillar 3: Service delivery and technical competency

NMIM's scores in Pillar 3 were notably lower compared to the other pillars, signalling a need for more concerted efforts for these building blocks. The assessment revealed that the knowledge and experience required for metrologists and other technical posts need to be defined more clearly. More capacity building is required for personnel with technical roles. The more developed a country's NMI, the more skilled and highly trained employees need to be (Kellermann, 2019b). Currently NMIM is focusing on building its capacity with respect to developing CRMs since its staff already includes many experts in the fields of organic chemistry, inorganic chemistry and gas analysis. These experts have received training from the NMIs in Korea, the Netherlands, Australia, the United Kingdom and China.

Additionally, participation in interlaboratory and key comparisons provides information on an NMI's ability to deliver accurate measurement results, which is essential for accreditation and establishing calibration and measurement capability (CMC). As a full member of the BIPM and a signatory to the CIPM MRA, Malaysia participates in CIPM key comparisons and regional metrology organisation (RMO) key comparisons. However, the RDT assessment revealed that NMIM's participation in key comparisons arranged by the Asia Pacific Metrology Programme (APMP) was only ad-hoc. This could be one of the reasons for NMIM's low score in calibration and measurement capability (CMC). NMIM covers about 89% of the country's CMC needs, but its eligibility for its CMCs to be listed in the BIPM Key Comparison Database (KCDB) is still under review by BIPM. Currently, 129 of its CMCs are in the database. An NMI must meet several requirements before its CMCs are approved, one of which entails participating in reviewed and scientific comparisons that are organised by BIPM-recognised RMOs. With respect to calibration services, NMIM scored relatively high.

Pillar 4: External relations and recognition

With respect to Pillar 4, NMIM's performance was a bit weak. There is room for improvement in terms of training. Currently, most of the training for metrologists and technical workers is done on an ad-hoc basis. There is no long-term programme in place for higher-level training of specialist metrologists, new developments in metrology, or new metrology fields which NMIM intends to venture into. With respect to liaison with regional organisations, there is some room for improvement. Malaysia is a member of the Asia Pacific Metrology Programme (APMP), the Asia Pacific Legal Metrology Forum (APLMF), the ASEAN Consultative Committee on Standards and Quality (ACCSQ), and the ASEAN Consultative Committee on Standards and Quality on Legal Metrology (ACCSQ-WG3).

Furthermore, the country has signed several regional Mutual Recognition Agreements (MRA) related to metrology. For example, the CIPM MRA for CMC Area (General Physics and Ionization Radiation) and the APAC-MRA for calibration. However, the assessment revealed that NMIM participates in regional trade agreement-related metrology organisations or committees only about 75% of the time. These organisations play an important role in harmonising metrology activities within the region as defined by the trade agreement, and Malaysia must be represented. NMIM's score was the maximum for liaison with international organisations. Malaysia is a full member of the BIPM and a signatory to the CIPM-MRA and the Metre Convention. In addition, NMIM actively participates in activities by the General Conference of Weights and Measures (CGPM) and relevant consultative committees (CCs), as well as the National Conference of Standards Laboratories International (NCSLI).

The QI system requires co-ordination. Currently, NMIM, Designated Institutes (DIs) and JSM co-ordinate on an ad-hoc basis. Concerning DIs, while a formal mechanism exists for NMIM to recognise DIs as custodians of national measurement standards, the performance of these DIs is not monitored systematically. Finally, with respect to stakeholder engagement, the only shortfall revealed was the frequency of meetings with stakeholders to discuss metrology matters and provide recommendations to NMIM.

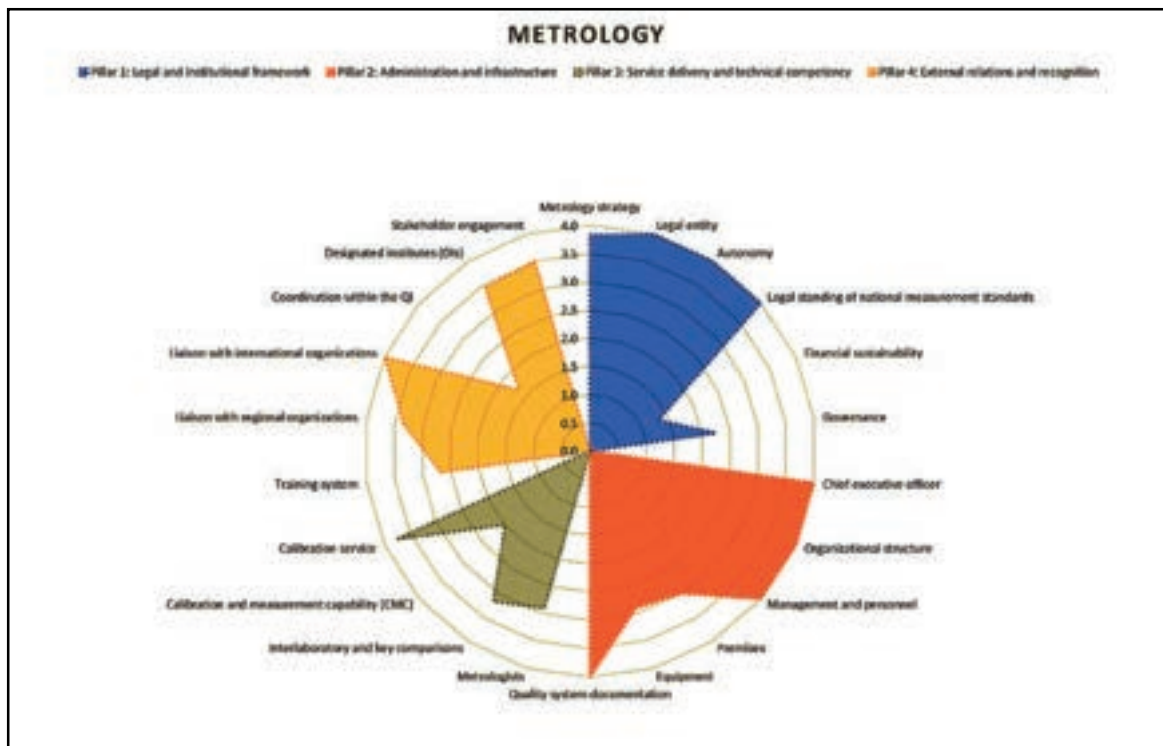


Figure 22: Rapid Assessment – Metrology

Source: Elaboration by consultants using the Rapid Diagnostic Tool (World Bank & PTB, n.d.) based on input from NMIM, the Department of Chemistry and the Malaysia Nuclear Agency.

Legal metrology

Legal metrology relates to the technical regulation aspect of metrology. Its main objective is to ensure the accuracy of measurements that influence the transparency of economic transactions, health and safety, and law enforcement. This can be achieved by enforcing preventive measures as well as repressive measures. Preventive measures include the calibration and verification of measuring instruments before they are marketed or put into operation and their recalibration after a specified period. Repressive measures involve market surveillance to uncover any illegal use of measuring equipment or noncompliance with pre-packaging requirements (Kellermann, 2019b).

An effective legal metrology system should include conformity assessment of measuring equipment, calibration and verification of measurement equipment in use; market surveillance of measuring equipment under a regulation; and pre-packaging controls of pre-packaged products (Kellermann, 2019c). These elements must be appropriately defined and

legitimised in legal metrology legislation and regulations. Given that legal metrology falls under the technical regulation regime, they must comply with the WTO TBT Agreement to avoid creating unnecessary trade barriers. It is recommended that countries consider the guidelines and model regulations published by the International Organisation of Legal Metrology (OIML), which were developed to promote the global harmonisation of legal metrology. Additionally, given that legal metrology aims to protect society, it must consider the needs of society as a whole and the level of development of the country.

The Ministry of Domestic Trade and Consumer Affairs (MDTCA) is responsible for legal metrology in Malaysia. Some of its functions include implementing the regulation on metric weights and measures and organising consumer education programmes to enhance consumer awareness and protection.

The World Bank's Rapid Diagnostic Tool was used to assess the level of development of legal metrology in Malaysia. A summary of the findings is presented in Figure 23. The assessment was categorised into four pillars with 20 building blocks. Overall, Malaysia performed relatively well in many of the building blocks, but it is evident in Figure 23 that greater effort is needed in some areas, particularly under Pillar 3 and Pillar 4.

Pillar 1: Legal and institutional framework

With respect to Pillar 1, while there is still some room for improvement, the scores for all the building blocks were relatively high. MDTCA has a legal metrology strategy that is aligned with OIML recommendations and an associated implementation plan in place. The only shortfall in this area was applying the strategy only to some of the authorities developing and implementing legal metrology instead of all of them. In Malaysia many industries are either directly or indirectly involved with measuring instruments. The legislation explicitly states the need for calibration and verification of instruments used for trade purposes. However, the legislation does not specify the need for calibration and verification of instruments that are not used for trade.

In addition, MDTCA has been established as a legal entity under the Weights and Measures Act 1972 (Act 71). Under Act 71, MDTCA is mandated to establish and maintain the legal

metrology system to safeguard the interests of the Malaysian population regarding measurements. The legislation is up to date, of an enabling nature and defines the governance, responsibilities, and functions of MDTCA. Its only shortcoming is that it does not make financial provisions for MDTCA. Furthermore, the governance of MDTCA is vested in a government department that has the mandate to approve the strategy, business plans and budgets.

The Director of Enforcement has a direct communication line to the Secretary-General and the MDTCA Minister to address legal metrology issues with political implications. The only shortfall in this area was related to the fact that the governance structure was not responsible for both the appointment and accountability of the director of legal metrology. Finally, the assessment revealed that MDTCA has a high level of financial sustainability, with adequate funding to cover most of its activities. While it was noted that there is usually a shortfall to fund regional and international commitments, this can be adjusted during the annual budget requests.

Pillar 2: Administration and infrastructure

With respect to Pillar 2, MDTCA scored the maximum in three of six building blocks. A director is responsible for MDTCA's legal metrology responsibilities, as mandated in the legislation – Act 71 and the Trade Descriptions Act 2011 (Act 730) – and the implementation of its medium- and long-term development plans. The director can execute their functions without undue external interference. In addition, the organisational structure of MDTCA facilitates the efficient and effective execution of all the regulations it is responsible for, and there are separate divisions that optimally support the main areas of legal metrology. The Enforcement Division of MDTCA is responsible for legal metrology, including the instruments used in trade. The only shortcoming in this area was related to financial support. Furthermore, most of the approved managerial and technical positions are filled; and the skill sets, responsibilities and KPIs for each position have been formally applied. The management and personnel have the appropriate skill sets, qualifications, training, and experience to carry out their tasks efficiently. In addition, the premises of MDTCA are appropriate and adequate for personnel. The head office and regional offices are appropriately located and housed in buildings with

acceptable working conditions, sufficient space, and amenities. Relevant authorities regularly inspect these premises to ensure they meet the required standards. Furthermore, legal metrology offices have appropriate inspection and metrology equipment as required by the regulations. Inspections of these offices are conducted on a systematic basis. Reference standards are maintained against which working standards and inspection equipment are calibrated continuously. These reference standards are calibrated against national measurement standards at predetermined intervals.

The weakest performance under Pillar 2 was seen in the quality management system building block. MDTCA has not yet implemented a formal quality management system that complies with ISO/IEC 17020 (requirements for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities), ISO/IEC 17025 (general requirements for the competence of testing and calibration laboratories) and/or ISO/IEC 17065 (conformity assessment — requirements for bodies certifying products, processes and services) as relevant; and has only been assessed internally to date. Compliance with these standards is not mandatory by law, but MDTCA is traceable to NMIM, which implements these standards. Nevertheless, MDTCA is in the process of implementing these standards.

Pillar 3: Service delivery and technical competency

With respect to Pillar 3, MDTCA scored the maximum in three of five building blocks. MDTCA has appointed trained and experienced technical staff to conduct the legal metrology testing, calibration, and verification. However, in Malaysia, it is more common for these services to be conducted by the private sector. The members of staff responsible for market surveillance are trained in their legal responsibilities and are granted inspector identification cards, which they must wear during field inspections. These identification cards are withdrawn once the staff member stops working for the legal metrology institution.

Additionally, MDTCA has a formal system in place to test and approve measuring equipment before it is allowed to be marketed to ensure it complies with stated regulations, including the acceptance of OIML and other relevant foreign certificates. This formal system is legitimised under Act 71, which MDTCA enforces. NMIM tests and inspects measuring

equipment and issues type approval certificates before they can enter markets. Since 2018, MDTCA has been performing market surveillance with respect to type approval certificates to ensure that only approved equipment is used to fulfil legal metrology requirements.

Furthermore, MDTCA can provide calibration and verification services for all measuring instruments subject to regulations; and has designated private sector organisations to provide calibration and verification services on its behalf in Malaysia's 13 states and three federal territories.

MDTCA uses and requires accreditation for the conformity assessment services performed by the De Metrology Sdn. Bhd. (DMSB) and the Metrology Corporation Malaysia Sdn. Bhd. (MCM), both perform verification and re-verification on behalf of MDTCA.

The assessment revealed that there is room for improvement in the market surveillance building block. While MDTCA has a market surveillance system in place, it only covers the measuring instruments for which it is responsible; it does not cover pre-packaging. Therefore, the impact of non-conforming pre-packaging and its associated risks are not taken into consideration in the market surveillance system and planning. Market surveillance is scheduled every month for all measuring equipment, and there are provisions for surveillance during the off schedule in response to complaints or requests of a court of law. With respect to pre-packaging, MDTCA only conducts testing for pre-packaged products if there are complaints about short weight.

The analysis also showed some shortfalls in the training system building block under Pillar 3. It is essential to have trained and skilled legal metrologists for the national legal metrology system to work efficiently and effectively (Kellermann, 2019b). Therefore, investing in training courses, either through MDTCA or tertiary education institutions, is crucial. According to the modus operandi of MDTCA, if there is a new instrument or some new technology that must be used in Malaysia, some members of staff, particularly from the Enforcement Division, participate in Training of Trainers (ToT) courses and then train other personnel. However, at the time of writing, training courses for legal metrologists were not available for some technologies. Furthermore, only about 66.66% of the technical staff at MDTCA received the

currently available training. Nevertheless, MDTCA has plans to train the remaining 33.33% of the technical staff.

Pillar 4: External relations and recognition

Despite scoring the maximum in two out of five building blocks, MDTCA's weakest performance in the overall assessment was seen in Pillar 4. Some shortcomings were revealed in the liaison with the regional organisation's building block. MDTCA is a full member of APLMF and has participated regularly in the APLMF Working Group. However, it does not participate in any regional trade agreement related to metrology organisations or committees. With respect to the liaison with international organisations building block, MDTCA scored the minimum. Despite having a relatively high level of maturity as the legal metrology authority, MDTCA is still only a corresponding member of OIML. This is because MDTCA relies on NMIM as the custodian and NMIM is still in the process of upgrading its OIML membership. This means that it does not actively participate in any OIML technical committees and is not a signatory of the OIML Certificate system. As a corresponding member, Malaysia only has observer status in OIML activities. As legal metrology authorities advance to a mature level, full OIML membership becomes a priority (Kellermann, 2019b). OIML is responsible for promoting the global harmonisation of legal metrology measures. Full membership allows countries to participate in the technical committees that develop national and regional requirements, and internationally recognised model regulations for legal metrology (Kellermann, 2019b). This allows full members to put issues that affect them on the agenda (Kellermann, 2019b).

MDTCA scored the maximum in the co-ordination with QI building blocks. There is a formal mechanism in place between MDTCA and NMIM and JSM which facilitates communication and co-ordination to address issues. MDTCA also actively participates in the technical committees of NMIM (and JSM) and uses the output in its work.

The assessment revealed some shortcomings concerning the designated organisation's building block. As the legal metrology regime matures, the demand for calibration and verification services will exceed the capacity of the legal metrology authority, and it will have

to designate technically competent organisations to render services on its behalf to meet the demand (Kellermann, 2019b). The legal metrology legislation in Malaysia allows MDTCA to designate both public and private sector organisations to provide legal metrology services on its behalf. In addition, there is a formal system in place to determine whether designated organisations continuously meet their designation requirements. If the organisations fail to meet these requirements, their designation is withdrawn. However, the designation is not dependent on accreditation to ISO/IEC 17020 or ISO/IEC 17025 as appropriate. Instead, MDTCA uses Act 71 as the designation criteria.

Finally, MDTCA scored the maximum in the consultative forum building block. A consultative forum for legal metrology is organised biannually where all the stakeholders of the QI – such as suppliers of measuring instruments, retail organisations, and consumer organisations – can provide input and raise issues regarding the legal metrology needs of the country. In addition, the legal metrology authority formally considers the recommendations that emerge from these consultative forums in the formulation of regulations for the country.

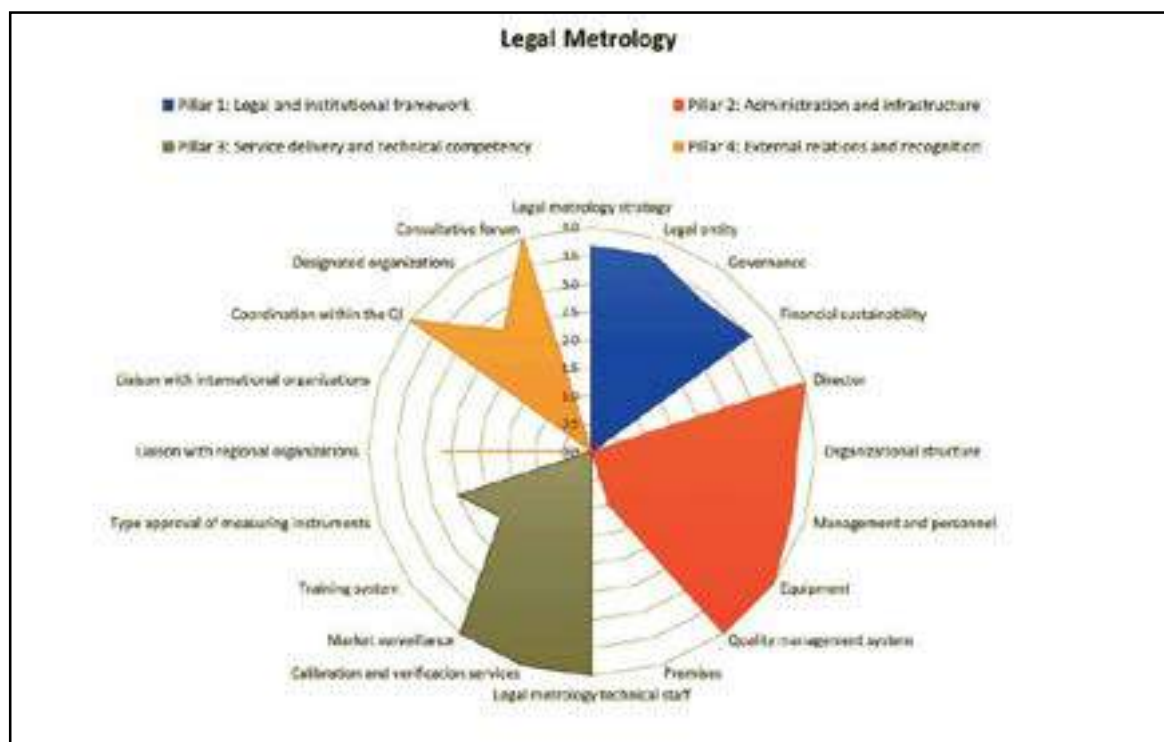


Figure 23: Rapid Assessment - Legal Metrology

Source: Elaboration by consultants using the Rapid Diagnostic Tool (World Bank & PTB, n.d.) based on input from MDTCA

4. Accreditation

Attestation of competence

Accreditation is the formal attestation or statement by an independent third party (the accreditation body) that a conformity assessment body (CAB) or calibration laboratory is competent to perform a specific conformity assessment activity or calibration service (Kellermann, 2019c).

Through accreditation, laboratories, inspection bodies, certification bodies, proficiency testing providers, and validation and verification bodies, gain formal recognition that they are technically competent to carry out specific activities within their scope.

Accreditation is essential for countries that rely on global trade as it facilitates international recognition systems for QI services (Kellermann, 2019c). This opens export markets to domestic industries and promotes industrial development by strengthening competition and creating market transparency (Kellermann, 2019c).

Accreditation reduces corruption as accredited organisations must demonstrate traceable results, annual audits, on-site assessments, peer evaluations, and records management (Kellermann, 2019c). Accreditation also contributes to the health and safety of society and the environment by assuring that service providers are competent and that their recommendations are relevant and trustworthy.

JSM as the National Accreditation Body

Malaysia has been working towards building accreditation in the country since the 1970s. Since 1996, JSM has served as the National Accreditation Body. Thus, the National Accreditation Body and the National Standards Body are under one organisation.

JSM is a signatory of the MLAs of International Accreditation Forum (IAF), the MRAs of the Asia Pacific Accreditation Co-operation (APAC)¹⁹ and the International Laboratory Accreditation Co-operation (ILAC). This means that JSM's accreditations are internationally recognised.

JSM was among the first APAC's Accreditation Bodies (ABs) to be evaluated remotely using an online meeting platform since the closing of international borders due to the COVID pandemic. In addition, the peer evaluation against ISO/IEC 17011 standard (general requirements for accreditation bodies assessing and accrediting CABs) was conducted remotely in October 2020 under the leadership of NSC of Thailand with members from American Association for Laboratory Accreditation (A2LA, USA), National Centre of Accreditation (NCA, Kazakhstan), Hong Kong Accreditation Service (HKAS, Hong Kong), Philippine Accreditation Bureau (PAB, The Philippines), National Accreditation Board for Certification Bodies (NABCB, India), National Accreditation Board for Education and Training (NABET, India), Standards Council of Canada (SCC, Canada), Bureau of Accreditation (BoA, Vietnam), National Accreditation Committee (KAN, Indonesia) and Arab Accreditation Co-operation (ARAC, Pan Arab).²⁰

According to the latest GQII data, in 2020, Malaysia ranked 50th out of 184 countries in accreditation (GQII, 2021).

Table 6 shows the numbers of JSM-accredited conformity assessment bodies. We distinguish between the accreditation of certification bodies (IAF-MLA) and laboratories (ILAC MRA).

Table 6 : Number of conformity assessment bodies accredited by JSM

Scope	Level 2	Level 3	2020	2021	Increase
IAF MLA	Product Certification	ISO/IEC 17065:2012	25	29	16%

¹⁹ APAC was established on 1 January 2019 by the amalgamation of two former regional accreditation co-operation bodies – the Asia Pacific Laboratory Accreditation Co-operation (APLAC) and the Pacific Accreditation Co-operation (PAC) (APAC, n.d.).

²⁰ JSM Annual Report 2020.

Scope	Level 2	Level 3	2020	2021	Increase
	Management System Certification	ISO/IEC 17021-1	74	84	14%
	Person Certification	ISO/IEC 17024:2012	5	6	20%
	Validation and Verification	ISO/IEC 17029:2019	0	0	
ILAC MRA	Testing	ISO/IEC 17025:2017	597	611	2%
	Medical Laboratories	ISO 15189:2012	69	76	10%
	Calibration	ISO/IEC 17025:2017	101	105	4%
	Inspection	ISO/IEC 17020:2012	17	21	24%
	Proficiency Testing	ISO/IEC 17043:2010	0	4	
	Reference Material Production	ISO 17034:2016	0	0	
	Biobanking Facilities	ISO 20387:2018	0	0	

Source: GQII data based on information from JSM

For certification bodies, JSM is active in the accreditation of products (ISO/IEC 17065:2012), management systems (ISO/IEC 17021-1) and persons certification bodies (ISO/IEC 17024:2012). While JSM is not yet active in accreditation of certification bodies for validation and verification (ISO/IEC 17029:2019), JSM has established the programme and is in the pilot phase to accredit its first validation and verification body.

For laboratories and inspection bodies, JSM accredits test and calibration laboratories (ISO/IEC 17025:2017), inspection bodies (ISO/IEC 17020:2012) and, since recently, also providers of proficiency tests (ISO/IEC 17043:2010). On the other hand, JSM is not active in the very new accreditation fields reference material production and biobanking. In view of the increasing production in the country of reference material, new opportunities arise here for the extension of the accreditation body's range of services.

Comparing 2020 and 2021, the number of conformity assessment bodies accredited by JSM has grown considerably. In particular, the number of accredited inspection bodies (24%), persons certification bodies (20%) and product certification bodies (16%) have increased.

Table 7 : Detailed count for Accreditation in Management System Certification

Level 2	Level 3	2020	2021	Increase
Food Safety	ISO 22000:2018, 2005 (FSMS)	11	12	9%
QMS	ISO 9001:2015 (QMS)	28	28	0%
Environmental	ISO 14001:2015 (EMS)	19	21	11%
Information Security	ISO/IEC 27001:2013 (ISMS)	2	3	50%
Energy	ISO 50001:2018, 2011 (EnMS)	1	1	0%
Medical Devices	ISO 13485:2016 (MDMS)	4	5	25%
Occupational Health and Safety	ISO 45001:2018 (previously OHSAS 18001)	13	18	38%

Source: Source: GQII data based on information from JSM

Table 7 shows accredited certification body numbers for different management systems. The number of bodies certifying ISO 9001:2015 (QMS) is the highest at 28 but remains constant. In contrast, the number of bodies for Information Security (ISO/IEC 27001:2013) grew from two to three from the period 2020 to 2021 and in Occupational Health and Safety (ISO 45001:2018) from 13 to 18. Overall, Malaysia has certification programmes for all known management system certifications.

Besides JSM, foreign accreditation bodies are also active in Malaysia. Figure 24 shows that the Singapore Accreditation Centre (SAC) accredits nine, the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) four, and ANSI National Accreditation Board (NAB) three, conformity assessment bodies. In addition, there are accreditations from Germany, the United Kingdom, China, Egypt, and other ABs from the United States of America.

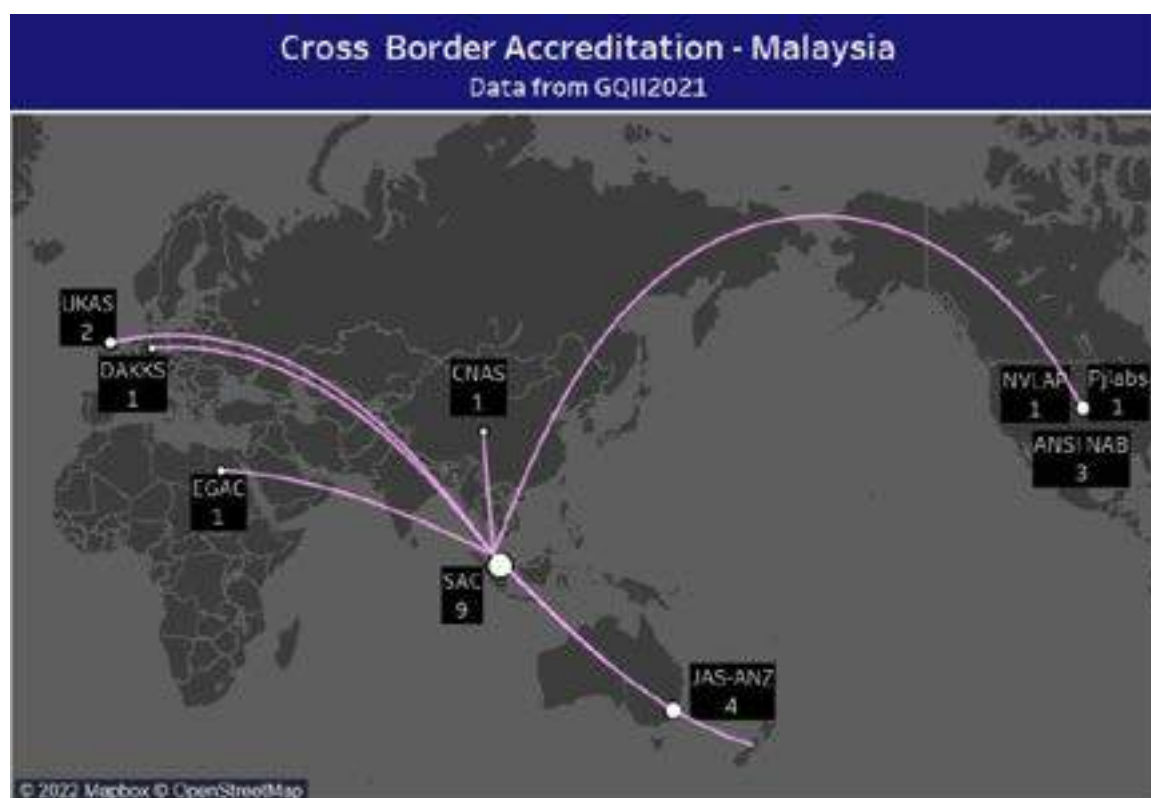


Figure 24: Accreditations of foreign bodies in Malaysia in 2021. Source GQII2021

In November 2020, JSM commissioned the consulting firm Roland Berger to study the awareness and effectiveness of MRAs in improving international market access for businesses (Berger 2020). The consultants surveyed over 250 companies, compliance consultancies, and regulators. They asked Malaysian entrepreneurs to what extent they benefit from the advantages of international recognition of conformity assessment.

Most entrepreneurs stated that Malaysian testing, inspection, and certification services are sufficient to access foreign markets for different products. However, most conformity assessment bodies felt companies needed to conduct duplicate accredited conformity assessment activities. The consultants assumed that the problem might lie with the regulators. More than half of the regulators did not recognise the accredited conformity assessment for exported or imported goods.

The study recommended increasing awareness of international markets, the export process, MRAs and their benefits to local entrepreneurs. There is also a need to improve the quality of

accredited conformity assessment services, increase international recognition of accredited conformity assessment services and make accredited conformity assessment services more accessible.

For this report, the ITC consultancy team assessed the level of maturity of Malaysia's NAB, namely JSM, by using the World Bank's Rapid Diagnostic Tool. A summary of the findings is presented in Figure 25. The assessment was divided into four pillars and 23 building blocks. The results revealed that the country is quite advanced in several areas of accreditation, while more concerted efforts are required for a few building blocks.

Malaysia performed well in several building blocks concerning Pillar 1: Legal and institutional framework. NAB has prepared an accreditation strategy – JSM's Strategic Plan 2022-2025 – and an implementation plan – JSM's Business Plan 2022 – both of which were approved on 14 December 2021.

JSM has been defined as a legal entity according to the Standards of Malaysia Act 1996 (Act 549). Therefore, it can be held legally responsible for its duties related to accreditation services and the national measurement accreditation system. However, Act 549 was last revised in 2012 and needs a review to ensure that it effectively covers new matters that have developed. Act 549 only spells general provisions on the governance (role and functions) of JSM as the review and approval processes are complex, requiring legal intervention. Nevertheless, new areas of standardisation and accreditation activities are covered in the five-year strategic plan and yearly business plan.

JSM has a high level of autonomy in carrying out its tasks as the NAB. However, it is restricted in terms of signing international agreements since approval from the Cabinet is first required. For accreditation, JSM has already obtained blanket approval from the Cabinet that enables JSM to extend its MRA/MLA scopes to the regional and international MRA/MLA that Malaysia is a party to. Concerning the legal standing of accreditation, the score was relatively high. The only shortfall was that accreditation was not the legally preferred method of demonstrating technical competency in designating QI service providers. This could hinder JSM from carrying out a significant responsibility as the NAB for the country – the independent attestation of the

technical competency of service providers operating in the realm of technical regulations and the market (Kellermann, 2019b). The biggest weakness in Pillar 1 was seen in governance. While a National Accreditation Committee (NAC) has been established, its role is primarily advisory.

Furthermore, the private sector accounts for 45-50% of the seats in NAC. Therefore, it is recommended that NAB follows an open and transparent governance model with meaningful input from stakeholders from both the private and public sectors (Kellermann, 2019b). Finally, JSM had the maximum score concerning financial sustainability –NAB has adequate funds to fulfil its responsibilities domestically, regionally, and internationally; and has a medium-term financial plan.

JSMs performed slightly better in Pillar 2: Administration and infrastructure, with a maximum score in three of the five building blocks. JSM's most significant shortcoming in this Pillar was due to the Chief Executive Officer (CEO) building block. While a full-time Director-General has been appointed to manage its day-to-day affairs, this Director-General is only accountable to the Minister and has no voting right in NAC. Furthermore, NAC is not mandated to systematically define and evaluate the Director-General's key performance criteria. JSM scored the maximum in organisational structure as various divisions handle the different scopes of accreditation. In addition, the maximum score was attained for management and personnel. All the managerial and technical posts have been filled, and the responsibilities and KPIs for each position have been formally defined. However, there is some room for improvement concerning premises. JSM is located in a building with acceptable working conditions and is easily accessible to its stakeholders. In addition, JSM had the maximum score for equipment since it is appropriately equipped to carry out its functions.

JSM performed the best in Pillar 3: Service delivery and technical competency, attaining the maximum score for all the building blocks. The lead assessors are selected for registration according to formal requirements aligned with IAF and ILAC and are adequately trained to maintain these registration criteria. The same can be said for assessors and technical experts. This is important for growing economies since a registered lead assessor, qualified assessors, and technical experts are needed to conduct assessments for accreditation (Kellermann,

2019b). In addition, JSM has established specialist technical committees, with both public and private sector representation, to provide input regarding the accreditation process and assessor training within each accreditation scope.

Furthermore, JSM has a formal quality management system that complies with ISO/IEC 17011. JSM provides an open and transparent system of applications, requirements, assessments, and approval processes regarding accreditation²¹. The accreditation process follows a clearly defined, publicly available list of steps and specific time limits for completing each step. Moreover, an accreditation approvals committee, independent of the assessment team, studies the organisation's evaluation and decides whether to grant or revoke accreditation. Once accreditation is granted, an accreditation certificate is issued, and the organisation is added to a post-accreditation surveillance and reassessment roster.

JSM ensures that a current list of accredited organisations²² is publicly available with the relevant information details on accredited scopes. At the time of writing, there were 799 accredited organisations listed. This number can be primarily attributed to Skim Akreditasi Makmal Malaysia (SAMM), a unified national laboratory accreditation scheme introduced in 1990. SAMM's main objective is to provide credible accreditation services to testing and calibration laboratories. SAMM-endorsed test reports and calibration certificates are internationally recognised through ILAC and APAC MRAs.

For Pillar 4: External relations and recognition, JSM scored the maximum in four out of the five building blocks. JSM has an effective training system in place. It can train its lead assessors, assessors, and technical experts, systematically assess their performance and maintain an up-to-date database with relevant information on their personnel. In addition, JSM has fostered strong liaisons with both regional and international organisations to ensure that its capability as a NAB is internationally recognised.

²¹ <https://www.jsm.gov.my/skim-akreditasi-makmal-malaysia-samm-#.YgS-Od9BzIU>

²² <https://www.jsm.gov.my/accredited-organisation-directories>

As previously mentioned, JSM is a member of APAC, IAF and ILAC and actively participates in programmes, information exchange groups, technical committees and assemblies organised by these bodies. At the regional level, JSM also participates in ACCSQ WG2- Working Group on Conformity Assessment and SMIIC Management of Accreditation Council. The only building block that JSM performed weakly under this pillar was its liaison within the QI. Co-ordination among the fundamental QI organisations – JSM and the NMIM in Malaysia’s case – is essential to ensure no gaps or overlaps in their service delivery or activities (Kellermann, 2019b). However, the assessment revealed that most of the co-ordination and interaction between JSM and NMIM occur on an ad-hoc basis. Nevertheless, Malaysia is in an excellent position to improve this aspect since JSM, which serves as both the NAB and the NSB, while NMIM, which serves as the country’s NMI, are governmental organisations under the same ministry.

JSM is continuously working towards improving its services as Malaysia’s NAB. JSM’s Business Plan 2022 and Strategic Plan 2022 – 2025 were approved in December 2021. Since then, some of the key deliverables that JSM has been focusing on in the short run include accrediting 50 new CABs, conducting 900 assessments for the applicant and accredited CABs, and launching its new website (Department of Standards Malaysia, n.d.-a). This is all part of JSM’s long-term plans to maintain credible accreditation services and strengthen its engagement with international accreditation networks (Department of Standards Malaysia, n.d.-b).

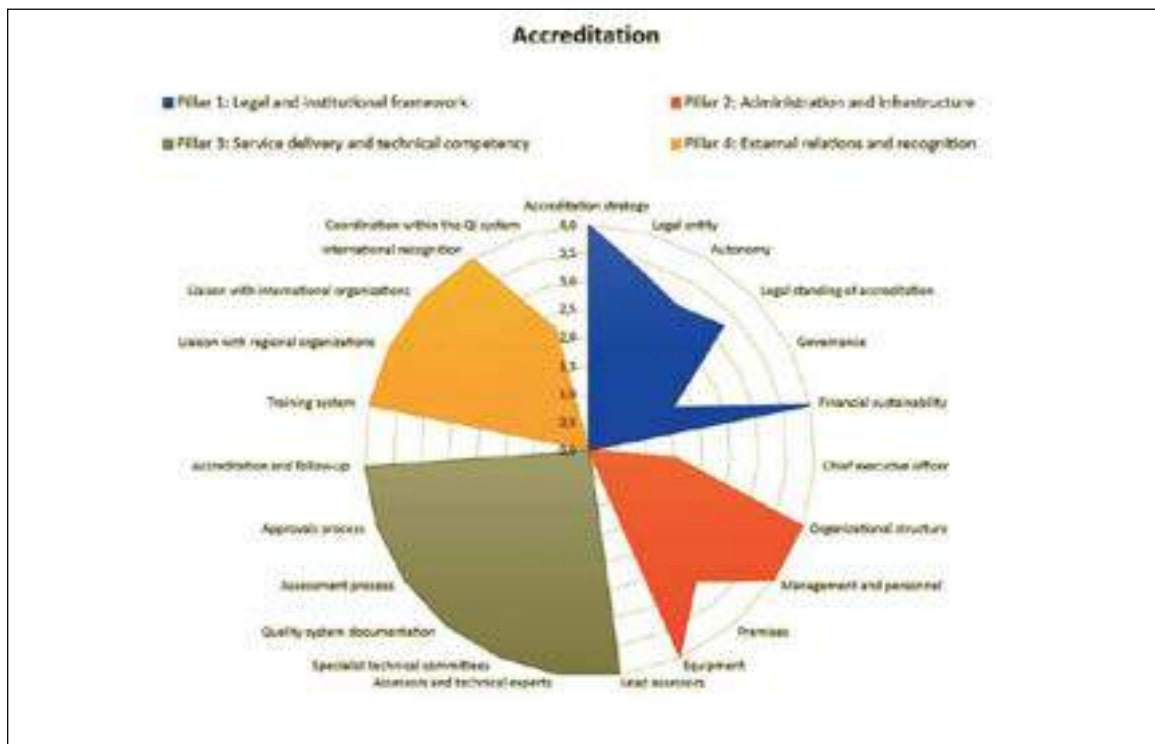


Figure 25: Rapid Assessment – Accreditation

Source: Elaboration by consultants using Rapid Diagnostic Tool (World Bank & PTB, n.d.)

JSM's accreditation body expects to launch its accreditation symbol in June 2022.²³ The JSM accreditation symbol has already been established and is currently pending formal registration with the Intellectual Property Corporation of Malaysia (MyIPO). In addition, JSM AB has numerous programmes and recognitions from credible national regulatory bodies, such as the Ministry of Domestic Trade and Consumer Affairs (MDTCA), Suruhanjaya Perkhidmatan Air Negara (SPAN), Energy Commission (ST), Jabatan Pengangkutan Jalan Malaysia (JPJ), the Malaysia Palm Oil Board (MPOB), the Malaysian Rubber Board (MRB) and the Malaysian Timber Certification Council (MTCC).

²³ <https://www.jsm.gov.my/accreditation#.YkicbS8RrUI> (Retrieved 02/04/2022).

5. *Conformity assessment*

Background

Conformity assessment is the collective term for several services based on the quality infrastructure (QI) core functions: standards, metrology, accreditation and market surveillance. It is defined as the demonstration that specified requirements of a product, process, system, person, or body that are fulfilled in ISO/IEC 17000 (Conformity Assessment) of ISO and IEC, and is typically conducted through quality assessment services, such as inspection, testing, and certification.

The specified requirements may typically be stated in regulations, standards, and technical specifications. Generally speaking, the elements of conformity assessment include inspection, testing, and certification used in all fields of investigation, innovation, process improvement, productivity, product development, product compliance, and many more (Kellermann, 2019c).

In many countries, the private sector provides conformity assessment services rather than governments. In contrast, governments retain responsibility for maintaining the fundamentals, which are standards, metrology, and accreditation. Typically, the more industrialised and the larger the economy, the more involved the private sector. Foreign direct investment has been a driving force for certification to international standards in many developing countries following the liberalisation of the market and the global harmonisation of standards.

This situation has given rise to several multinational conformity assessment bodies, most operating as private for-profit companies. Most of them are active in Malaysia, too.

Using the World Bank's Rapid Diagnostic Tool (RDT), the ITC consultancy team assessed the level of maturity of Malaysia's conformity assessment system. The assessment was divided into four pillars and the respective building blocks relevant for each. To get a broader view, the team collected responses from various Conformity Assessment Bodies (CAB) in each field:

inspection (4), testing (4), system certification (5) and product certification (5). In each area, the assessment results were compared and consolidated. If differences are stark, it is mentioned in the text below.

Representation of conformity assessment bodies in the Malaysian NQI system

There are about a thousand accredited conformity assessment bodies in Malaysia. More precisely, the JSM National Accreditation Body counts 625 testing laboratories, 109 calibration laboratories, 77 clinical laboratories, 128 certification bodies for management systems, 29 for product certification and six for persons certification. (Source GQII2021/ Mesopartner based on JSM data)

The conformity assessment bodies are primarily private companies, including public institutions, such as Food Safety and Quality Laboratories. However, multinational companies that offer their services worldwide also play a significant role.

Conformity assessment bodies are part of the quality infrastructure that provides services directly to companies. Although conformity assessment bodies are often market-based competitors, they have organised themselves into associations in many countries and globally.

One international example is the TIC Council²⁴, representing the Testing, Inspection and Certification (TIC) sector, formed in 2018 from the merger of the former global TIC industry organisations, namely International Federation of Inspection Agencies (IFIA) and International Confederation of Inspection and Certification Organisations (CEOC). The organisation sees itself as the new voice of the testing, inspection and certification industry, bringing together more than 90 member companies and organisations worldwide to speak with one representative.

The TIC Council advocates with governments and key stakeholders for practical solutions that protect the public, facilitate trade and promote innovation. With the expertise and

²⁴ <https://www.tic-council.org>

competence of its members, the TIC Council is a resource for policymakers worldwide on how the use of TIC services adds value to society and promotes best practices in safety, quality, health, ethics and sustainability. In addition, the TIC Council supports the development of international standards and regulations that protect consumers without hindering innovation or placing unnecessary burdens on industry.

The TIC Council has national organisations in China and India. The TIC Council India²⁵ represents mainly the international and local companies for testing, inspection and certification. The TIC Council India is registered as an independent legal entity.

A local example is the Association of Accredited Laboratories Operating in Malaysia (Persatuan Makmal Akreditasi Malaysia).²⁶ The association was established on 24 February 2016 and provides a platform for discussion and collaboration among the members of the association, training and education for laboratory staff, as well as spreading awareness on good laboratory practices and professional practices. At the same time, Persatuan Makmal Akreditasi Malaysia supports the exchange of laboratories with JSM.

Inspections

Inspection examines a product design, process, or installation and determines its conformity with specific requirements or based on professional judgement, with general requirements.

Inspection of a process may include inspection of persons, facilities, technology, and methodology (ISO/IEC 17000). Inspection, therefore, consists of the concepts of information gathering (which could include testing and measuring), observation (including the conditions), and forming a judgement on the suitability for use or compliance with requirements. The definition also indicates that inspection is not limited to products or manufacturing processes. Inspection is also applied in diverse activities such as design verification, installation and

²⁵ <https://www.tic-council.org/regions/india>

²⁶ <https://www.makmal-malaysia.org.my>.

commissioning of equipment, in-service monitoring, regulatory affairs, financial auditing, and failure investigations (Kellermann, 2019c).

According to the RDT used, the inspection assessment is summarised in Figure 20.

Pillar 1: Legal and institutional framework

According to two out of four participating CABs,²⁷ an inspection services strategy and implementation plan are in place in Malaysia. There are designated inspection bodies for the domestic and regional markets.

Apart from Nuklear Malaysia, which seems to be unique, the inspection bodies are independent and impartial legal entities that are financially sustainable.

²⁷ The CABs participating in the RDT inspection assessment are the Food Safety and Quality Division under MOH, PUSPAKOM SDN. BHD., SIRIM QAS and the Nuklear Malaysia Inspection Service.

Inspections

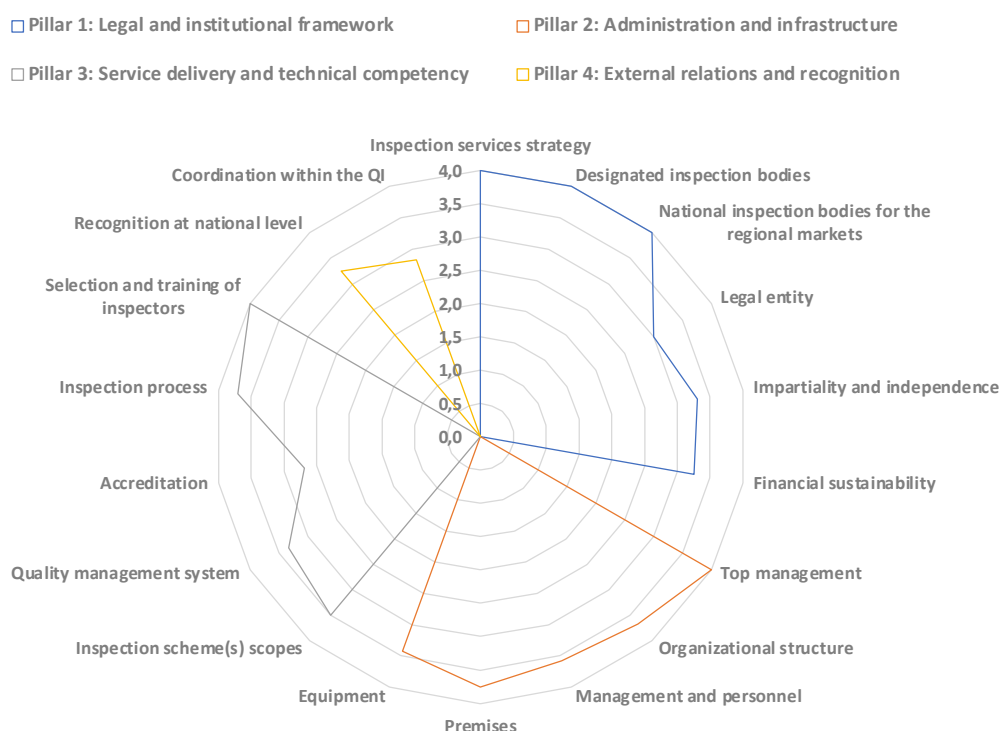


Figure 26: Rapid Assessment – Inspections

Source: Elaboration by consultants using Rapid Diagnostic Tool (World Bank & PTB, n.d.)

Pillar 2: Administration and infrastructure

All inspection bodies have dedicated and responsible top management. In most cases, managerial and technical posts are filled with individuals complying with the specified job requirements. The organisational structures across all participating CABs are almost perfect. The same applies to the appropriateness and adequacy of premises and working conditions. IT system equipment and Internet presence leave room for improvement, though.

Pillar 3: Service delivery and technical competency

In 2021, 21 inspection bodies were accredited by JSM in Malaysia, including two CABs participating in this assessment. One CAB under MOH is not accredited. Another inspection

body dealing with nuclear energy has received accreditation from a different accreditation body.

For this reason, the building block Accreditation performs only moderately. The same applies to the establishment and operation of Quality Management Systems, a precondition for accreditation.

The other building blocks in the pillar, inspection scheme scopes, inspection process and particularly inspectors' training and selection are in good condition across all participating CABs.

Pillar 4: External relations and recognition

The weakest pillar is pillar 4. While a regulatory authority has designated all inspection bodies, not all are adequately accredited, i.e. their competence is not proven. There seems to be an inspection body association in Malaysia, but not all inspection bodies are voluntary members. It is not in all regulatory domains that a technical regulation co-ordination office co-ordinates the inspection activities. For instance, co-ordination occurs in vehicle and nuclear inspection domains, but not for food inspection or welding inspection.

Testing

Testing determines the characteristics of a product or commodity and, in the QI context, the evaluation thereof against the requirements of a standard (ISO/IEC 17000:Conformity Assessment—Vocabulary and General Principles). The output of a test laboratory is a test report or a test certificate. The scope of testing is immense, and it ranges from mechanical, electrical, metallurgical and civil engineering, and biological and chemical sciences to food technology, fibre technology, and many other areas. Testing can be of a destructive or non-destructive nature. It can be mundane, extremely complex, or anything in between. It can involve routine, state-of-the-art, or cutting-edge technology. Although testing is usually seen in a laboratory, it can also occur in the field or on-site, following delivery and installation (Kellermann, 2019c).

, Figure 27 summarises testing assessment²⁸ based on the RDT.

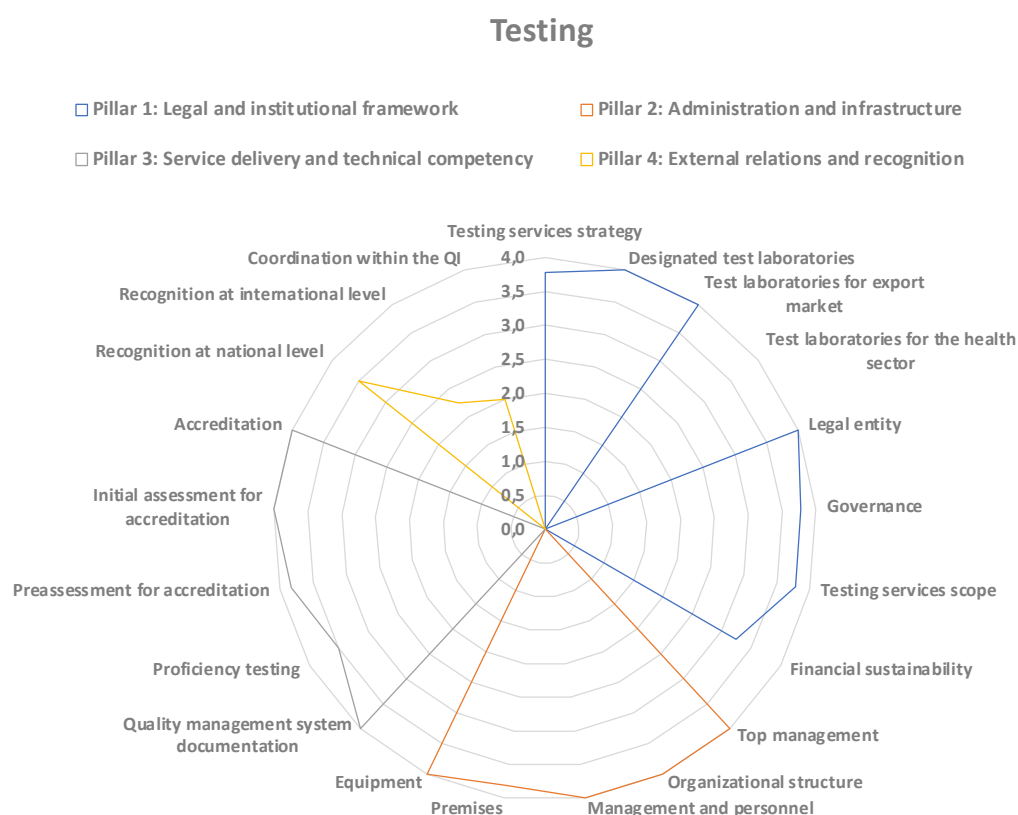


Figure 27: Rapid Assessment – Testing

Source: Elaboration by consultants using Rapid Diagnostic Tool (World Bank & PTB, n.d.)

Pillar 1: Legal and institutional framework

The legal and institutional framework for testing in Malaysia appears to be strong. A testing services strategy is in place with all the necessary elements and an implementation plan. A system of designating test laboratories is formalised and practised. Details of the designated test laboratories are publicly available. Testing services for export markets are strategised, and the government is actively pursuing recognition agreements of the national laboratories by regulatory authorities in relevant export markets. The government and the private sector

²⁸ Four testing labs participated in the RDT assessment: Food Safety and Quality Division under MOH, SIRIM QAS, Makmal Bioserasi and MyCO2.

actively co-ordinate recognition arrangements in export markets. As medical testing laboratories have not participated in the assessment, this building block requires a separate assessment.

The legal and institutional framework of the individual laboratories participating in the assessment is also good. They are all established as legal entities with clearly defined governance structures, functions and finance mechanisms. In all cases, institutional governance is characterised by independent boards responsible for business strategy and budget, appointing leadership positions, and establishing new units. Mostly, testing scopes are clearly defined and based on quantified market demand. Revenues are sufficient to cover 100% of costs (two institutions), 70% (one) or just 50% (one). Expenses for continued accreditation of the test laboratories are earmarked in the costs. Financial plans extend to at least 1-3 years (one), but mostly 3-5 years (three).

Pillar 2: Administration and infrastructure

All participating laboratories employ dedicated top management responsible for all laboratory matters without outside interference. The organisational structures show distinct entities accountable for the testing services, different divisions per testing scope and responsible unit heads. All approved managerial and technical positions are filled and equipped with KPIs. Most premises meet the physical requirements with environmental controls, access controls and appropriate office space. Test equipment is installed, fully functional and maintained, and calibrated.

Pillar 3: Service delivery and technical competency

The building blocks of pillar three are also performing well. Overall, formal quality management system documentation (per ISO/IEC 17025) is in place. All test laboratories participate in proficiency testing (PT) with other laboratories. The PT providers are accredited in most cases (75%).

In 2021, 611 testing laboratories and 76 medical laboratories were accredited by JSM in Malaysia. The participating testing laboratories are all included in the list of JSM accredited laboratories, including earlier pre-assessments and initial assessments.

Pillar 4: External relations and recognition

All participating laboratories are recognised at the national level through accreditation and, most of them (3/4), through designation by a regulatory authority. A national testing laboratory association is established but only relevant for private laboratories, i.e. two out of four participating laboratories. The association offers training and lobbying services to its members. A central regulatory office is actively co-ordinating the activities of test laboratories.

Medical testing

The RDT contains a dedicated set of questions for test laboratories in the health sector. Four medical labs were contacted, interviewed and requested to complete the RDT testing questionnaire. Figure 28 shows the aggregated results.

Testing (Medical labs)

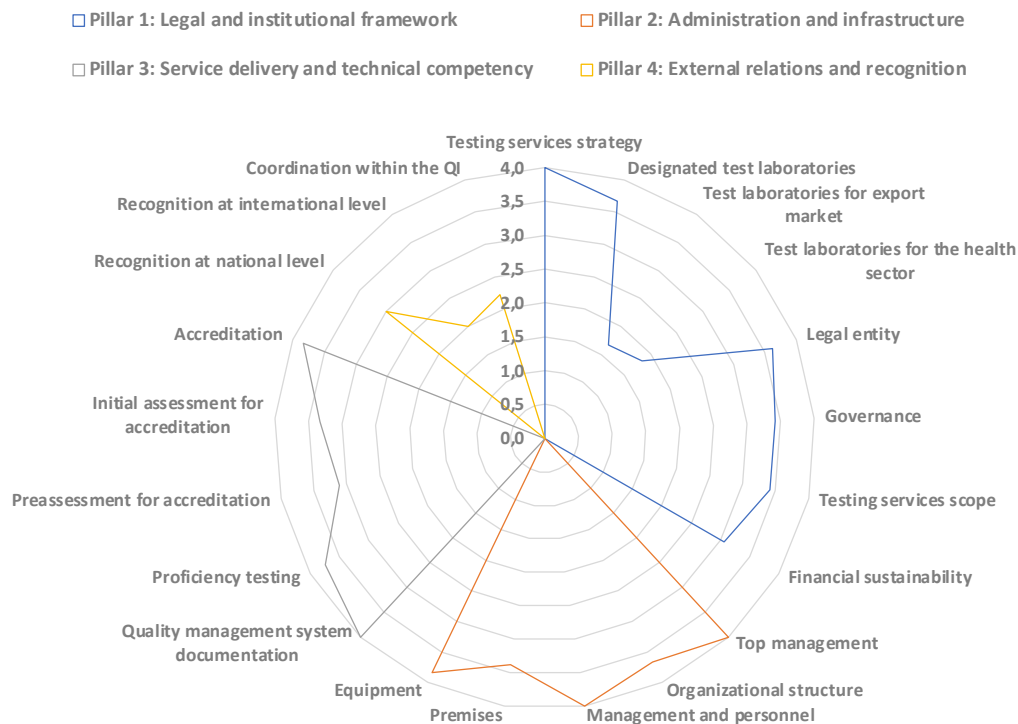


Figure 28: Rapid Assessment – Medical Testing

Source: Elaboration by consultants using Rapid Diagnostic Tool (World Bank & PTB, n.d.)

As the assessment results in all pillars are similar to the general testing labs described above (see Figure 27), it is worthwhile to discuss the technical competence and the legal recognition of medical laboratories in Malaysia specifically. The RDT assessment shows that the medical dimension of testing is relatively weak (1.8 out of possible 4.0 points). There is some confusion between the laboratories regarding whether medical laboratories in the health sector must be “registered” or “designated” by the relevant health authority. Moreover, details of registered or designated medical laboratories are not readily available publicly.

However, the main reason for the modest result of medical testing is that accreditation to ISO 15189 (Medical laboratories) is not a prerequisite for the registration or designation of medical laboratories in Malaysia, which all participating laboratories confirmed. The accreditation of medical laboratories according to ISO 15189 builds on ISO/IEC 17025

(Competence of testing and calibration laboratories) and ISO 9001 (Quality Management System). The ISO 15189 standard is a tool to demonstrate medical laboratories' competence and ensure timely, accurate and credible results. This is because the services of medical laboratories are essential for diagnosing and assessing the health of patients.

Until 2020, JSM had accredited 69 medical laboratories according to ISO 15189:2012. This number increased to 76 accredited medical laboratories in 2021. For this recent surge in accreditation, the COVID-19 pandemic played an essential role as the regulatory requirements from flight agencies indicated that tests should be from accredited laboratories. However, there is still a lot of potential for medical laboratories in Malaysia to be accredited, but there are challenges to overcome. A primary challenge is the need to upgrade the physical infrastructure and equipment of some medical facilities which were established many years ago. Other limitations include human resource capacity and funding. Especially for smaller laboratories, getting accredited can seem challenging, intimidating, and overwhelming. A cluster system is practised in Malaysia to manage this situation, where one hospital acts as the lead hospital and others as subsidiaries. The lead hospital gets accredited and then provides guidance and assistance for the subsidiaries to get accredited, too.

Product certification

Product certification is the mechanism whereby a certification organisation attests those products—either a batch or the continuous production thereof—have been inspected and tested by it and that the products collectively comply with specified requirements, usually contained in a standard (ISO/IEC 17000: Conformity Assessment—Vocabulary and General Principles). The attestation by the certification body is in the form of a certificate supported by a product certification mark that the manufacturer is entitled to affix on the product after being licensed to do so. Therefore, the certification body visibly endorses the quality of the product (Kellermann, 2019c).

Figure 29 summarises the consolidated assessment of product certification in Malaysia. In the assessment, four CABs²⁹ participated, of which one certifies halal products, and the other was the Malaysian Communications and Multimedia Commission (MCMC), which is a regulatory authority. MCMC³⁰ has registered a certification body, SIRIM QAS International Sdn. Bhd. (SQASI), to certify communications equipment.³¹ SQASI, however, participated as a product certifier that certifies all kinds of products from plastics and cement to ceramic products and electric appliances.

Pillar 1: Legal and institutional framework

Looking at Malaysia's product certification services situation, the participating CABs confirm that there is a product certification strategy in place with all necessary elements and an implementation plan. In the sectors of food safety, halal and communication (and possibly other sectors), national product certification schemes are operated. In the case of food safety and halal, the product certification schemes are formally recognised within ASEAN through multilateral recognition agreements (MRA).

In 2009, SIRIM QAS International Sdn. Bhd. in collaboration with SME Corporation Malaysia launched the National Mark of Malaysian Brand³². This certification scheme aims to highlight quality, excellence and distinction of products and services from Malaysian companies, particularly SMEs (SME Corp. Malaysia, 2022). In addition, some regulated products in

²⁹ The following four CABs participated in the assessment: Food Safety and Quality Programme (FSQP) under MOH, SIRIM QAS, Jabatan Kemajuan Islam Malaysia (JAKIM), and the Malaysian Rubber Board (MRB).

³⁰ The MCMC regulates the supply and use of communications equipment according to the Communications and Multimedia (Technical Standards) Regulations 2000 (TSR 2000). As provided under the Communications and Multimedia Act 1998, MCMC may register certifying agencies for the purposes of certifying compliance of communications equipment with codes or standards.

³¹ To enforce technical regulations, the competent ministries and agencies are usually in charge of market surveillance which includes the use of conformity assessment services. These services can be provided in-house by the regulators own CABs or outsourced by using external CABs. In any case, the CABs should be accredited, demonstrating their technical competence and independence.

³² In order to carry the National Mark of Malaysian Brand, participating Malaysian companies must comply with stringent standards and meet the qualifying criteria. Authorisation to carry the Mark must be renewed on a two-year basis (SME Corp. Malaysia, 2022).

Malaysia, such as electrical appliances, communications and multimedia equipment, and motorcyclist helmets must be affixed with SIRIM labels (SIRIM QAS International Sdn. Bhd., 2022). SIRIM labels can also be affixed to some non-regulated products conditional on certification from SIRIM QAS International Sdn. Bhd. (SIRIM QAS International Sdn. Bhd., 2022).

A system of designating product certification bodies is practised but not legalised. Interestingly, accreditation is not a precondition for designation. Details of designated product certification bodies are publicly available.

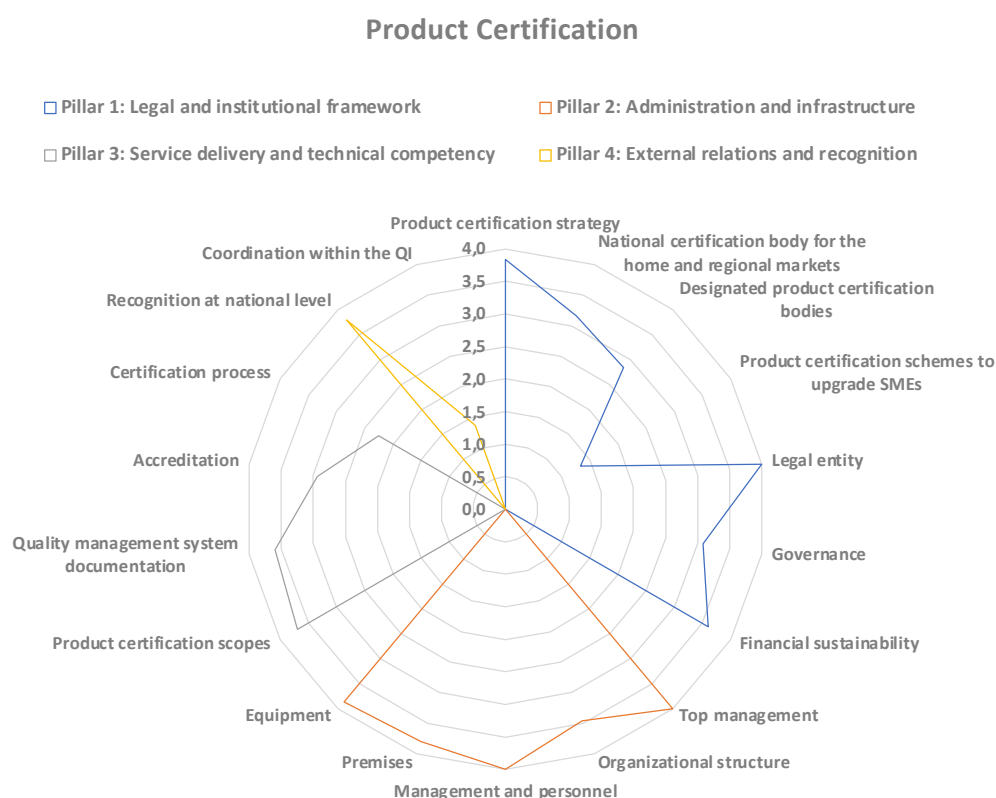


Figure 29: Rapid Assessment – Product Certification

Source: Elaboration by consultants using Rapid Diagnostic Tool (World Bank & PTB, n.d.)

The individual product certification bodies are established as legal entities with independent boards. Board members are primarily knowledgeable of the product certification scope. However, not all boards are solely responsible for all business functions and decisions.

Revenues and funding sustain the certification bodies. Funds are put aside to finance regular accreditation costs. Financial plans cover 1-3 years (three CABs) or 3-5 years (two).

Pillar 2: Administration and infrastructure

Top management with all necessary responsibilities is in place in all CABs. Below the top management, all managerial and technical positions are filled and assessed by achieving their respective KPIs. Not all CABs operate separate divisions for various scopes, but all have established independent approval committees and impartiality committees. Most CABs' premises are adequate in light of the defined requirements. IT system equipment, IT network and internet presence are mainly appropriate.

Pillar 3: Service delivery and technical competency

The product certification scopes and the standards they are based on are clearly defined and oriented towards market needs. Apart from the Food Safety and Quality Programme (FSQP), the types of product certification schemes are indicated. Formal quality management system documentation is in place or currently implemented.

In 2021, 29 product certification CABs were actively accredited by JSM. This includes JAKIM, SIRIM QAS and MRB. FSQP is not a certification body, hence the certification issued by FSQD is not accredited under JSM.

The product certification process across all participating CABs seems to be in good order, including the application process, review of QMS documentation, onsite audits, product sampling, and external review of audits.

Pillar 4: External relations and recognition

At the national level, regulatory agencies accept the certification mark of product certification bodies. Regulatory authorities have designated all participating product certification bodies for rendering services in their specific domains.

Within the quality infrastructure system in Malaysia, a formal certification body association does not exist. However, there is an informal network for the main players of the private sector to discuss common certification issues and activities. Also, technical regulation co-ordination offices only operate in some domains, such as communication, or are currently set up for halal products.

Management System Certification

Management system certification is all about building confidence in the supplier. It is the mechanism whereby a certification organisation attests that a management system of a manufacturer, producer, supplier, or service provider has been assessed by it and that the management system complies with specified requirements, usually contained in a standard (ISO/IEC 17000: Conformity Assessment—Vocabulary and General Principles).³ The attestation by the certification body is in the form of a certificate, frequently supported by material that the certified company can use in marketing. Therefore, the certification body also visibly endorses the supplier's management system. The certification organisation, in turn, is accredited, thereby completing the “chain of confidence” (Kellermann, 2019c).

Figure 30 depicts the aggregated assessment of system certification in Malaysia.

The system certification bodies participating in the RDT survey were FSQP under MOH, SIRIM QAS, NIOSH Certification, AJA EQS Certification and TUV Nord (Malaysia).

System Certification

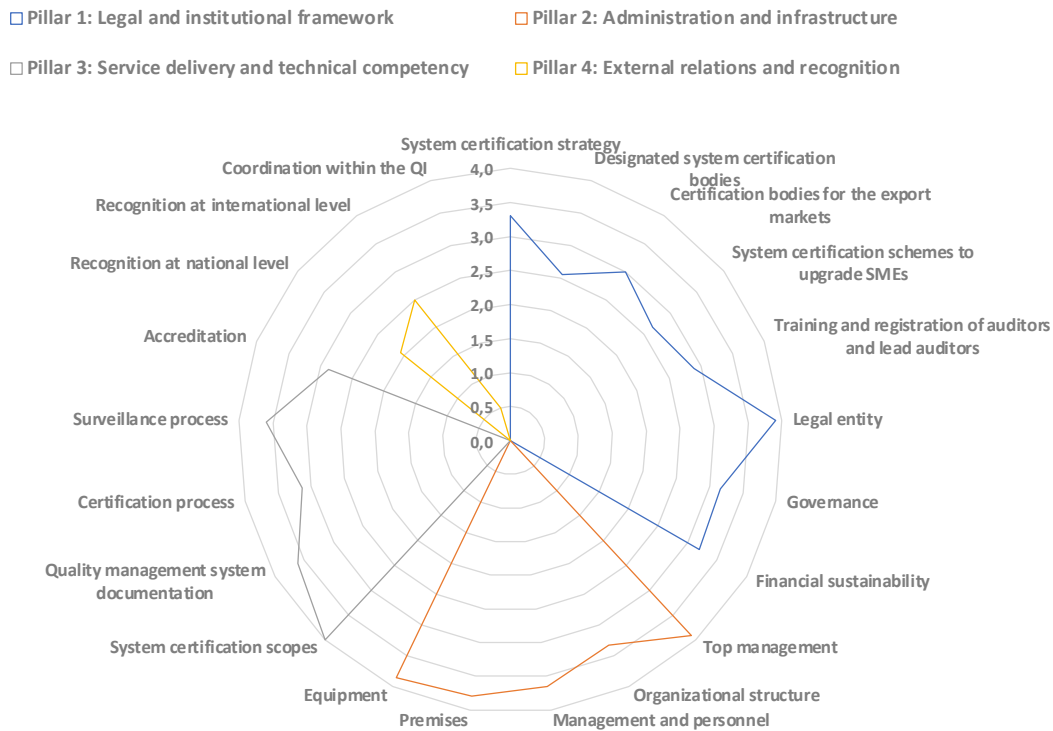


Figure 30: Rapid Assessment – System Certification

Source: Elaboration by consultants using Rapid Diagnostic Tool (World Bank & PTB, n.d.)

Pillar 1: Legal and institutional framework

Most participating CABs recognise a system certification strategy with the most necessary elements and an implementation plan at the national level. On the other hand, there is a varying perception about whether a system of designated system certification bodies is in place and details are publicly available. Similarly, CABs perceive the status of identifying export sectors and their system certification requirements differently. Also, whether formal government-led projects have been started to develop the required system certification capacity in the country or whether this is left to the market is disputed.

According to some CABs, a national system certification scheme to upgrade small and medium enterprises (SMEs) is in place, including consultancy services and government support. Quality

management system auditor and lead auditor training schemes are available, including a registration scheme for the assessors and a mechanism to maintain their registration.

All participating CABs are legal entities with independent boards whose members know the system certification scopes. However, not in all cases do the boards possess sole decision-making powers over critical matters of the CAB.

Although all institutions sustain funding for accreditation, some can cover only parts of their expenses through revenue and funding.

Pillar 2: Administration and infrastructure

Effective top management responsible for the technical management and the quality and integrity of the system certification body's services is in place with all surveyed organisations.

Not all participating system certification bodies have organisational structures divided into divisions that support their scopes of certification. However, all comply with accreditation requirements, such as an independent certification committee and an impartiality committee.

Management and personnel are employed with the appropriate skill sets assured by proper training, qualifications, and experience for the management and technical knowledge required by the various system certification scopes of the system certification bodies surveyed. The system certification bodies occupy premises accessible to their customers, with minimum environmental disturbances and optimum service delivery. The premises of only one CAB require an upgrade.

An effective and efficient Intranet is available, and IT equipment is installed and maintained. Again, one CAB needs to upgrade its IT system. Appropriate quality management systems (e.g., ISO/IEC 17021) formalised in relevant quality system documentation are in place or being implemented.

Pillar 3: Service delivery and technical competency

The scopes of system certification services provided by all participating system certification bodies are clearly defined and based on market demand.

In 2021, 128 management system certification CABs were actively accredited by JSM. Compared to the number of 78 CABs in 2020, this is a growth rate of 64%. The QI sub-sector of system certification is growing strongly. 4/5 surveyed certification bodies have been pre-assessed, subjected to an initial assessment, and accredited to ISO/IEC 17021 for all or some of their scopes.

Again 4/5 system certification bodies follow a certification process according to the requirements of ISO/IEC 17021 and IAF guidance documents. The post-certification process system certification bodies complies only in one case with the requirements of ISO/IEC 17021 and IAF guidance documents. Others follow these processes partially.

Pillar 4: External relations and recognition

Pillar 4 in system certification is relatively weak. While internationally recognised accreditation bodies accredit almost all CABs, only one has been designated by a regulatory authority. Co-operative ventures to conduct audits on behalf of private sector certification schemes are rare. Also, the co-ordination between the system certification bodies of Malaysia is not managed through a voluntary association.

6. Quality promotion

In the current modern and digital world, which encourages rapid growth in international trade, countries are now focusing on factors that enable enterprises to compete in new markets (World Bank, 2018). To compete in these new markets, the policymakers' agencies should be able to demonstrate, create awareness of, and promote the quality and safety of goods and services to comply with the international standards in the targeted markets. Hence, a well-functioning and structured quality infrastructure is crucial for any standard to have value to the buyers and sellers (El Araby, 2015). In addition, international organisations like the International Trade Centre (ITC) and the United Nations Industrial Development Organisation (UNIDO) also encourage inclusive and Sustainable Industrial Development

through SDG 9 to “Build resilient infrastructure, promote inclusive and sustainable industrialisation and foster innovation”. This is mainly to encourage and strengthen the QI of the developing countries by promoting public awareness.

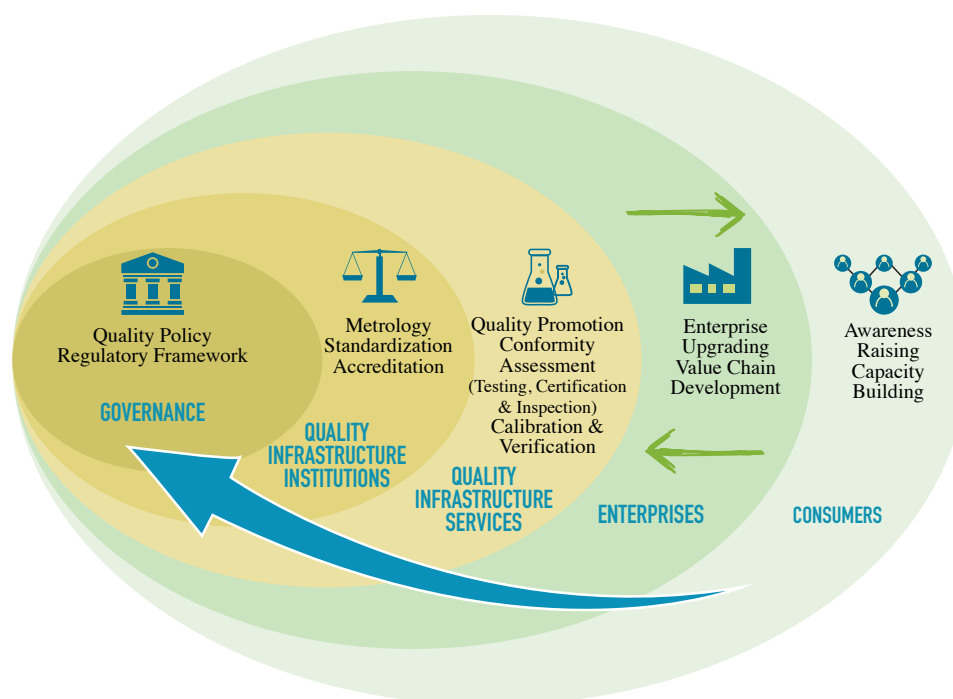


Figure 31: Quality Infrastructure System
Source: UNIDO (2016a)

As seen in Figure 31, one of the main components of the QI system is quality promotion. In developing countries, government agencies are likely to construct and manage the QI system, including creating awareness and promoting QI, as they have more experience and can share the quality inputs across the nation. The QI activities of sensitisation and marketing should be at the meta-level to promote a culture of quality (Harmes-Liedtke, 2010).

Quality promotion in Malaysia

In general, the information on NQI is expected to be channelled through the official quality agencies via websites, social media, and other printed media. In the case of Malaysia, the awareness and information on the QI is still at the infancy stage with minimum access to QI information on the websites and social media platforms of the leading quality agencies; MITI, MPC, JSM, SIRIM Berhad and NMIM. The information on QI may be found at these links below:

- MITI: <https://www.miti.gov.my/>
- JSM: <https://www.jsm.gov.my>
- SIRIM Berhad: <https://www.sirim.my/>
- Malaysia National Metrology Institute: <https://nmim.gov.my/>
- Malaysia Productivity Corporation: <http://www.mpc.gov.my>

It is evident on these websites that the concept of QI, which is increasingly popular in the international context, is still largely unknown in Malaysia. A basic search on the websites of the above leading agencies clearly shows that there are currently no leads and links to introduce the QI to its users in Malaysia. So far, information on the quality infrastructure can only be found regarding the individual components.

Besides the websites, there is also a lack of awareness and promotion of the QI, its benefits and other essential information on the above agencies' social media platforms. These are used mainly by owners to share updates on the happenings related to them constantly. For example, a quick check on the JSM Facebook page shows constant posting and updates. However, the last posting on QI dates back to 2017. This indicates a gap in the knowledge of QI and the dire need for QI promotion in Malaysia. The same is found with SIRIM Berhad.

Likewise, on the NMIM website, there is minimal information on the QI, with only one link found to illustrate the NQI system³³. NMIM plays a vital role in disseminating measurement traceability to the whole country based on the International System of Units. Like other world standard laboratories, NMIM has a great responsibility to ensure the national metrology infrastructures meet and comply with the global measurement standards. However, unlike the JSM and SIRIM Berhad Facebook pages, NMIM has not actively used the platform for updates on NMIM and other related information. However, MPC is actively promoting the productivity initiatives listed on its website and other social media platforms, including Facebook, Instagram, YouTube and Twitter.

³³ Illustration on the National Quality Infrastructure System in Malaysia ([NMIM - National Metrology Institute of Malaysia. - National Quality Infrastructure](#))

Although quality promotion is barely promoted by the agencies above, it is important to note that the overall quality matters are investigated seriously in Malaysia. This can be seen with the existence of the Institute of Quality Malaysia (IQM). IQM is a professional body established in 1979 under the Societies Act (1966) to represent the quality practitioners in Malaysia. IQM aims to promote the advancement of quality and its application to industry and business in Malaysia.

Additionally, the Quality Community of Malaysia was established to share knowledge on quality management and operation excellence in Malaysia. The Quality Community of Malaysia works towards fostering a quality culture within the community and industry, disseminating information about quality management and best practices within the community and across industries, and encouraging networking among members related to quality management and operational excellence. MPC has introduced two initiatives for this purpose, namely Productivity in Context and Enterprise Productive. Enterprise Productive has a dynamic approach to standardising its best practices in operations management to help organisations in need of guidance and leadership (nurturing and coaching) to execute improvement projects with a more structured, systematic and effective approach.

While Malaysia also presents Quality Service Awards to businesses that achieve customer excellence, these awards are not in line with the quality infrastructure category and not widely informed. In addition, JSM developed *“Advocating Standards and Conformance Through Education - A Strategy Paper 2017- 2020”* which covered directives and action plans for advocating standards through education activities from year 2017 to 2020. Several programmes have been conducted, including programmes for academic institutions such as awareness seminars, symposiums, and capacity-building programmes. JSM is reviewing and updating the standards education programme to ensure that it is aligned with current demand and good practices.

Thus far, there is no overarching framework for disseminating a quality culture in Malaysia. The individual activities to inform companies and consumers are fragmented. The role of these government agencies to have a clear link to QI is vital for quality promotion, as stated in the

QI system in Figure 31. A quality policy should therefore contain its communication strategy and plan.

D. Benchmarking of the NQI

NQI system comparison

Malaysia's QI in an international comparison

Quality infrastructure systems are constituted at the national level. The evolution of these systems responds to the national context, needs and specificities. At the same time, international trends in trade and development shape a national QI system.

International institutions, such as the International Trade Centre (ITC) of the World Trade Organisation (WTO) and other members of the Global Network of Quality Infrastructure (INetQI), promote the exchange of experiences between countries. Although each country needs to develop its quality infrastructure, the practices and policies of other countries can be inspiring and helpful.

At this point, the ITC team will compare the stage of development of Malaysia's quality infrastructure with the systems of other advanced economies. By analysing the Global Quality Infrastructure Index (GQII) data, the development status of Malaysia's QI and its components can be ranked. In addition, the structural elements of the various systems will be outlined to classify the peculiarities of the Malaysian system.

To select the benchmark countries, the authors applied the following criteria:

- Leading countries in their context.
- Experience with National Quality Policy.
- From different world regions.
- Easy access to resource persons.

Australia, Germany, Indonesia, and Mexico became the partner countries that should inform Malaysia's QI assessment.

The proposed benchmark countries represent advanced QI systems on different continents. Given the scope of the consultancy assignment, the comparison with the four countries seems feasible. The proposed countries that have more advanced QI systems according to the Global Quality Infrastructure Index (GQII) (Malaysia's QI ranks 40 out of 184 economies) are:

- Australia (GQII rank 11): the country is one of the global pioneers of quality infrastructure. With the National Association of Testing Authorities (NATA), the country has the world's first-ever accreditation body. Australia is currently undergoing a fundamental reform of its metrology system. In standardisation, the country leads important committees for future technologies. With Malaysia, Australia shares the location in the Asia-Pacific region.
- Germany (GQII rank 1) has the vastest experience in metrology and overall well-developed quality infrastructure. As part of the European Union, Germany can offer lessons to be learned from regional QI co-operation. Furthermore, Germany is an example of QI supporting a leading export economy in practice.
- Indonesia (GQII rank 26): Indonesia is one of the most populous countries in the world and a neighbour of Malaysia. The NQI is similarly developed to Malaysia's and faces similar challenges.
- Mexico (GQII rank 18) is an export-rich economy and part of the North American Free Trade Area (NAFTA). At the same time, the country is part of the Pacific region. Currently, Mexico is introducing a new quality law that fundamentally reorganises the national quality infrastructure. The example of Mexico highlights the challenges of developing an NQP in an emergent economy.

A combination of reasons led the CT to propose Australia, Germany, Indonesia, and Mexico and as benchmark countries. Each country has a leadership role in its region in developing national quality infrastructure and policy. At the same time, each country represents a different reality and culture, which shows how QI should be designed according to local conditions. Moreover, the Consultancy team knows the reality of QI in detail in all countries.

The QI model for each country should be specifically designed to suit the country's social, economic, and industrial situation and needs. The needs and focus areas also evolve according to global and technological changes and development.

Qualitative comparison

Dimensions for structural comparison:

- Governance mechanism
 - Leadership (Ministry)
 - Co-ordination (Council)
 - Policy and strategy (QP)
- System overview: Organisation and relationships between system components
 - Standardisation
 - Accreditation and conformity assessment
 - Metrology
 - Technical regulation
- Strengths and weaknesses/Inspirational practices

Germany

Germany is one of the leading export nations. The world-famous attribute "Made in Germany" expresses the entrepreneurial spirit and quality awareness. Therefore, maintaining and modernising an infrastructure that safeguards and expands this level of quality is a core task of German economic and technology policy. In addition to standardisation and legal metrology, a reliable quality infrastructure includes conformity assessment, i.e. the testing and certification of the fulfilment of specified requirements for products and services. Furthermore, the quality infrastructure consists of the so-called accreditation, which describes the proof of competence of conformity assessment bodies by an independent body.

QI-area	Standardisation	Accreditation	Metrology	Technical regulation
Bodies	DIN (general) and DKE (electrical, electronic & information technologies) private, non-profit	DAkkS (“one AB per economy”) private, non-profit, designated by the federal government	National Metrology Institute of Germany (PTB); federal institute, the highest institution for scientific, industrial, and legal metrology weights and measures offices of the federal states and municipalities Designated institutes BAM, German Federal Office of Consumer Protection and Food Safety (BVL) and UBA	Central Authority of the Federal States for Safety Engineering (ZLS)

Source: ITC consultants

The legal framework and the institutions of the quality infrastructure are determined not only by national but also by European and international requirements, for example, in the technical harmonisation of the EU single market or within the framework of the Agreement on Technical Barriers to Trade (TBT) of the World Trade Organisation (WTO).

The Federal Ministry for Economic Affairs and Climate Protection (BMWK) co-ordinates the activities of the national quality infrastructure. The National Metrology Institute is an autonomous federal authority under the BMWK. The standardisation bodies and the accreditation body are private and independent but act on behalf of the public and represent Germany in European and international professional associations.

There is no formalised, overarching quality policy and no formal co-ordinating body in Germany. Moreover, the use of the term quality infrastructure is relatively new and has been pioneered by the work of QI-related development co-operation.

In addition, BMWK has launched the Global Project Quality Infrastructure (GPQI). Under the leadership of the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ), it is to conduct technical policy dialogues on quality infrastructure topics and thus promote internationally harmonised quality infrastructure systems.

The quality infrastructure institutions in Germany, especially PTB and DIN, are among the global pioneers in their fields. Due to the German economy's export strength, the country's quality infrastructure has developed widely. Currently, the institutions of the quality infrastructure are involved in developing industrial policy topics of the future, such as digitalisation/Industry 4.0 and the circular economy. In these projects, the institutions rely on their scientific expertise and the active participation of the private sector.

BMWK only has an orchestrating role since the legal framework is primarily carried out at the European level through Germany's membership in the European Union. The federal states have many competencies in technical regulations and legal metrology through the federal system.

Germany's strong commitment to QI-related development co-operation is noteworthy. The International Department of PTB carries out projects to strengthen QI in developing and emerging countries on behalf of the Ministry for Economic Co-operation and Development.

[Australia](#)

Despite significant reforms, Australia has not yet developed an explicit overarching strategy or a formal NQP (Harmes-Liedtke, 2021). As mentioned in Box 1, until now the Australian government has primarily prioritised deregulation (Harmes-Liedtke, 2021). The Australian QI-system is characterised by close co-operation between private and public institutions. The Commonwealth Department of Industry, Science, Energy and Resources has a co-ordinating and supporting role. NMIA is an institute under the Department of Industry, Science, Energy

and Resources. The other core institutions – Standards Australia, NATA, and JAS-ANZ - are independent. Their integration into the National Quality System is regulated by an individual Memorandum of Understanding (MoU) with the Australian Government. All institutions of the Australian Quality Infrastructure must generate most of their resources themselves.

QI-area	Standardisation	Accreditation	Metrology	Technical regulation
Bodies	Standards Australia, national peak standards development organisation, not-for-profit, non-government organisation	National Association of Testing Authorities, Australia (NATA) Joint Accreditation System of Australia and New Zealand (JAS-ANZ)	National Measurement Institute, Australia (NMIA) Designated institutes: Australian Nuclear Science & Technology Organisation For ionising radiation: activity of radionuclides ANSTO Menai Australian Radiation Protection and Nuclear Safety Agency For ionising radiation: exposure to ionising radiation, the absorbed dose of ionising radiation	Australian Competition and Consumer Commission (ACCC) in collaboration with the different States and territories. Australian Pesticides and Veterinary Medicines Authority Therapeutic Goods Administration Australian Industrial Chemicals Introduction Scheme Electrical Regulatory Authorities Council Food Standards Australia New Zealand

QI-area	Standardisation	Accreditation	Metrology	Technical regulation
			ARPANSA	Gas Technical Regulators Committee The Department of Infrastructure, Transport, Regional Development and Communications

Mexico

Mexico is a strong exporting nation and part of the United States-Mexico-Canada Agreement (USMCA), which came into force on 1 July 2020. At the same time, Mexico published a quality infrastructure law. The Mexican Ministry of Economy (*Secretaría de Economía*) sets the legal framework, co-ordinates the system through the National QI Commission and oversees central NQI institutions, such as the National Metrology Institute (CENAM). At the same time, the Ministry of Economy supports competition between different standardisation and accreditation organisations.

QI-area	Standardisation	Accreditation	Metrology	Technical regulation
Bodies	Several private standardisation bodies	Mexican Accreditation Entity (EMA) and recently, Mexican Accreditation (MAAC) and SIAAC	CENAM Designated Institutes National Institute of Ecology and Climate Change (INECC) For concentration of ozone in ambient air	Dirección General de Normas (DGN, by its initials in Spanish) of the Ministry of Economy

QI-area	Standardisation	Accreditation	Metrology	Technical regulation
			National Institute for Nuclear Research (ININ) For ionising radiation	

Indonesia

Strengthening the National Quality Infrastructure system is one of the Government of Indonesia's efforts to ensure the quality of products and their access to international markets.³⁴ To this end, Indonesia, with support from the European Union through the Trade Support Program II (TSP II), has developed a National Quality Assurance framework and an Export Quality Infrastructure system (ARISE+ Indonesia, 2021).

The National Standardisation Agency of Indonesia (Badan Standardisasi Nasional or BSN) was established in 1997 under Presidential Decree No. 13/1997 and was improved with a new mandate under Presidential Decree No. 166/0111.³⁵ BSN is a government institution, but not a department or a ministry, having the responsibility to develop and promote national standardisation in Indonesia. Separately, the National Accreditation Body of Indonesia was established in 2000 under Presidential Decree No. 166/0111 to become the accreditation body in Indonesia. Its main function is to establish an accreditation system and to grant accreditation in certain fields, including testing and calibration laboratories, certification bodies, and inspection bodies.

The Indonesian National Standard (Standar Nasional Indonesia or SNI) applies to certain designated goods, services, systems, and processes in Indonesia and businesses responsible

³⁴ <https://ariseplus-indonesia.org/en/activities/perspectives/stepping-stone-to-building-strong-national-quality-assurance-and-export-quality-infrastructure.html>

³⁵ https://www.eria.org/RPR_FY2015_No.15.pdf

for such items may choose to conform to its requirement to obtain SNI certifications. Relevant technical committees formulate SNIs in accordance with the nationally agreed mechanism of standard formulation and generally align SNIs with international standards whenever possible. The affixing of the SNI mark on the product or service is an indication that it meets the standard requirements. While SNIs are primarily voluntary, those related to safety, security, health, and environmental conservation may be mandatory.

The issuance of SNIs as mandatory standards falls under the authority of government ministries, such as the Ministry of Trade, the Ministry of Industry, and the Ministry of Agriculture, as well as certain agencies that function to regulate their respective responsibilities including the Agency for Drug and Food Control. Once a ministry promulgates an SNI as mandatory, the standard becomes a requirement of the market. It may be noted that mandatory SNIs take effect in a non-discriminatory manner – they are applicable for both foreign and domestic goods.

QI-area	Standardisation	Accreditation	Metrology	Technical regulation
Bodies	National Standardisation Agency of Indonesia (BSN)	Komite Akreditasi Nasional (KAN)	<p>Directorate for National Measurement Standards of Mechanics, Radiation, and Biology and Directorate for National Measurement Standards of Thermoelectric and Chemistry, National Standardisation Agency of Indonesia SNSU-BSN</p> <p>Designated Institute: Center for Technology of Radiation</p>	<p>Ministry of Trade (MoT)</p> <p>Ministry of Marine Affairs & Fishery (MMAF)</p> <p>Ministry of Agriculture (MoA)</p> <p>BPOM (Agency for Food & Drugs)</p> <p>Ministry of Industry (Mol)</p> <p>Ministry of Transportation (MoTr)</p>

QI-area	Standardisation	Accreditation	Metrology	Technical regulation
			Safety and Metrology/ National Nuclear Energy Agency (PTKMR – BATAN)	Ministry of Environment (MoE) Ministry of Forestry (MoFo) Ministry of Public Works (MoPW) Ministry of Manpower (MoMP) Ministry of Health (MoH)

The Indonesian Government institutions involved in the field of technical regulations are shown in the above table. The regulatory system is overlapping in many fields and is not transparent. The only exception is the Ministry of Marine Affairs and Fishery (MMAF) that is the sole authority in its value chains. There is no umbrella law on regulations nor is there a single institution on regulatory affairs.³⁶

Indonesia is politically stable and yet dynamic – not only because of its young population. Intending to expand markets and drive further digital and industrial development, Indonesia is aiming to increase technical alignment and harmonise standards with international quality infrastructure (QI).³⁷

The country actively engages in QI and participates in international QI organisations. Nevertheless, the potential for further harmonisation remains. A concrete example of how the country is addressing this challenge is in its efforts to increase the number of adopted and

³⁶ https://eeas.europa.eu/archives/delegations/indonesia/documents/more_info/pub_2011_idnexport_en.pdf

³⁷ <https://www.gpqi.org/indonesia.html>

implemented international standards and to achieve recognition of laboratory test results in various industry sectors of mutual interest.

Quantitative benchmarking

To assess the development status of Malaysian QI in international comparison, the ITC consultants use data from the GQII, the only database in the world that compiles a database and global QI ranking of 184 countries based on the data published by the QI bodies themselves. The GQII is maintained by the consulting firms Mesopartner PartG (Germany) and Analiticar (Argentina) and hosted at the Technical University of Berlin (Germany).

Table 8 : GQII global and sub ranking

GQII 2020 Global Ranking and Sub Rankings					
Economy	Global Quality Infrastructure Index 2020	Rank GQII 2020	Rank GQII Metrology	Rank GQII Standard	Rank GQII Accreditation
Germany	99.5	1	2	2	2
Australia	95.4	11	8	19	6
Mexico	92.6	18	16	40	8
Indonesia	89.2	26	35	36	18
Malaysia	86.3	40	37	21	50

Table 8 shows the GQII ranking based on 2020 data. Germany's quality infrastructure has the first rank with a score of 99.5 out of a total of 100 possible points. Among the other comparator countries, Australia ranks 11th, Mexico 18th, Indonesia 26th, and Malaysia 40th.

It is striking that the ranking in the individual components – metrology, standardisation, and accreditation – is different. For example, Germany ranks 2nd worldwide in all components. In contrast, Australia with a ranking of 6, Mexico (8) and Indonesia (18) are comparatively strong around the sub-ranking of accreditation.

In the case of Malaysia, on the other hand, the standard component is comparatively strong at rank 21. The country ranks 37th in metrology and 50th in accreditation.

Table 9 : GQII 2020-subcomponents by economies/countries

GQII 2020: Subcomponents by economy										
Economy	CMC Coverage	Total K&SC	CABs Calibration laboratories ISO/IEC 17025	Participation in Consultative Committees	Total ISO MS Certificates	Technical Committee Observing Member	Technical Committee Participating Member	CABs Products, processes and services ISO/IEC 17065	CABs Quality management systems ISO 9001	CABs Testing laboratories ISO/IEC 17025
Germany	100%	759	512	10	67,356	41	699	340	131	2,436
Australia	100%	319	298	5	10,587	85	285	48	89	2,479
Mexico	89%	281	353	8	10,538	55	90	68	58	1,011
Indonesia	78%	84	223	0	9,752	170	100	75	52	1,181
Malaysia	95%	95	94	0	13,710	130	162	29	78	587

Note: 2021 data for Malaysia ISO/IEC 17065

Table 9 provides additional information on the data basis of the ranking—the first four columns of data relating to metrology competence. For example, Germany is represented in all ten Consultative Committees of the CIPM. Also, the German NMI, together with the designated institutes, covers all metrology areas with CMCs. As a result, the number of key and supplementary comparisons (K&SC) was 729 in 2020. Furthermore, there were 512 accredited calibration laboratories in Germany.

Australia and Mexico are also strongly represented in the CIPM Consultative Committees. Both countries had very high levels of CMC coverage, with a significant number of K&SCs at 319 and 281, respectively. In contrast, Indonesia and Malaysia are not represented in the CIPM Consultative Committees. In terms of CMC coverage, Malaysia – like Mexico – had a coverage of 89%, whereas Indonesia was at 78%. In contrast, there were more calibration laboratories in Indonesia (223) than in Malaysia (94).

The following three columns of Table 9 refer to the competencies in standardisation. According to ISO Survey 2020, Germany leads with 67,356 ISO 9001 certified organisations, followed by Malaysia with 13,710, Australia with 10,587 and Indonesia with 9,752.

Countries can participate in the ISO Technical Committees as participants (P) or observers (O). For example, Germany participates in 699 TCs as a P-member; Australia (285), Malaysia (162), Indonesia (100), and Mexico (90) following close behind. Conversely, Indonesia with 170 and Malaysia with 130 are often represented as O-members.

The last three columns of Table 9 refer to accreditation competencies. Australia leads the ranking of accredited testing laboratories according to ISO/IEC 17025 with 2,479. Germany follows this with 2,436, Indonesia with 1,181, Mexico with 1,011 and Malaysia with 587 accredited test laboratories.

According to ISO 9001, Germany is again in the lead with 340 and 131 accredited certification bodies, respectively, in the certification of product certification bodies and quality management systems. On the other hand, Malaysia shows the lowest values in all accreditation areas.

Table 10 : GQII 2020-Accreditation membership and CABs count

GQII 2020: Accreditation membership and CABs count						
Economy	Body ID	IAF Status	ILAC Status	RAO Status	RAO	CABs count
Germany	DAKKS	signatory	signatory	signatory	EA	4,600
Australia	ALAB	signatory	signatory	associate	APAC	0
	JAS-ANZ-AU	signatory	signatory	signatory	APAC	347
	NATA	No	signatory	signatory	APAC	3,163
Mexico	EMA	signatory	signatory	signatory	APAC & IAAC	2,094
Indonesia	KAN	signatory	signatory	signatory	APAC	1,804
Malaysia	DSM	signatory	signatory	signatory	APAC	838

Table 10 gives an overview of the comparison of countries' memberships in regional and international accreditation co-operation bodies. All countries in the comparison are members of the co-operation bodies and signatories of their MLAs/MRAs. These memberships and the signing of MLAs or MRAs guarantee the international recognition of the certifications and test results of accredited conformity assessment bodies.

Correlations

To better interpret the GQII ranking, we present correlations with key economic and development indicators in the following diagrams.

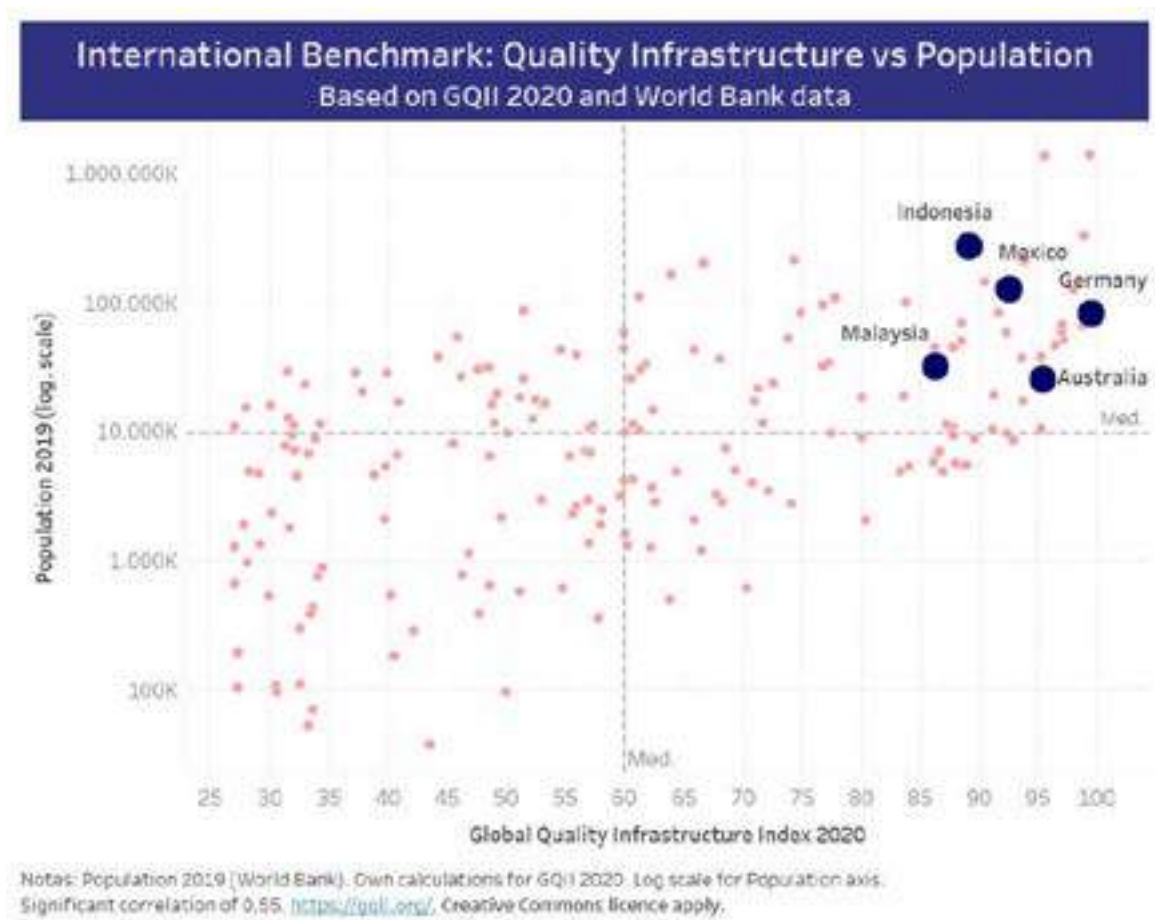


Figure 32 : Global Quality Infrastructure Index 2020 - International Benchmark: Quality infrastructure vs population

Figure 32 shows the relationship between the 2019 population size, plotted on a logarithmic scale, and the GQII ranking. All countries have relatively large populations, and their QI is highly developed. However, a detailed comparison shows Australia's QI to be more developed for the population size; the opposite is true for Indonesia. Overall, both variables correlate significantly but weakly (coefficient 0.55).

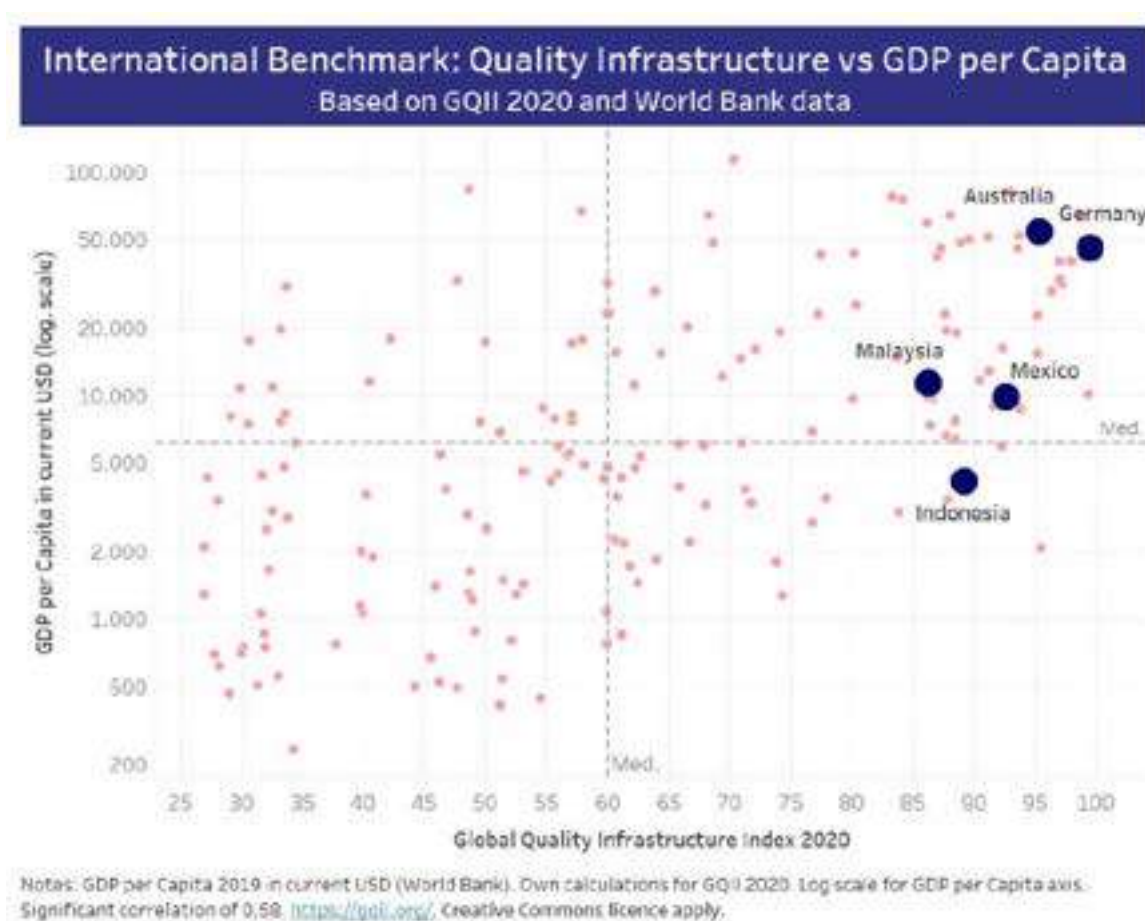


Figure 33 : Global Quality Infrastructure Index 2020 - International Benchmark: Quality Infrastructure vs GDP per capita

Figure 33 makes the relationship between the economic strength, measured on a logarithmic scale of GDP per capita, to QI development level. The two countries, Australia, and Germany, with the highest GDP per capita, have the most developed QI. On the other hand, in countries with lower per capita income, the QI in Malaysia, Mexico and Indonesia are far but relatively less developed. In this case, there is also a significant but weak correlation (0.58).

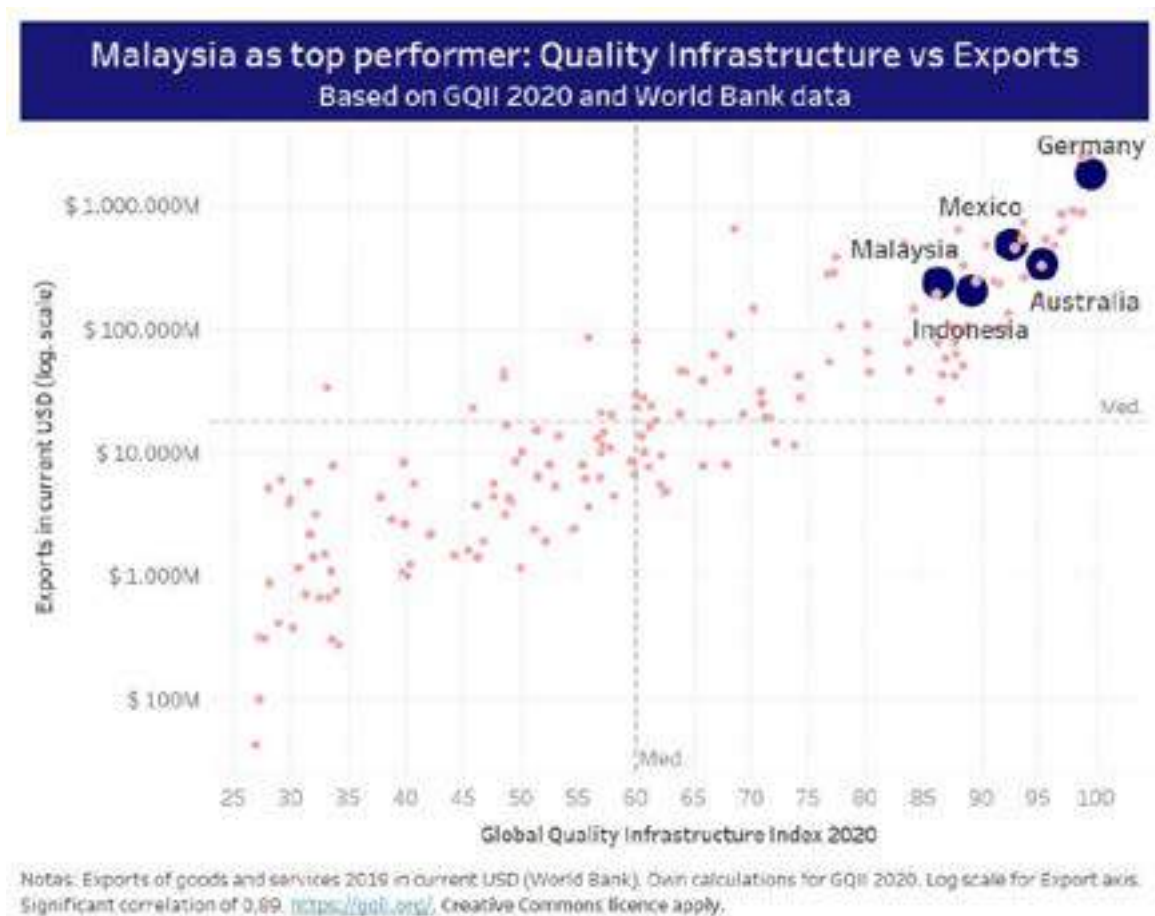


Figure 34 : Global Quality Infrastructure Index 2020 – Malaysia as top performer: Quality infrastructure vs exports

The correlation (0.89) between a country's exports and QI development is robust. Figure 34 shows that all comparator countries are export- and QI-strong. The values of both variables are highest for Germany, followed by Australia, Mexico, Indonesia, and Malaysia.

Overall, the GQII values show that Malaysia's QI is well developed and appropriate according to the country's size and population and its export strength.

V. USER NEEDS AND SERVICE GAPS

A. Background

Gaining a clear understanding of the needs and demand for QI services in a country is important because it completes the data required to make sound decisions on QI development programmes and their scope. On the one hand, this report is about the diagnostics of the supply side of QI services in Malaysia (using the RDT method). On the demand side, it is also crucial to identify the priority needs of private sector clients. A proper demand assessment is critical to both the capacity building of the QI and the identification of effective reforms.

B. NQI user survey

The consultant team conducted an adequately designed enterprise survey across all economic sectors to understand the current and future demand of NQI users in Malaysia. In close co-ordination with MITI, JSM and NMIM, the consultants collected 420 responses via an online survey, which exceeded the targeted number of completed questionnaires (270). To determine the target sample size of 270 enterprises, the team adopted the World Bank Enterprise Survey methodology, which generates a large enough sample size to conduct statistically robust analyses with levels of precision at a minimum of 7.5% precision for 90% confidence intervals³⁸. All sectors in the Malaysian economy have been considered and then aggregated into agriculture, mining, manufacturing, construction, trade and services (see Table 11 and Figure 35).

³⁸ www.enterprisesurveys.org

Table 11 : Actual NQI user survey sample matrix

	<i>Services</i>	<i>Trade</i>	<i>Construction</i>	<i>Manufacturing</i>	<i>Agriculture</i>	<i>Mining</i>	<i>Structure by size</i>
Structure by sector	43%	6%	6%	40%	4%	1%	
Total	182	27	26	166	16	3	420
Large	53	3	7	72	8	0	34%
Medium	35	7	12	46	1	3	25%
Small	63	14	7	43	4	0	31%
Micro	31	3	0	5	3	0	10%

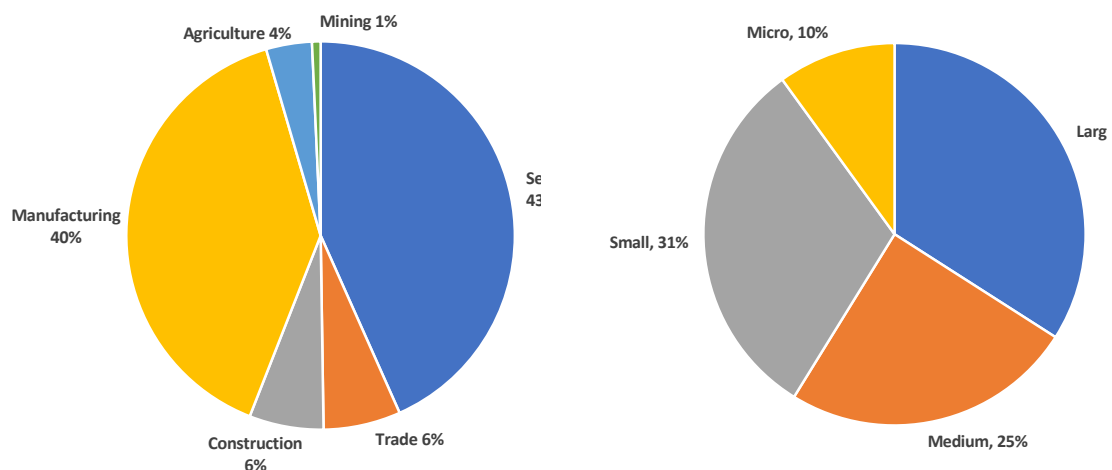


Figure 35: Actual sample structure by sectors and company size of the NQI user survey in Malaysia in 2022

Small and large enterprises are represented by about a third each, medium-sized enterprises by a quarter, and micro-enterprises by 10%. This sample structure does not fully represent the structure of the real economy in Malaysia, where micro-enterprises are dominant by almost half of the share of enterprises. However, it was challenging to realise a precise target structure through an open online survey disseminated through leading NQI institutions and selected business associations.

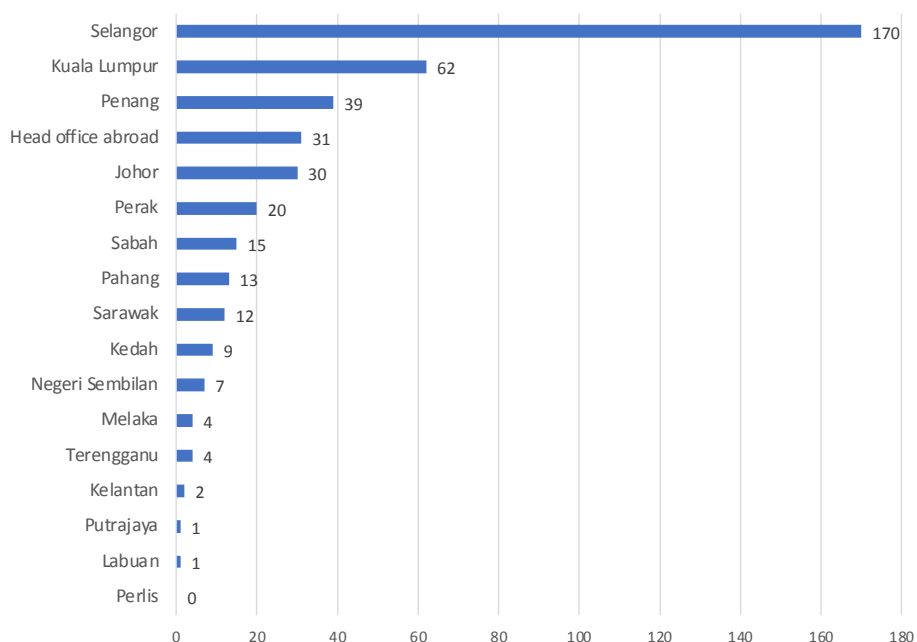


Figure 36: Location of surveyed enterprises

Out of 420 surveyed enterprises, 40% are located in the economically strong Selangor state, encircling the capital Kuala Lumpur. About 15% are from the capital city and 9% from Penang Island. More than 7% of respondents are multinational enterprises with headquarters abroad. From the two states in East Malaysia, Sabah and Sarawak, 27 enterprises participated in the survey (about 6.5%).

C. Company characteristics

Among the surveyed enterprises, almost two-thirds are exporting (60%), either goods only (36%), services only (20%) or both (14%). But also, for those companies selling their products or offering their services on domestic markets only, quality infrastructure services could be essential to assure quality and prove it to the customers.

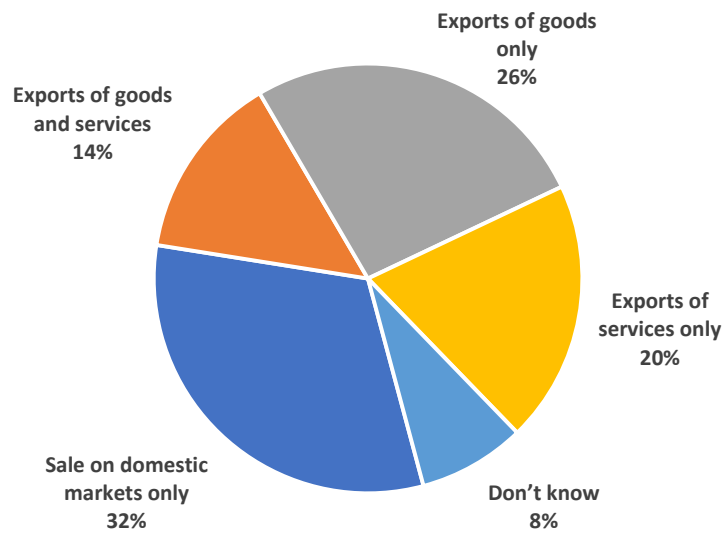


Figure 37: Enterprise sales in export and domestic markets

Only 21% of surveyed companies do not face quality or quality assurance issues (Figure 38). The biggest headache for almost half of the enterprise sample is complying with mandatory technical regulations imposed by the government. But also, the challenge to follow the requirements of voluntary standards relevant to the value chain they are part of is a critical matter for about a third of all companies (31%). The most pressing product-specific quality issue is consistently maintaining the quality of products or services at a high level that meets customer expectations (22%).

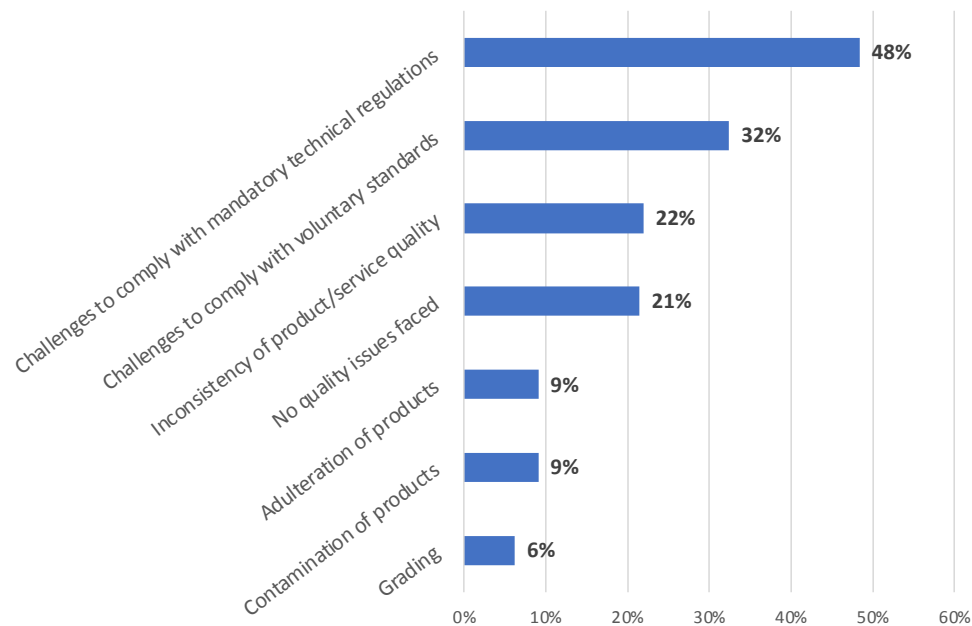


Figure 38: Quality issues surveyed that enterprises need to address

Other quality issues that are potentially harmful to customers and affect the price negatively, such as adulteration of products or contamination with foreign matters, chemical substances or infestation with bacteria or pests, are experienced by only 9% each. Grading into product quality categories, which allows for price differentiation and higher revenues, 6% of enterprises perceive this as a significant challenge.

D. NQI services: standardisation

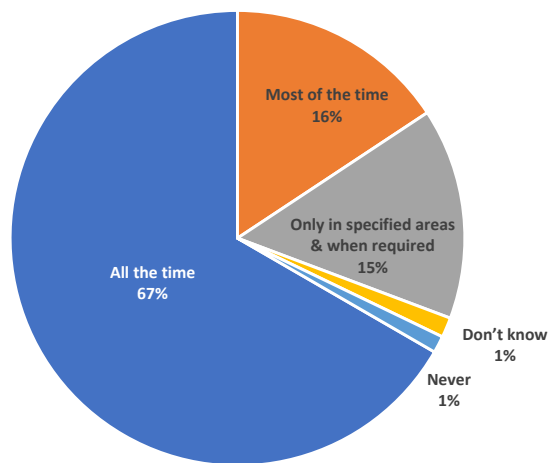


Figure 39: Referring to standards when manufacturing products or delivering services

Figure 39 shows that standards are prevalent in the Malaysian economy, determining how products are manufactured and services delivered. 98% of enterprises refer to standards, either all of the time (67%), most of the time (16%) or occasionally when required (15%).

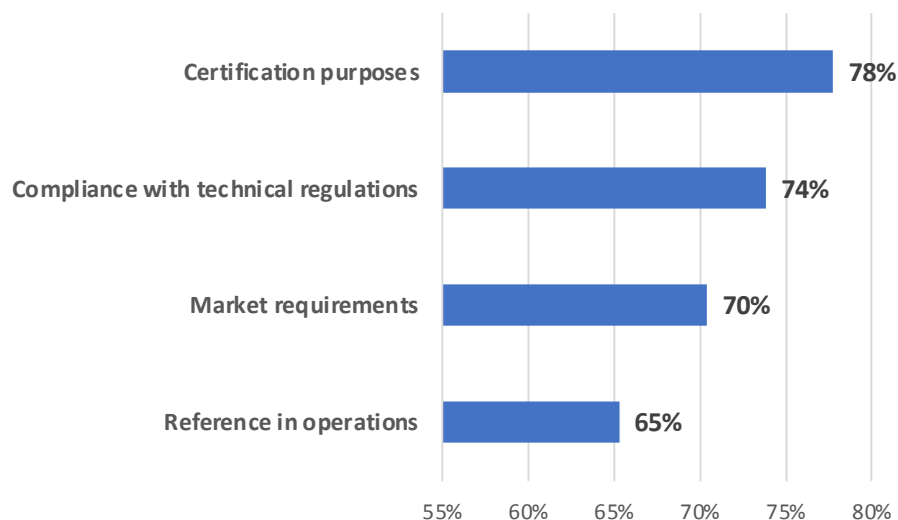


Figure 40: Purposes of using standards

The purposes of using standards vary among respondents. The prevailing purpose is the certification of products, management systems or personnel (78%), which confirms the remarkable growth rate of accreditations of system certification bodies in Malaysia in recent years. The ISO survey 2020³⁹ emphasises the popularity of management system certification in Malaysia in the global context. Regarding the number of certificates, Malaysia ranks 16th for the ISO 9001 quality management standards, 15th for the ISO 22000 Food safety management system standards and 23rd for the ISO 14001 Environmental management system standard – all in a global context out of 195 countries.

³⁹ <https://www.iso.org/the-iso-survey.html>

Compliance with mandatory requirements set by technical regulations (76%) is another primary reason why companies need to look into specifications laid out in regulations and the standards they are based on.

Even if not certified, many companies embedded in global or domestic value chains are part of industry-wide standard schemes that define market requirements concerning product or service specifications. Given this situation, 70% of surveyed enterprises use the respective standards as a reference to produce goods or deliver services.

In general, standards play a role as a reference in all facets of business operations, such as prescribing test methods, specifying standard operation procedures or describing good practices. This is relevant for 65% of respondents.

79% agree with the statement that in their industry, sector or focus area, standards are usually available and easily accessible. 16% disagree with this statement, and 5% are not informed.

E. NQI services: conformity assessment

Malaysian enterprises use all the typical conformity assessment services. Most popular, as already described above, are certification services. About two-thirds of enterprises in the sample get their products or systems certified. This is an outstanding share.

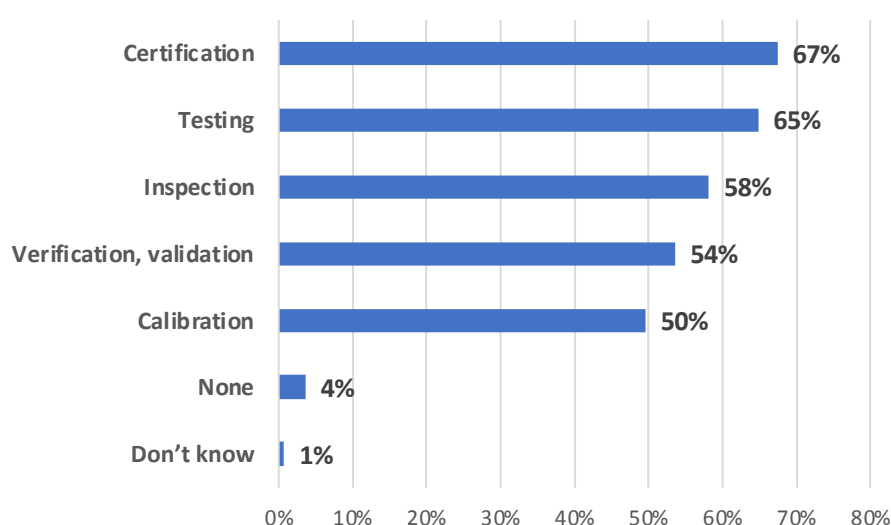


Figure 41: Types of conformity assessment services used by enterprise sample

Testing is almost equally important (65%). Considering the strong export orientation (40% of the survey sample exports goods), the frequency of product testing does not come as a surprise. Also, many of those enterprises selling on domestic markets might need to undergo testing procedures according to respective sector regulations.

58% of enterprises experience quality inspections, which can be regulatory measures as part of Malaysia's inspection policy or private inspection services as an element of the voluntary standards companies are committed to.

Finally, verification, validation and calibration of a company's measuring instruments are further QI services for which about half of the enterprises are requesting.

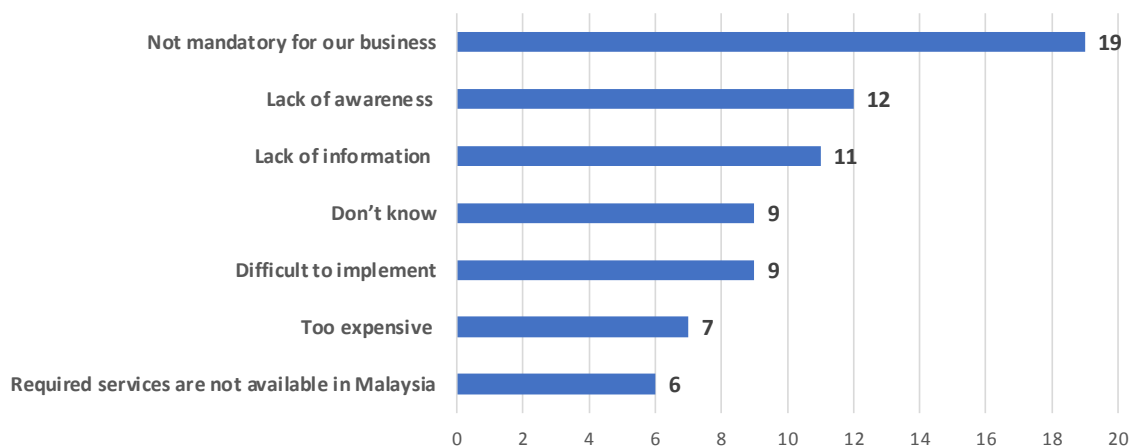


Figure 42: Reasons for not using conformity assessment services

However, a few enterprises in the sample (4%) manage to operate without using any conformity assessment services. Dominant reasons are that some enterprises do not have to use QI services, are unaware of such services or lack any information about them. Some consider QI services too tricky to implement or too expensive. Only a few do not find their required services offered in Malaysia.

On the other hand, most enterprises use QI services and assess them as very relevant (51%) or at least relevant (32%) for developing their core business. Another 12% find conformity assessment services somewhat relevant (see Figure 43).

Attaching such a high level of importance to a specific type of services that enterprises need to operate creates expectations on service quality, costs, availability and accessibility.

Figure 44 shows the origin of conformity assessment services providers used by Malaysian companies. About half of the respondents use both Malaysian and international service providers, while 17% prefer international service providers operating in the Malaysian market for conformity assessment services.

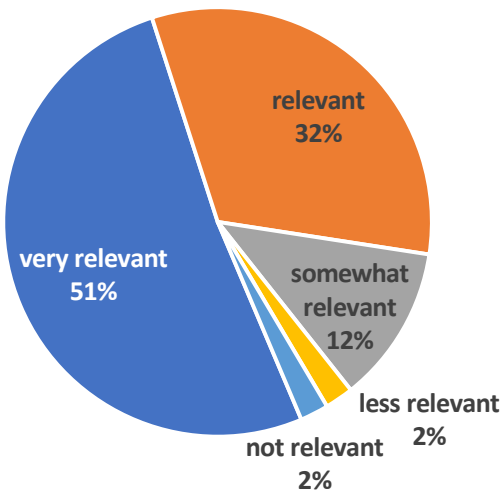


Figure 43: Relevance of conformity assessment services for developing core business

The remaining share of enterprises focuses on services provided by Malaysian service providers.

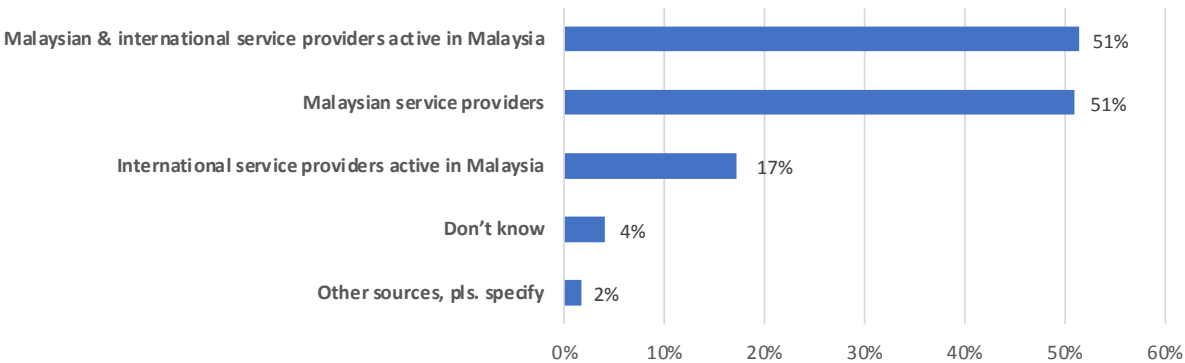


Figure 44: Type of QI service providers used

The user assessment of the conformity assessment services sheds an interesting light on these services' availability, price, and quality (Figure 45). There is a relatively high level of satisfaction with service availability and quality. More than 70% of customers assess both features as excellent or good. Another approximate quarter of users finds availability or quality still acceptable (22% and 25%, respectively). Only a minimal share regard availability (7%) and quality (3%) as poor or very poor.

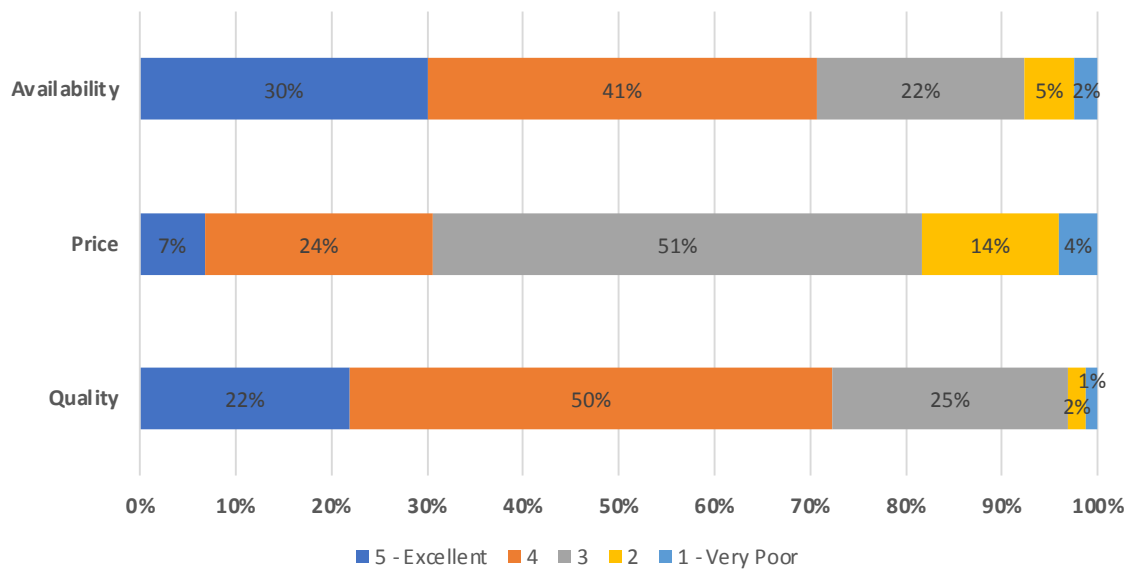


Figure 45: User assessment of conformity assessment services

Not surprisingly, the price of QI services is assessed more critically. While a third of the users are happy with the service prices, another half consider the costs acceptable. About 18% wish for more inexpensive services to be offered to them.

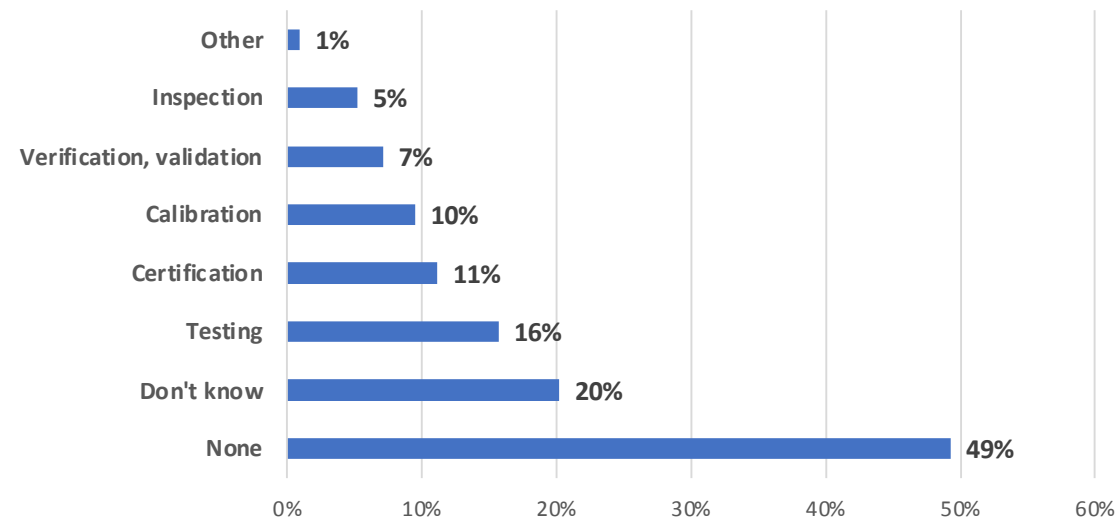


Figure 46: Lacking conformity assessment services

Looking deeper into service availability, half of the respondents are satisfied with the offers in the market, and another fifth is insecure about whether additional services are needed. The remaining third of companies would prefer to have further testing (16%), certification (11%) or calibration services (10%). Other service needs (verification, validation and inspection) are requested by less than 10% of customers.

Examples of unsatisfied testing demands collected by the user survey include identification of impurity (pharmaceutical industry), EN388 tests, pipe coating testing services (Oil & Gas industry), quantification of actives in products (herbal and nutrient elements), specific microbiological testing and biocompatibility testing, urine testing for N,N-Dimethylformamide (DMF) exposure (Occupational Health Biological Monitoring), biodegradation testing or nitrosamine analysis.

The need for the calibration of specific technical instruments is identified by the survey, such as calibration of strain transducer, gas analysers, sound level meter/dosimeter, fuel flow meter, UV spectrometer, EMC test equipment, cleanroom air particle counter, vibration devices, pressure equipment directive (PED) and power tools related calibration service (based on ISO 5393: **Rotary tools for threaded fasteners — performance test method**).

In addition, some conformity assessment services seem to be available only in West Malaysia. An example is smoke meter calibration services not being offered in Sarawak. Also, it is pointed out that SIRIM QAS does not operate any laboratory or testing equipment in Sabah state.

F. NQI services: accreditation

Accreditation is the third-party attestation of a conformity assessment body that demonstrates its competence and impartiality to perform specific quality assessment tasks. Accreditation is critical in countries dependent on global trade because of its facilitating role in the international recognition of QI services (Kellermann, 2019c).

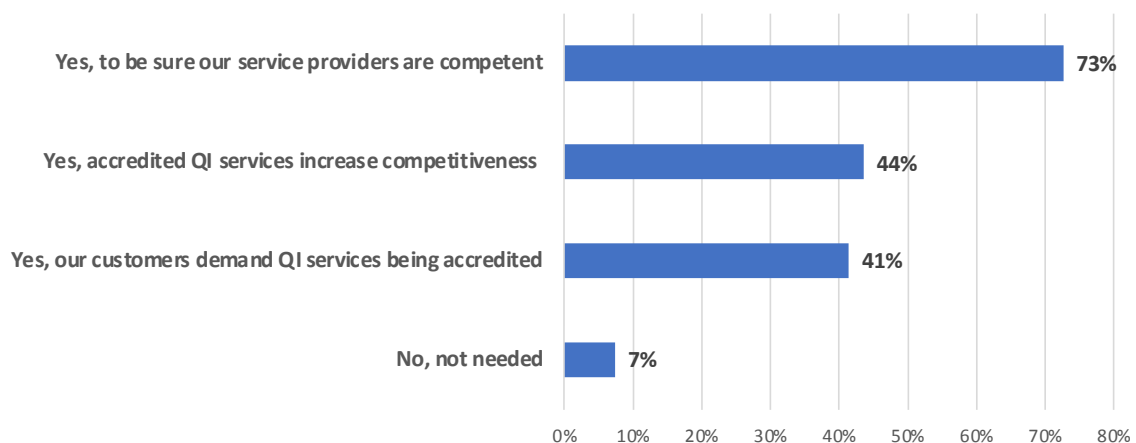


Figure 47: Attaching importance to the accreditation of QI services

Many enterprises in the survey sample (44%) are aware of the importance of accreditation for their market opportunities and competitiveness (Figure 47). About three-quarters of respondents highlight that they look for accredited QI service providers to ensure that they are competent when delivering the required services. The proof of competence is also vital for the customers of QI service providers but also their customers. 41% of respondents confirm that their customers insist on accepting only accredited QI services. A meagre 7% of respondents do not see a need for accredited services. This small group of QI service users is not aware of accreditation or does not recognise the benefits for them. Some shy away from

the additional costs, as accredited services are usually more costly than non-accredited services.

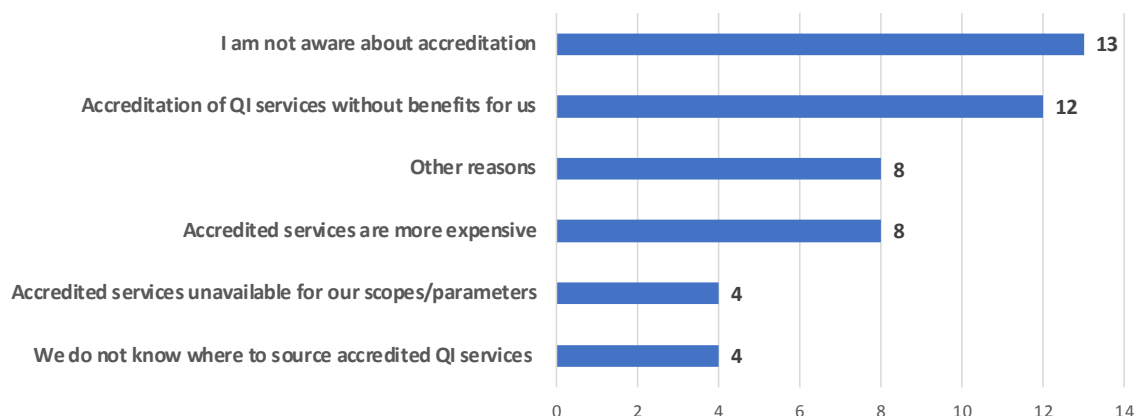


Figure 48: Reasons for not attaching importance to accreditation of QI services

A few company representatives mention that accredited services are not available for the scope needed, or they do not know where to source them.

G. Market surveillance

Market surveillance is an essential instrument for the enforcement of technical regulations. The purpose of market surveillance is to ensure that the products placed on the market comply with the requirements of the relevant technical regulation to ensure health, safety, and environmental integrity. Market surveillance is also essential from an economic actors' view as it helps curb unfair competition (Kellermann, 2019c).

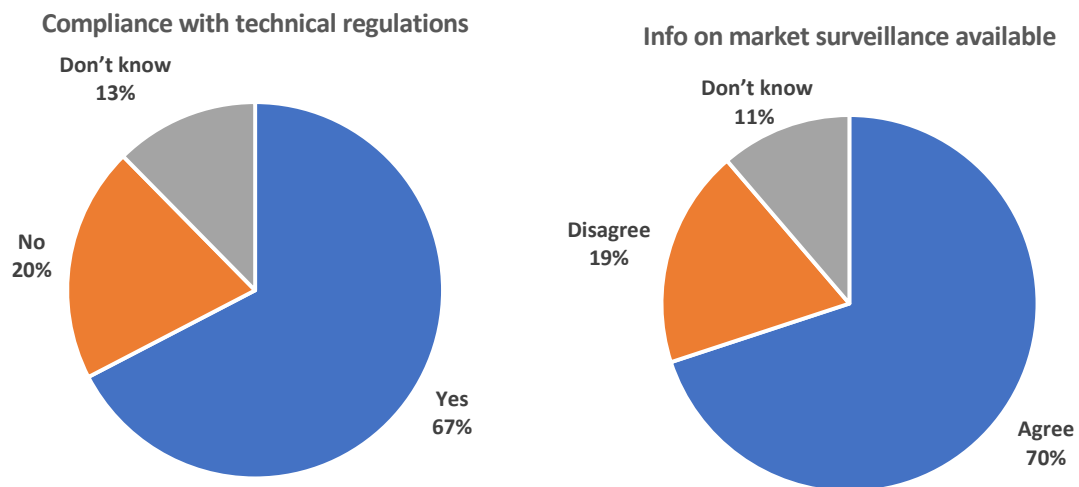


Figure 49: Compliance with technical regulations and availability of information on market surveillance

67% of enterprise survey respondents confirm that their products or services need to comply with technical regulations and legal requirements before entering the domestic market in Malaysia (Figure 49). 20% deny such an obligation, while a surprisingly high 13% are unaware.

The government ensures compliance with technical regulations through market surveillance, which may include manufacturers' premises and warehouses to ensure all producers' continued compliance of products with technical regulations. 70% of the survey respondents confirm that the information on market surveillance for their products or services conducted by authoritative bodies is readily available and easy to follow. Still, 19% of respondents disagree with this statement, and 11% are not informed.

VI. CONCLUSIONS AND POLICY RECOMMENDATIONS

In this chapter, the ITC consultants summarise the results of Malaysia's QI assessment in a SWOT analysis.

The *strengths and weaknesses* relate to the issues of Malaysia's QI described in Chapter IV. These include the legal framework and the institutional setting. Looking at the benchmark countries helps identify gaps in the development of Malaysia's QI and inspiring practices. Taking on a demand-driven perspective, the user needs described in Chapter V are also analysed here.

The *opportunities and threats* analyse the NQI environment. Here, the consultancy team addresses national and international developments in the socioeconomic, geopolitical and ecological context (Chapter III) and recent developments in the quality infrastructure at the global level.

Table 12: Strengths and weaknesses of the Malaysian QI system

Themes	Strengths	Weaknesses
General NQI system setup/ governance & leadership	<p>Malaysia's QI system has evolved over the years and serves the industrial needs.</p> <p>MITI has been identified as the leading ministry of QI agencies.</p>	<p>Lack of clarity on who oversees the overall NQI system prior to MITI being identified as the ministry leading the QI agencies.</p> <p>QI is technically and strategically a new area of expertise of MITI.</p> <p>Lack of planning and strategy on quality promotion by the government.</p> <p>Overlaps and inconsistencies in regards of roles and responsibilities in QI. For instance, the placement of the WTO TBT Enquiry and Notification Point</p>

Themes	Strengths	Weaknesses
		<p>under SIRIM STS while JSM serves as the Secretariat for the NMC and the lack of communication between both bodies.</p> <p>Additionally, the development of industry standards by SIRIM Berhad despite not being officially designated or recognised as Standard Development Organisation (SDO) by NSB.</p> <p>Absence of a central monitoring system leads to a lack of information exchange and co-ordination between NQI agencies.</p>
Legal framework and institutional setting, including TR regime	<p>Existence of a legal base for standardisation, accreditation, and metrology.</p> <p>GRP system is continuously upgraded.</p>	<p>Lack of overarching QI legislation. The legislation addresses the main elements of QI individually but there is no co-ordination among them, and they do not consider the reality of Malaysia's QIS, which developed according to demand over time.</p> <p>QI legislation needs revision.</p> <p>Some regulators do not absorb GRP fully. This was noted during interactions with regulators in preparation for the NQI assessment, particularly with respect to the RDT responses.</p>
Technical regulations	Clear separation between standards and technical regulations.	NMC's co-ordination is not consistent and timely to represent Malaysia's interest in WTO. As revealed in an interview with NMC, meetings take place

Themes	Strengths	Weaknesses
	A National Mirror Committee (NMC) is established for TBT co-ordination.	biannually and often there is insufficient time between NMC meetings and WTO TBT meetings to discuss TBT issues that affect Malaysia in sufficient detail.
Standard system	<p>The standard development process is established and working.</p> <p>Currently, there is a broad coverage of Malaysian standards.</p> <p>Malaysian standards are informed by international standards.</p> <p>Malaysia is participating in the ASEAN and APEC SCSC activities of standard harmonisation.</p> <p>A National Standardisation Programme is in place.</p>	<p>Malaysian standards are not covering key economic areas like aerospace and finance as mentioned in the MP12.</p> <p>Malaysia's participation in international standard-making is limited. Malaysia participates actively in only about 30-49% of technical committee meetings of international standardisation organisations and there is no established NMC to discuss draft international standards before submitting feedback on behalf of Malaysia.</p> <p>There is no regime of a standards development organisations (SDO) beyond JSM.</p> <p>SIRIM Berhad's role in developing industrial standards is not fully integrated into a National Standardisation Programme.</p>
Metrology system	High-level international recognition of Malaysia's measurement capabilities (CMCs at CIPM).	<p>Malaysia does not have full membership at OIML (only corresponding).</p> <p>Metrology in chemistry is still in an early development phase (i.e., no</p>

Themes	Strengths	Weaknesses
	<p>Designated institutes have broadened the metrology capabilities in specific areas.</p> <p>There is a broad coverage of accredited calibration services.</p> <p>Close working relation between NMIM and W&M department at MDTCA.</p>	<p>CMCs, no reference material produced).</p> <p>NMIM does not cover all SI areas.</p>
Accreditation system	<p>JSM is the signatory of the international MRA/MLA.</p> <p>There is broad coverage of accreditation areas.</p> <p>There is a significant number and constant growth of accredited CABs.</p>	<p>Activities of foreign ABs in Malaysia are not fully co-ordinated. According to the rules in the international accreditation community (IAF and ILAC), accreditation bodies should not compete, especially in the same areas. If foreign ABs operate in Malaysia, they should inform JSM.</p>
Conformity assessment system	<p>A broad range of services offered.</p> <p>System certification is growing fast (Malaysia is under the top 25 of the ISO Survey in popular certification schemes).</p> <p>CABs are quite developed.</p>	<p>Lack of co-ordination and associations of CABs,</p> <p>The reporting of SIRIM QAS under MITI could generate a conflict of interests.</p> <p>Existence of gaps in accreditation of CABs used by regulators (i.e., food safety certification). Some ministries are using laboratories and inspection bodies which are not accredited.</p> <p>Accreditation to ISO 15189 is not a prerequisite for the registration or designation of medical laboratories in Malaysia.</p>

Themes	Strengths	Weaknesses
Quality promotion	<p>Existence of basic promotion activities on QI components by JSM, NMIM and CABs.</p> <p>Existence of quality awards in MY.</p>	<p>QI terms and concepts are not well known in Malaysia.</p> <p>QI bodies' websites do rarely refer to QI and the NQI system.</p> <p>The Communication department of MITI and other ministries are uninformed about NQI.</p>
User perspective	<p>Users are largely satisfied with the delivery, quality and price of QI services.</p> <p>Most sampled enterprises consider QI as important for their needs.</p> <p>Strong demand for accredited CA services.</p>	<p>A significant number of users (15%) say they are not informed.</p> <p>Services are concentrated in the central area of Malaysia and not throughout the country.</p> <p>Knowledge gap by the enterprise on which TR to comply with.</p>

Table 13: Opportunities and threats of the NQI environment

Themes	Opportunities	Threats
Megatrends - Climate change & climate neutral economy, geopolitics, digitalisation & industry 4.0; inequality/ migration	<p>Developing QI services for renewable energy and energy efficiency/circular economy.</p> <p>Digital transformation of QI services (efficiency, cost reduction).</p> <p>Technological disruption through Industry 4.0 opens opportunities for Quality Infrastructure 4.0.</p>	<p>Under-demand by industry due to a lack of quality awareness.</p> <p>Absence of policy to regulate renewable energy generation and distribution.</p> <p>Lack of needed capacity/ resources to respond to new requirements.</p> <p>MLA/MRA regime under threat because of geopolitical conflicts. The ongoing war</p>

Themes	Opportunities	Threats
	<p>Regional (subnational) inequality: making QI services available everywhere.</p> <p>QI for the health sector available (private and public).</p> <p>Expanding QI services beyond trade.</p>	<p>between Russia and the Ukraine; as well as conflicts of interest between the USA and China could weaken the MLA/MRA system.</p>
Trends in International Trade and Development	<p>Presence of E-certification, traceability.</p> <p>Onshoring of supply chains creates QI service opportunities in the home country.</p> <p>Lengthy shipping time leads to higher intensive conformity assessment.</p> <p>Increase of voluntary sustainability standards (VSS).</p>	<p>High costs to set up traceability in e-certification.</p> <p>Fraud /falsification of e-certification.</p> <p>Lack of capacity (HR, training).</p> <p>The credibility of QI services is questioned by customers abroad (due to delays in shipping).</p> <p>Challenges to the global trade system, like increased protectionism, could endanger the prominent role of QI in technical regulation.</p>
Trends in Global Quality Infrastructure	<p>Quality Infrastructure 4.0.</p> <p>The International System of Measurements (SI) has become independent from physical standards.</p> <p>Growth of metrology in chemistry and biology.</p>	<p>Incremental adjustments, no big bang adjustments possible (lagging behind).</p> <p>The geopolitical conflicts i.e. around China's standardisation strategy could endanger the unified global standard system.</p>

Themes	Opportunities	Threats
	<p>Linking standardisation work with development goals/ SDGs (London declaration).</p> <p>QI Communication and sensitisation become a non-technical QI component.</p>	
Malaysia's Policy Priorities	<p>Meeting the QI service requirements of prioritised sectors (under MP12).</p> <p>Check other areas of MP12 where QI can supportive.</p>	<p>Policymakers are not sufficiently aware of QI.</p> <p>Lack of needed capacity/ resources to meet new requirements.</p>
Socioeconomic Situation and Post-pandemic Recovery	<p>Development of new QI services in the health sector.</p> <p>Business continuity certification.</p> <p>Innovation in the delivery of QI services (remotely, digitally).</p>	<p>Over-investment in services/mechanisms/capacity that become obsolete.</p> <p>Low sustainability in maintaining certain certifications.</p>

Combinations

The ITC consultants combine the individual points based on the factors listed above. During this process, the internal issues are combined with external issues in each case. Consequently, four cross-connections are made: strengths with opportunities, strengths with threats, weaknesses with opportunities and weaknesses with threats.

Based on these crosswise connections, suitable recommendations for measures, actions and strategies are developed, which correspond to the objectives of the analysis. Eventually, these recommendations for action can be summarised as building-up (strengths-opportunities), protecting (strengths-risks), catching-up (weaknesses-opportunities) and avoiding (weaknesses-risks).

The combination of the internal and external analysis generates strategic options and general recommendations for further developing the NQI in Malaysia.

Table 14: Combinations matrix

Internal/external	Opportunities	Threats
Strengths	Building-up – What are the strengths that create new opportunities?	Protecting – What strengths can minimise risks?
Weaknesses	Catching up – How to overcome weaknesses to take advantage of new opportunities?	Avoiding – Don't let weaknesses become risks!

Below are the combinations between two SWOT dimensions each, from which the consultancy team derived recommendations.

Table 15: SO - Building on - Strengths that create new opportunities

Strengths	Opportunities	Recommendations
CABs are quite developed.	Developing QI services for renewable energy and energy efficiency/circular economy.	Support existing QI service providers to develop new services to meet market opportunities.
	Regional (subnational) inequality: making QI services available everywhere.	Support territorial expansion of QI service providers.
Significant number and constant growth of accredited CABs.	Development of new QI services in the health sector.	Setup an overall QI communication and quality promotion strategy. A communication plan with clear targets and responsibilities, along with a timeline, the stakeholder
	Onshoring of supply chains creates QI service opportunities in the home country.	

Strengths	Opportunities	Recommendations
	Lengthy shipping time leads to higher intensive conformity assessment.	responsible and a budget should be developed to disseminate information about QI to all societal groups.
	QI Communication and sensitisation become a non-technical QI component.	
Strong demand for accredited CA services.	Business continuity certification.	Exploration of new business opportunities for the accreditation body, i.e., expanding accreditation service to conformity assessment used by local government and other public entities outside the trade sector.
Malaysia's QI system has evolved over the years and serves the industrial needs.	E-certification, traceability.	Enable QI bodies for digital transformation.
	Quality Infrastructure 4.0.	
	Technological disruption through Industry 4.0 opens opportunities for Quality Infrastructure 4.0.	
	Digital transformation of QI services (efficiency, cost reduction).	
	Innovation in the delivery of QI services (remotely, digitally).	
Malaysia's QI system has evolved over the years and serves the industrial needs.	Meeting the QI service requirements of prioritised sectors (under MP12).	Supporting existing QI providers to provide QI

Strengths	Opportunities	Recommendations
		services specifically targeted to MP12 sectors.
Existence of a legal base for standardisation, accreditation, and metrology.	<p>Linking standardisation work with development goals/ SDGs (London declaration).</p> <p>Increase of voluntary sustainability standards (VSS) (industry standards / SIRIM Berhad).</p>	Develop a standardisation strategy to address new opportunities.
A National Standardisation Programme in place.		
The standard development process is established and working.		
Malaysian standards are informed by international standards.		
Broad coverage of Malaysian standards.		
Strong demand for accredited CA services.	Global growth of number and scopes of accreditation within the signatories of IAF MLA and ILAC MRA .	Promote the development and international recognition of newer accreditations schemes (e.g. certified reference materials and biobanking).
Broad coverage of accredited calibration services.		
Broad coverage of accreditation areas.		
Close working relation between NMIM and W&M department MDTCA.	The International System of Measurements (SI) has become independent of physical standards.	Develop an integrated strategy for the Malaysian Metrology system.
High level international recognition of Malaysia's		

Strengths	Opportunities	Recommendations
measurement capabilities (CMCs at CIPM).	Growth of metrology in chemistry and biology.	
Designated institutes broaden the metrology capabilities in specific areas.		

Table 16: ST – Protecting – Strengths can minimise risks

Strengths	Threats	Recommendations
Basic promotion activities on QI components by JSM, NMIM and CABs.	Under-demand by industry due to a lack of quality awareness.	Develop an overall QI communication strategy which will be co-ordinated by a ministry selected to lead its implementation.
Existence of quality awards in Malaysia.		
MITI has been identified as the leading ministry of QI agencies.	Lack of capacity (HR, training).	QI capacity building activities for MITI.
	Policymakers are not sufficiently aware of QI.	
National Mirror Committee (NMC) is established for TBT co-ordination.	Policymakers are not sufficiently aware of QI.	Sensitisation sessions for all policymakers on GRP for TR.
GRP system is currently continuously updated.	Absence of policy to regulate renewable energy generation & distribution.	
Malaysia is participating in the ASEAN & APEC SCSC activities of standard harmonisation.	MLA/MRA regime under threat because of geopolitical conflicts.	Dialogue of Malaysian representatives in international QI organisations about experiences.
	The geopolitical interest of China could endanger the	

Strengths	Threats	Recommendations
JSM is a signatory of the international MRA/MLA.	unified global standard system.	
	Absence of policy to regulate renewable energy generation & distribution.	
Clear separation between standards and technical regulations.	Challenges to the WTO system could endanger the prominent role of QI in technical regulation.	Development of standards for SMEs and small domestic organisations.
System certification is growing fast (Malaysia is under the top 25 of ISO Survey on certification schemes).	Low sustainability in maintaining certain certifications.	Promotion of QI stakeholder forum for different conformity assessment areas.
	Overinvestment in services/mechanisms/capacity that become obsolete.	
Users are largely satisfied with the delivery, quality and price of QI services.	Lack of needed capacity/resources to meet new requirements.	Systematic QI service gap analysis for key sectors. Development of QI promotion strategies for selected key sectors.
A broad range of offered services.	The credibility of QI services is questioned by customers abroad (due to delay in shipping).	
Most sampled enterprises consider QI as important for their needs.		

Table 17: WO – Catching up – Overcome weaknesses to take advantage of new opportunities

Weaknesses	Opportunities	Recommendations
The Communication department of MITI and		Design and launch a comprehensive QI sensitisation

Weaknesses	Opportunities	Recommendations
other ministries are uninformed about NQI.	QI Communication and sensitisation become a non-technical QI component.	<p>campaign with multiple targets: users, regulators, QI bodies.</p> <p>Dissemination campaign of MPC among regulators at the national and state level on the new NPGRP (2021).</p>
QI terms and concept are not well known in Malaysia.		
QI bodies' websites have very limited information and rarely refer to QI and the NQI system.		
Some regulators do not absorb GRP fully.		
A significant number of users (15%) say they are not informed.		
Knowledge gap by an enterprise on which TR to comply with.		
Malaysian standards are not covering key economic areas like aerospace and finance as mentioned in the MP12.	Technological disruption through Industry 4.0 opens opportunities for Quality Infrastructure 4.0.	Concerted CAB effort (assoc.): QI service needs analysis in the key sector (MP12 sectors, energy, health, advanced manufacturing), followed by QI service design/adjustments.
	Meeting the QI service requirements of prioritised sectors (under MP12).	
	Developing QI services for renewable energy and energy efficiency/circular economy	

Weaknesses	Opportunities	Recommendations
	Development of new QI services in the health sector	
Malaysia's participation in international standard-making is limited.	Increase of voluntary sustainability standards (VSS) (industry standards/SIRIM Berhad). Linking standardisation work with development goals/SDGs (London declaration).	Develop a Malaysia standardisation strategy that defines roles in standardisation, introduces a SDO regime, considers industry-needs and sustainability.
There is no regime of a standards development organisation (SDO) beyond JSM.		
SIRIM Berhad's role in developing industrial standards is not fully integrated in a National Standardisation Strategy (NSS).		
Services are concentrated in the central area of Malaysia and not throughout the country.	Regional (subnational) inequality: making QI services available everywhere.	Levelling-up the accessibility of QI services across Malaysia by a country-wide needs analysis, opening new branches of QI bodies (where feasible) and offer digital delivery of services elsewhere.
	Digital transformation of QI services (efficiency, cost reduction).	
	Innovation in the delivery of QI services (remotely, digitally).	
No clear commitment of Malaysian government to QP.	Business continuity certification.	MP13 development to embrace NQI as a prominent topic and how to harness it to respond to global mega-trends.
	E-certification, traceability.	
	Localisation/onshoring of supply chains create QI	

Weaknesses	Opportunities	Recommendations
	service opportunities in the home country.	
	Lengthy shipping time leads to higher intensive conformity assessment.	
NMIM does not cover all SI areas.	<p>Growth of metrology in chemistry and biology.</p> <p>The International System of Measurements (SI) has become independent of physical standards.</p>	Facilitate dialogue between NMIM and leading metrology institutes abroad, e.g. PTB, on corresponding to latest challenges and opportunities in metrology.
Malaysia does not have full membership at OIML (only corresponding).		
Metrology in chemistry is still in an early development phase (i.e., no CMCs, no reference material produced).		
Overlaps and inconsistencies in regard to roles and responsibilities in QI.	Renewal and co-creation of NQI in Malaysia.	Develop an NQP for Malaysia; in the process involve all key QI bodies grasping their role in the NQI system and getting involved in re-designing the NQI architecture in Malaysia.
The reporting of SIRIM QAS under MITI can generate a conflict of interests.		
Gaps of accreditation of CABs used by regulators (i.e., food safety certification).		

Weaknesses	Opportunities	Recommendations
Limited autonomy of AB being a government agency.		
Limited autonomy of AB under the roof of JSM.		
Lack of co-ordination and associations of CABs.		
Absence of a central monitoring system leads to a lack of information exchange and co-ordination between NQI agencies.		
QI is technically and strategically a new area of expertise of MITI.		
Lack of clarity on who oversees the overall NQI system prior to MITI being identified as the ministry leading the QI agencies.		
Activities of foreign ABs in Malaysia are not fully co-ordinated.		
Lack of overall QI legislation.	Regular update of laws and regulations in Malaysia to new developments and realities.	Based on a future NQP agreement, amend/modernise the QI legislation (relevant laws, regulations) and disseminate them widely.
QI-legislations are in need of revision.		

Weaknesses	Opportunities	Recommendations
Accreditation to ISO 15189 is not a prerequisite for the registration or designation of medical laboratories.	QI for the health sector available (private and public).	Support the accreditation of medical laboratories in Malaysia to give them international recognition and increase service demand (patients, insurances, other testing customers).

Table 18: WT - Avoiding - Don't let weaknesses become risks!

Weakness	Threats	Recommendations
<p>Lack of clarity on who oversees the overall NQI system prior to MITI being identified as the ministry leading the QI agencies.</p> <p>QI is technically and strategically a new area of expertise of MITI.</p>	Challenges to the WTO system could endanger the prominent role of QI in technical regulation.	NQI development needs to integrate into Malaysia's global trade strategy.
	MLA/MRA regime under threat because of geopolitical conflicts.	
	The geopolitical interest of China could endanger the unified global standard system.	
	Overinvestment in services/mechanisms/capacity that become obsolete.	
QI terms and concept are not well known in Malaysia.	Policymakers are not sufficiently aware of QI.	Development of an integrated QI sensitisation strategy.
QI bodies' websites do rarely refer to QI and the NQI system.		

Weakness	Threats	Recommendations
The Communication department of MITI and other ministries are uninformed about NQI.	Under-demand by industry due to a lack of quality awareness.	
A significant number of users (15%) say they are not informed.		
NMIM does not cover all SI areas.	Absence of policy to regulate renewable energy generation & distribution.	Strengthen the prospective capacity of QI bodies developing new services.
Gaps of accreditation of CABs used by regulators (i.e., food safety certification).	Incremental adjustments, no big bang adjustments possible (lagging behind).	
	Low sustainability in maintaining certain certifications.	
Absence of a central monitoring system leads to a lack of information exchange and co-ordination between NQI agencies. NMC's co-ordination is not consistent and timely to represent Malaysia's interest at WTO.	High costs to set up traceability.	Promote digitalisation of QI services using blockchain technology. Improving the financing of QI bodies and strengthening their financial autonomy.
	Fraud /falsification of e-certification.	
	Lack of needed capacity/resources to respond to new requirements.	

Table 19 summarises all 43 recommendations elaborated through the SWOT analysis and structured by relevant themes. The recommendations are still generic by nature and address more the 'what' than the 'how'. The refinement of the recommendations will take place during Phase 2 of the assignment, when the NQP will be elaborated including a detailed implementation plan.

Table 19: Conclusions on key recommendations

Themes	Recommendations
General NQI system setup/governance & leadership	<ol style="list-style-type: none"> 1. Develop an NQP for Malaysia; in the process involve all key QI bodies grasping their role in the NQI system and getting involved in re-designing the NQI architecture in Malaysia. 2. QI knowledge upgrade of QI lead organisations, such as MITI. 3. Develop a QI intelligence system to monitor QI progress and conduct foresight exercises. 4. MP13 development embracing NQI as a prominent topic and harnessing NQI to respond to global mega-trends.
Legal framework	<ol style="list-style-type: none"> 5. Based on a future NQP agreement, amend/modernise the QI legislation (relevant laws, regulations) and disseminate them widely.
Standards system	<ol style="list-style-type: none"> 6. Evaluate the design of a broader SDO system under JSM's co-ordination. 7. Develop a Malaysia standardisation strategy that defines roles in standardisation, introduces a SDO regime, and considers industry needs and sustainability. 8. Development of standards for SMEs and small domestic organisations. 9. Development of Malaysian standards for new economic sectors prioritised in MP12.
Metrology system	<ol style="list-style-type: none"> 10. Develop an integrated strategy for the Malaysian Metrology system. 11. Facilitate dialogue between NMIM and leading metrology institutes abroad on responding to the latest challenges and opportunities in metrology. 12. Set up a special programme to strengthen metrology in chemistry.
Legal metrology	<ol style="list-style-type: none"> 13. MDTCA should collaborate more with NMIM concerning the upgrade of the country's OIML membership. Full membership brings many benefits. 14. Increase the number of implemented OIML recommendations (currently (2017) 14 of more than 100). 15. Increase competencies of legal metrology in the field of chemistry and biology.

Themes	Recommendations
	16. Accreditation of MDTCA's QMS (e.g., for market surveillance activities). 17. Training courses for legal metrologists in all new technologies.
Accreditation system	18. Develop an accreditation strategy and plan to address new opportunities. 19. Exploration of new business opportunities for the accreditation body. 20. Building JSM's capacity accrediting reference material production and biobanking. 21. Increased co-ordination with key QI bodies in Malaysia beyond an ad hoc basis to prevent gaps and overlaps. 22. Support the accreditation of medical labs in Malaysia to give them international recognition and increase service demand (patients, insurances, other testing customers).
Technical regulations	23. GRP sensitisation sessions for policymakers to develop technical regulations. 24. NPGRP dissemination campaign by MPC targeting regulators at all levels.
Conformity assessment system	25. The strengthening and establishment of associations for different areas of conformity assessment, following the example of Persatuan Makmal Akreditasi Malaysia ⁴⁰ (PMAM) (Malaysia Accredited Laboratory Association). 26. Concerted CAB effort (assoc.): QI service needs analysis in the key sector (MP12 sectors, energy, health, advanced manufacturing), followed by QI service design / adjustments.

⁴⁰ Persatuan Makmal Akreditasi Malaysia (PMAM) or also known as the Malaysia Accredited Laboratories Association is a non-governmental organisation (NGO) formed through the initiative of JSM to bring together all accredited laboratories under the Laboratory Accreditation Scheme of Malaysia (Skim Akreditasi Makmal Malaysia or SAMM), as well as other laboratories operating in the country, to promote laboratory activities in Malaysia.

With a vision to be at the 'Forefront of International Standards in the region', PMAM aims to enhance awareness in good lab practices as well as professional practices. The association also intends to be the official representative of all accredited laboratories in Malaysia and the main representative in discussions with JSM. PMAM helps to provide training and education as well as a common platform for discussion and co-operation between member laboratories in Malaysia.

Themes	Recommendations
	27. Regular application of the RDT tool to monitor the progress of the QI components.
All QI bodies	<p>28. Support QI service providers to develop new services to meet market needs.</p> <p>29. Strengthen the future capacity of QI bodies to develop new services.</p> <p>30. Integrate NQI development needs in Malaysia's global trade strategy.</p> <p>31. Dialogue of Malaysian representatives in international QI organisations about experiences.</p> <p>32. Enable QI bodies for digital transformation.</p> <p>33. Greater co-ordination of QI bodies under the purview of MITI.</p>
A sectoral approach to QI	<p>34. Levelling-up the accessibility of QI services by a country-wide needs analysis, opening new branches of QI bodies, offering digital services elsewhere.</p> <p>35. QI service gap analysis for key sectors.</p> <p>36. Development of QI promotion strategies for selected key sectors.</p> <p>37. Supporting existing QI providers to provide services specifically targeted to the MP12 sector.</p>
A territorial approach to QI	<p>38. Support territorial expansion of QI service providers.</p> <p>39. Analyse Malaysian QI service export opportunities, e.g., to Brunei.</p>
Quality promotion	<p>40. Set up an overall QI communication and quality promotion strategy.</p> <p>41. Design and launch a comprehensive QI sensitisation campaign with multiple targets: users, regulators, QI bodies.</p>
User perspective	<p>42. Regular QI user survey across sectors and regions in the country to identify satisfaction with existing services and identify new service requirements.</p> <p>43. Extension of Quality Awards Schemes to get more engagement from users (and service providers).</p>

GLOSSARY

Accreditation: Third-party verification of a conformity assessment body conveying formal demonstration of its competence and impartiality to carry out specific quality assessment tasks.

Calibration: The determination, by comparison with a measurement standard, of the correct value of reading on a measuring instrument.

Certification: Third-party attestation that products, services, processes, management systems and persons conform to established standards.

Civil Society: Society is considered as a community of citizens; linked by common interests and collective activity, legal or otherwise, and seen as a social sphere separate from both the state and the economic market.

Code of Good Practice: The Code of Good Practice, Annex 3 of the WTO TBT Agreement, provides disciplines, including those related to transparency, for the preparation, adoption, and application of standards by standardising bodies. The Code's acceptance is voluntary and open to any standardising body, whether central government, local government, or non-governmental and regional standardising bodies.

Competitiveness: A country's ability to sell goods and services (under free and fair conditions) in markets while maintaining and expanding the real incomes of its people over the long term.

Mandatory Standard: A declared national standard, which has been accorded compulsory status by the Minister of Trade

and Industry, in accordance with the Standards Act. A compulsory standard has the force of law. A compulsory standard falls under the definition of Technical Regulation of the WTO TBT Agreement and must comply with the accords included in said agreement.

Conformity Assessment: Demonstration that specified requirements relating to a product, service, process, person, or body are fulfilled; typically conducted through quality assessment services such as inspection (desk and field reviews, physical examination, and performance analysis), laboratory testing and certification.

Consumer Protection: Protection of the safety and interests of buyers of goods and services against low quality or dangerous products that are not fit for their end use and advertisements that deceive people.

Demand-oriented: A customer driven good or service.

Enquiry Point: A focal point, established under the WTO Agreement on Technical Barriers to Trade, where other WTO Members can request and obtain information and documentation on a member's technical regulations, standards, and conformity assessment procedures, whether impending or adopted, as well as on participation in bilateral or plurilateral standards-related agreements, international or regional standardising bodies and conformity assessment systems.

Good Regulatory Practice: Good Regulatory Practice (GRP) are internationally recognised processes, systems, tools, and methods for improving

the quality of new and existent regulations. GRP systematically implements public consultation and stakeholder engagement as well as impact analysis of Government proposals before they are implemented to make sure they address important problems and are fit for purpose and deliver what they are set out to achieve.

Goods: Commodities such as are the subject of trade or commerce and include services, processes, and practices.

Health Protection: A term used to encompass a set of activities within the Public Health function. It involves ensuring the safety and quality of food, water, air, and the general environment preventing the transmission of diseases.

Industrial Metrology: The area of metrology that assures the accuracy of the instruments used and measurements made.

Innovation: The implementation of a new or significantly improved product, service process, a new marketing method, or a new organisational method in business practices, workplace organisation, or external relations.

Inspection: Examination of a product, process etc., and determination of its conformity with specific requirements or, based on professional judgement, with general requirements, e.g., supply chain assessments, market surveillance etc.

Legal Metrology: That area of metrology that concerns the regulation of weighing and measuring instruments used in commercial transactions.

Legitimate Objectives: The WTO TBT Agreement specifies that technical regulations shall not be more trade-

restrictive than necessary to fulfil a legitimate objective. Legitimate objectives specified under the TBT Agreement are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information related to processing technology or intended end-uses of products.

Metrology: Science of accurate, reliable, and traceable measurement: scientific (artefact standards), industrial (calibration) and legal (verification) metrology.

MyMudah: MyMudah initiatives is strengthened with the establishment of MyMudah Unit in all ministries, government agencies, state governments, local authorities and business associations. This unit aims to conduct a planned review of regulations to facilitate the business environment to boost productivity and competitiveness.

Productivity: The ratio of inputs (labour and capital) to output (goods and services), measuring how efficiently inputs are used to produce output. There are two kinds of productivity measures, a MFP measure (relating a measure of output to a bundle of inputs) and a single factor productivity measure (relating a measure of output to a single measure of input). MFP is a measure of the residual GDP growth unaccounted for by capital and labour force growth and measures the combined productivity of different inputs. Measuring MFP involves significant data requirements. Also, as an indicator that combines multiple inputs, it is less able to inform specific measures to increase productivity. On the other hand, a

single factor productivity measure, such as labour productivity, is easier to measure and communicate at the national, sector and enterprise level, as it is able to clearly guide key initiatives to create value for the overall economy. Hence, a single factor productivity measure, labour productivity, will be the measure used throughout this Blueprint. At the national level, labour productivity is typically expressed as the ratio of value add to total employment. At the sector level, labour productivity can be expressed as the ratio of value add to the sector's total employment. Value add is the measure of the sector's contribution to GDP, measured by the value generated in each stage of production.

Quality Culture: A culture of quality consciousness and continuous improvement.

Quality Infrastructure Institutions or Quality Institutions: Organisations at the national and regional level that provide quality infrastructure services, such as Standards and Technical Regulations Development, Accreditation, Metrology, Conformity Assessment and Quality Promotions. Institutions may come from the public, private or civil society sectors, etc.

Quality Infrastructure Services or Quality-related Services (QI Services): Services provided by Quality Infrastructure Institutions.

Quality Infrastructure (National and Regional): The institutional framework, including its systems and people, is involved in the development and implementation of standards and technical regulations, metrology, accreditation, conformity assessment services and the promotion of quality involved in

strengthening the quality competitiveness of the goods and services produced or provided at the national and regional levels with the aim of: increasing and facilitating trade, boosting industrial and State efficiency and effectiveness, supporting the development of the MSME, promoting consumer welfare and safety and contributing to energy security and the preservation of the environment. The five components of quality infrastructure – Standards & Technical Regulations, Metrology, Accreditation, Conformity Assessment and Quality Promotion (marketing & communication, information & awareness, education, etc.) – can be applied at the national level (National Quality Infrastructure) and complemented at the regional level – (Regional Quality Infrastructure).

Quality: The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs (i.e., fit for purpose). It is demonstrated by the degree of customer satisfaction.

Standardisation: A framework or methodology to ensure that the process for formulation, publication, and implementation of guidelines, rules, and specifications for common and repeated use achieves uniformity in each context, discipline, or field. It includes transparency and consensus for the most efficient use of research, development, and production resources.

Standards: Document approved by a recognised body, that provides, for common and repeated use, rules, guidelines, and characteristics for products or related processes and production methods, with which compliance is voluntary. It may also include or deal

exclusively with terminologies, symbols, packaging, marking, or labelling requirements as they apply to a product, process, or production method.

Sustainable Development: Development that meets the needs of the present without compromising the ability of future generations to meet their own needs; includes economic, social, environmental, and technological resilience as well as other factors.

Technical Barriers to Trade (TBT): A category of non-tariff barriers to trade or measures that countries use to regulate markets, protect their consumers, or preserve their natural resources (among other legitimate objectives), but they also can be used unnecessarily to discriminate against imports to protect domestic industries or restrict regional or international trade.

Technical Regulation: Document which lays down product characteristics or their related processes and production methods, including the applicable administrative and conformity assessment provisions, with which compliance is mandatory, usually for consumer health and safety and environmental protection.

Testing: Determination of one or more characteristics of an object of conformity assessment, according to a procedure e.g., analytical, calibration, medical etc.

World Trade Organisation (WTO) Technical Barriers to Trade (TBT) Agreement: An agreement that aims to ensure that product regulations, standards and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade. At the same time, it recognises World Trade

Organisation members' rights to implement non-discriminatory measures to achieve legitimate policy objectives, such as protection of human health and safety, or protection of the environment. The TBT agreement requires members in most circumstances to base their measures on international standards to facilitate trade. It provides a list of trade facilitation measures. Through its transparency provisions, it also aims to create a predictable trading environment.

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The project team has engaged different quality infrastructure institutions and key stakeholders throughout the duration of the assessment and mapping exercise via meetings, workshop, surveys and informal discussions on the subject matters related to assessment of the national quality infrastructure (NQI). The engagement sessions were held at various premises and through online platforms. The assessment report targets a range of NQI stakeholders, representing federal and state governments, international organisations, academia, associations and industry players. All the valuable inputs from the various stakeholders were discussed, analysed and consolidated to shape this report.

Project Team	Technical Committee	Steering Committee
<ol style="list-style-type: none"> 1. Consultant Team (CT) 2. International Trade Centre (ITC) 3. Department of Standards Malaysia (JSM) 4. Ministry of International Trade and Industry (MITI) 5. Malaysia Productivity Corporation (MPC) 6. National Metrology Institute of Malaysia (NMIM) 7. SIRIM Standards and Training Services Sdn. Bhd. 	<ol style="list-style-type: none"> 1. Trade Policy and Facilities Division, Ministry of International Trade and Industry (MITI) 2. Bilateral Economic and Trade Relations Division, Ministry of International Trade and Industry (MITI) 3. Industrial Development Division, Ministry of International Trade and Industry (MITI) 4. Food Safety and Quality Division, Ministry of Health Malaysia (MOH) 5. Medical Device Authority (MDA) 6. National Pharmaceutical Regulatory Agency (NPRA) 7. Ministry of Domestic Trade and Consumer Affairs, now known as Ministry of Domestic Trade and Cost of Living Affairs 8. Ministry of Agriculture and Food Industries (MAFI), now known as Ministry of Agriculture and Food Security 9. Ministry of Plantation Industries and Commodities (MPIC) 10. Ministry of Transport Malaysia (MOT) 11. Department of Environment (DOE) 12. National Solid Waste Management Department (JPSPN) 13. Royal Malaysian Customs Department 14. Fire & Rescue Department of Malaysia 	<ol style="list-style-type: none"> 1. Ministry of International Trade and Industry (MITI) 2. Ministry of Works (KKR) 3. Ministry of Transport (MOT) 4. Ministry of Domestic Trade and Consumer Affairs, now known as Ministry of Domestic Trade and Cost of Living Affairs 5. Ministry of Agriculture and Food Industries (MAFI), now known as Ministry of Agriculture and Food Security 6. Ministry of Plantation Industries and Commodities (MPIC) 7. Ministry of Transport Malaysia (MOT) 8. Ministry of Environment and Water (KASA), now known as Ministry of Natural Resources, Environment and Climate Change 9. Ministry of Energy and Natural Resources (KeTSA), now merged under Ministry of Natural Resources, Environment and Climate Change 10. Ministry of Communications and Multimedia (K-KOMM), now known as Ministry of Communications and Digital 11. Ministry of Housing and Local Government (KPKT), now known as Ministry of Local Government Development 12. Ministry of Health (MOH) 13. Economic Planning Unit (EPU)

Project Team	Technical Committee	Steering Committee
	15. Local Government Department (JKT) 16. Department of Occupational Safety and Health (DOSH) 17. National Water Services Commission (SPAN) 18. Energy Commission (ST) 19. Malaysian Communications and Multimedia Commission (MCMC) 20. Malaysian Construction Industry Development Board (CIDB) 21. Federal Agricultural Marketing Authority (FAMA) 22. Malaysian Cocoa Board (LKM) 23. Malaysian Palm Oil Board (MPOB) 24. Malaysian Productivity Corporation (MPC) 25. National Metrology Institute Malaysia (NMIM) 26. SIRIM Berhad 27. Federation of Malaysian Manufacturers (FMM) 28. Persatuan Makmal Akreditasi Malaysia (PMAM)	14. Royal Customs Department of Malaysia (KASTAM) 15. Persatuan Makmal Akreditasi Malaysia (PMAM) 16. Federation of Malaysian Manufacturers (FMM) 17. Malaysian Service Providers Confederation (MSPC) 18. Malaysian International Chamber of Commerce and Industry (MICCI) 19. Federation of Malaysian Consumers Associations 20. Akademi Sains Malaysia 21. Malaysian Productivity Corporation (MPC) 22. Majlis Standard dan Akreditasi Malaysia (MSDAM)

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2	Christian Schoen	Mesopartner (Germany)
3	Dr. Vathana Bathmanathan	Universiti Tenaga Nasional, Malaysia

LIST OF RAPID DIAGNOSTIC TOOL (RDT) RESPONDENTS:

1. Ministry of Transport (MOT)
2. Ministry of Housing and Local Government (KPKT)
3. Ministry of Domestic Trade and Consumer Affairs (KPDNHEP)
4. Department of Local Government (JKT)
5. Food Safety and Quality Division, Ministry of Health Malaysia (MOH)
6. Malaysian Communications and Multimedia Commission (MCMC)
7. Malaysian Construction Industry Development Board (CIDB)
8. Federal Agricultural Marketing Authority (FAMA)
9. Medical Device Authority (MDA)
10. National Pharmaceutical Regulatory Agency (NPRA)
11. Fire and Rescue Department Malaysia (BOMBA)
12. Malaysian Palm Oil Board (MPOB)
13. National Water Services Commission (SPAN)
14. Malaysia Productivity Corporation (MPC)
15. Ministry of Utility Sarawak
16. Ministry of Public Health, Housing and Local Government Sarawak
17. Testing Division, Department of Agriculture Sarawak
18. Plant Biosecurity and Quarantine Division, Department of Agriculture Sarawak
19. Department of Veterinary Services Sarawak
20. Land and Survey Department Sarawak
21. Forest Department Sarawak
22. Natural Resources and Environment Board (NREB) Sarawak
23. Security and Enforcement Unit, Chief Minister Department, Sarawak
24. Sarawak Rivers Board
25. Sarawak Timber Industry Development Corporation
26. Sarawak Forestry Corporation
27. Ministry of Local Government and Housing, Sabah
28. Sabah Forestry Department
29. Sabah State Attorney General's Chamber
30. Sabah Wildlife Department
31. Environment Protection Department, Sabah
32. Dewan Bandaraya Kota Kinabalu
33. Standardisation Division, Department of Standards Malaysia
34. Accreditation Division, Department of Standards Malaysia
35. Department of Chemistry Malaysia (JKM)
36. National Metrology Institute Malaysia (NMIM)
37. SIRIM STS Sdn. Bhd.
38. SIRIM QAS International Sdn. Bhd.
39. NIOSH Certification Sdn. Bhd.
40. Jabatan Kemajuan Agama Islam Malaysia (JAKIM)
41. Malaysia Rubber Board (LGM)
42. Institute of Medical Research (IMR)
43. Malaysia Nuclear Agency Inspection Service
44. TUV NORD (M) Sdn. Bhd.

- 45. AJA EQS Certification (M) Sdn. Bhd.
- 46. MyCO2 Sdn. Bhd.
- 47. Hospital Selayang
- 48. University Malaya Medical Centre (UMMC)
- 49. Pantai Premier Pathology Sdn. Bhd.
- 50. Makmal Bioserasi, Centre for Research and Instrumentation Management (CRIM),
Universiti Kebangsaan Malaysia
- 51. Puspakom Sdn. Bhd.

National Quality Infrastructure (NQI) User Survey

Malaysia NQI

The **National Quality Infrastructure (NQI)** refers to the **public and private institutional framework needed to implement the services of metrology, standardisation, accreditation, and conformity assessment (certification, testing and inspection)**. The importance of NQI is as follows:

1. NQI services enhance market access and increase competitiveness in domestic and global markets.
2. The recognition of NQI results between trading countries boosts productivity by reducing trade costs, avoiding testing and inspection duplication, streamlining operations, and eliminating restrictive regulations.
3. The NQI framework provides benefits from quality-assured and standardised production processes and inter-operability between manufacturers along value chains in industries and across borders.
4. The NQI framework stimulates innovation and technology diffusion through standards-setting and adoption.
5. The NQI framework promotes public policy objectives by effectively enforcing technical regulations, which safeguard public health and safety and ensure consumer, environmental and social protection.

The Department of Standards Malaysia (JSM) under the Ministry of International Trade and Industry (MITI) is involved in an exercise to assess the NQI of Malaysia. The programme is funded by the ARISE Plus Programme of the European Union and managed by the International Trade Centre (ITC) of the World Trade Organisation (WTO). This programme aims to assess the current NQI ecosystem of Malaysia, identify implementation gaps, and provide recommendations for improvement. The output of the assessment will also be used to develop a National Quality Policy (NQP) for Malaysia to enhance Malaysia's NQI governance further.

This survey collects the views and needs of users of quality infrastructure services. The project team invites you as a business owner or entrepreneur to complete this questionnaire. Completing the questionnaire will require about 10 minutes of your time. Your answers will help align the NQI service offers with user requirements and expectations and will thus constitute an essential input into improving the NQI system.

Your data will be treated confidentially and used anonymously, exclusively as information for the NQI assessment.

We appreciate your co-operation!

General information

1. What is the size of the company you represent?

(only one answer allowed)

- ☐ Micro (< RM 300,000 sales turnover OR < 5 employees)
- ☐ Small (sales turnover RM 300,000 to < RM 15 mil OR 5 to < 75 employees [for manufacturing companies] OR sales turnover RM 300,000 to < RM 3 mil OR 5 to < 30 employees [for service companies])
- ☐ Medium (sales turnover RM 15 mil to < RM 50 mil OR 75 to < 200 employees [for manufacturing companies] OR sales turnover RM 3 mil to < RM 20 mil OR 30 to < 75 employees [for service companies])
- ☐ Large (sales turnover of \geq RM 50 mil OR \geq 200 employees [for manufacturing companies] OR sales turnover of \geq RM 20 mil OR \geq 75 employees [for service companies])

2. What is the sector focus of your company?

(up to three answers allowed)

- Mining
- Agriculture
- Manufacturing
- Information Technology and Communication
- Trade (Retail/ Wholesale)
- Tourism
- Education
- Health
- Other (Specify)

3. Does your company export any goods or services?

(only one answer allowed)

- Our company only sells in domestic markets
- Our company exports both goods and services
- Our company exports goods only
- Our company exports services only
- Don't know

4. In which state is your company's headquarters located?

(only one answer allowed)

- Selangor
- Johor
- Sabah
- Sarawak
- Perak
- Kedah
- Kuala Lumpur
- Penang

- Kelantan
- Pahang
- Terengganu
- Negeri Sembilan
- Melaka
- Perlis
- Labuan
- Putrajaya
- The head office is abroad/outside Malaysia (specify country)

5. What quality issues do your company typically needs to address?

(multiple answers allowed)

- Challenges to comply with voluntary standards
- Challenges to comply with mandatory technical regulations
- Inconsistency of product/service quality
- Grading
- Contamination of products
- Adulteration of products
- Others, please specify _____
- No quality issues faced

National Quality Infrastructure (QI) services

Standardisation

6. Does your company refer to standards (national/regional or international standards) when manufacturing products or delivering services?

- All the time
- Most of the time
- Only in specified areas and when required
- Never
- Don't know

7. If the answer is from "a, b or c" for Q6, please specify why your company typically uses standards.
(multiple answers allowed)

- Certification purposes (management system/person/product, etc)
- Market requirements (product/service specifications)
- Reference in operations (test methods, specifications, good practices, etc)
- Compliance to mandatory requirements set by technical regulations
- Others, please specify _____
- Don't know

8. In my industry/sector/focus area, standards are usually available and easily accessible.

- Agree

- b. Disagree
- c. I don't know

Conformity Assessment

9. What conformity assessment services is your company using to address any quality issues/comply with market needs or mandatory requirements?
- a. Testing
 - b. Certification
 - c. Inspection
 - d. Calibration
 - e. Verification, validation
 - f. Others, please specify _____
 - g. None
 - h. Don't know
10. [If "None" in Q9], Please indicate the reason why your organisation does not use conformity assessment services:
- a. Lack of awareness
 - b. Lack of information
 - c. Too expensive
 - d. Difficult to implement
 - e. Not mandatory for our business
 - f. Required services are not available in Malaysia
 - g. Don't know
11. How relevant is the use of these conformity assessment services to develop your core business?
- a. Very relevant
 - b. Somewhat relevant
 - c. Not relevant
 - d. Don't know
12. Are the conformity assessment services required by your company available locally?
- a. Yes
 - b. No
 - c. Don't know
13. [If yes in Q12], what type of service providers supply conformity assessment services to your company?
(multiple answers allowed)
- a. Malaysian service providers
 - b. International service providers operating in Malaysia
 - c. Malaysian and international service providers operating in Malaysia
 - d. Other sources, please specify
 - e. Don't know
14. How would you rate the quality of domestic Conformity Assessment services your company uses?
- 1 2 3 4 5

Very poor --- Excellent

15. [If yes in Q12], How would you assess the price of local Conformity Assessment services used?

1 2 3 4 5

Very expensive – expensive – reasonable – inexpensive – very inexpensive

16. [If no in Q12], what conformity assessment services are lacking?

- a. Testing – please specify type: _____
- b. Certification – please specify type: _____
- c. Inspection – please specify type: _____
- d. Calibration – please specify type: _____
- e. Verification, validation – please specify type: _____
- f. Others, please specify: _____

(Only one answer allowed)

Accreditation

17. Does your company attach importance to the accreditation of conformity assessments services used?
(multiple answers allowed)

- a. Yes, as we want to be sure that our service providers are competent
- b. Yes, as our current customers demand the QI services be accredited
- c. Yes, as the accreditation of QI services increases our competitiveness in new markets
- d. No, not needed

18. If the answer is “no” for Q17, please specify why:
(multiple answers allowed)

- a. We do not know where to source accredited QI services
- b. Accredited services are not available for the scopes/parameters required by us
- c. The accreditation of QI services does not render any benefits for us
- d. Accredited services are more expensive
- e. I am not aware about accreditation
- f. Others, please specify: _____

Market surveillance

19. Do your products/services need to comply with any technical regulations (legal requirements) before entering the domestic market?

- a. Yes
- b. No
- c. Don't know

20. If the answer is 'yes' in Q19, please state the relevant regulation(s)

21. Information on market surveillance for your products/services conducted by authoritative bodies is readily available and easy to follow

- d. Agree
- e. Disagree
- f. Don't know

Additional comments

22. Feel free to share any comments or suggestions that would help to improve the quality of your products/services or the performance of your sector.

Answer text

23. If you are willing to share the name of your company and of a contact person, we will send you a summary report of the survey afterwards.

Name of company (optional): _____

Contact person details (optional): _____

Name/position: _____

Telephone number: _____

Email: _____

Accreditation						
Element	Information sources	Benchmark and questions	Scoring	Score	Comments: What is your score based on? Please provide information and links.	
Pillar 1: Legal and institutional framework						
1) Accreditation strategy	<ul style="list-style-type: none">NAB/RAB board or council papersNAB/RAB websiteRelevant ministry (e.g., Trade and Industry) websiteAnnual reports of the NAB/RAB	An accreditation strategy giving effect to the implementation of the quality policy with regard to accreditation of QI service providers in both the state-regulated and the market-driven areas is in place. It covers the accreditation of inspection bodies, testing and calibration laboratories, and certification bodies based on international standards.				
		a. Is an accreditation strategy in place?	Yes=4 Developed, but not approved=2 Being developed=1 No=0			
		b. Does the accreditation strategy include all the necessary elements, namely <ul style="list-style-type: none">Priorities for the establishment and maintenance of the national accreditation systemAccreditation of conformity assessment service providers for the implementation of technical regulationsAccreditation as a measure of the quality of conformity assessment services in the marketBuilding capacity in the NAB/RAB to fulfill its responsibilities in the most innovative, effective, and efficient way	Yes=1 Yes=1 Yes=1 Yes=1			
		c. Is an implementation plan for the accreditation strategy in place and being followed?	Yes=4 Developed, but not yet followed=2 Under development=1 No=0			
		Aggregate score: Accreditation strategy (a+b+c)/3			0.0	
2) Legal entity	<ul style="list-style-type: none">Accreditation Act, decree, regulation, or similar, if relevantArticles of incorporation if relevantFormal agreements between the government and the NAB/RABNAB/RAB website and annual reports	The national accreditation body (NAB) or regional accreditation body (RAB) exists as a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for its responsibilities regarding its accreditation services and the national measurement accreditation system.				
		a. Has the NAB/RAB been established as a legal entity—that is, by legislation or by articles of incorporation?	Yes=4 In preparation=1 No=0			
		b. Have the following been provided for in the legislation or articles of incorporation? <ul style="list-style-type: none">Council or board of the NAB/RABFinances of the NAB/RABEstablishment of the accreditation systemDesignated international or regional liaisonLast review or revision less than 5 years agoLast review or revision 5–10 years agoLast review or revision 10–15 years agoLast review or revision more than 15 years ago	Yes=1 Yes=1 Yes=1 Yes=1 Yes=4 Yes=2 Yes=1 Yes=0			
		Aggregate score: Legal entity (a+b+c)/3			0.0	
3) Autonomy	<ul style="list-style-type: none">Accreditation Act, decree, regulation or similar, if relevantArticles of incorporation if relevantNAB/RAB council or board policy papersNAB/RAB website and annual reportsGovernment regulations regarding rules of employment in the case of the NAB being a governmental or public body	The NAB/RAB and its board or council has the mandate to effectively manage the affairs of the NAB/RAB without undue outside interference or restrictions.				
		a. The NAB/RAB and its board or council can decide on the following: <ul style="list-style-type: none">Grant or revoke accreditation (this is fundamental)Determine the positions and staffing of its workforceDetermine the salaries of its workforceSet accreditation feesDetermine its own budgetCreate new administrative divisionsOffer new service or initiate new activitiesSolicit membership in international accreditation organizations and sign international agreements	Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5			
		Aggregate score: Autonomy AutoSum			0.0	

4) Legal standing of accreditation	<ul style="list-style-type: none"> • Accreditation Act, decree, regulation or similar, if relevant • Formal government mandate of the NAB/RAB 	<p>The role of accreditation is clearly articulated in relevant legislation—that is, especially in the realm of technical regulation or implementation of other legislative instruments based on the outcome of QI service delivery.</p> <p>a. Is the establishment and maintenance of the national accreditation system provided for in legislation?</p> <p>b. Is accreditation the preferred methodology established in legislation for demonstrating the technical competence of QI service providers in the country?</p> <p>c. Is accreditation the legally preferred methodology for demonstrating technical competency in designating QI service providers operating in the field of technical regulations or other regulatory measures utilizing conformity assessment services?</p> <p>d. Has the NAB (whether public or private) been given an unequivocal mandate by the government to provide accreditation services required in the implementation of regulations?</p>	<p>Yes=4 Needs updating=1 No=0</p> <p>Yes=4 Partially=2 No=0</p> <p>Yes=4 Considered as such without legal certainty=1 No=0</p> <p>Yes=4 Considered as such without legal certainty=1 No=0</p> <p>(a+b+c+d)/4</p>		
5) Governance	<ul style="list-style-type: none"> • Accreditation Act, decree, regulation or similar • Articles of incorporation if relevant • NAB/RAB council or board policy papers • NAB/RAB website and annual reports • Government regulations regarding public entities • NAB/RAB council or board committee structures 	<p>The NAB/RAB has a board or council with fiduciary responsibilities and that approves the NAB/RAB strategy, consisting of members from the public and private sectors with specific knowledge regarding accreditation and market realities.</p> <p>a. Is the governance of the NAB/RAB vested in an independent board or council?</p> <p>b. Is the private sector represented in the board or council, and if so, what is the percentage representation?</p> <p>NOTE: If a board or council does not exist, then the score for this question remains = 0</p> <p>c. Does the board or council appoint the director or CEO?</p>	<p>Yes=4 Partially independent=1 No=0</p> <p>Yes=0 Yes=1 Yes=2 Yes=3 Yes=4</p> <p>Board or council recommends=3 Minister appoints independently=2 None of the above=0</p>		
6) Financial sustainability	<ul style="list-style-type: none"> • Accreditation strategy • Annual NAB/RAB business plans • Annual government budget allocations • Annual reports of the NAB/RAB • Monthly and annual financial statements of the NAB/RAB 	<p>The finances from government, income from accreditation services, financial support from industry, and other sources are adequate to ensure the financial sustainability of the NAB/RAB in the medium to long term.</p> <p>a. Have adequate funds been committed for the continued existence of the NAB/RAB, e.g., by the government or any other entity or entities?</p> <p>b. Is specific funding (from the government or any other entity or entities or special fund) earmarked for the international and regional commitments of the NAB/RAB?</p> <p>c. Is a formal financial plan established for the medium term, that is, the following 3–5 years?</p>	<p>Aggregate score: Governance (a+b+c)/3</p> <p>Yes=4 Yes=3 Yes=2 Yes=1 Yes=0</p> <p>Every year there is a shortfall=2 No=0</p> <p>Yes=4 1-3 years=2 No=0</p> <p>Aggregate score: Financial sustainability (a+b+c)/3</p>		

Pillar 2: Administration and infrastructure					
7) Chief executive office	<ul style="list-style-type: none"> Relevant legislation (Accreditation Act or similar) if relevant Articles of incorporation if relevant Official ministerial decisions Board or council decisions and minutes Official CEO job description Agreed-upon CEO key performance indicators 	<p>A director or a CEO (whatever the title) with responsibilities to lead the organization and oversee the day-to-day affairs of the NAB/RAB is appointed.</p> <p>a. Has a full-time director or CEO been appointed with clear responsibilities to lead and manage the day-to-day affairs of the NAB/RAB?</p> <p>b. Is the director or CEO fully accountable to the board or council?</p> <p>c. Is the director or CEO a full member of the board or council?</p> <p>d. Are the key performance criteria for the director or CEO defined and evaluated at least annually by the board or council?</p>	<p>Yes=4 Acting=2 No=0</p> <p>Yes=4 Accountable to minister and board or council=2 Accountable to minister only=1 No=0</p> <p>Yes=4 No voting right=1 No=0</p> <p>Yes=4 Informally=2 No=0</p>		
8) Organizational structure	<ul style="list-style-type: none"> Approved organizational structure Board or council decisions Ministerial decisions Financial system documentation 	<p>An organizational structure that optimally supports the subject fields in which the NAB/RAB is offering accreditation services is in place, together with the relevant accreditation approvals committee, technical committees, and an advisory committee.</p> <p>a. Irrespective of whether the NAB/RAB is part of a larger organization or not, is it a clearly identifiable and separate entity responsible for all the functions of an NAB/RAB?</p> <p>b. Does the NAB/RAB have different divisions, each responsible for a specific accreditation field, e.g., calibration laboratories, test laboratories, product certification bodies, management system certification bodies, and so on?</p> <p>c. Does the NAB/RAB have the following structures in place?</p> <p><input type="checkbox"/> Accreditation approvals committee</p> <p><input type="checkbox"/> Training division</p> <p><input type="checkbox"/> Accreditation advisory forum</p>	<p>Yes=4 Integrated with another service (e.g., standards) but not separated=1 No=0</p> <p>Yes, each service clearly identifiable=4 Mostly, some are still mixed=2 No=0</p> <p>Yes=2 Yes=1 Yes=1</p>	0.0	
9) Management and personnel	<ul style="list-style-type: none"> Approved organizational structure Actual staffing levels Staff turnover figures 	<p>Management and personnel with the appropriate skill sets assured by appropriate training, qualifications, and experience for the management and technical knowledge required by the various activities of the NAB/RAB are appointed.</p> <p>a. Are the approved managerial posts filled?</p> <p><input type="checkbox"/> 90-100% <input type="checkbox"/> 80-89% <input type="checkbox"/> 70-79% <input type="checkbox"/> 60-69% <input type="checkbox"/> < 60%</p> <p>b. Are the approved technical posts filled?</p> <p><input type="checkbox"/> 90-100% <input type="checkbox"/> 80-89% <input type="checkbox"/> 70-79% <input type="checkbox"/> 60-69% <input type="checkbox"/> < 60%</p> <p>c. Are the responsibilities and key performance indicators (KPIs) of each of the managers in (a) formally defined?</p> <p>d. Are the responsibilities and key performance indicators (KPIs) of each of the technical posts in (b) formally defined?</p>	<p>Aggregate score: Organizational structure (a+b+c)/3</p> <p>Yes=4 Yes=3 Yes=2 Yes=1 Yes=0</p> <p>Yes=4 Yes=3 Yes=2 Yes=1 Yes=0</p> <p>Yes=4 Responsibilities yes, KPIs no=2 No=0</p> <p>Yes=4 Responsibilities yes, KPIs no=2 Partially=1 No=0</p>	0.0	

10) Premises	<ul style="list-style-type: none">• Review of office space and meeting rooms• Location of the NAB/RAB in relation to other QI entities	The NAB/RAB as a premier QI organization occupies premises appropriate to its status, accessible to its customers, yet conducive for maintaining confidentiality, with minimum environmental disturbances and facilitating optimum service delivery.	a. Is the NAB/RAB housed in appropriate premises, easily accessible by clients (for example, not in the middle of town with traffic problems), and have adequate parking (that is, not haphazardly all over the sidewalk)?	Yes=4 Partially=2 No=0	
		b. Is the NAB/RAB housed in premises that allow for acceptable working conditions for employees (light, ventilation, temperature, space available, furniture, and so on)?	Yes=4 Needs upgrading=1 No=0		
		c. Do the premises have adequate meeting rooms for technical committee meetings?	Yes=4 Inadequate=1 No=0		
		Aggregate score: Premises (a+b+c)/3			0.0
11) Equipment	<ul style="list-style-type: none">• Consideration of effectiveness and efficiency of the IT system• Consideration of access control of the IT system	An effective and efficient intranet is available, and IT equipment (servers, computers, printers, digital projectors, and so on) is installed and maintained, including appropriate confidentiality measures.	a. Is the appropriate IT system equipment available for administration of the accreditation work and effective communication within the organization (including desktop computers, digital projectors for meeting rooms, and so on)?	Yes=4 Must be upgraded=2 Partially=1 No=0	
		b. Is an IT network available and operational for effective electronic communication to and from the outside world, especially through the internet?	Yes=4 Must be upgraded=1 No=0		
		c. Is the appropriate presence on the internet in place, with an up-to-date website containing all relevant NAB/RAB documentation and details of its accredited companies?	Yes=4 Must be upgraded=2 Partially=1 No=0		
		Aggregate score: Equipment (a+b+c)/3			0.0
Pillar 3: Service delivery and technical competency					
12) Lead assessors	<ul style="list-style-type: none">• Lead assessor database of the NAB/RAB• Formal job description of lead assessors• Personnel records regarding education, training, and experience of lead assessors• Annual training plans and concomitant records of lead assessors• Assessment reports	Lead assessors—who are selected, trained, and registered for specific accreditation scopes—to lead the assessment teams are available.	a. Does the NAB/RAB have pool of registered lead assessors, and are the relevant details of the lead assessors contained in a formal register?	Yes, for all accreditation scopes=4 Not yet for all accreditation scopes=2 Yes, but not yet formally registered=1 No=0	
		b. Does the NAB/RAB have a formal set of criteria for the selection and registration of lead assessors that meets ILAC and IAF criteria?	Yes=4 In preparation=1 No=0		
		c. Does the NAB/RAB ensure that the lead assessors are properly trained and that they maintain their registration criteria?	Training yes, maintaining registration no=1 No=0		
		Aggregate score: Lead assessors (a+b+c)/3			0.0
13) Assessors and technical experts	<ul style="list-style-type: none">• Assessor and technical expert database of the NAB/RAB• Formal job descriptions of assessors and technical experts• Personnel records regarding education, training, and experience of assessors and technical experts• Annual training plans and concomitant records of assessors and technical experts• Assessment reports	Registered assessors and technical experts are available who are trained and experienced regarding the specific scope and technology of the organization being assessed.	a. Does the NAB/RAB have a pool of registered assessors and technical experts, the details of which are contained in a formal register?	Yes, for all accreditation scopes=4 Not yet for all accreditation scopes=2 Yes, but not yet formally registered=1 No=0	
		b. Does the NAB/RAB have a formal set of criteria for the selection and registration of assessors and technical experts that meets ILAC and IAF criteria?	Assessors yes, technical experts no=2 In preparation=1 No=0		
		c. Does the NAB/RAB ensure that the assessors and technical experts are properly trained and that they maintain their registration criteria?	Training yes, maintaining registration no=1 No=0		
		Aggregate score: Assessors and technical experts (a+b+c)/3			0.0

14) Specialist technical committees	• List of working groups • Working group minutes, decisions and recommendations • NAB/RAB responses to working group recommendations	Specialist technical committees that can provide relevant guidance to the NAB/RAB regarding the accreditation process and the training and experience of assessors and technical experts for each accreditation scope, are established and active.	a. Has the NAB/RAB established specialist technical committees or working groups for each of the accreditation scopes it provides services in?	Yes=4 In some=2 Ad hoc meetings only=1 No=0		
		b. Are the specialist technical committees or working groups representative of experts from all the stakeholders in both the public and private sector?	Yes=4 Partially=2 Lack experts=1 No=0			
		c. Does the NAB/RAB consider the recommendations of the specialist committees or working groups and can implementation thereof be demonstrated?	Yes=4 Partially=2 Difficult to demonstrate=1 No=0			
		Aggregate score: Specialist technical committees (a+b+c)/3	0.0			
15) Quality system documentation	• The NAB/RAB quality system and its compliance with ISO/IEC 17011 • Quality system documentation and its revision control system • Official website of the NAB/RAB	An open and transparent system of applications, requirements, assessments, and approvals process regarding accreditation (including the publicly available information on accredited organizations)—all of which are compliant with ISO/IEC 17011 and the interpretation documents of ILAC and the IAF—is available.	a. Has the NAB/RAB implemented a formal quality management system in accordance with ISO/IEC 17011?	Yes, externally evaluated=4 Yes, not externally evaluated=3 Being implemented=2 Being developed=1 No=0		
		b. Is the application, requirements, assessments, and approval process documentation publicly available, e.g., on the NAB/RAB website?	Yes=4 Some elements still missing=2 In process of being developed=1 No=0			
		c. Are the details of the accredited organizations publicly available and up-to-date, e.g., on the NAB/RAB website?	Yes, up-to-date=4 Yes, needs updating=2 Only available on request=1 No=0			
		Aggregate score: Quality system documentation (a+b+c)/3	0.0			
16) Assessment process	• Quality system documentation • Assessment applications • Preassessment reports • Assessment reports	The accreditation process initiated by an application includes defined steps—documentation review, preassessment, assessment team selection, on-site assessment, and closing out of nonconformities—before an accreditation decision is made.	a. Does the formal accreditation process include the following distinct steps?	o Formal application o Preassessment of documentation o Assessment team selection o On-site assessment o Closeout of nonconformities Yes=0.5 Yes=1 Yes=0.5 Yes=1 Yes=1		
		b. Does the NAB/RAB provide for specific time limits for the completion of the accreditation process steps within its publicly available documentation?	Yes, both for the NAB/RAB and applicant=4 Yes, for the applicant only=2 Yes, for the NAB/RAB only=2 No=0			
		c. Does the NAB/RAB evaluate its performance regarding the time taken for accreditation process steps, report it as a nonconformity when relevant, and implement formal corrective action?	Yes, continuously=4 Ad hoc reviews=2 Only when challenged by applicants=1 No=0			
		Aggregate score: Assessment process (a+b+c)/3	0.0			

17) Approvals process	<ul style="list-style-type: none">• Quality system documentation• Assessment reports• Accreditation approvals committee minutes and decisions	An accreditation approvals committee, independent from the assessment team and charged with the responsibility to grant or revoke accreditation, is in place and operational.	a. Has the NAB/RAB established an independent accreditation approvals committee?	Yes, for all accreditations=4 Ad hoc, when considered necessary=2 No=0		
			b. Is the accreditation approvals committee independent from the assessment team?	Yes, always=4 Most of the time=2 No=0		
			c. Does the accreditation approvals committee make its decisions in accordance with formal and known guidelines?	Yes, always=4 Most of the time=2 Depend only on expertise of committee members=1 No=0		
			Aggregate score: Approvals process (a+b+c)/3	0,0		
18) Accreditation and follow-up	<ul style="list-style-type: none">• Quality system documentation• Database of accredited organizations• Surveillance reports• Reassessment reports• Reissue of accreditation certificates records	An accreditation certificate is issued, carefully detailing the scope of accreditation. The details of the accredited company are published in the publicly available database of the NAB/RAB, and it is placed on the postaccreditation surveillance and reassessment roster.	a. Does the NAB/RAB issue an accreditation certificate complete with detailed scope for a specific time period?	Yes=4 No time period=2 Scope not detailed on certificate=1 No=0		
			b. Does the NAB/RAB place the accredited company on the surveillance roster with audit visits scheduled at intervals corresponding to international good practices and mindful of the stability of the newly established systems, that is, at least every six months or annually? (NOTE: Score is 0 if procedures are in place but the body has yet to carry out annual visits.)	Yes=4 Surveillance visits annually=2 Surveillance visits ad hoc=1 No=0		
			c. Does the NAB/RAB conduct a complete reassessment of all accreditation elements after three years for extending the accreditation?	Yes=4 Only important elements reassessed=2 No reassessment conducted, continued accreditation depends on audit results=1 No=0		
			Aggregate score: Accreditation and follow-up (a+b+c)/3	0,0		
Pillar 4: External relations and recognition						
19) Training system	<ul style="list-style-type: none">• Training programs for lead and technical assessors• Database of lead and technical assessors and their personnel records	A formal training system to train lead assessors, assessors, and technical experts as well as a register of their education, training, and technical and assessment experience are in place. (NOTE: Not to be confused with 12(c) and 13(c). While the focus is similar 12(c) and 13(c) is whether the NAB/RAB has trained people on board, here we want to know whether the NAB/RAB can train these people themselves.)	a. Does the NAB/RAB have a formal training program for the following? <div><input type="radio"/> Lead assessors</div> <div><input type="radio"/> Assessors</div> <div><input type="radio"/> Technical experts</div>	Yes=1 Yes=1 Yes=1		
			b. Does the NAB/RAB have complete and up-to-date records of all their lead assessors, assessors, and technical experts for the following? <div><input type="radio"/> Education</div> <div><input type="radio"/> Experience</div> <div><input type="radio"/> Assessor training</div>	Yes=1 Yes=1 Yes=2		
			c. Does the NAB/RAB have a system in place whereby the performance of lead assessors, assessors, and technical experts is reviewed on an ongoing basis? <div><input type="radio"/> Lead assessors</div> <div><input type="radio"/> Assessors</div> <div><input type="radio"/> Technical experts</div>	Yes=1,5 Yes=1,5 Yes=1		
			Aggregate score: Training system (a+b+c)/3	0		

20) Liaison with regional organizations	<ul style="list-style-type: none"> Membership of the NAB/RAB in the recognized regional coordination body or group Reports of NAB/RAB participation in the regional activities Regional trade agreement membership status of the country Relevant regional treaties, protocols, agreements, or legislation Annual reports of the NAB/RAB NAB/RAB internal reports or regional accreditation activities and meetings 	<p>The NAB/RAB is an active member of a regional cooperation body or group recognised by ILAC and the IAF. In addition, if based in a country party to a regional trade agreement, the NAB/RAB is an active participant in concomitant regional accreditation organizations or committees to represent the interests of its country.</p> <p>a. Is the NAB/RAB a full and active member of the relevant ILAC- or IAF-recognized regional cooperation body or group?</p> <p>b. Does the NAB/RAB participate actively in regional trade agreement-related accreditation organizations or committees? <i>NOTE: These regional organizations or committees are usually established to harmonize accreditation activities within the region defined by the trade agreement. They are not the same as the regional cooperation bodies or groups.</i></p>	<p>Member and signatory of both ILAC and IAF regional cooperation bodies=4</p> <p>Member and signatory of one of ILAC or the IAF regional cooperation bodies=3</p> <p>Member, but not signatory of recognition arrangements=2</p> <p>Ad hoc involvement=1</p> <p>Yes=4</p> <p>Less than 75% of the time=2</p> <p>Less than 50% of the time=1</p> <p>No=0</p>		
		Aggregate score: Liaison with regional organizations (a+b)/2	0.0		
21) Liaison with international organizations	<ul style="list-style-type: none"> Accreditation strategy and its implementation plans ILAC and IAF membership data ILAC and IAF technical committee data Annual reports of the NAB/RAB Business plans and minutes of the NAB/RAB technical committees Formal communication records of the NAB/RAB with ILAC and the IAF Timing agreement with a signatory NAB/RAB 	<p>The country is a member of ILAC and the IAF if it is a signatory of the multilateral recognition arrangements, or an associate member if it is not. The NAB/RAB is actively involved in relevant committees, subcommittees, and information exchange groups of ILAC and the IAF.</p> <p>a. Is the NAB/RAB a member of ILAC and the IAF?</p> <p>b. Does the NAB/RAB participate actively in the ILAC and IAF general assemblies?</p> <p>c. Does the NAB/RAB actively participate in relevant ILAC and IAF committees, subcommittees, and information exchange groups?</p>	<p>Member and signatory of both=4</p> <p>Member and signatory of either ILAC or the IAF=2</p> <p>Associate member of both=2</p> <p>Associate member of either ILAC or the IAF=1</p> <p>No=0</p> <p>Yes every time=4</p> <p>Intermittently=2</p> <p>No=0</p> <p>Yes, on a continuous basis=4</p> <p>Intermittently=2</p> <p>No=0</p>		
		Aggregate score: Liaison with international organizations (a+b+c)/3	0.0		
22) International recognition	<ul style="list-style-type: none"> Formal application for signatory status Time schedule for peer review program Peer review reports ILAC and IAF website information on signatory status 	<p>The NAB/RAB is a signatory of the multilateral recognition arrangements of ILAC and the IAF, thereby giving it international recognition.</p> <p>a. Has the NAB/RAB been peer-reviewed by a team of experts from the relevant regional cooperation body or group?</p> <p>b. Has the NAB/RAB become a signatory to the ILAC and IAF accreditation scopes it provides accreditation services in?</p>	<p>Yes, and all nonconformities closed out=4</p> <p>Yes, but nonconformities still need to be closed out=2</p> <p>No, but has been planned=1</p> <p>No=0</p> <p>Yes, both ILAC and the IAF=4</p> <p>Yes, some scopes still pending=3</p> <p>Only ILAC or the IAF signed, the other pending=2</p> <p>Only ILAC or the IAF signed, the other not applied for=1</p> <p>No=0</p>		
		Aggregate score: International recognition (a+b)/2	0.0		

Accreditation

Standards					
Element	Information sources	Benchmark and questions	Scoring	Score	Comments: What is your score based on? Please provide information and links.
Pillar 1: Legal and institutional framework					
1) Standards strategy	<ul style="list-style-type: none"> Annual reports of the NSB NSB website Relevant ministry (e.g., Trade and Industry) website Annual reports of the NSB 	A standards strategy giving effect to the implementation of the quality policy regarding standards development, publication, and information is in place. It covers standards to be developed in the short to medium term, information systems, getting stakeholder support, and building capacity in the NSB to implement the strategy.			
		a. Is a standards strategy in place?	Yes=4 Developed, but not approved=2 Being developed=1 No=0		
		b. Does the standards strategy include all the necessary elements, namely	o Sections identified for standards to be developed o Information systems to be established o Stakeholder engagement o Human resource development	Yes=1 Yes=1 Yes=1 Yes=1	
		c. Is an implementation plan for the standards strategy in place and being followed?	Yes=4 Developed, but not yet followed=2 Under development=1 No=0		
		Aggregate score: Standards strategy (a+b+c)/3		0.0	
2) Legal entity	<ul style="list-style-type: none"> Standards Act, decree, regulation, or similar 	The national standards body (NSB) exists as a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for its standards development and publication activities.			
		a. Has the NSB been established as a legal entity, i.e., by legislation or by articles of incorporation?	Yes=4 In preparation=1 No=0		
		b. Have the following been provided for in the legislation or articles of incorporation?	o Council or board of the NSB o Finances of the NSB o Development and publication of national standards o International or regional liaison	Yes=1 Yes=1 Yes=1 Yes=1	
		c. Is the legislation or articles of incorporation up-to-date, i.e., has it been reviewed recently?	o Last review or revision less than 5 years ago o Last review or revision 5–10 years ago o Last review or revision 10–15 years ago o Last review or revision more than 15 years ago	Yes=4 Yes=2 Yes=1 Yes=0	
		Aggregate score: Legal entity (a+b+c)/3		0.0	
3) Autonomy	<ul style="list-style-type: none"> Standards Act, decree, regulation, or similar Articles of incorporation as a private company NSB council or board policy papers NSB website and annual reports Government regulations regarding rules of employment in the case of the NSB being a governmental or public body 	The NSB and its council or board has the mandate to effectively manage the affairs of the NSB without undue interference or restrictions.			
		o Adopt and revoke standards o Determine the positions and staffing of its workforce o Determine the salaries of its workforce o Create new administrative divisions o Determine its own budget o Determine the fees or standards publications o Offer new services or initiate new activities o Solicit membership in international or regional standardizing organizations and sign international agreements	Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5		
		The NSB and its board or council can decide on the following:			
		Aggregate score: Autonomy (Sum total)		0.0	
		The national standards have legal standing within the legal system of the country, even though they are voluntary in WTO TBT Agreement context.			
4) Legal standing of national standards	<ul style="list-style-type: none"> Standards Act, decree, regulation, or similar Formal agreement between the NSB and government Official government journal or gazette or similar 	a. Do the national standards enjoy legal standing above any other normative document published by others through a legislative instrument (e.g., legislation, regulation, or decree)?	Yes=4 Partially=2 No=0		
		b. Are regulatory authorities mandated through this legal instrument to reference national standards simply by number, date, and title?	Yes=4 Partially=2 No=0		
		c. Is the copyright of national standards safeguarded through this legislative instrument, even when referenced in technical regulations or sanitary and phytosanitary measures?	Yes=4 Copyright not protected when referenced=2 No=0		
		Aggregate score: Legal standing of national standards (a+b+c)/3		0.0	

5) Governance	<ul style="list-style-type: none"> Standards Act, decree, regulation, or similar Articles of incorporation as a private company NSB council or board policy papers NSB website and annual reports Government regulations regarding public entities NSB council or board committee structures 	<p>The NSB has a board or council with fiduciary responsibilities and that approves the NSB strategy, consisting of members from the public and private sectors with specific knowledge regarding standardization and market realities.</p> <p>a. Is the governance of the NSB vested in an independent board or council?</p> <p>b. Is the private sector represented in the board or council, and if so, what is the percentage representation?</p> <p>c. Does the Board/Council appoint the Director/CEO?</p>	<p>Yes=4 Partially independent=2 No=0</p> <p>Yes=0 Yes=1 Yes=2 Yes=3 Yes=4</p> <p>Board or council recommends=3 Minister appoints independently=2 None of the above=0</p>		
6) Financial sustainability	<ul style="list-style-type: none"> National quality policy Annual government budget allocations Annual reports of the NSB Monthly and annual financial statements of the NSB Monthly figures for standards sales 	<p>The finances from government, membership fees, sales of standards and information, financial support from industry, and other sources are adequate to ensure the financial sustainability of the NSB in the medium to long term.</p> <p>a. Have adequate funds been committed for the continued existence of the NSB, e.g., by the government or any other entity or entities?</p> <p>b. Do the funding agents, such as government or any other entity or entities, provide specifically for funding the development of national standards?</p> <p>c. Are there specifically earmarked funds available for the standards information center (e.g., by the government, especially if it is also the national WTO TBT Enquiry Point)?</p> <p>d. Is specific funding (from the government or any other entity or entities or special fund) earmarked for the international and regional commitments of the NSB?</p> <p>e. Is a formal financial plan established for the medium term, i.e., the following 3–5 years?</p>	<p>Aggregate score: Governance (a+b+c)/3</p> <p>Yes=4 Yes=3 Yes=2 Yes=1 Yes=0</p> <p>Every year there is a shortfall=2 No=0</p> <p>Yes=4 Yes=3 Yes=2 Yes=1 Yes=0</p> <p>Every year there is a shortfall=2 No=0</p> <p>Yes=4 Yes=3 Yes=2 Yes=1 Yes=0</p> <p>Aggregate score: Financial sustainability (a+b+c+d+e)/5</p>		0.0
7) Chief executive officer	<p>Relevant legislation (i.e. Standards Act or similar) or articles of incorporation</p> <ul style="list-style-type: none"> Official Ministerial decisions Board/Council decisions and minutes Official CEO job description Agreed CEO key performance indicators 	<p>A director or a CEO with responsibilities to lead the organization and oversee the day-to-day affairs of the NSB is appointed.</p> <p>a. Has a full-time director or CEO been appointed with clear responsibilities to lead and manage the NSB?</p> <p>b. Is the director or CEO fully accountable to the board or council?</p> <p>c. Is the director or CEO a full member of the board or council?</p> <p>d. Are the key performance criteria for the director or CEO defined and evaluated at least annually by the board or council?</p>	<p>Yes=4 Acting=2 No=0</p> <p>Yes=4 Accountable to minister and board or council=2 Accountable to minister only=1 No=0</p> <p>Yes=4 No voting right=1 No=0</p> <p>Yes=4 Informally=2 No=0</p> <p>Aggregate score: Chief executive officer (a+b+c+d)/4</p>		0.0

		The organizational structure of an NSB should have divisions that optimally support the standards development process consisting of (i) standards development; (ii) standards editing, approval, and publication; and (iii) standards information and sales.			
		a. In respect of whether the NSB is part of a larger organization, does it have a clearly identifiable and separate department for standards development, publication, and information?	Yes=4 Integrated with one other service, e.g., metrology=2 No=0		
		b. Does the NSB have clearly identifiable and separate divisions within the standards department of (a) for the following? <input type="checkbox"/> Standards development <input type="checkbox"/> Editing <input type="checkbox"/> Standards information and sales <input type="checkbox"/> National WTO TBT Enquiry Point [for information only]	Yes=1 Yes=1 Yes=1 Yes=1 Yes=4 Participates in executive meetings but is not a full member=1 No=0		
		c. Is the head of the standards department a full member of the NSB executive?	No=0		
		<i>For information only:</i>			
		d. Is the NSB one of the following? (i) Government department (ii) Organization of public law (i.e., statutory body) (iii) Private company without gain (iv) Private company for gain	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No		
		e. Does the NSB provide conformity assessment services?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
		f. Is the NSB involved in the development and implementation of technical regulations (including mandatory or compulsory standards)?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
		Aggregate score: Organizational structure (a+b+c)/3	0.0		
		Management and personnel are appointed who have the appropriate skill sets assured by appropriate training, qualifications, and experience for the management, technical knowledge, project management skills and language proficiency required by the various activities of the standards value chain,			
		a. Are the approved managerial posts filled? <input type="checkbox"/> 90–100% <input type="checkbox"/> 80–89% <input type="checkbox"/> 70–79% <input type="checkbox"/> 60–59% <input type="checkbox"/> < 60%	Yes=4 Yes=3 Yes=2 Yes=1 Yes=0		
		b. Are the approved technical posts filled? <input type="checkbox"/> 90–100% <input type="checkbox"/> 80–89% <input type="checkbox"/> 70–79% <input type="checkbox"/> 60–59% <input type="checkbox"/> < 60%	Yes=4 Yes=3 Yes=2 Yes=1 Yes=0		
		c. Are the responsibilities and key performance indicators (KPIs) of each of the managers in (a) formally defined?	Yes=4 Responsibilities yes, KPIs no=2 No=0		
		d. Are the responsibilities and key performance indicators (KPIs) of each of the technical posts in (b) formally defined?	Yes=4 Responsibilities yes, KPIs no=2 Partially=1 No=0		
		Aggregate score: Management and personnel (a+b+c+d)/4	0.0		
		The NSB, as a premier CI organization, occupies premises appropriate to its status, accessible to its customers, with minimum environmental disturbances and facilitating optimum service delivery.			
		a. Is the NSB housed in appropriate premises, i.e., is it easily accessible by clients (e.g., not in the middle of town with traffic problems); are access roads dust-free (e.g., tarred and without potholes); and is adequate parking available (e.g., not haphazardly all over the sidewalk)?	Yes=4 Partially=2 No=0		
		b. Is the NSB housed in premises that allow for acceptable working conditions for employees (light, ventilation, temperature, space available, furniture, and so on)?	Yes=4 Needs upgrading=1 No=0		
		c. Do the premises have adequate meeting rooms for technical committee meetings?	Yes=4 Inadequate=1 No=0		
		d. Is the standards information center easily accessible and invitingly organized (i.e., not stuck away far from the entrance or in a poorly maintained, dark uninviting place)?	Yes=4 Stuck away far from entrance=2 No=0		
		Aggregate score: Premises (a+b+c+d)/4	0.0		
		An effective and efficient intranet is available, and IT equipment (servers, computers, printers, digital projectors, and so on) is installed and maintained.			
		a. Is the appropriate IT equipment available for standards development work (desktop computers, digital projectors for meeting rooms, and so on)?	Yes=4 Must be upgraded=2 Partially=1 No=0		
		b. Is an IT network available and operational for effective electronic communication to and from the outside world, especially through the internet?	Yes=4 Must be upgraded=1 No=0		
		c. Is an intranet available for effective electronic communication within the NSB?	Yes=4 Must be upgraded=2 Partially=1 No=0		
		Aggregate score: Equipment (a+b+c)/3	0.0		
3) Organizational structure	• Approved organizational structure • Board or council decisions • Ministerial decisions • Financial system documentation				
9) Management and personnel	• Approved organizational structure • Actual staffing levels • Staff turnover figures				
10) Premises	• Consideration of the NSB premises in relation to design, access, and maintenance • Review of technical committee meeting rooms and facilities • Review of the standards information center				
11) Equipment	• Consideration of the NSB intranet system and its connectivity to the internet in relation to access and maintenance • Review of availability of IT equipment and services to relevant staff • Review of the standards information center's IT equipment and maintenance				

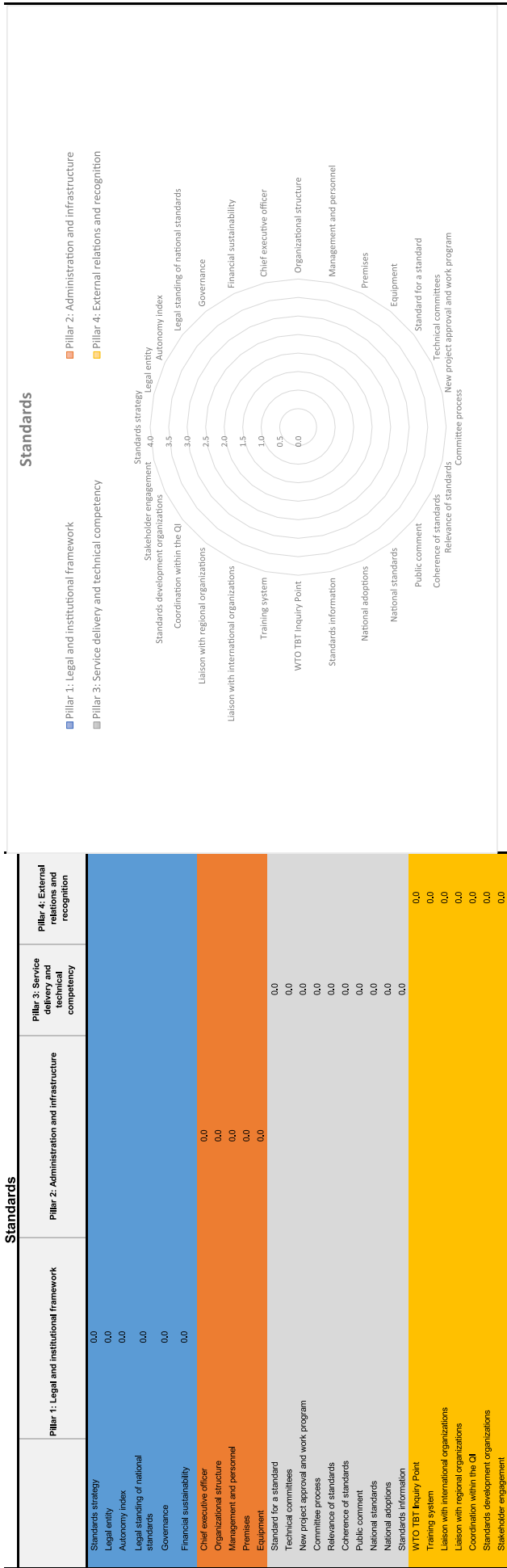
Pillar 3: Service delivery and technical competency				
	The policies, procedures, and work instructions for the development of standards have been developed, implemented, and maintained and are publicly available.			
12) Standard for a standard	a. Has a publicly available "standard for a standard" been developed, approved, and used by all technical committees and the NSB as the guiding document for standards development?	Yes=4 Approved but not fully implemented=2 In preparation=1 No=0		
	b. Has a complete set of internal procedures and work instructions in the manner of ISO 9001 documentation requirements been developed, implemented, and maintained for the complete standards development process?	Yes=4 Needs revision=3 Being implemented=2 Being developed=1 No=0		
	c. Has an editing manual been developed and implemented to ensure the consistency and quality of published standards?	Yes=4 Needs revision=3 Being implemented=2 Being developed=1 No=0		
	Aggregate score: Standard for a standard (a+b+c)/3		0.0	
13) Technical committees	Standards are developed by technical committees (including subcommittees and working groups) representative of interested parties (e.g., ministries, public authorities, business, industry, consumers, academia, and civil society) as established by the NSB.			
	a. Technical committees are	Yes=1 o Established based on a needs analysis o Not limited to any particular number of participants o Open to all interested parties o Approved by the council or board		
	b. Is participation in technical committees widely advertised, thereby reaching industry, authorities, academia, and NGOs?	Yes=1 Yes=2 No=0		
	c. Does the NSB endeavor to balance membership among important stakeholders?	Yes=2 Partially=1 No=0		
	d. Are members of technical committees paid a sitting fee of any sort? NOTE: "Fee" means all TC members are paid to attend. "Limited fee" means reimbursement of travel costs for members.	Yes=0 Limited fee=1 Only some participants=2 No=4		
	e. Are "mirror committees" for international or regional standards development identified from among the normal list of technical committees?	Yes=4 Mostly=2 Mirror committees are separate=1 No mirror committees exist=0		
	Aggregate score: Technical committees (a+b+c+d+e)/4		0.0	
14) New project approval and work program	The NSB evaluates each request for the development of a new standard regarding its relevance and available resources and adds it to its work program, which is made known publicly every six months in a manner compliant with WTO TBT Agreement requirements.			
	a. Does the NSB follow a formal procedure for the evaluation of new project proposals with the following elements? NOTE: Each of the sub-elements counts 1 point if present; the table in the next column indicates the score.	6 out of 6 elements=4 4 or 5 out of 6 elements=3 2 or 3 elements out of 6=2 1 or 2 elements out of 6=1 Included in work program without evaluation=0		
	b. Is the work program for standards projects developed and updated continuously as new projects are approved?	Yes=4 Updated quarterly=3 Updated six-monthly=2 Updated annually=1 No=0		
	c. Is the work program made public on the website of the NSB at least every six months? NOTE: This is a WTO TBT Agreement Annex 3 requirement.	Continuously updated=4 Every six months=3 Annually=2 No=0		
	Aggregate score: New project approval and work programme (a+b+c)/3		0.0	

15) Committee process	<ul style="list-style-type: none"> Standard for a standard Formal technical committee meeting procedures Technical committee business plans Schedules of technical committee meetings Working documentation of technical committees and their circulation Minutes of technical committee meetings 	Technical committees' processes are managed effectively and efficiently by the NSB secretariat, i.e., committees work programs exist and are followed, meetings are held at appropriate intervals, minutes are circulated promptly, and complete documentation is provided in a timely manner for participants to prepare properly for meetings.		
		a. Does a formal work program exist for each of the technical committees, is it circulated to committee members, and is it used to manage committee activities?	Yes=4 Mostly=2 Sometimes=1 No=0	
		b. Are technical committee meetings held at reasonable intervals that allow all stakeholders to attend them, and are meeting dates communicated in a timely manner for all to attend? NOTE: By organizing meetings every week or every two weeks to "speed up" the process is counterproductive, because most industry representatives may not attend. A meeting every two or three months may be a better approach, for example, provided the documentation is complete.	Yes=4 Mostly=2 Sometimes=1 No=0	
		c. Are minutes of the meeting (highlighting decisions and agreed-upon changes to draft documents) circulated promptly, i.e., within a week after the meeting?	Yes always=4 Mostly=2 No=0	
16) Relevance of standards	<ul style="list-style-type: none"> Standard strategy Standard for a standard New work item approval criteria Internal standards development procedures Percentage of national standards based on international standards Percentage of standards more than five years old List of standards not reviewed within five years 	d. Is the documentation in a format that facilitates the discussion on technical requirements? NOTE: The documentation could be a draft text for a new standard, a copy of a regional or international standard to be adopted, or text fully updated by decisions of the previous meeting. If international or regional standards need to be translated to facilitate a proper discussion, this should be arranged by the secretariat before the meeting, not during the meeting as this would waste time.	Always=4 Mostly=3 Sometimes=2 Translated during meeting=1 No=0	
		Published national standards facilitate trade, prevent unnecessary trade barriers, do not distort the market, respond to regulatory and market needs, and take technological development into account.	Aggregate score: Committee process (a+b+c+d)/4	
		a. Does the NSB have a formal system in place to inform technical committees regarding the latest scientific and technological developments as standards are developed?	Yes=4 Ad hoc=2 No=0	
		b. Does the NSB have a formal system in place to ensure that standards, as they are developed by technical committees, are based on performance criteria rather than descriptive characteristics?	Yes=4 Ad hoc=2 No=0	
17) Coherence of standards	<ul style="list-style-type: none"> Standards strategy Scopes of technical committees of NSB and SDOs Editing manual 	c. Does the NSB have a formal system in place to review published standards at least every five years to either affirm, revise, or withdraw them to ensure their continued relevance?	Yes=4 Not fully implemented=2 Ad hoc=1 No=0	
		The collection of national standards does not have any overlaps in scope between standards, and the same commodity or service is not dealt with in two or more standards with the possibility of differences in requirements.	Aggregate score: Relevance of standards (a+b+c)/3	
		a. Does the NSB have a formal system in place to ensure that national standards developed by various technical committees (including SDOs if they exist) do not have a similar or overlapping scope? NOTE: An SDO (standards development organization) is an organization recognized by the NSB to develop standards that are then published as national standards by the NSB.	Yes=4 Ad hoc=2 Only when highlighted=1 No=0	
		b. Does the NSB have a formal system in place to ensure that national standards developed by various technical committees (including SDOs if they exist) do not overlap in any of their requirements in order to avoid confusion in their application?	Yes=4 Ad hoc=2 Only when informed by outside entities about overlaps=1 No=0	
18) Public inquiry	<ul style="list-style-type: none"> Standard for a standard Internal standards development procedures Records of public comment periods NSB website Records of collected comments Technical committee records and minutes Formal feedback to interested parties on comments 	c. Does the NSB have a formal system in place to revise a national standard once an international or regional standard with similar scope is published and is known to differ from the national standard?	Yes=4 Ad hoc=2 No=0	
		Draft national standards, once the technical committee has completed work and reached consensus, are circulated for public comment for at least 60 days.	Aggregate score: Coherence of standards (a+b+c)/3	
		a. Are all draft national standards circulated widely for public comment for at least 60 days after the technical committees have completed their deliberations and before they are presented for approval and publication? NOTE: This is a WTO TBT Agreement Annex 3 requirement. Circulation should be effected by making it known on the NSB website to the general public as well as by targeting important stakeholders such as authorities and business associations individually.	Yes=4 Only to selected entities=2 No=0	
		b. Are all comments collated by the secretariat and presented to the technical committee for consideration?	Always=4 Selected cases only=2 NSB deals with comments=1 No=0	
		c. Are entities making substantive comments invited by the technical committee to discuss issues in person?	Yes=4 Selected cases only=2 No=0	
		Aggregate score: Public inquiry (a+b+c)/3		0.0

19) National standards	<ul style="list-style-type: none"> Board or council minutes Standards Approvals Committee minutes Standards sales information and records Standards catalog Analysis of average age of standards List of standards older than five years 	Comments from the public inquiry are considered by the technical committee, consensus is reached, and the final draft standard is edited for compliance with stated norms before it is presented for approval and subsequent publication.	<p>a. Are all draft national standards edited by an entity independent from the secretariat for consistency with the approved editing manual before being presented for approval?</p> <p>b. Are draft national standards presented for approval in a manner that ensures a decision for publication within the shortest time possible? <i>NOTE: This is a WTO TBT Agreement Annex 3 requirement. If the council or board approves the draft national standard for publication and it meets only three or four times annually, it should contemplate setting up a Standards Approval Committee consisting of council or board members and NSB senior management that meets more regularly, e.g., every two weeks or monthly.</i></p> <p>c. Once the draft national standard has been approved, does it get published in the shortest time possible? <i>NOTE: Publication could be by printing hard copies, but that takes time and wastes precious resources. It is far more efficient to publish electronically and provide print-on-demand copies for customers requiring them.</i></p>	<p>Yes=4 Mostly=2 No=0</p>	
				<p>Yes=4 Approvals take place three to four times a year=2 Minister has to approve national standards=1 No=0</p>	
				<p>Within two weeks=4 Within a month=2 Takes longer than a month=0 (a+b+c)/3</p>	0.0
20) National adoptions	<ul style="list-style-type: none"> Number and percentage of international standards adopted as national standards Standard for a standard Internal NSB procedures 	<p>The NSB uses international standards, where they exist or where their completion is imminent, as a basis for national standards except where such international standards would be ineffective or inappropriate, e.g. country specificities of the product (service), insufficient level of protection, fundamental climatic or geographical factors, or fundamental technological problem.</p> <p>a. Does the NSB have a formal policy to adopt international or regional standards wherever possible?</p> <p>b. What percentage of the national standards are adoptions of international standards?</p> <p>c. Does the NSB use ISO/IEC Guide 21 to indicate the extent to which national standards are adoptions of international standards (i.e., identical, modified, or not identical)?</p>	<p>Aggregate score: National standards</p>	<p>Yes=4 Practiced, but not a formal policy=2 Decision left to technical committee=1 No=0</p>	
				<p>Yes=4 Yes=3 Yes=2 Yes=1 Yes=0</p>	
				<p>Always=4 Partially=2 No=0 (a+b+c)/3</p>	0.0
21) Standards information	<ul style="list-style-type: none"> Extent of the standards information and sales services Standards sales figures 	<p>The NSB has a standards information service able to provide information on national, regional, and international standards to interested parties in hard copy and electronically.</p> <p>a. Is a fully functional standards information center established with full information on the following?</p> <p>b. Is the standards information center system based fully on a modern IT system, i.e., can customers search and review standards online?</p> <p>c. Is a print-on-demand system installed and fully functional for standards sales on-site?</p> <p>d. Can standards be ordered, paid for (e.g., by credit card), and downloaded online?</p> <p>e. Is the standards sales information collected and evaluated to determine customer profiles, most popular standards, and trends over time for use in future planning?</p>	<p>Aggregate score: Standards information</p>	<p>Yes=1 Yes=1 Yes=1 Yes=1 Yes=4</p>	
				<p>Must be modernized=2 Only catalog online=1 No=0</p>	
				<p>Needs upgrading=2 No=0 Payment only from within the country=1 No=0 Collected but not analyzed=1 No=0 (a+b+c+d+e)/5</p>	0.0

Pillar 4: External relations and recognition							
22) WTO TBT Inquiry Point	<ul style="list-style-type: none">• Extent of services provided by the national WTO TBT Inquiry Point• Records of inquiries submitted over time• Website of the NSB• Database of the NSB regarding WTO TBT notifications	The WTO TBT Inquiry Point is able to provide information to WTO member states regarding standards, technical regulations, conformity assessment services, and regional or international memberships related to these. In addition, the WTO TBT Inquiry Point provides an early warning system for exporters providing information on technical regulations to be implemented by trading partners.					
		a. Can the WTO TBT Inquiry Point provide country-related information on the following? <ul style="list-style-type: none">o Technical regulations implemented by all regulatory authoritieso Standards utilized in all the technical regulations of the countryo Conformity assessment regimes for standards and technical regulationso International and regional cooperation agreements regarding conformity assessment	Yes=1				
		b. Does the WTO Inquiry Point analyze the WTO TBT notifications on a weekly basis?	Yes=1				
		c. Does the WTO Inquiry Point provide "early warning" information to relevant stakeholders either specifically or through the NSB website?	Yes=4				
		d. Does the WTO Inquiry Point collate comments on WTO TBT notifications for later consideration by the relevant ministry and for forwarding it to the country's Geneva WTO representative?	Only when asked=1				
	23) Training system	<ul style="list-style-type: none">• Training programs• Training records	For information only: Designated WTO TBT Inquiry Point <ul style="list-style-type: none">o National standards bodyo Ministry responsible for tradeo Other	Yes=4			
			The NSB provides appropriate training, and keeps record thereof, for technical committee chairpersons and secretariats as well as for standards information personnel to ensure a consistent high quality in developing standards.	Yes=4			
			a. Does the NSB provide formal training programs for its personnel involved in standards development (i.e., secretaries), publication, and information (either in-house or external)?	Selected posts only=3 On-the-job training only=2 Ad hoc training=1 No=0			
			b. Are personnel formally evaluated annually in accordance with agreed-upon key performance criteria to determine their effectiveness, efficiency, and future training needs?	Yes=4			
			c. Are complete training records available for all NSB personnel?	Informal evaluation =1 No=0			
24) Liaison with international organizations	<ul style="list-style-type: none">• Standards strategy and its implementation plans• ISO and IEC membership data• ISO and IEC technical committee data• Annual reports of the NSB• Business plans and minutes of the NSB technical and mirror committees• Formal communication records of the NSB with the ISO and IEC	d. Does the NSB regularly (e.g., annually) provide formal training courses for technical committee chairpersons?	Yes=4 Ad hoc=1 No=0				
		Aggregate score: Training system (a+b+c+d)/4			0.0		
		The NSB has secured the appropriate level of membership of international standardizing organizations relevant to the country (e.g., ISO, IEC, CAC, and the Iike) and is actively engaged in their standards development activities.	Yes=4				
		a. Does the NSB have a board- or council-approved strategy for its involvement in international standardizing organizations, including active participation in their technical committees?	In process of development=2 Informal=1 No=0				
		b. Is the NSB a member of the ISO, IEC, or CAC at the appropriate level, or should this be enhanced?	Yes=4 Requires enhancement=2 No=0				
		c. What percentage of the technical committees of which the NSB is a P-member does it actively participate in, i.e., which meetings are actually attended?	<80%=4 70-89%=3 50-69%=2 30-49%=1 <30%=0				
		d. In what percentage of the technical committees in which the NSB is a P-member is voting with comments on draft international standards completed only after discussion at the relevant national mirror committee?	<80%=4 70-89%=3 50-69%=2 30-49%=1 <30%=0				
		Aggregate score: Liaison with international organizations (a+b+c+d)/4			0.0		

25) Liaison with regional organizations	<ul style="list-style-type: none"> Regional membership status of the country Relevant regional treaties, protocols, agreements, or legislation Catalog entries of regional standards adopted by the NSB Annual reports of the NSB NSB internal reports of regional standards body meetings 	<p>If based in a country that is a party to a regional trade agreement, the NSB is an active participant in any regional standardization organization representing the interests of its country.</p> <p>a. Is the NSB a full and active member of relevant regional standardization organizations where required?</p> <p>b. Does the NSB participate in regional standards-setting activities where these take place?</p> <p>c. Does the NSB adopt regional standards once they are approved as required (e.g., as provided for in the region's directives, protocols, regional legislation, and so on)? <i>NOTE: In most common markets, regional standards must be adopted at the national level within a specified period (e.g., six months), and national standards of similar scope have to be withdrawn.</i></p>	<p>Yes=4 Ad hoc involvement=2 No=0</p>	
			<p>Always=4 Half the time=2 Ad hoc=1 No=0</p>	
			<p>Yes=4 Not 100%=3 Ad hoc but more than 30%=2 Less than 30%=1 No=0</p>	
			<p>Aggregate score: Liaison with regional organizations (a+b+c)/3</p> <p>No=0</p>	0.0
26) Coordination within the QI	<ul style="list-style-type: none"> Line ministry policies, pronouncements, and documentation Quality council (or similar) documentation and minutes of meetings Technical regulation coordination office mandate and pronouncements 	<p>A formal coordination mechanism is in place among the NSB, NMI, and NAB to ensure a unified basis for calibration, conformity assessment, and market surveillance activities of the QI.</p> <p>a. Does a formal mechanism exist between the NSB, NMI, and NAB managements as well as their line ministries where issues can be discussed annually or every six months, and can coordination be fostered?</p> <p>b. Is it possible for the CEOs of the NSB, NMI, and NAB to attend each other's council or board meetings as a matter of course as observers?</p> <p>c. Has the government established a quality council or forum or similar where all stakeholders of the QI can provide input and raise issues?</p> <p>d. Do representatives of the NMI and NAB participate regularly in technical committees of the NSB?</p>	<p>Yes=4 Ad hoc=2 No=0</p>	
			<p>Yes=4 Only on invitations=2 No=0</p>	
			<p>Yes=4 Ad hoc=2 No=0</p>	
			<p>Yes=4 Ad hoc=2 No=0</p>	
27) Standards development organizations (SDOs)	<ul style="list-style-type: none"> NSB legislation or articles of incorporation Formal NSB procedures for registering SDOs Official registration documentation of SDOs Work programs of the NSB and SDOs Annual reports of the NSB Standards catalog of the NSB Minutes of quality council or CEO coordination meetings 	<p>A mechanism is in place whereby the NSB can formally recognize standards development organizations (SDOs)—such as ministries, professional societies, and academic institutions compliant with international and regional obligations—to also develop national standards.</p> <p>a. Does the NSB have a formal and legally sound mechanism to recognize SDOs?</p> <p>b. Does the NSB formally evaluate compliance of SDOs with international and regional obligations such as the WTO TBT Agreement before recognizing them?</p> <p>c. Does the NSB coordinate the work programs of SDOs with its own every six months to ensure that overlaps do not occur?</p>	<p>Yes=4 Ad hoc recognition=1 No=0</p>	
			<p>Yes=4 Ad hoc=2 No=0</p>	
			<p>Yes=4 Annually=2 Ad hoc=1 No=0</p>	
			<p>Aggregate score: Standards development organizations (SDOs) (a+b+c)/3</p> <p>No=0</p>	0.0
28) Stakeholder engagement	<ul style="list-style-type: none"> Standards strategy and its implementation Communication strategy or plan and its implementation Minutes of a quality forum or similar open stakeholder meeting Key performance indicators of senior management Stakeholder mapping results 	<p>The NSB continuously identifies its stakeholders, communicates clearly with them, and gains their support and participation in the development and implementation of national, regional, and international standards.</p> <p>a. Does the NSB continuously map its stakeholders in the following?</p> <ul style="list-style-type: none"> Government domain (QI organizations, regulatory authorities, ministries, and so on) Business sector beneficiaries (industry, suppliers, traders, importers, and so on) Society beneficiaries (society, NGOs, consumer protection, and so on) Influencers (business associations, media, trade unions, and so on) <p>b. Does the NSB follow a deliberate strategy to communicate with all stakeholders to stress the importance of standards, their implementation, and the role of the NSB?</p> <p>c. Does the NSB follow a deliberate strategy to involve all stakeholders in standards development?</p> <p>d. Has the NSB established a quality forum or similar where any stakeholder can participate to provide recommendations to the NSB on standardization matters, and does it meet regularly?</p>	<p>Yes=1 Yes=1 Yes=1 Yes=1 Yes=4 Ad hoc=2 No=0</p>	
			<p>Common lists=2 Ad hoc=1 No=0</p>	
			<p>Yes, meets twice annually =4 Yes, meets annually=3 Ad hoc meetings=2 No=0</p>	
			<p>Aggregate score: Stakeholder engagement (a+b+c+d)/4</p> <p>No=0</p>	0.0



Testing					
Element	Information sources	Benchmark and questions	Scoring	Score	Comments: What is your score based on? Please provide information and links.
Building blocks of a country's testing laboratories sector					
1) Testing services strategy	<ul style="list-style-type: none">Relevant government policies, strategies, and implementation plansReview of the extent of government laboratory capacity and capabilitiesRelevant ministry (e.g., Trade and Industry, Science and Technology, or the like) websites	A testing services strategy giving effect to the implementation of the quality policy regarding testing services in the country is in place. It contains the government's responsibilities regarding the establishment of test laboratories, the liberalization of testing services in respect of regulatory measures, and the role of accreditation in demonstrating the technical competency of testing services.			
		a. Is a testing services strategy in place?	Yes=4 Developed, but not approved=2 Being developed=1 No=0		
		b. Does the testing services strategy include all the necessary elements (including productivity and innovation), namely <ul style="list-style-type: none">Provision for the establishment and maintenance of the testing services in the public sectorTesting services given access in regulatory measuresAccreditation as a measure of the technical competency of testing services in both the public and private sectorsBuilding capacity in testing services to meet the need of the markets in the most innovative, effective, and efficient ways	Yes=1 Yes=1 Yes=1 Yes=1		
		c. Is an Implementation Plan for the Testing Services Strategy in place and being followed?	Yes=4 Developed, but not yet followed=2 Under development=1 No=0		
		Aggregate score: Testing services strategy (a+b+c)/3			0.0
2) Designated test laboratories	<ul style="list-style-type: none">Accreditation Act, decree, regulation, or similar if relevantRelevant legislative instruments of ministriesOfficial lists of designated laboratories for the regulatory domain	Test laboratories in both the public and private sectors, mandated to provide testing services for regulatory purposes, are designated by the relevant authorities based on their technical competence (i.e., accreditation) and their legal liability in the country.			
		a. Is a system of designating test laboratories for regulatory purposes formalized in legislation and practiced in the country?	Yes=4 Practiced but not formalized in legislation=2 Ad hoc practice=1 No=0		
		b. Have the following been provided for in the legislation for the designation of test laboratories? <ul style="list-style-type: none">Designation of public sector and private sector test laboratories possibleAccreditation is a precondition for designationLegal liability in the country is a preconditionLocal and foreign laboratories are includedDetails available on internet sites	Yes=1 Yes=1 Yes=1 Yes=1 Yes=1		
		c. Are the details of designated test laboratories publicly available? <ul style="list-style-type: none">Name and contact detailsScope of testing for regulatory purposesDesignating authority	Yes=1 Yes=1 Yes=1		
		Aggregate score: Designated test laboratories (a+b+c)/3			0.0
3) Test laboratories for export markets	<ul style="list-style-type: none">Export policies and strategiesRecognition agreements between the government and export market authoritiesOfficial lists of recognized laboratories in the export marketsLists of recognized testing laboratories of the IEC and OIML schemes, European Commission, UNECE 1958 MRA, and so on.	Test laboratories to provide testing services for major exported products are recognized by the export market authorities.			
		a. Is an export strategy or policy containing details on the establishment of test laboratories for the export of products from the country in place and being implemented?	Yes=4 Developed but not yet implemented=2 Under development=1 No=0		
		b. Is the government actively pursuing recognition agreements of the national laboratories by regulatory authorities in relevant export markets?	Yes, and laboratories for major export products are recognized=4 Yes, but only one or two laboratories have so far been recognized=2 Yes, but no laboratories yet recognized=1 No=0		
		c. Are the government and private sector actively pursuing and coordinating recognition arrangements for recognition of national laboratories in export markets?	Yes, and some laboratories have been recognized=4 Yes, but coordination not happening=2 Incidental or ad hoc recognition achieved=1 No=0		
		Aggregate score: Test laboratories for export markets (a+b+c)/3			0.0

		Medical laboratories to provide testing services for the health sector are technically competent and are recognized by the health authorities.			
		a. Are medical laboratories in the health sector required to be "registered" or "designated" by the relevant health authorities?	Yes in all health sectors=4 Yes but not in all health sectors=2 No=0		
		b. Is accreditation to ISO 15189 a prerequisite for the registration or designation of medical laboratories?	Yes required by legislation=4 Yes but the standard is different from ISO 15189=2 Required as a decision by the relevant health authority or health insurance organizations=2 Only required on an ad hoc basis=1 No=0		
		c. Are the details of registered or designated medical laboratories publicly available?	Yes internet-based=4 Yes information available on request from health authorities=2 No=0		
		Aggregate score: Test laboratories for the health sector (a+b+c)/3	0.0		
NOTE: BUILDING BLOCKS 1 TO 4 DEAL WITH THE LABORATORY SITUATION OF THE COUNTRY AS A WHOLE, WHEREAS THE BUILDING BLOCKS 5 TO 22 ARE RELEVANT FOR AN INDIVIDUAL LABORATORY					
Pillar 1: Legal and institutional framework					
5) Legal entity	<ul style="list-style-type: none"> Relevant legislative instruments of ministries Relevant articles of incorporation 	<p>The test laboratory, whether from the public or private sector, is a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for the outcome of its testing services.</p> <p>a. Is the test laboratory established as a legal entity, i.e., by legislation or by articles of incorporation?</p> <p>b. Have the following been provided for in the legislation or articles of incorporation?</p> <ul style="list-style-type: none"> Governance of the test laboratory Functions of the test laboratory Finances of the test laboratory <p>Aggregate score: Legal entity (a+b)/2</p>	<p>Yes=4 In preparation=1 Unknown=0 Yes=1.5 Yes=1.5 Yes=1</p>		
6) Governance	<ul style="list-style-type: none"> Legislative instrument establishing the test laboratory if relevant Articles of incorporation if relevant Government decisions or decrees if relevant Official organizational structure Annual reports of the test laboratory 	<p>The test laboratory has a board or council, which could be the governance of the larger entity the laboratory is part of, with fiduciary responsibilities and that approves the test laboratory strategy, consisting of members with specific knowledge regarding the testing scope of the laboratory and market realities.</p> <p>a. Is the governance of the test laboratory vested in an independent board or council?</p> <p>b. Do the board or council members have relevant knowledge and experience of the testing scope of the laboratory and its market?</p> <p>c. Is the board or council of the test laboratory solely responsible for the following?</p> <ul style="list-style-type: none"> Business strategy or plan Annual budget Establishment of new business units Appointment of the head of the test laboratory <p>Aggregate score: Governance (a+b+c)/3</p>	<p>Yes=4 Partially independent=1 No=0 Yes=4 Partially=2 No=0 Yes=1 Yes=1 Yes=1</p>		
7) Testing scope	<ul style="list-style-type: none"> Quality management system documentation Test laboratory website Test laboratory marketing material and brochures Accreditation records 	<p>The scope of testing services provided by the test laboratory is clearly defined and based on market needs.</p> <p>a. Is the scope of testing services offered by the test laboratory clearly and formally defined?</p> <p>b. Is the scope of testing based on a demonstrable market demand?</p> <p>c. Has the market demand been quantified in the following ways?</p> <ul style="list-style-type: none"> The total value of current testing The total value of testing in the near future, i.e., five years The recognition requirements for testing for the export market, e.g., accreditation, and so on The number of public and private laboratories providing such testing <p>Aggregate score: Testing scope (a+b+c)/3</p>	<p>Yes=4 Not defined in detail but generally indicated=2 No=0 Yes=4 Parts thereof, yes=2 Not known=0 Yes=1 Partially=0.3 Unknown or no=0 Yes=1 Partially=0.3 Unknown or no=0 Yes=1 Partially=0.3 Unknown or no=0 Yes, complete list=1 Yes, only partially complete=0.3 Not known or no=0</p>		
		Aggregate score: Testing scope (a+b+c)/3	0.0		

Pillar 2: Administration and infrastructure

12) Premises	• Review of laboratory accommodation in the light of defined requirements.	The premises of the test laboratory are arranged, with regard to technical requirements and environmental influences, to ensure the optimum accuracy levels of testing activities for each testing scope.	Yes=4 Some need upgrading=3 Generally in need of upgrading=2 Inadequate in many respects=1 No=0		
		a. Do each of the laboratories, offices, and other buildings meet the physical requirements for each of the testing scopes and their accuracy levels?	Yes=4 In need of upgrading=2 Inadequate in many respects=1 No=0		
		b. Do the environmental controls of the laboratories meet the requirements of each of the testing scopes and their accuracy levels?	Yes=4 In need of upgrading=2 Inadequate in many respects=1 No=0		
		c. Is appropriate access control to the laboratories in place?	Yes=4 In need of upgrading=2 Inadequate in many respects=1 No=0		
		d. Is appropriate office space for staff outside of the laboratories provided as well as meeting rooms for individual customer discussions?	Yes=4 In need of upgrading=2 Inadequate in many respects=1 No=0		
		Aggregate score: Premises (a+b+c+d)/4		0.0	
13) Equipment	• Review of laboratory testing and IT equipment in the light of defined requirements	The test equipment as required for each test scope is in place and fully operational.	Yes=4 Approximately half the needs covered=2 Approximately a quarter of the needs covered=1 Less than quarter of the needs covered=0 No=0		
		a. Has the test laboratory installed the required test equipment as required by each of its testing scopes?	Yes=4 Mostly=2 Many are not=1 No=0		
		b. Is the test equipment fully functional and properly maintained?	Yes=4 Approximately half the calibrations done=2 Approximately a quarter of the calibration done=1 Less than quarter of the calibration done=0 No=0		
		c. Is the test equipment calibrated traceably to national standards in accordance with manufacturers' recommendations?	Yes=4 Approximately half the calibrations done=2 Approximately a quarter of the calibration done=1 Less than quarter of the calibration done=0 No=0		
				Aggregate score: Equipment (a+b+c)/3	
Pillar 3: Service delivery and technical competency					
15) Quality management system documentation	• Quality management documentation • Internal audit results • Management review records • Accreditation records	An appropriate quality management system (e.g., ISO/IEC 17025 or similar) formalized in relevant quality system documentation is in place. NOTE: The documentation will be common to all laboratories.	Yes, externally evaluated=4 Yes, not externally evaluated=3 Being implemented=2 Being developed=1 No=0		
		a. Does the test laboratory have a formal quality management system documentation (e.g., in accordance with ISO/IEC 17025 or similar) in place?			
16) Proficiency testing	• Proficiency testing participation records • Interlaboratory comparison results • List of proficiency testing providers in the country or region • Accreditation assessment reports	Interlaboratory proficiency testing—providing information regarding the ability of the test laboratory to deliver accurate test results underpinning its accreditation—is conducted regularly.	Yes=4 Ad hoc=1 No=0		
		a. Does the test laboratory participate in proficiency testing with other laboratories in the country or region?	Yes, always=4 Yes, most of the time=3 No, accreditation applied for=2 No=0		
		b. Are the proficiency test providers used by the test laboratory accredited to ISO/IEC 17043?			
		Aggregate score: Proficiency testing (a+b)/2		0.0	

17) Preassessment for accreditation	<ul style="list-style-type: none"> • Accreditation application • Assessment result of the quality management system documentation • Preassessment record • Records of the doseout of nonconformities 	Following documentation review after application for accreditation, the preassessment has been conducted with a positive outcome.	a. Has the laboratory requested accreditation for all its testing scopes? b. Have preassessments been conducted by the accreditation body for all its scopes to determine whether a quality management system is in place? c. Have all the identified nonconformities been addressed?	Yes=4 About half=2 Less than a quarter=1 Just one or two=0 All scopes=4 About half the scopes=2 Less than a quarter of the scopes=1 Just one or two=0 Yes=4 About half=2 Less than a quarter=1 Just one or two=0 Aggregate score: Preassessment for accreditation (a+b+c)/3		
		Following the preassessment after application for accreditation, the initial assessment has been conducted with a positive outcome.	a. Has an initial assessment been conducted for all the testing scopes of the laboratory? b. Have all the identified nonconformities been addressed? c. Have all the nonconformities been cleared by the accreditation body?	Yes=4 About half=2 Less than a quarter=1 Just one or two=0 Yes=4 About half=2 Less than a quarter=1 Just one or two=0 Aggregate score: Initial assessment for accreditation (a+b+c)/3		
		Accreditation, as defined in the scope of the accreditation certificate, has been granted, and the test laboratory maintains it. <i>NOTE: The scopes of all the test laboratories collectively should be the criteria.</i>	a. Has accreditation been granted to the test laboratory for its testing scopes? b. Are the accreditation details of the test laboratory publicly available, e.g., on the accreditation body website? c. Is the test laboratory maintaining its accreditation, e.g., are annual fees paid and follow-up audits conducted?	Yes, all scopes=4 Yes, for about half the testing scopes=2 Yes, for one or two testing scopes=1 No=0 Some information still missing=2 No=0 Yes=4 Fallen behind with fees=2 Audit findings are not addressed=1 No=0 Aggregate score: Accreditation (a+b+c)/3		
						0.0
Pillar 4: External relations and recognition						
20) Recognition at national level	<ul style="list-style-type: none"> • Official lists of accredited test laboratories • Official lists of regulatory authorities regarding designated test laboratories 	The test laboratory is recognized at the national level through accreditation and designation where relevant.	a. Has the test laboratory been accredited to ISO/IEC 17025 or ISO 15189? b. Has the test laboratory been designated by a regulatory authority for rendering services in specific regulatory domains?	Yes, for most of its scopes=4 Yes, for a few of its scopes=2 No, but has applied for accreditation=1 No=0 Yes=4 No, but designation has been applied for=1 No=0 Aggregate score: Recognition at national level (a+b)/2		
		The test laboratory is recognized internationally through accreditation or a sectoral scheme such as IEC schemes for electrotechnical products, OIML schemes for legal metrology instruments, and the UNECE 1958 Agreement on the testing of automotive components.	a. Has the test laboratory been accredited to ISO/IEC 17025 or ISO 15189? By an internationally recognized accreditation body? b. Has the test laboratory been accredited through sectoral schemes such as IEC schemes for electrotechnical products, OIML schemes for legal metrology instruments, and the UNECE 1958 Agreement on the testing of automotive components?	Yes, for most of its scopes=4 Yes, for a few of its scopes=2 No, but has applied for accreditation=1 No=0 Yes, for those relevant=4 No, but has applied for accreditation=1 No=0 Unknown=0 Aggregate score: Recognition at international level (a+b)/2		
						0.0
Pillar 4: External relations and recognition						
21) Recognition at international level	<ul style="list-style-type: none"> • Testing strategy and its implementation plans • ILAC membership data • Official data of the IEC and OIML schemes • Official data of the UNECE 1958 Agreement and its signatory countries • Other international recognition systems relevant to the country 	The test laboratory is recognized internationally through accreditation or a sectoral scheme such as IEC schemes for electrotechnical products, OIML schemes for legal metrology instruments, and the UNECE 1958 Agreement on the testing of automotive components.	a. Has the test laboratory been accredited to ISO/IEC 17025 or ISO 15189? By an internationally recognized accreditation body? b. Has the test laboratory been accredited through sectoral schemes such as IEC schemes for electrotechnical products, OIML schemes for legal metrology instruments, and the UNECE 1958 Agreement on the testing of automotive components?	Yes, for most of its scopes=4 Yes, for a few of its scopes=2 No, but has applied for accreditation=1 No=0 Yes, for those relevant=4 No, but has applied for accreditation=1 No=0 Unknown=0 Aggregate score: Recognition at international level (a+b)/2		
						0.0

22) Coordination within the QI	<ul style="list-style-type: none">Regulatory authority policies, pronouncements, and documentationTesting laboratory association documentation and minutes of meetingsTechnical regulation coordination office mandate and pronouncements	Coordination between the test laboratories of the country is fostered through voluntary test laboratory associations and through a technical regulation coordination office where established.						
		a. Is a national testing laboratory association established in the country with the following attributes?				Yes=1		
		o Voluntary membership				Yes=1		
		o Coordination of practical training among members				Yes=1		
		o Lobbying of government				Yes=1		
		b. Is a technical regulation coordination office or similar actively coordinating the activities of test laboratories within the regulatory domain?				Yes=1		
		o Communication strategy to highlight value of technically competent testing services				Yes=4		
		Technical regulation office being established=1						
		No formal coordination takes place=0						
		Aggregate score: Coordination within the QI (a+b)/2					0.0	

Testing

Pillar 1: Legal and institutional framework

Pillar 2: Administration and infrastructure

Pillar 3: Service delivery and technical

Pillar 4: External relations and recognition

	Pillar 1: Legal and institutional framework	Pillar 2: Administration and infrastructure	Pillar 3: Service delivery and technical	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	0.0			
Top management		0.0		
Organizational structure		0.0		
Management and personnel		0.0		
Premises		0.0		
Equipment		0.0		
Quality management system documentation			0.0	
Proficiency testing			0.0	
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				0.0

■ 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

Designated test laboratories

Test laboratories for export market

Test laboratories for the health sector

Legal entity

Governance

Testing services scope

Financial sustainability

Top management

Organizational structure

Management and personnel

Premises

Equipment

Quality management system documentation

Proficiency testing

Preassessment for accreditation

Initial assessment for accreditation

Accreditation

Recognition at national level

Recognition at international level

Coordination within the QI

Metrology						
Element	Information sources	Benchmark and questions	Scoring	Score	Comments: What is your score based on? Please provide information and links.	
Pillar 1: Legal and institutional framework						
1) Metrology strategy	<ul style="list-style-type: none">NMI board or council papersNMI websiteRelevant ministry (e.g., Trade and Industry) websiteAnnual report of the NMI	A metrology strategy giving effect to the implementation of the quality policy regarding scientific, legal, and industrial metrology is in place. It covers the establishment of national measurement standards, the national metrology infrastructure, international recognition, and the capacity of the NMI and the private sector to implement the strategy.				
		a. Is a metrology strategy in place?	Yes=4 Developed, but not approved=2 Not developed=1 No=0			
		b. Does the metrology strategy include all the necessary elements as required by the demand, namely: <ul style="list-style-type: none">o Priorities for the establishment and maintenance of national measurement standardso Metrological level of national measurement standards, i.e. primary or secondary levelo International and regional liaison to gain international recognitiono Moving of calibration services from the government sector to the private sector	Yes=1 Yes=1 Yes=1 Yes=1			
		c. Is an implementation plan for the metrology strategy in place and being followed?	Yes=4 Developed, but not yet followed=2 Under development=1 No=0			
		Aggregate score: Metrology strategy (a+b+c)/3			0.0	
2) Legal entity	<ul style="list-style-type: none">Metrology Act, decree, regulation, or similarNMI website and annual reports	The national metrology institute (NMI) exists as a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for national measurement standards and the national metrology system.				
		a. Has the NMI been established as a legal entity, i.e., by legislation or by articles of incorporation?	Yes=4 In preparation=1 No=0			
		b. Have the following been provided for in the legislation or articles of incorporation? <ul style="list-style-type: none">o Council or board of the NMIo Finances of the NMIo Establishment of measurement system (e.g., SI system)o International or regional liaison	Yes=1 Yes=1 Yes=1 Yes=1			
		c. Is the legislation or articles of incorporation up-to-date, i.e., has it been reviewed recently? <ul style="list-style-type: none">o Last review or revision less than 5 years agoo Last review or revision 5–10 years agoo Last review or revision 10–15 years agoo Last review or revision more than 15 years ago	Yes=4 Yes=2 Yes=1 Yes=0			
		Aggregate score: Legal entity (a+b+c)/3			0.0	
3) Autonomy	<ul style="list-style-type: none">Metrology Act, decree, regulation, or similarNMI website and annual reportsGovernment regulations regarding rules of employment in the case of the NMI being a governmental or public body	The NMI and its board or council has the mandate to effectively manage the affairs of the NMI without undue outside interference or restrictions.				
		<div>The NMI and its board or council can decide on the following:</div> <ul style="list-style-type: none">o Decide which measurement standards are considered to be the national standardso Officially designate other institutions to be custodians of national measurement standardso Determine the positions and staffing of its workforceo Determine the salaries of its workforceo Determine / define its own budget and incomeo Create new administrative divisionso Offer new services or initiate new activitieso Solicit membership in international or regional metrology organizations and sign international agreements	Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5			
		Aggregate score: Autonomy index			0.0	
		National measurement standards are identified and given legal certainty through appropriate legislation and listing in an official government publication.				
		a. Is the establishment and maintenance of national measurement standards provided for in legislation?	Yes=4 Partially=2 No=0			
4) Legal standing of national measurement standards	<ul style="list-style-type: none">Metrology Act, decree, regulation, or similarFormal agreement between the NMI and governmentOfficial government journal or gazette or similar	b. Are the national measurement standards established with known accuracy, are they uniquely identified, and are they made known in an official government publication?	Yes=4 Needs updating=2 No=0			
		c. Are the national measurement standards given the preeminent position in relation to other measurement equipment regarding legal metrology?	Yes=4 Considered as such without legal certainty=1 No=0			
		Aggregate score: Legal standing of national measurement standards (a+b+c)/3			0.0	

5) Governance	<ul style="list-style-type: none">• Metrology Act, decree, regulation, or similar• NMI website and annual reports• Government regulations regarding public entities• NMI council or board committee structures• NMI council or board	The NMI has a board or council with fiduciary responsibilities and that approves the NMI strategy, consisting of members from the public and private sectors with specific knowledge regarding metrology and market realities.	a. Is the governance of the NMI vested in an independent board or council?	Yes=4 Partially independent=2 No=0		
		b. Is the private sector represented in the board or council, and if so, what is the percentage representation?	<ul style="list-style-type: none">o Less than 5%o 5–10%o 16–30%o 31–50%o More than 50%	Yes=0 Yes=1 Yes=2 Yes=3 Yes=4		
		c. Does the board or council appoint the director or CEO?		Yes=4 Board or council recommends=3 Minister appoints independently=2 None of the above=0		
		Aggregate score: Governance (a+b+c)/3			0.0	
		The finances from government, income from metrology services, financial support from industry and other sources are adequate to ensure the financial sustainability of the NMI in the medium to long term.				
6) Financial sustainability	<ul style="list-style-type: none">• National quality policy• Annual reports of the NMI• Monthly and annual financial statements of the NMI	a. Have adequate funds been committed for the continued existence of the NMI, e.g., by the government or any other entity or entities?	<ul style="list-style-type: none">o 100% of need coveredo 85% of need coveredo 70% of need coveredo 50% of need coveredo Less than 50% of need covered	Yes=4 Yes=3 Yes=2 Yes=1 Yes=0		
		b. Do the funding agents, such as government or any other entity or entities, provide specific budgets for funding the establishment and maintenance of national measurement standards?		Yes=4 Every year there is a shortfall=2 No=0		
		c. Is specific funding (from the government or any other entity or entities or special fund) earmarked for the international and regional commitments of the NMI?		Yes=4 Every year there is a shortfall=2 No=0		
		d. Is a formal financial plan established for the medium term, i.e., the following 3–5 years?		Yes=4 1–3 years=2 No=0		
		Aggregate score: Financial sustainability (a+b+c+d)/4			0.0	
Pillar 2: Administration and infrastructure						
7) Chief executive officer	<ul style="list-style-type: none">• Relevant legislation (i.e., Metrology Act or similar)• Board or council decisions and minutes• Official CEO job description• Agreed-upon CEO key performance indicators	A director or a CEO (whatever the title) with responsibilities to manage the day-to-day affairs of the NMI is appointed.		Yes=4 Larger organization's head acts as CEO or director=3 Acting=2 No=0		
		a. Has a full-time director or CEO been appointed with clear responsibilities for the day-to-day management of the NMI?		Yes=4 Accountable to minister and board or council=2 Accountable to minister only=1 No=0		
		b. Is the director or CEO fully accountable to the board or council?		Yes=4 No voting right=1 No=0		
		c. Is the director or CEO a full member of the board or council?		Yes=4 Informally=2 No=0		
		d. Are the key performance criteria for the director or CEO defined and evaluated at least annually by the board or council?		Yes=4 No=0		0.0
Aggregate score: Chief executive officer (a+b+c+d)/4						

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11) Equipment	<ul style="list-style-type: none">Consideration of the NMI metrology fields of activityDemonstrable metrology needs of the countryReview of national measurement standardsReview of working reference measurement standardsReview of maintenance measures for all measuring equipment	The national measurement standards and reference standards for accuracy, as defined by the needs of the country for each of the relevant metrology fields, are in place and fully operational.	Yes=4 Approximately half the needs covered=2 Approximately a quarter of the needs covered=1 Less than quarter of the needs covered=0		
			Yes=4 Approximately half the needs covered=2 Approximately a quarter of the needs covered=1 Less than quarter of the needs covered=0		
			Yes=4 Mostly=2 Many are not=1 No=0		
		Aggregate score: Equipment (a+b+c)/3	0.0		
12) Quality system documentation	Consideration of the NMI formal quality system and its compliance with known international standards such as ISO/IEC 17025	An appropriate quality management system (e.g., ISO/IEC 17025 or similar) formalized in relevant quality system documentation is in place.	Yes, externally evaluated=4 Yes, not externally evaluated=3 Being implemented=2 Being developed=1 No=0		
		a. Does the NMI have a formal quality management system (e.g., ISO/IEC 17025 or similar) implemented?			
		Aggregate score: Quality system documentation (a)	0.0		
Pillar 3: Service delivery and technical competency					
13) Metrologists	<ul style="list-style-type: none">Approved organizational structureFormal job descriptionsPersonnel records regarding education, training, and experienceAnnual training plans and concomitant records	Trained and experienced metrologists, at the level required by each of the metrology fields and their sophistication, are employed.	Yes=4 Mostly=2 In progress=1 No=0		
		a. Are the training and experience requirements for each of the metrologist and other technical posts clearly defined, and are they applied?	Yes=4 Partly=2 No=0		
		b. Have the metrologists gained the relevant experience in more advanced NMIs?	Yes=4 Partly=2 No=0		
		c. Have the technical personnel who develop and maintain measuring equipment and environmental controls been provided with the relevant training and experience?	Yes=4 Partly=2 No=0		
		Aggregate score: Metrologists (a+b+c)/3	0.0		
14) Interlaboratory and key comparisons	<ul style="list-style-type: none">Key Comparison Database (KCDB) of the BIPMInterlaboratory comparison reports of the NMIResults of key comparisons of RMOsResults of key comparisons of the BIPM and consultative committees (CC)	Interlaboratory or key comparisons providing information regarding the NMI's ability to deliver accurate measurement results underpinning accreditation or the NMI's calibration and measurement capabilities (CMCs) are conducted regularly.	Yes, foreseen in actual planning=4 Ad hoc=1 No=0		
		a. Does the NMI participate in interlaboratory comparisons with other laboratories in the country or region?	Yes, always=4 Selected metrology fields only=3 Ad hoc=2 Only when donor funds are available=1 No=0		
		b. Does the NMI participate in key comparisons arranged by the regional metrology organization (RMO) of the region?			
			Aggregate score: Interlaboratory and key comparisons (a+b)/2	0.0	

15) Calibration and measurement capability (CMC)	The NMI (as a member or associate member of the BIPM) has achieved international recognition through listing of its CMCs in the BIPM database.																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																		
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19) Liaison with international organizations	<ul style="list-style-type: none">• Metrology strategy and its implementation plans• BIPM and OIML membership data• BIPM and OIML technical committee data• Annual reports of the NMI• Business plans and minutes of the NMI technical and mirror committees• Formal communication records of the NMI with BIPM and OIML	<p>The country is a full member of the BIPM if it is a signatory of the Metre Convention, or an associate member if it is not. The NMI is actively involved in the country's participation within the Metre Convention organizations, e.g., the CGPM and consultative committees (CCs).</p> <p>a. Is the country a signatory of the Metre Convention and a full member of the BIPM, or an associate member if not?</p> <p>b. Does the country participate in the CGPM activities?</p> <p>c. Does the NMI participate in relevant CCs?</p>	Yes=4 Neither=0 Yes, country and NMI participation=4 Only country without NMI (NMI still to be established)=2 NMI participates in NMI Directors Meeting only=1 No=0 All committees relevant for the country=4 Half the committees relevant for the country=1 Not yet=0 (a+b+c)/3			
		<p>Aggregate score: Liaison with international organizations</p> <p>There is active coordination between the NAB, NMI, and NSB to foster a unified basis for the calibration and conformity assessment activities within the QI, e.g., the NMI participates in NSB and NAB technical committees, and an exchange of relevant information takes place continuously regarding standardization, metrology, and accreditation needs of the country.</p> <p>a. Does a formal mechanism exist between the NSB, NMI, and the NAB managements as well as their line ministries whereby issues can be discussed annually or every six months, and coordination can be fostered?</p> <p>b. Is it possible for the CEOs of the NSB, NMI, and NAB to attend each other's council or board meetings as a matter of course as observers?</p> <p>c. Has the government established a quality council or forum or similar where all stakeholders of the QI can provide input and raise issues regarding the metrology needs of the country?</p>	Yes=4 Ad hoc=2 No=0 Yes=4 Only on invitation=2 No=0 Yes=4 Ad hoc=1 No=0 (a+b+c)/3		0.0	
	20) Coordination within the QI	<ul style="list-style-type: none">• Line ministry policies, pronouncements, and documentation• Quality council (or similar) documentation and minutes of meetings• Technical regulation coordination office mandate and pronouncements• NSB and NAB technical committee membership	<p>Aggregate score: Liaison within the QI</p> <p>A formal mechanism exists for the NMI to recognize designated institutes (DIs) to act as custodians of national measurement standards in technologies not covered by the NMI, e.g., nuclear technology, metrology in chemistry, and so on.</p> <p>a. Does the NMI have a formal and legally sound mechanism to designate other metrology institutions as custodians of national measurement standards?</p> <p>b. When designating an institution, which of the following elements does the NMI consider?</p> <p>c. Does the NMI monitor the performance of the DI regarding its activities and CMCs at regular intervals?</p>	Yes=4 No=0 Yes=1 Yes=1 Yes=1 Six-monthly=4 Annually=3 Ad hoc=2 Only when there is a complaint=1 No=0 (a+b+c)/3		
	21) Designated institutes (DIs)	<ul style="list-style-type: none">• NMI legislation• Formal procedures for designating institutes• Official designation documentation of DIs• BIPM records of NMIs and DIs• Work programs of the NMI and DIs• Annual reports of the NMI	<p>Aggregate score: Designated Institutes (DIs)</p> <p>A system in place whereby the NMI identifies its stakeholders, communicates clearly with them, and gains their support and participation in the development and maintenance of national measurement standards and the national metrology system.</p> <p>a. Does the NMI map its stakeholders in the following and keep it up to date?</p> <p>b. Does the NMI follow a deliberate strategy to communicate with all stakeholders to stress the importance of standards, their implementation, and the role of the NMI?</p> <p>c. Does the NMI follow a deliberate strategy to involve all stakeholders in the decisions to establish national measurement standards and the national metrology system?</p> <p>d. Has the NMI established a metrology forum or similar where any stakeholder can participate to provide recommendations to the NMI on metrology matters, and does it meet regularly?</p>	Yes=4 No=0 Yes=1 Yes=1 Yes=1 Yes=4 Ad hoc=2 No=0 Yes, for every new project=4 Public sector stakeholders only=2 Ad hoc=1 No=0 Yes, meets twice annually =4 Yes, meets annually=3 Ad hoc meetings=2 No=0 (a+b+c+d)/4		0.0
22) Stakeholder engagement	<ul style="list-style-type: none">• Metrology strategy and its implementation• Communication strategy or plan and its implementation• Minutes of a metrology forum or similar open stakeholder meeting• Key performance indicators of senior management• Stakeholder mapping results					

Metrology				
	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	0.0			
Legal entity	0.0			
Autonomy	0.0			
Legal standing of national metrology institute	0.0			
Financial sustainability	0.0			
Governance	0.0			
Chief executive officer		0.0		
Organizational structure		0.0		
Premises		0.0		
Equipment		0.0		
Quality system documentation		0.0		
Metrologists			0.0	
Interlaboratory and key comparisons			0.0	
Calibration and measurement capability (CMC)			0.0	
Calibration services			0.0	
Training system				0.0
Liaison with regional organizations				0.0
Liaison with international organizations				0.0
Coordination within the QI				0.0
Designated institutes (DIs)				0.0
Stakeholder engagement				0.0



Legal Metrology

Legal Metrology					
Element	Information sources	Benchmark and questions	Scoring	Score	Comments: What is your score based on? Please provide information and links.
Pillar 1: Legal and institutional framework					
1) Legal metrology strategy	<ul style="list-style-type: none">• Relevant ministry (e.g., Trade and Industry) website• Relevant ministry papers• Legal metrology authority website• Annual reports of the legal metrology authority	A legal metrology strategy giving effect to the implementation of the quality policy regarding the establishment and maintenance of a legal metrology system in the country is in place.	Yes=4 Applicable only to some authorities=3 Developed, but not yet approved=2 Being developed=1 No=0 Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5 Yes=0.5 Developed, but not yet implemented=1 No=0		
		a. Has a legal metrology strategy applicable to all authorities developing and implementing legal metrology been developed and approved?			
		b. Does the legal metrology strategy cover the following? <ul style="list-style-type: none">o Promulgation of new or revised legislationo Road map for implementation of legal metrology measures over time regarding specific measuring equipment, whether related to trade, law enforcement, or health and safetyo Alignment of regulations with OIML recommendationso Introduction of prepackaging requirements or the revision of older regulationso Establishment of legal metrology inspection offices across the countryo Capacity development regarding transport, inspection equipment, and so on, for market effective surveillanceo Training system for legal metrology expertso Road map for liberalization of calibration and verification activities, i.e., designation of private sector organizations to take over these functions from the state			
		c. Has an implementation plan been developed and approved, and is it being implemented?			
		The legal metrology authority is a legal entity, or a defined part of a legal entity, with the mandate to establish and maintain the legal metrology system in order to safeguard the interests of society regarding measurements.	(a+b+c)/3	0.0	
2) Legal entity	<ul style="list-style-type: none">• Legal metrology Act, decree, regulations, or similar• Legal metrology authority's website and annual reports	a. Has the legal metrology authority been established as a legal entity, i.e., by legislation?	Yes=4 In preparation=1 No=0		
		b. Have the following been provided for in the legislation? <ul style="list-style-type: none">o Governance of the legal metrology authorityo Finances of the legal metrology authorityo The overall legal metrology system of the countryo International or regional liaisono Last review or revision less than 5 years agoo Last review or revision 5–10 years agoo Last review or revision 10–15 years agoo Last review or revision more than 15 years ago	Yes=1 Yes=1 Yes=1 Yes=1 Yes=4 Yes=2 Yes=1 Yes=0		
		c. Is the legislation up-to-date, i.e., has it been reviewed recently?			
		Aggregate score: Legal entity (a+b+c)/3		0.0	
		The governance of the legal metrology authority is vested in a government department or in a council that has the mandate to approve strategy, business plans, and budgets and that holds the director to account.			
3) Governance	<ul style="list-style-type: none">• Legal metrology act, decree, regulation, or similar• Ministerial decrees if relevant• Legal metrology authority council policy papers• Legal metrology authority website and annual reports• Government regulations regarding public entities	a. Is the governance of the legal metrology authority vested in a high-level government official or an independent council with appropriate knowledge regarding legal metrology matters and market needs?	Yes=4 Knowledge levels could be better=2 No=0 Yes, formal=4 Through more than one level of bureaucracy=2 Yes, ad hoc=1		
		b. Does the director of the legal metrology authority have a direct communications line to the relevant political level to deal with legal metrology issues that have a possible political fallout?			
		c. Does the governance structure appoint the director of legal metrology and hold him or her to account?			
		Aggregate score: Governance (a+b+c)/3		0.0	

4) Financial sustainability	<ul style="list-style-type: none"> National quality policy Annual government budget allocations Annual reports of the legal metrology authority Monthly and annual financial statements of the legal metrology authority 	The finances from government, income from legal metrology services, and financial support from industry and other sources are adequate to ensure the financial sustainability of the legal metrology authority in the medium to long term.	<input type="checkbox"/> 100% of need covered <input type="checkbox"/> 85% of need covered <input type="checkbox"/> 70% of need covered <input type="checkbox"/> 50% of need covered <input type="checkbox"/> Less than 50% of need covered	Yes=4 Yes=3 Yes=2 Yes=1 Yes=0 Every year there is a shortfall=2 No=0 Every year there is a shortfall=2 No=0 Yes=4 Every year there is a shortfall=2 No=0 Yes=4 2-3 years=2 1 year only=1 No=0	0.0
		Aggregate score: Financial sustainability (a+b+c+d)/4			
		Pillar 2: Administration and infrastructure			
		<ul style="list-style-type: none"> Relevant legislation (i.e., Legal Metrology Act or similar) Official ministerial decisions Council decisions and minutes if relevant Official CEO job description Agreed-upon CEO key performance indicators 	The legal metrology authority is managed by a director (whatever the actual title) who has the authority to ensure compliance of measuring equipment and prepackaging in the market falling within the scope of the regulations that the legal metrology authority is responsible for.	Yes=4 Part of a bigger organization, without its own director=2 No=0 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Aggregate score: Director (a+b)/2 0.0	0.0
5) Director	<ul style="list-style-type: none"> Approved organizational structure Ministry or council decisions Ministerial decisions Financial system documentation 	The organizational structure of the legal metrology authority facilitates the effective and efficient execution of all regulations it is responsible for, and it has divisions that optimally support the legal metrology subject fields.	Yes=4 Partially=2 No=0 Yes, throughout the country=4 Partially some areas still to be established=2 Only the head office is operational=1 No=0 Yes=1 Yes=1 Yes=1 Yes=1 Aggregate score: Organizational structure (a+b+c)/3 0.0	0.0	
6) Organizational structure	<ul style="list-style-type: none"> Approved organizational structure Training records of staff Appointment and withdrawal records of legal metrology inspector certificates Actual staffing levels Staff turnover figures 	Management and personnel are in place with the appropriate skill sets assured by appropriate training, qualifications, and experience for the management and technical knowledge required by the regulation scopes with specific emphasis on legal metrologists.	Yes=4 Yes=3 Yes=2 Yes=1 Yes=0 Yes=4 Yes=3 Yes=2 Yes=1 Yes=0 Not for all posts=2 Skill sets and responsibilities yes, KPIs no=1 No=0 Yes=4 Not for all posts=2 Skill sets and responsibilities yes, KPIs no=1 No=0 Aggregate score: Management and personnel (a+b+c+d)/4 0.0	0.0	
7) Management and personnel	<ul style="list-style-type: none"> Approved organizational structure Training records of staff Appointment and withdrawal records of legal metrology inspector certificates Actual staffing levels Staff turnover figures 	Management and personnel are in place with the appropriate skill sets assured by appropriate training, qualifications, and experience for the management and technical knowledge required by the regulation scopes with specific emphasis on legal metrologists.	Yes=4 Yes=3 Yes=2 Yes=1 Yes=0 Yes=4 Yes=3 Yes=2 Yes=1 Yes=0 Not for all posts=2 Skill sets and responsibilities yes, KPIs no=1 No=0 Yes=4 Not for all posts=2 Skill sets and responsibilities yes, KPIs no=1 No=0 Aggregate score: Management and personnel (a+b+c+d)/4 0.0	0.0	

<p>8) Premises</p> <ul style="list-style-type: none"> • Consideration of the legal metrology authority premises in relation to design, environmental controls, access, and maintenance • Review of laboratories and environmental controls • Review of office space and meeting rooms • Technical requirements as advised by experts in specific legal metrology fields 	<p>Appropriate accommodation for head office staff and technical activities is provided as well as appropriate accommodation in provincial or local offices for legal metrologists and their inspection equipment.</p> <p><i>NOTE: Premises for testing activities are covered in the section on testing.</i></p> <p>a. Is the legal metrology authority head office housed in appropriate premises that allow for acceptable working conditions for employees (light, ventilation, temperature, space available, furniture, and so on)?</p> <p>b. Are the legal metrology authority provincial or local offices housed in appropriate premises that allow for acceptable working conditions for employees (light, ventilation, temperature, space available, furniture, and so on)?</p> <p>c. Is appropriate space available for the following?</p> <ul style="list-style-type: none"> o Storage for inspection equipment where it maintains its integrity o Storage space for storing product samples for a specific time without deterioration 	<p>Yes=4 Needs upgrading=1 No=0</p> <p>Yes, all of them=4 Yes, but some need upgrading=2 No=0</p> <p>Yes=2 Needs upgrading=1 No=0</p> <p>Yes=2 Needs upgrading=1 No=0</p> <p>Aggregate score: Premises (a+b+c)/3</p>	<p>0.0</p>	
<p>9) Equipment</p> <ul style="list-style-type: none"> • Consideration of the legal metrology fields of activity • Demonstrable metrology equipment needs of the legal metrology authority • Review of reference measurement standards • Review of working standards • Review of inspection equipment • Review of maintenance measures for all measuring equipment 	<p>Legal metrology offices are issued with appropriate metrology and inspection equipment. Working standards, traceably calibrated to national measurement standards, are maintained against which working metrology and inspection equipment is calibrated continuously.</p> <p><i>NOTE: Testing equipment is covered in the section on testing.</i></p> <p>a. Have the legal metrology offices been issued with all the metrology and inspection equipment as determined by the regulations they are responsible for?</p> <p>b. Are working standards, traceably calibrated to national measurement standards, been established against which metrology and inspection equipment can be calibrated?</p> <p>c. Is all metrology and inspection equipment continuously calibrated against the working standards?</p>	<p>Yes, all of them=4 Mostly, some equipment still missing=2 Partially, more than half the equipment still missing=1 No=0</p> <p>Yes, in all cases=4</p> <p>Mostly, some standards still missing or not traceably calibrated=2 Partially, more than half the standards still missing or not traceably calibrated=1 No=0</p> <p>Yes, all of them=4 Mostly, some equipment lacking=2 More than half the equipment lacking=1 No=0</p> <p>Aggregate score: Equipment (a+b+c)/3</p>	<p>0.0</p>	
<p>10) Quality management system</p> <ul style="list-style-type: none"> • Consideration of the legal metrology authority's formal quality management system and its compliance with relevant standards such as ISO/IEC 17020 and ISO/IEC 17025 	<p>A quality management system in accordance with ISO/IEC 17020 (inspection), ISO/IEC 17025 (test laboratory), and/or ISO/IEC 17065 (product certification), as relevant, has been implemented and is maintained.</p> <p>a. Has the legal metrology authority implemented a formal quality management system in accordance with ISO/IEC 17020, ISO/IEC 17025, and/or ISO/IEC 17065 as relevant?</p> <p>b. Has the quality management system of the legal metrology authority been independently assessed and certified?</p>	<p>Yes=4 Being implemented=1 No=0</p> <p>Yes=4 Independently assessed, but not certified=2 Internally assessed=1 No=0</p> <p>Aggregate score: Quality management system (a+b)/2</p>	<p>0.0</p>	
	<p>Pillar 3: Service delivery and technical competency</p>			
<p>11) Legal metrology technical staff</p> <ul style="list-style-type: none"> • Approved organizational structure • Formal job descriptions • Personnel records regarding education, training, and experience • Annual training plans and concomitant records • Legal metrology inspector training records • Records of legal metrology inspector cards issued and withdrawn 	<p>Trained and experienced technical staff to conduct the legal metrology testing, calibration, and verification have been appointed. Legal metrology staff involved in market surveillance are trained in their legal responsibilities and issued with inspector identification cards.</p> <p>a. Does the legal metrology authority have the trained and experienced staff to conduct measuring equipment testing, calibration, and verification for the types of measuring equipment covered by regulations?</p> <p>b. Are the legal metrology inspectors formally trained regarding their legal rights and responsibilities as detailed in the legal metrology regulations?</p> <p>c. Are the legal metrology inspectors issued with an inspectors identification card (whatever its name) that identifies them as inspectors, that they must show when in the field inspecting, and that is withdrawn when they leave the legal metrology authority service?</p>	<p>Yes for all equipment=4 More than half but not all equipment=3 About half the equipment=2 Less than half the equipment=1 No=0</p> <p>Yes, with a written examination=4 Yes, but no written examination=2 New inspectors learn from older ones=1 No=0</p> <p>Yes=4 Not officially withdrawn at end of service=0 No=0</p> <p>Aggregate score: Legal metrology technical staff (a+b+c)/3</p>	<p>0.0</p>	

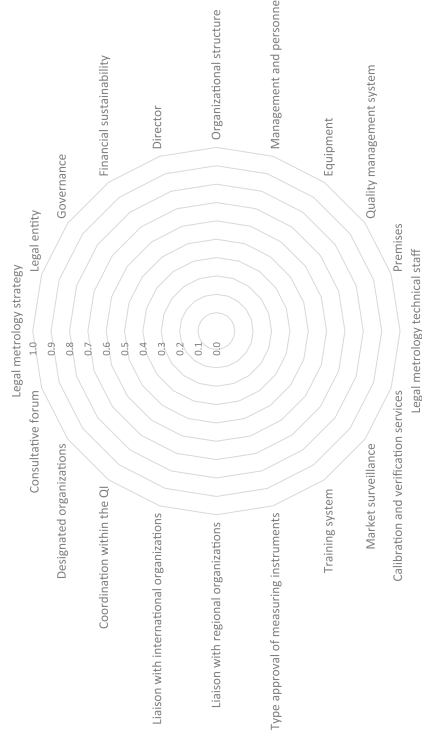
12) Type approval of measuring instruments	<ul style="list-style-type: none"> Formal type approval procedures of the legal metrology authority Type approval records of the legal metrology authority 	The legal metrology authority has a formal system in place to test and approve measuring equipment before it is allowed to be marketed to ensure it complies with stated regulations, including the acceptance of OIML and other relevant foreign certificates.	Yes, conducts own tests or accepts OIML test reports=4 Yes, only accepts own testing results=2 Issues type approval certificates on supplier evidence=1 No=0 Yes, active market surveillance=4 Ad hoc market surveillance=2 Only when complaints are received=1 No=0 Yes=4 Rely totally on the supplier to do so=2 No=0		
		a. Does the legal metrology authority issue a "type approval certificate" (however named) after a measuring device has been tested against technical requirements contained in the relevant regulations, which allows the supplier to market the equipment? b. Does the legal metrology authority ensure (e.g., through market surveillance) that only measuring equipment with a type approval certificate is used in trade, health services, environmental control, and law enforcement, where this is a legal metrology requirement? c. Does the legal metrology authority have a formal system in place to ensure that new measuring equipment is calibrated and verified before placing it into operation?	Aggregate score: Type approval of measuring instruments (a+b+c)/3 No=0	0.0	
		The legal metrology authority provides calibration and verification services for equipment subject to regulation insofar as designated organizations are not in a position to do so.	Yes, fully=4 No, but accredited calibration laboratories have been established to do so=4 Not fully, but more than half=3 About half=2 Less than half=1 No=0 Yes, the important instruments are provided for=4 Partially=2 No=0 Yes=4 In process to implement=1 No=0		
		a. Can the legal metrology authority provide calibration and verification services for all the measuring instruments subject to regulations? b. Does the legal metrology authority have the resources (e.g., transport, portable calibration equipment, and so on) to provide calibration and verification services in the field? c. Has the legal metrology authority designated other organizations to provide calibration and verification services on its behalf?	Aggregate score: Calibration and verification services (a+b+c)/3 No=0	0.0	
14) Market surveillance	<ul style="list-style-type: none"> Market surveillance planning documents Market surveillance records Records of sanctions instituted 	A market surveillance system is in place covering all measuring equipment and prepackaging subject to regulation for which the legal metrology authority is responsible.	Yes=4 Partially=2 No=0		
		a. Has the legal metrology authority established a market surveillance system covering all instruments and prepackaging for which it is responsible? b. Is the market surveillance regime based on a continuous risk assessment of the impact that nonconforming measuring equipment or prepackaging could have and the possibility of such an impact happening? c. In planning market surveillance, does the legal metrology authority follow the principles of proportionality, i.e., the action taken is in accordance with the level of risk or nonconformity and is not more onerous on the economic entity than necessary? d. Does the legal metrology authority plan for scheduled market surveillance as well as off-schedule surveillance in response to a complaint or at the request of a court of law?	Yes, in all cases=4 Mostly, some not=2 All products are treated identical=1 No=0 Yes=4 Off-schedule inspections are squeezed in=2 Inspections are implemented in an ad hoc way=1 No=0 Aggregate score: Market surveillance (a+b+c+d)/4 No=0	0.0	
		Training courses, provided either by the legal metrology authority or a tertiary education institution, for the training of legal metrologists are available.	Yes, for all technologies=4 Not all, but more than half=2 About half=1 Less than half=0 No=0 100%=4 About two-thirds=3 About half=2 Less than half=1 No=0		
		a. Are formal training courses for legal metrologists, whether provided by the legal metrology authority or by tertiary education institutions, available in the country? b. Have all technical staff of the legal metrology authority been through the courses in (a)?	Aggregate score: Training system (a+b)/2 No=0	0.0	
15) Training system	<ul style="list-style-type: none"> Training programs Training records 				

Pillar 4: External relations and recognition				
		The legal metrology authority participates actively in regional legal metrology activities its country is part of, including participation in relevant technical committees at the regional level.		
16) Liaison with regional organizations	<ul style="list-style-type: none"> • Membership of the legal metrology authority in the OIML liaison organizations • Reports of participation of the legal metrology authority in the regional organization's activities • Regional trade agreement membership status of the country • Relevant regional treaties, protocols, agreements, or legislation on legal metrology • Annual reports of the legal metrology authority • Internal reports of regional metrology body meetings 	a. Is the legal metrology authority a full and active member of the relevant OIML-recognized regional liaison organization, e.g., APLMF, COOMET, EMLMF, WELMEC, AFRIMETS, SADCMEI, SIM, and so on?	Yes=4 Associate member only=2 Ad hoc involvement=1 A relevant liaison organization does not yet exist=0 No=0	
		b. Does the legal metrology authority participate actively in regional trade agreement-related metrology organizations or committees? NOTE: These regional organizations or committees are usually established to harmonize metrology activities within the region defined by the trade agreement. They are not of necessity the same as the OIML-recognized liaison organizations.	Continuously in all the relevant ones=4 Ad hoc=2 Only when donor funding is available=1 No=0	
		c. Does the legal metrology authority participate actively in relevant technical committees of regional legal metrology organizations?	Continuously in all the relevant ones=4 Ad hoc=2 Only when donor funding is available=1 No=0	
		Aggregate score: Liaison with regional organizations (a+b+c)/3	0.0	
17) Liaison with international organizations	<ul style="list-style-type: none"> • Legal metrology strategy and its implementation plans • OIML membership data • OIML technical committee data • Annual reports of the legal metrology authority • Business plans and minutes of the legal metrology authority technical committees • Formal communication records of the legal metrology authority with the OIML 	The country is a member of the OIML, and the legal metrology authority participates actively in the relevant technical committees and is a signatory of the OIML Certification System.	Yes=4 Is a corresponding member=2 Has applied for membership=1 No=0	
		a. Is the legal metrology authority a full member of the OIML?	Yes=4 Participates only in the international conferences=1 No=0	
		b. Does the legal metrology authority participate actively in relevant OIML technical committees?	Yes=4 No=0	
		c. Is the legal metrology authority a signatory of the OIML Certificate System?	Yes=4 No=0	
		Aggregate score: Liaison with international organizations (a+b+c)/3	0.0	
18) Coordination within the QI	<ul style="list-style-type: none"> • Line ministry policies, pronouncements, and documentation • Legal metrology authority annual reports • Minutes of liaison meetings between the legal metrology authority and the NSB, NMI, and NAB • Technical regulation coordination office mandate and pronouncements 	The legal metrology authority provides calibration and verification services for equipment subject to regulation insofar as designated organizations are not in a position to do so.		
		a. Does a formal mechanism exist between the legal metrology authority and the NSB, NMI, and the NAB managements as well as their line ministries whereby issues can be discussed annually or every six months, and coordination can be fostered?	Yes=4 Ad hoc=2 No=0	
		b. Does the legal metrology authority provide feedback through the mechanism in (a) on progress regarding coordination?	Yes always=4 Ad hoc=1 No=0	
		c. Does the legal metrology authority participate actively in relevant technical committees of the NMI, NSB, and the NAB and use the output thereof in its work?	Yes all three=4 Yes two of the three=2 One of the three=1 No=0	
		Aggregate score: Coordination within the QI (a+b+c)/3	0.0	
19) Designated organizations	<ul style="list-style-type: none"> • Legal metrology legislation and regulations • Formal procedures for designating institutes • Official documentation of designated organizations • Work program of the legal metrology authority • Annual reports of the legal metrology authority 	The legal metrology authority designates competent organizations to provide legal-metrology-related services on its behalf.		
		a. Does the legal metrology legislation mandate the legal metrology authority to designate others, whether public or private sector organizations, to provide legal metrology services on its behalf?	Yes=4 No, but it is done anyway=2 No, and it is not done=0	
		b. Does the legal metrology authority use accreditation to ISO/IEC 17020 or ISO/IEC 17025 as appropriate, together with the legal liability aspects at the national level of the to-be-designated organization, as criteria for its designation?	Accredited not always=2 No=0	
		c. Does the legal metrology authority have a formal system in place to determine whether designated organizations continuously meet their designation requirements, and does it withdraw designation when requirements are not met?	Yes at least annually=4 Ad hoc when complaints are received=2 No relies on the accreditation body only=0	
		Aggregate score: Designated organizations (a+b+c)/3	0.0	

	Stakeholders such as the suppliers of measuring instruments, retail organizations, and consumer organizations can participate in a consultative forum to provide advice to the legal metrology authority regarding their needs.			
	<ul style="list-style-type: none"> • Legal metrology strategy and its implementation • Communication strategy or plan and its implementation • Minutes of consultative forum meetings • Key performance indicators of senior management • Stakeholder mapping results 	<p>a. Has the government established a consultative forum (i.e., a legal metrology forum or similar) where all stakeholders of the QI can provide input and raise issues regarding the legal metrology needs of the country?</p> <p>b. Does this consultative forum meet regularly, e.g., at least once or twice annually?</p> <p>c. Does the legal metrology authority formally consider the recommendations of the consultative forum and provide feedback on progress in this respect?</p>	<p>Yes=4 Ad hoc=1 No=0</p> <p>Yes=4 Ad hoc meetings only=1 No=0</p> <p>Yes always=4 50% of the time=2 Considers them but provides no feedback=1 No=0</p>	
20) Consultative forum				
Aggregate score: Consultative forum (a+b+c)/3				
Legal Metrology				
	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 strateg	0.0			
Legal entity	0.0			
Governance	0.0			
Financial sustainability	0.0			
Director		0.0		
Organizational structure		0.0		
Management and personnel		0.0		
Equipment		0.0		
Quality management system		0.0		
Premises		0.0		
Legal metrology technical staff			0.0	
Calibration and verification services			0.0	
Market surveillance			0.0	
Training system			0.0	
Type approval of measuring instruments			0.0	
Liaison with regional organizations				0.0
Liaison with international organizations				0.0
Coordination within the QI				0.0
Designated organizations				0.0
Consultative forum				0.0

Legal Metrology

- Pillar 1: Legal and institutional framework
- Pillar 2: Administration and infrastructure
- Pillar 3: Service delivery and technical competency
- Pillar 4: External relations and recognition



Element	Information sources	Benchmark and questions	Scoring	Score	Comments: What is your score based on? Please provide information and links.
Inspection					
Legal and institutional framework, inspection services sector					
1) Inspection services strategy	<ul style="list-style-type: none">• Relevant government policies, strategies, and implementation plans• Review of extent of public sector inspection body capacity and capabilities• Government purchasing documentation• Relevant ministry (e.g., Trade and Industry, Science and Technology, Health, Agriculture, and the like) websites	An inspection services strategy giving effect to the implementation of the quality policy regarding inspection services in the country is in place. It contains the government's responsibilities regarding inspection, the liberalization of inspection services in respect to regulatory measures, and the role of accreditation in demonstrating technical competency of inspection bodies.			
		a. Is an inspection services strategy in place?	Yes=4 Developed, but not approved=2 Under development =1 No=0		
		b. Does the inspection services strategy include all the necessary elements, namely <ul style="list-style-type: none">o Priorities for the establishment and maintenance of inspection services in the public sectoro Provision for the liberalization of inspection services in support of regulatory measures, i.e., private sector inspection bodies given access in regulatory measureso Accreditation as a measure of the technical competency of inspection bodies in both the public and private sectorso Building capacity in inspection services to meet the needs of the regulatory authorities and the markets in the most innovative, effective, and efficient ways	Yes=1 Yes=1 Yes=1 Yes=1 Yes=4 Developed, but not yet followed=2 Under development=1 No=0		
		c. Is an implementation plan for the inspection services strategy in place and being followed?	Yes=4 Developed, but not yet followed=2 Under development=1 No=0		
		Aggregate score: Inspection services strategy	(a+b+c)/3	0.0	
2) Designated inspection bodies	<ul style="list-style-type: none">• Accreditation Act, decree, regulation, or similar if relevant• Relevant legislative instruments of ministries• Accreditation body lists of accredited inspection bodies• Official lists of designated inspection bodies for the regulatory domain	Inspection bodies mandated to provide inspection services in the regulatory domain should be designated by the relevant authorities based on their technical competence (e.g., accreditation to ISO/IEC 17020) and their legal liability in the country.			
		a. Is a system of designating inspection bodies for regulatory purposes formalized in legislation and practiced in the country?	Yes=4 Only public sector inspection bodies are allowed=2 Ad hoc practices=1 No=0 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1		
		b. Has the following been provided for in the legislation for the designation of inspection bodies? <ul style="list-style-type: none">o Designation of public sector and private sector inspection bodies possibleo Accreditation is a precondition for designationo Legal liability in the country is a preconditiono Local and foreign inspection bodies are includedo Details available on internet sites	Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1		
		c. Are the details of designated test laboratories publicly available? <ul style="list-style-type: none">o Name and contact detailso Scope of inspection functions for regulatory purposeso Designating authority	Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1		
		Aggregate score: Designated inspection bodies	(a+b+c)/3	0.0	
3) National inspection bodies for the regional markets	<ul style="list-style-type: none">• Government export policies and strategies• Recognition agreements between the government and regional common market authorities• Records of notification of designated inspection bodies within the regional common market	Inspection bodies providing inspection services in the context of a regional common market are recognized by the relevant authorities and the regional market.			
		a. Is the principle in operation that a product legally marketed in one member of the common market can also be marketed in the other members of the common market without further inspection and testing?	Yes=4 In principle, but issues still exist=2 No=0		
		b. Is a system in operation whereby the work of inspection bodies in one member country of the common market is accepted by other member countries?	Yes=4 In principle, but issues still exist=2 No=0		
		c. Is the designation of inspection bodies by regulatory authorities throughout the common market based on accreditation to ISO/IEC 17020?	Yes=4 In principle, but issues still exist=2 No=0		
		Aggregate score: National inspection bodies for the regional markets	(a+b+c)/3	0.0	

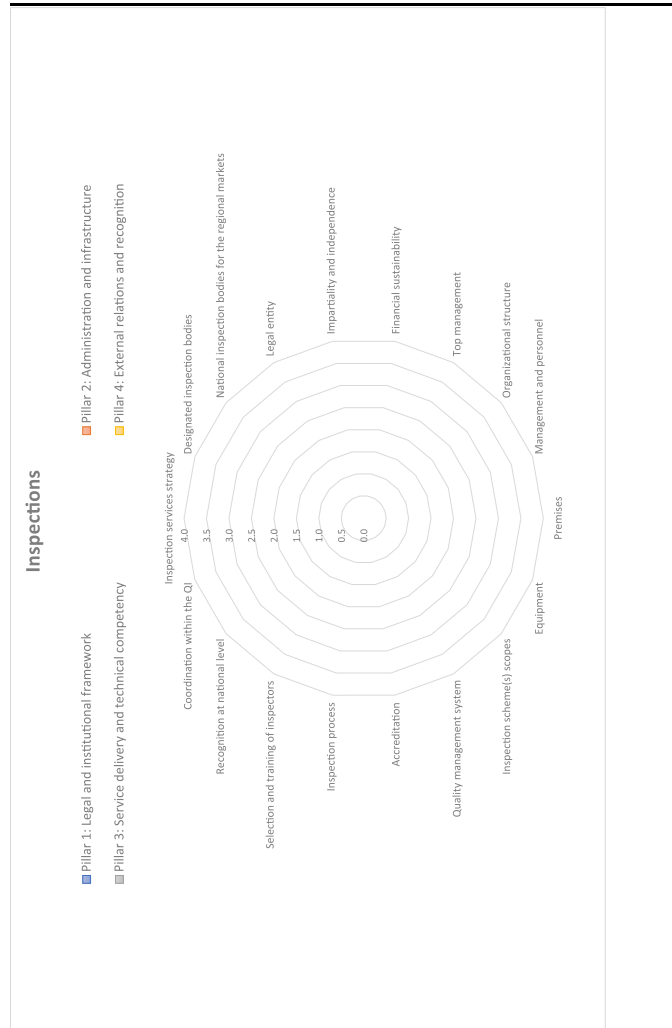
NOTE: BUILDING BLOCKS 1 TO 3 DEAL WITH THE INSPECTION SERVICES SITUATION OF THE COUNTRY AS A WHOLE, WHEREAS THE BUILDING BLOCKS 4 TO 18 ARE RELEVANT FOR AN INDIVIDUAL INSPECTION SERVICE ORGANIZATION					
Pillar 1: Legal and institutional framework, inspection service entity					
4) Legal entity	<ul style="list-style-type: none"> Relevant legislative instruments of ministries Relevant articles of incorporation 	The inspection body, whether from the public or private sector, is a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for the outcome of its inspection services.	Yes=4 In preparation=1 Unknown=0 Yes=1.5 Yes=1.5 Yes=1		
		a. Is the inspection body established as a legal entity, i.e., by legislation or by articles of incorporation? b. Have the following been provided for in the legislation or articles of incorporation? o Governance of the inspection body o Functions of the inspection body o Finances of the inspection body	(a-b)/2	0.0	
		The systems within the inspection body ensure that inspection activities are undertaken impartially and that commercial, financial, or other pressures do not compromise its impartiality.			
5) Impartiality and independence	<ul style="list-style-type: none"> Legislative instrument establishing the inspection body if relevant Articles of incorporation if relevant Government decisions or decrees if relevant Official organizational structure Annual reports of the inspection body 	a. Does the inspection body have a formal system in place to ensure that it is not involved in the design, manufacture, supply, or operation of the item to be inspected? b. Can the inspection body demonstrate that commercial, financial, or other pressures do not have an influence on its inspection decisions? c. Has the inspection body identified the risks to its impartiality related to its ownership, governance, shared resources, and payment of commissions? d. Has the inspection body implemented formal systems to counter the risks identified in (c) above?	Yes=4 Informal system=2 No=0 Yes=4 Demonstration difficult=2 No=0 Yes=4 In process of identifying the risks=2 No=0 Yes=4 Formal systems developed but not yet fully operational=2 Informal systems=1 No=0		
		The income from inspection services, industry financial support, and other sources are adequate to ensure the financial sustainability of the inspection body in the medium to long term.		0.0	
6) Financial sustainability	<ul style="list-style-type: none"> Annual government budget allocations Annual government fee prescriptions in the regulatory inspection domain Inspection body business plans Annual reports of the inspection body Monthly and annual financial statements of the inspection body 	a. Is the income from inspection services and additional funds from other sources adequate for the continued existence of the inspection body? o 100% of need covered o 85% of need covered o 70% of need covered o 50% of need covered o Less than 50% of need covered b. Is specific funding (e.g., income from inspection services, the government, or any other entity or entities or special fund) earmarked for the continued accreditation of the inspection body? c. Is a formal financial plan established for the medium term, i.e., the following 3-5 years?	Yes=4 Yes=3 Yes=2 Yes=1 Yes=0 Yes=4 Every year there is a shortfall=2 No=0 Yes=4 2-3 years=2 1 year=1 No=0		
		Aggregate score: Financial sustainability (a-b+c)/3		0.0	
Pillar 2: Administration and infrastructure					
7) Top management	<ul style="list-style-type: none"> Governance structure decisions and minutes Official top management job descriptions Agreed-upon top management key performance indicators 	An effective top management responsible for the technical management and for the quality and integrity of the inspection body's services is in place.			
		a. Does the inspection body have a top management dedicated to managing the affairs of the inspection body? b. Is the top management of the inspection body responsible for the following without undue interference from outside? o Operates as the link between the inspection body and the governance structure o Oversees the development, marketing, promotion, delivery, and quality of inspection services o Recommends the annual budget for approval and manages the inspection body resources within the approved budget o Oversees the identification of resource requirements and possible funding sources	Yes=4 Part of a bigger organization without its own top management=2 No=0 Yes=1 Yes=1 Yes=1		
		Aggregate score: Top management (a-b)/2		0.0	

		An organizational structure that optimally supports the inspection scopes of the inspection body is in place.			
				Yes=4 Integrated with other services (e.g. design, manufacturing) but separated=2 Integrated with other services=1 No=0	
8) Organizational structure	<ul style="list-style-type: none"> Approved organizational structure Governance structure decisions Financial system documentation 	<p>a. Irrespective of whether the inspection body is part of a larger organization, is it a clearly identifiable and separate entity responsible for all the inspection services within its defined scope?</p> <p>b. Does the inspection body have different divisions, each responsible for a specific inspection scope to facilitate accreditation?</p> <p>c. Are heads of laboratory appointed who take responsibility for the integrity of inspection services and countersign inspection reports?</p>	<p>Yes, each service clearly identifiable=4 Mostly, some are still mixed=2 No=0</p> <p>Yes=4 Mostly, some still need to be appointed=2 No=0</p>		
			Aggregate score: Organizational structure (a+b+c)/3	0.0	
		Management and personnel are employed who have the appropriate skill sets assured by appropriate training, qualifications, and experience for the management and technical knowledge required by the various inspection scopes of the inspection body.			
9) Management and personnel	<ul style="list-style-type: none"> Approved organizational structure Approved criteria for technical staff Actual staffing levels Staff turnover figures Selection, training, and monitoring records of inspectors 	<p>a. Are the approved managerial posts filled with persons complying fully with requirements specified in (c) below?</p> <p>b. Are the approved technical posts filled with persons complying fully with requirements specified in (d) below?</p> <p>c. Are the following formally defined for each of the managers in (a)?</p> <p>d. Are the following formally defined for each of the technical posts in (b)?</p>	<p>o 90–100% o 80–89% o 70–79% o 60–69% o < 60% o 90–100% o 80–89% o 70–79% o 60–69% o < 60% o Training and experience o Registration as a professional o Responsibilities o Key performance indicators o Training and experience o Registration as a professional o Responsibilities o Key performance indicators</p> <p>Yes=4 Yes=3 Yes=2 Yes=1 Yes=0</p> <p>Yes=4 Yes=3 Yes=2 Yes=1 Yes=0</p> <p>AI=1, Some=0.3 AI=1, Some=0.3 AI=1, Some=0.3 AI=1, Some=0.3 AI=1, Some=0.3 AI=1, Some=0.3 AI=1, Some=0.3 AI=1, Some=0.3</p>		
			Aggregate score: Management and personnel (a+b+c+d)/4	0.0	
10) Premises	<ul style="list-style-type: none"> Review of inspection body accommodation in the light of defined requirements 	<p>a. Is the inspection body housed in appropriate premises, i.e., it is easily accessible by clients (e.g., not in the middle of town with traffic problems) and has adequate parking (e.g., not haphazardly all over the sidewalk)?</p> <p>b. Is the inspection body housed in premises that allow for acceptable working conditions for employees (light, ventilation, temperature, space available, furniture, and so on)?</p> <p>c. Do the premises have adequate meeting rooms for discussions with customers?</p>	<p>Yes=4 Partially=2 No=0</p> <p>Yes=4 Needs upgrading=1 No=0</p> <p>Yes=4 Inadequate=1 No=0</p>		
			Aggregate score: Premises (a+b+c)/3	0.0	
11) Equipment	<ul style="list-style-type: none"> Consideration of effectiveness of the choice and acquisition of inspection equipment Consideration of the formal control system over inspection equipment, including maintenance and calibration intervals, and records Consideration of the validation and updating mechanisms and records of computer software Consideration of access control of the IT system 	<p>a. Is the appropriate IT system equipment available for administration of the inspection work and effective communication within the organization (e.g., desktop computers, digital projectors for meeting rooms, and so on)?</p> <p>b. Is an IT network available and operational for effective electronic communication to and from the outside world, especially through the internet?</p> <p>c. Is the appropriate internet presence in place, with an up-to-date website containing all relevant product certification scheme documentation and details of the certified companies?</p>	<p>Yes=4 Must be upgraded=2 Partially=1 No=0</p> <p>Yes=4 Must be upgraded=2 Partially=1 No=0</p> <p>Yes=4 Must be upgraded=2 Partially=1 No=0</p>		
			NOTE: Requirements for equipment for testing, which may be part of the inspection body function, are dealt with in the testing section. Aggregate score: Equipment (a+b+c)/3	0.0	

Pillar 3: Service delivery and technical competency				
	The inspection body must have a clear description of the inspection schemes it provides, including their applicability regarding national or international standards.			
12) Inspection scheme(s) scopes	a. Has the inspection body clearly defined the scope of the inspection schemes it wishes to offer?	Yes=4 In general, but not specific=2 No=0		
	b. Are the inspection schemes listed in (a) defined in terms of standards or technical regulations?	Yes, all of them=4 Mix of defined and general=2 No=0		
	c. Does the inspection body provide inspection services based on knowledge of the market demand?	Yes, proper market analysis done=4 Yes, based on general knowledge of market=2 Offer inspection services without much market knowledge=1 No=0		
		(a+b+c)/3	0.0	
13) Quality management system	An appropriate quality management system (e.g., ISO/IEC 17020 or similar) formalized in relevant quality system documentation is in place.			
	a. Has the inspection body implemented a formal quality management system (e.g., ISO/IEC 17020 or similar)?	Yes, externally evaluated=4 Yes, not externally evaluated=3 Being implemented=2 Being developed=1 No=0		
	b. Does the inspection body meet the requirements additional to the requirements of ISO/IEC 17020 imposed by the regulatory authorities for inspection services in the relevant regulatory domain regarding the quality management system?	Yes, externally evaluated=4 Yes, not externally evaluated=3 Being implemented=2 Being developed=1 No=0		
	c. Does the inspection body have formal systems in place to notify relevant regulatory authorities regarding nonconformities it uncovers during inspection work in the regulatory domain?	Yes=4 Yes, but informal=2 No=0		
		(a+b+c)/3	0.0	
14) Accreditation	The inspection body has been preassessed, subjected to the initial assessment, and accredited to ISO/IEC 17020.			
	a. Has the inspection body been preassessed to determine whether a formal quality management system is in place?	Yes, and all nonconformities have been addressed=4 Yes, but nonconformities are still being addressed=2 No=0		
	b. Has an initial assessment been conducted by the accreditation body regarding the quality management system documentation implementation and the operations of the inspection body?	Yes, and all the nonconformities have been addressed=4 Yes, but nonconformities are still being addressed=2 No=0		
	c. Has the inspection body been accredited to ISO/IEC 17020?	Yes, for all its scopes=4 Yes, for some of its scopes=3 Waiting for the accreditation body decision=2 No=0		
	d. Has the inspection body been designated by the relevant regulatory authority for rendering services in the regulatory domain?	Yes=4 No, but designation has been applied for=2 No=0		
		(a+b+c+d)/4	0.0	
Aggregate score: Accreditation				

15) Inspection process	<ul style="list-style-type: none"> Inspection body quality management and process documentation Standards and technical regulation requirements Inspection reports and records Inspector(s) records Inspection body website 	The approach and processes the inspection body follows complies with the technical inspection requirements for the product, process, or service as stated in standards, technical regulations, or other contractual documents, and they are in line with the requirements of ISO/IEC 17020 or similar standards used for its accreditation.			
		a. Does the inspection body have a system in place that ensures that inspection procedures as stated in the relevant standards, contracts, or in-house requirements of clients are followed?	Yes=4 Mostly, sometimes different methodologies are followed=2 No=0		
		b. When inspection procedures are not stated in the relevant standard or contained in contract documentation, does the inspection authority develop its own, fully documented procedures?	Yes, always=4 Most of the time=2 Procedures decided by inspector, not fully documented=1 No=0		
		c. Does the inspection body formally ensure that it has the necessary expertise and resources before accepting an inspection task?	Yes=4 Most of the time=2 No=0		
		d. Does the inspection body have formal procedures in place to ensure that samples taken for testing and inspection are properly identified and kept such that they do not deteriorate or get damaged?	Yes=4 Most of the time=2 No=0		
		Aggregate score: Inspection process inspections to be carried out.	(a+b+c+d)/4	0.0	
16) Selection and training of inspectors	<ul style="list-style-type: none"> Inspection body quality management and process documentation Standards and technical regulation requirements Inspector selection, training, and mentoring records 	The personnel responsible for inspections have appropriate qualifications, training, experience, and a satisfactory knowledge of the requirements of the			
		a. Does the inspection body have a formal system in place to ensure that inspectors are selected regarding their training and experience concomitant with the specific requirements of the product, its manufacture, and operation or the service to be inspected?	Yes=4 Mostly formal, but some informal elements inevitable=2 No=0		
		b. Does the inspection body monitor the performance of the inspectors to ensure continuous optimum performance?	Yes, all the time=4 Yes, at selected intervals in the year=2 Depend only on feedback from the customers=1 No=0		
		c. Does the inspection body ensure that the inspectors keep up-to-date with new technologies through continuous training and mentoring?	Company programmes in place for all inspectors=4 Left to inspectors to keep up themselves=2 No=0		
		Aggregate score: Selection and training of inspectors	(a+b+c)/3	0.0	
Pillar 4: External relations and recognition					
17) Recognition at national level	<ul style="list-style-type: none"> Official lists of accredited inspection bodies Official lists of regulatory authorities regarding designated inspection bodies 	Recognition at the national level is facilitated by accreditation to the relevant international standard (e.g., ISO/IEC 17020) followed by designation by a regulatory authority in the case of technical regulation, and by the market in the case of selecting an inspection body.			
		a. Has the inspection body been accredited to ISO/IEC 17020?	Yes, for all of its scopes=4 Yes, for a few of its scopes=2 No, but has applied for accreditation=1 No=0		
		b. Has the inspection body been designated by a regulatory authority for rendering services in specific regulatory domains?	Yes=4 No, but designation has been applied for=1 No=0		
		Aggregate score: Recognition at national level	(a+b)/2	0.0	
		Coordination between the inspection bodies of the country is based on activities managed through voluntary associations.			
18) Coordination within the QI	<ul style="list-style-type: none"> Regulatory authority policies, pronouncements, and documentation Inspection body association(s) documentation and minutes of meetings Technical regulation coordination office mandate and pronouncements 	a. Is an inspection body association established in the country with the following attributes?	o Voluntary membership o Coordination of practical training among members o Lobbying of government o Communication strategy to highlight value of technically competent inspection services	Yes=1 Yes=1 Yes=1 Yes=1	
		b. Is a technical regulation coordination office or similar actively coordinating the activities of inspection bodies within the regulatory domain?	Technical regulation office in the process of being established=1 No formal coordination takes place=0	Yes=4 Yes=1 Yes=1 Yes=4	
		Aggregate score: Coordination within the QI	(a+b)/2	0.0	

Inspection		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	0.0				
Impartiality and independence	0.0				
Financial sustainability	0.0				
Top management	0.0				
Organizational structure	0.0				
Management and personnel	0.0				
Premises	0.0				
Equipment	0.0				
Inspection scheme(s)					
scopes				0.0	
Quality management system				0.0	
Accreditation				0.0	
Inspection process				0.0	
Selection and training of inspectors				0.0	
Recognition at national level					0.0
Coordination within the QI					0.0



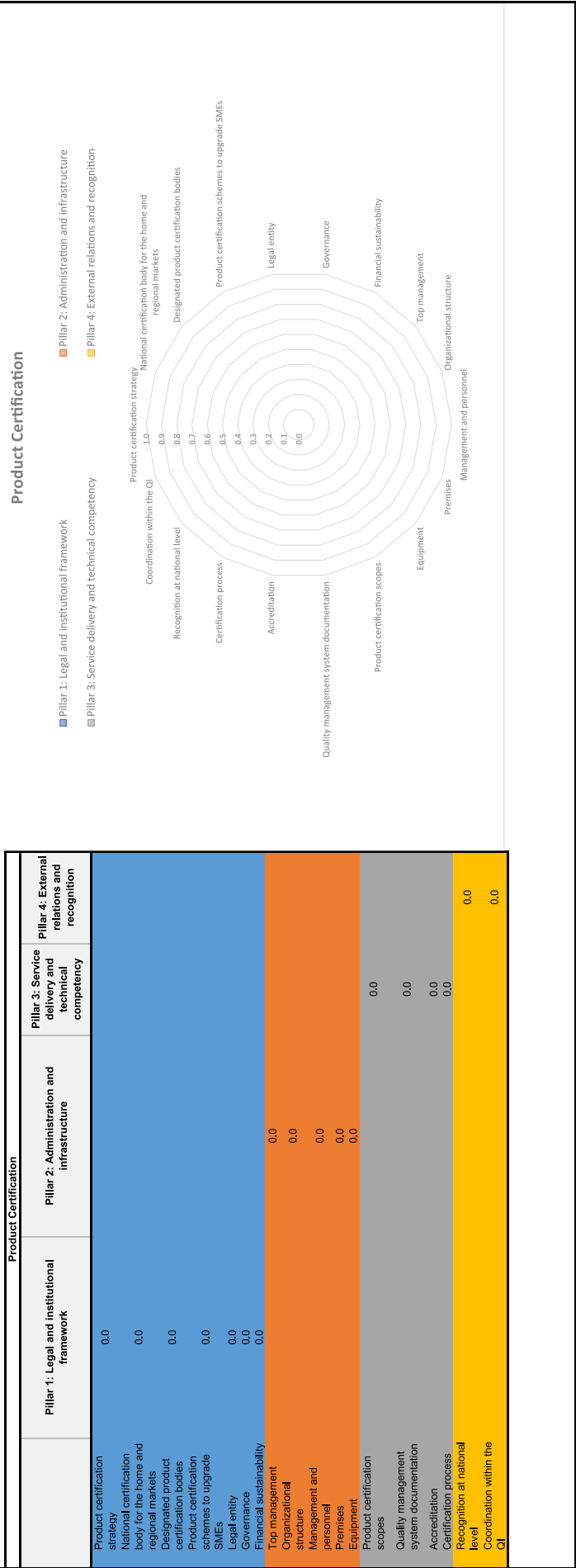
Product Certification					
Element	Information sources	Benchmark and questions	Scoring	Score	Comments: What is your score based on? Please provide information and links.
Legal and institutional framework, product certification sector					
1) Product certification strategy	<ul style="list-style-type: none"> Relevant government policies, strategies, and implementation plans Review of the extent of public sector certification body capacity and capabilities Government purchasing documentation Relevant ministry (e.g., Trade and Industry, Science and Technology, Health, Agriculture, and the like) websites 	A product certification strategy giving effect to the implementation of the quality policy regarding product certification services in the country is in place. It contains the government's responsibilities regarding a national product certification scheme, the liberalization of product certification services regarding regulatory measures, and the role of accreditation in demonstrating technical competency of product certification bodies.			
		a. Is a product certification strategy in place?	Yes=4 Developed, but not approved=2 Basic developed=1 No=0		
		b. Does the product certification strategy include all the necessary elements, namely: <ul style="list-style-type: none"> Provision for the establishment and maintenance of product certification in the public sector Provision for the liberalization of product certification in support of regulatory measures, i.e., private sector product certification given access in regulatory measures Accreditation as a measure of the technical competency of product certification in both the public and private sectors Building capacity in product certification to meet the need of the markets in the most innovative, effective, and efficient ways 	Yes=1 Yes=1 Yes=1 Yes=1		
		c. Is an implementation plan for the product certification strategy in place and being followed?	Yes=4 Developed, but not yet followed=2 Under development=1 No=0		
		Aggregate score: Product certification strategy (a+b+c)/3		0.0	
2) National certification body for the home and regional markets	<ul style="list-style-type: none"> Government export policies and strategies Recognition agreements between the government and regional common market authorities Market intelligence regarding relevant product certification in the regional common market Communication and advertising strategies to target the home and regional common markets 	Certification bodies providing product certification services for products for the local market and the regional common market are recognized by the relevant market and its authorities.			
		a. Does the NSB or another certification body operate a national product certification scheme?	Yes=4 No, but one is being established=1 No=0		
		b. Is the product certification body operating the national product certification scheme accredited to ISO/IEC 17065?	Yes=4 No, but accreditation has been applied for=1 No=0		
		c. Does the national product certification scheme enjoy a legal monopoly in the country, i.e., are other product certification schemes disallowed?	No=4 Others are allowed but none are available=2 Yes=0		
		d. Is the national product certification scheme formally recognized within the region through a multilateral recognition agreement (MRA) or regional legislation?	Yes, but scheme still has to be accredited=1 No=0		
		Aggregate score: National certification body for the home and regional market (a+b+c+d)/4		0.0	
3) Designated product certification bodies	<ul style="list-style-type: none"> Accreditation Act, decree, regulation, or similar, if relevant Relevant legislative instruments of ministries Official lists of designated certification bodies for the regulatory domain 	Product certification bodies mandated to provide product certification services in the regulatory domain should be designated by the relevant authorities based on their technical competence, i.e., accreditation, and their legal liability in the country.			
		a. Is a system of designating product certification bodies for regulatory purposes formalized in legislation and practiced in the country?	Yes=4 Practiced but not formalized in legislation=2 Ad hoc practice=1 No=0		
		b. Has the following been provided for in the legislation for the designation of product certification bodies? <ul style="list-style-type: none"> Designation of public sector and private sector product certification body possible Legal liability in the country is a precondition Local and foreign product certification bodies are included Details available on internet sites Name and contact details Scope of certification services for regulatory purposes Designating authority 	Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1		
		c. Are the details of designated product certification bodies publicly available?	Yes=1 No=0		
		Aggregate score: Designated product certification bodies (a+b+c)/3		0.0	

4) Product certification schemes to upgrade small and medium enterprises (SMEs)	<ul style="list-style-type: none"> Formal documentation of government support programs for the certification of products manufactured by SMEs Records of financial support to SMEs once certification has been granted Official lists of certified SMEs by certification bodies 	SMEs are supported through government programs to obtain product certification in order to upgrade the quality of their products.		Yes=4 No, but one is being established=1 No=0				
		a. Is a specific national product certification scheme available for SMEs to upgrade the quality of their products?		Yes=4 No, but a scheme is being implemented=1 No=0				
		b. Are consultancy services available to SMEs wishing to gain product certification?		Yes=4 No, but a scheme is being implemented=1 No=0				
		c. Does the government support the implementation of the national product certification scheme for SMEs in material ways, e.g., through use of product certification mark for state purchases, payback of fees, and so on?		Yes=4 No, but support is being planned=1 No=0				
		Aggregate score: Product certification schemes to upgrade SMEs (a+b+c)/3		0.0				
NOTE: BUILDING BLOCKS 1 TO 4 DEAL WITH THE PRODUCT CERTIFICATION SERVICES SITUATION OF THE COUNTRY AS A WHOLE, WHEREAS THE BUILDING BLOCKS 5 TO 18 ARE RELEVANT FOR AN INDIVIDUAL PRODUCT CERTIFICATION ORGANIZATION								
Pillar 1: Legal and institutional framework, product certification service entity								
5) Legal entity	<ul style="list-style-type: none"> Relevant legislative instruments of ministries Relevant articles of incorporation 	The product certification body, whether from the public or private sector, is a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for the outcome of its product certification services.		Yes=4 In preparation=1 Unknown=0				
		a. Is the product certification body established as a legal entity, i.e., by legislation or by articles of incorporation?		Yes=4 In preparation=1 Unknown=0				
		b. Have the following been provided for in the legislation or articles of incorporation?		Yes=1.5 o Governance of the product certification body o Functions of the product certification body o Finances of the product certification body Yes=1				
		Aggregate score: Legal entity (a+b)/2		0.0				
		The product certification body has a board or council with fiduciary responsibilities and that approves the product certification body strategy, consisting of members with specific knowledge regarding the product certification scope of the certification body and market realities.		Yes=4 Partially independent=1 No=0				
6) Governance	<ul style="list-style-type: none"> Legislative instrument establishing the certification body if relevant Articles of incorporation if relevant Government decisions or decrees if relevant Official organizational structure Annual reports of the certification body 	a. Is the governance of the product certification body vested in an independent board or council?		Yes=4 Partially independent=1 No=0				
		b. Do the board or council members have relevant knowledge and experience of the product certification scope of the certification body and its market?		Yes=4 Partially=2 No=0				
		c. Is the board or council of the product certification body solely responsible for the following?		Yes=1 o Business strategy or plan o Annual budget o Establishment of new business units o Appointment of the head of the product certification body Yes=1				
		Aggregate score: Governance (a+b+c)/3		0.0				
		The income from product certification, industry financial support, and other sources are adequate to ensure the financial sustainability of the product certification body in the medium to long term.		Yes=4 o 100% of need covered o 85% of need covered o 70% of need covered o 50% of need covered o Less than 50% of need covered Yes=4 Every year there is a shortfall=2 No=0				
7) Financial sustainability	<ul style="list-style-type: none"> Annual government budget allocations Certification body business plans Annual reports of the certification body Monthly and annual financial statements of the certification body 	a. Is the income from product certification services and additional funds from other sources adequate for the continued existence of the product certification body?		Yes=4 o 100% of need covered o 85% of need covered o 70% of need covered o 50% of need covered o Less than 50% of need covered Yes=4 Every year there is a shortfall=2 No=0				
		b. Is specific funding (e.g., income from product certification services, the government, or any other entity or entities or special fund) earmarked for the continued accreditation of the product certification body?		Yes=4 Every year there is a shortfall=2 No=0				
		c. Is a formal financial plan established for the medium term, i.e., the following 3-5 years?		Yes=4 1-3 years=2 No=0				
		Aggregate score: Financial sustainability (a+b+c)/3		0.0				
		The income from product certification, industry financial support, and other sources are adequate to ensure the financial sustainability of the product certification body in the medium to long term.		Yes=4 o 100% of need covered o 85% of need covered o 70% of need covered o 50% of need covered o Less than 50% of need covered Yes=4 Every year there is a shortfall=2 No=0				
Pillar 2: Administration and infrastructure								
8) Top management	<ul style="list-style-type: none"> Governance structure decisions and minutes Official top management job descriptions Agreed-upon top management key performance indicators 	An effective top management responsible for the technical management and for the quality and integrity of the product certification body's services is in place.		Yes=4 Part of a bigger organization without its own top management=2 No=0				
		a. Does the product certification body have a top management dedicated to managing the affairs of the product certification body?		Yes=4 Part of a bigger organization without its own top management=2 No=0				
		b. Is the top management of the product certification body responsible for the following without undue interference from outside?		Yes=1 o Operates as the link between the product certification body and the governance structure o Oversees the development, marketing, promotion, delivery, and quality of product certification services o Recommends the annual budget for approval and manages the product certification body resources within the approved budget o Oversees the identification of resource requirements and possible funding sources Yes=1				
		Aggregate score: Top management (a+b)/2		0.0				
		The income from product certification, industry financial support, and other sources are adequate to ensure the financial sustainability of the product certification body in the medium to long term.		Yes=4 o 100% of need covered o 85% of need covered o 70% of need covered o 50% of need covered o Less than 50% of need covered Yes=4 Every year there is a shortfall=2 No=0				

9) Organizational structure	<ul style="list-style-type: none"> Approved organizational structure Governance structure decisions Financial system documentation 	The product certification body's organizational structure has divisions that support its scopes of certification and complies with accreditation requirements such as an independent certification committee and an impartiality committee.	<p>a. Has the product certification body established separate divisions for its various scopes of certification to enhance technical competence and facilitate accreditation?</p> <p>b. Has the product certification body established an independent approvals committee as required by ISO/IEC 17065?</p> <p>c. Has the product certification body established an impartiality committee as required by ISO/IEC 17065?</p>	<p>Yes, clearly defined=4 Some smaller schemes mixed with larger schemes=2 No=0</p> <p>Yes, for all scopes=4 Not for all scopes=2 No=0</p> <p>Yes=4 No, in the process of establishment=1 No=0</p>		
		Aggregate score: Organizational structure (a+b+c)/3	0.0			
		Management and personnel are employed with the appropriate skill sets assured by appropriate training, qualifications, and experience for the management and technical knowledge required by the various product certification scopes of the product certification body.	<p>a. Are the approved managerial posts filled?</p> <p>o 90–100% o 80–89% o 70–79% o 60–69% o < 60% o 90–100% o 80–89% o 70–79% o 60–69% o < 60%</p> <p>b. Are the approved technical posts filled?</p> <p>o 90–100% o 80–89% o 70–79% o 60–69% o < 60%</p> <p>c. Are the responsibilities and key performance indicators (KPIs) of each of the managers in (a) formally defined?</p> <p>d. Are the responsibilities and key performance indicators (KPIs) of each of the technical posts in (b) formally defined?</p>	<p>Yes=4 Yes=3 Yes=2 Yes=1 Yes=0</p> <p>Yes=4 Yes=3 Yes=2 Yes=1 Yes=0</p> <p>Yes=4 Responsibilities yes, KPIs no=2 No=0</p> <p>Yes=4 Responsibilities yes, KPIs no=3 Partially=2 No=0</p>		
		Aggregate score: Management and personnel (a+b+c+d)/4	0.0			
		The product certification body occupies premises accessible to its customers, with minimum environmental disturbances and facilitating optimum service delivery.	<p>a. Is the product certification body housed in appropriate premises, i.e., it is easily accessible by clients (e.g., not in the middle of town with traffic problems) and has adequate parking (i.e., not haphazardly all over the sidewalks)?</p> <p>b. Is the product certification body housed in premises that allow for acceptable working conditions for employees (light, ventilation, temperature, space available, furniture, and so on)?</p> <p>c. Do the premises have adequate meeting rooms for discussions with customers?</p>	<p>Yes=4 Partially=2 No=0</p> <p>Yes=4 Needs upgrading=1 No=0</p> <p>Yes=4 Inadequate=1 No=0</p>		
11) Premises	<ul style="list-style-type: none"> Review of certification body accommodation in the light of defined requirements 	Aggregate score: Premises (a+b+c)/3	0.0			
		An effective and efficient intranet is available, and IT equipment (servers, computers, printers, digital projectors, and so on) is installed and maintained.	<p>a. Is the appropriate IT system equipment available for administration of the product certification work and effective communication within the organization (e.g., desktop computers, digital projectors for meeting rooms, and so on)?</p> <p>b. Is an IT network available and operational for effective electronic communication to and from the outside world, especially through the internet?</p> <p>c. Is the appropriate internet presence in place, with an up-to-date website containing all relevant product certification scheme documentation and details of the certified companies?</p>	<p>Yes=4 Must be upgraded=2 Partially=1 No=0</p> <p>Yes=4 Must be upgraded=2 Partially=1 No=0</p> <p>Yes=4 Must be upgraded=2 Partially=1 No=0</p>		
		Aggregate score: Equipment (a+b+c)/3	0.0			
		Consideration of effectiveness and efficiency of the IT system				
		Consideration of access control of the IT system				
12) Equipment	<ul style="list-style-type: none"> Consideration of effectiveness and efficiency of the IT system Consideration of access control of the IT system 	Aggregate score: Equipment (a+b+c)/3	0.0			
		Consideration of effectiveness and efficiency of the IT system				
		Consideration of access control of the IT system				
		Aggregate score: Equipment (a+b+c)/3	0.0			
		Consideration of effectiveness and efficiency of the IT system				

Pillar 3: Service delivery and technical competency				
		The scope of product certification services provided by the product certification body is clearly defined and based on market needs.		
13) Product certification scopes	<ul style="list-style-type: none"> Market needs Scope of certification 	a. Is the scope of product certification services offered by the product certification body clearly and formally defined?	Yes=4 Not defined in detail but generally indicated=2 No=0	
		b. Is the scope of certification based on demonstrable market needs?	Yes=4 Parts thereof, yes=2 Not known=0	
		c. Are the standards, national or international, on which the product certification scheme is based, clearly defined?	Yes=4 Not defined in detail but generally indicated=2 No=0	
		d. Is the type of product certification scheme, as defined in ISO/IEC 17067, clearly indicated for each of the product certification schemes?	Yes=4 No, but one of the ISO/IEC 17067 schemes is consistently followed=2 No=0	
			Aggregate score: Product certification scopes (a+b+c+d)/4	0,0
14) Quality management system documentation	<ul style="list-style-type: none"> Quality management documentation Internal audit results Management review records Accreditation records 	An appropriate quality management system (e.g., ISO/IEC 17065 or similar) formalized in relevant quality system documentation is in place.		
		a. Does the product certification body have a formal quality management system documentation (e.g., ISO/IEC 17065 or similar) implemented?	Yes, externally evaluated=4 Yes, not externally evaluated=3 Being implemented=2 Being developed=1 No=0	
		The product certification body has been preassessed, subjected to the initial assessment, and accredited to ISO/IEC 17065.	(a)	0,0
15) Accreditation	<ul style="list-style-type: none"> Accreditation application Assessment result of the quality management system documentation Preassessment record Records of the closure of nonconformities Initial assessment reports and records List of identified nonconformities Accreditation certificate Public records of accreditation body 	a. Has the product certification body been preassessed to determine whether or not a formal quality management system is in place?	Yes, and all nonconformities have been addressed=4 Yes, but nonconformities are still being addressed=2 No=0	
		b. Has an initial assessment been conducted by the accreditation body regarding the implementation of the quality management system documentation and the operations of the product certification body?	Yes, and all the nonconformities have been addressed=4 Yes, but nonconformities are still being addressed=2 No=0	
		c. Has the product certification body been accredited to ISO/IEC 17065?	Yes, for all its scopes=4 Yes, for some of its scopes=2 Waiting for the accreditation body decision=1 No=0	
		Aggregate score: Accreditation (a+b+c)/3	(a+b+c)/3	0,0
16) Certification process	<ul style="list-style-type: none"> Certification body quality management and process documentation Application records Audit reports and records Test reports and records Certification person(s) records Certification body website 	The processes the product certification body follows to certify a product comply with the requirements of ISO/IEC 17065 (or similar).		
		a. Does the application for product certification include the necessary information of the company to enable the product certification body to determine the scope of certification and prototype product testing as well as to appoint a team leader for the audit?	Yes=4 Yes, but some further information has to be obtained through communications=2 No=0	
		b. Does the product certification body evaluate the company's quality management system documentation for adequacy before arranging for an audit and prototype testing?	Yes=4 Audit and prototype testing arranged before the adequacy audit=1 No=0	
		c. Does the product certification body conduct a full audit on-site including the following?	<input type="checkbox"/> Implementation and effectiveness of the quality management system <input type="checkbox"/> Manufacturing controls <input type="checkbox"/> Inspection processes <input type="checkbox"/> Product testing processes	Yes=1 Yes=1 Yes=1 Yes=1
		d. Does the product certification body take samples of the products for prototype testing?	Yes=4 Company provides prepared samples=2 Company test results accepted=1 No=0	
		e. Do authorized persons or a committee totally independent of the audit team review the audit and test reports and decide whether to grant certification or not?	Yes=4 Decision made by team leader=1 No=0	
			Aggregate score: Certification process (a+b+c+d)/5	(a+b+c+d)/5

Pillar 4: External relations and recognition						
		The product certification body is recognized at the national level through accreditation and designation where relevant.				
17) Recognition at national level	<ul style="list-style-type: none">Official lists of accredited certification bodiesOfficial lists of regulatory authorities in respect of designated certification bodies	a. Is the product certification body's certification mark accepted by the regulatory agencies as evidence of product compliance with technical regulation requirements?	Yes, for all of its scopes=4 Yes, for a few of its scopes=2 No, but has applied for accreditation=1 No=0			
		b. Has the product certification body been designated by a regulatory authority for rendering services in specific regulatory domains?	Yes=4 No, but designation has been applied for=1 No=0			
		Aggregate score: Recognition at national level (a+b)/2			0.0	
		Coordination between the product certifications bodies of the country is based on activities managed through voluntary associations.				
18) Coordination within the QI	<ul style="list-style-type: none">Regulatory authority policies, pronouncements, and documentationCertification body association documentation and minutes of meetingsTechnical regulation coordination office mandate and pronouncements	a. Is a certification body association established in the country with the following attributes?	<ul style="list-style-type: none">o Voluntary membershipo Coordination of practical training among memberso Lobbying of governmento Communication strategy to highlight value of technically competent product certification services	Yes=1 Yes=1 Yes=1 Yes=1		
		b. Is a technical regulation coordination office or similar actively coordinating the activities of product certification bodies within the regulatory domain?	Yes=4 Technical regulation office being established=1 No formal coordination takes place=0			
		Aggregate score: Coordination within the QI (a+b)/2			0.0	



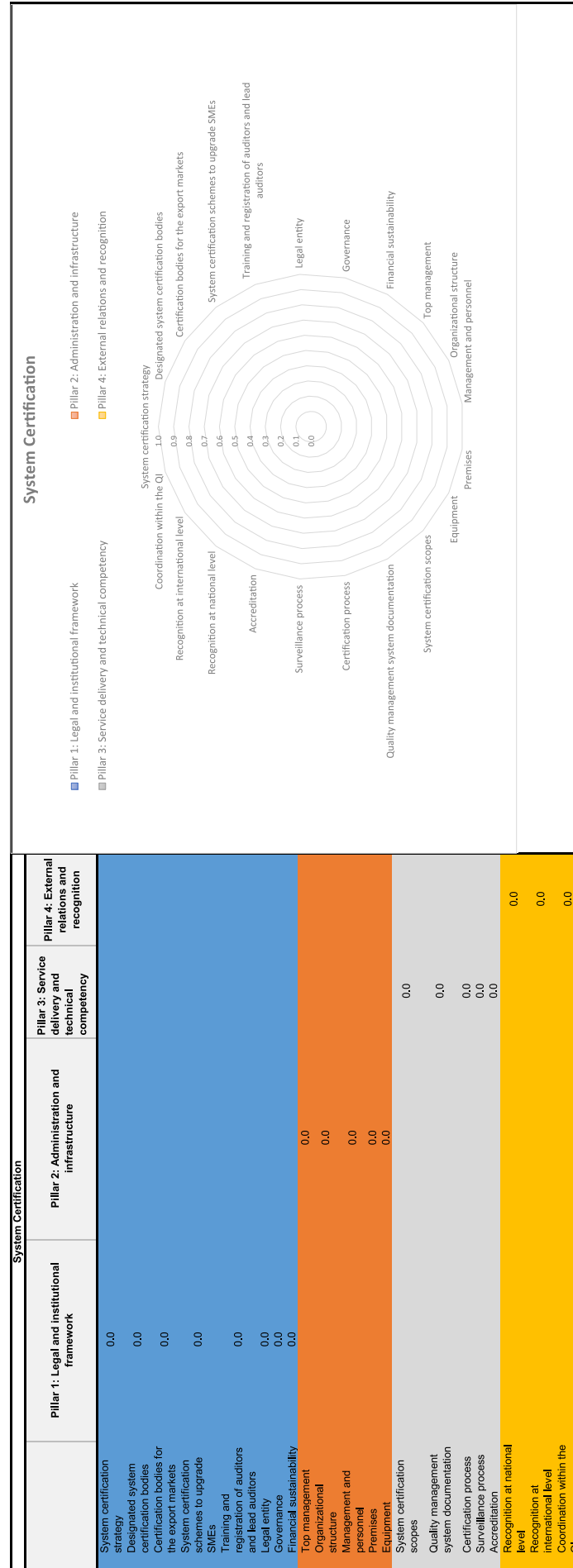
System Certification					
Element	Information sources	Benchmark and questions	Scoring	Score	Comments: What is your score based on? Please provide information and links.
Legal and institutional framework, system certification sector					
1) System certification strategy	• Relevant government policies, strategies, and implementation plans • Review of the extent of public sector certification body capacity and capabilities • Relevant ministry (e.g. Trade and Industry, Science and Technology, and so on) websites	A system certification strategy giving effect to the implementation of the quality policy regarding system certification services in the country is in place. It contains the government's responsibilities regarding a national system certification scheme, the liberalization of system certification services regarding regulatory measures, and the role of accreditation in demonstrating the technical competency of system certification bodies.			
		a. Is a system certification strategy in place?	Yes=4 Developed, but not approved=2 Being developed=1 No=0		
		b. Does the system certification strategy include all the necessary elements, namely o Priorities for the establishment and maintenance of system certification in the public sector o Provision for the liberalization of system certification in support of regulatory measures, i.e., private sector system certification given access in regulatory measures o Accreditation as a measure of the technical competency of system certification in both the public and private sectors o Building capacity in system certification to meet the needs of the markets in the most innovative, effective, and efficient ways	Yes=1 Yes=1 Yes=1 Yes=1 Yes=4 Developed, but not yet followed=2 Under development=1 No=0		
		c. Is an implementation plan for the system certification strategy in place and being followed?	Yes=1 Yes=4 Developed, but not yet followed=2 Under development=1 No=0		
		Aggregate score: System certification strategy (a+b+c)/3			0.0
2) Designated system certification bodies	• Accreditation Act, decree, regulation, or similar if relevant • Relevant legislative instruments of ministries • Official lists of designated certification bodies for the regulatory domain	System certification bodies mandated to provide system certification services in the regulatory domain are designated by the relevant authorities based on their technical competence (i.e., accreditation) and their legal liability in the country.			
		a. Is a system of designating system certification bodies for regulatory purposes formalized in legislation and practiced in the country?	Yes=4 Practiced but not formalized in legislation=2 Ad hoc practice=1 No=0		
		b. Has the following been provided for in the legislation for the designation of system certification bodies? o Designation of public sector and private sector system certification body possible o Accreditation is a precondition for designation o Legal liability in the country is a precondition o Local and foreign system certification bodies are included o Details available on internet sites o Name and contact details o Scope of certification services for regulatory purposes o Designating authority	Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1		
		c. Are the details of designated test laboratories publicly available?	Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1		
		Aggregate score: Designated system certification bodies (a+b+c)/3			0.0
3) Certification bodies for the export markets	• Government export policies and strategies • Recognition agreements between the government and export market authorities • Market intelligence regarding relevant system certification in the export markets	System certification bodies providing system certification services for major exporting companies are recognized by the export market and its authorities.			
		a. Are the export sectors of the country for which system certification is a prerequisite to export successfully, clearly identified?	Knowledge complete=4 Known in part=2 Knowledge incidental=1 No=0		
		b. Are the system certification requirements for each of the identified export sectors known, e.g. ISO 9001, HACCP, GLOBAL G.A.P., and so on?	Knowledge complete=4 Known in part=2 Knowledge incidental=1 No=0		
		c. Has the country established formal projects to develop the required system certification capacity, as detailed in (b) above, as well as the concomitant capacity for their accreditation?	Yes=4 Ad hoc projects=2 Left to market=1 No=0		
		Aggregate score: Certification bodies for the export markets (a+b+c)/3			0.0
4) System certification schemes to upgrade small and medium enterprises (SMEs)	• Formal documentation of government support programs for the certification of SMEs • Records of certification bodies • Records of financial support to SMEs once certification has been granted • Official lists of certified SMEs by certification bodies	SMEs are supported through government programs to obtain system certification in order to upgrade the quality of their systems and services.			
		a. Is a national scheme in place for SMEs to implement quality management systems and obtain certification?	Yes=4 No, but one is being established=1 No=0		
		b. Are consultancy services available to SMEs wishing to gain system certification?	Yes=4 No, but a scheme is being implemented=1 No=0		
		c. Does the government support the SMEs in material ways to implement quality management schemes and obtain certification, e.g., through use of system certification for state purchases, payback of fees, and so on?	Yes=4 No, but support is being planned=1 No=0		
		Aggregate score: System certification schemes to upgrade SMEs (a+b+c)/3			0.0

<p>5) Training and registration of auditors and lead auditors</p>	<ul style="list-style-type: none"> Public information of relevant multinational auditor registration schemes Public information of the national auditor registration scheme 	<p>Auditors and lead auditors for system certifications audits are appropriately trained, gain relevant experience, and are registered as such.</p> <p>a. Are quality management system auditor and lead auditor training schemes available in the country?</p> <p>b. Is a national scheme established by government or through an association of certification bodies available and used for the registration of quality management system auditors and lead auditors?</p> <p>c. Are mechanisms in place to ensure that the auditors and lead auditors, once registered, maintain their registration through appropriate auditing activities?</p>	<p>Able to meet demand=4 Just one or two, cannot meet demand=2 No=0</p> <p>Yes=4 Only foreign schemes are utilized=2 No=0</p> <p>Yes=4 Left to the certification bodies=2 No=0</p>			<p>0.0</p>
<p>NOTE: BUILDING BLOCKS 1 TO 5 DEAL WITH THE SYSTEM CERTIFICATION SERVICES SITUATION OF THE COUNTRY AS A WHOLE, WHEREAS THE BUILDING BLOCKS 6 TO 21 ARE RELEVANT FOR AN INDIVIDUAL SYSTEM CERTIFICATION ORGANIZATION</p>						
<p>Pillar 1: Legal and institutional framework, system certification service entity</p>						
<p>6) Legal entity</p>	<ul style="list-style-type: none"> Relevant legislative instruments of ministries Relevant articles of incorporation 	<p>The system certification body, whether from the public or private sector, is a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for the outcome of its system certification services.</p> <p>a. Is the system certification body established as a legal entity, i.e., by legislation or by articles of incorporation?</p> <p>b. Have the following been provided for in the legislation or articles of incorporation?</p> <ul style="list-style-type: none"> Governance of the system certification body Functions of the system certification body Finances of the system certification body 	<p>Yes=4 In preparation=1 Unknown=0</p> <p>Yes=1.5 Yes=1.5</p>			<p>0.0</p>
<p>7) Governance</p>	<ul style="list-style-type: none"> Legislative instrument establishing the certification body if relevant Articles of incorporation if relevant Government decisions or decrees if relevant Official organizational structure Annual reports of the certification body 	<p>The system certification body has a board or council with fiduciary responsibilities and that approves the system certification body strategy, consisting of members with specific knowledge regarding the system certification scope of the certification body and market realities.</p> <p>a. Is the governance of the system certification body vested in an independent board or council?</p> <p>b. Do the board or council members have relevant knowledge and experience of the system certification scope of the certification body and its market?</p> <p>c. Is the board or council of the system certification body solely responsible for the following?</p> <ul style="list-style-type: none"> Business strategy or plan Annual budget Establishment of new business units Appointment of the head of the system certification body 	<p>Yes=4 Partially independent=1 No=0</p> <p>Yes=4 Partially=2 No=0</p> <p>Yes=1 Yes=1 Yes=1</p>			<p>0.0</p>
<p>8) Financial sustainability</p>	<ul style="list-style-type: none"> Annual government budget allocations Certification body business plans Annual reports of the certification body Monthly and annual financial statements of the certification body 	<p>The income from system certification, industry financial support, and other sources is adequate to ensure the financial sustainability of the system certification body in the medium to long term.</p> <p>a. Is the income from system certification services and additional funds from other sources adequate for the continued existence of the system certification body?</p> <p>b. Is specific funding (e.g., income from system certification services, the government, or any other entity or entities or special fund) earmarked for the continued accreditation of the system certification body?</p> <p>c. Is a formal financial plan established for the medium term, i.e., the following 3–5 years?</p>	<p>Yes=4 100% of need covered 85% of need covered 70% of need covered 50% of need covered Less than 50% of need covered</p> <p>Yes=4 2-3 years=2 1 year only=1 No=0</p>			<p>0.0</p>
<p>Aggregate score: Financial sustainability (a+b+c)/3</p>						

Pillar 2: Administration and infrastructure				
9) Top management	<ul style="list-style-type: none"> Governance structure decisions and minutes Official top management job descriptions Agreed-upon top management key performance indicators 	An effective top management responsible for the technical management and for the quality and integrity of the system certification body's services is in place.	a. Does the system certification body have a top management dedicated to managing the affairs of the system certification body?	Yes=4 Part of a bigger organization without its own top management=2 No=0
			b. Is the top management of the system certification body responsible for the following without undue interference from outside?	Yes=1 Yes=1 Yes=1 Yes=1
			Aggregate score: Top management (a+b)/2	
			0.0	
10) Organizational structure	<ul style="list-style-type: none"> Approved organizational structure Governance structure decisions Financial system documentation 	The system certification body's organizational structure has divisions that support its scopes of certification and complies with accreditation requirements such as an independent certification committee and an impartiality committee.	a. Has the system certification body established separate divisions for its various scopes of certification to enhance technical competence and facilitate accreditation, e.g. ISO 9001, ISO 14001, HACCP, and so on?	Yes, clearly defined=4 Some smaller schemes mixed with larger schemes=2 No=0
			b. Has the system certification body established an independent approvals committee as required by ISO/IEC 17021?	Yes, for all scopes=4 Not yet for all scopes=2 No=0
			c. Has the system certification body established an impartiality committee as required by ISO/IEC 17021?	Yes=4 No, in the process of establishment=1 No=0
			Aggregate score: Organizational structure (a+b+c)/3	
11) Management and personnel	<ul style="list-style-type: none"> Approved organizational structure Approved criteria for technical staff Actual staffing levels Staff turnover figures Registration records of auditors and lead auditors 	Management and personnel are employed who have the appropriate skill sets assured by appropriate training, qualifications, and experience for the management and technical knowledge required by the various system certification scopes of the system certification body.	a. Are the approved managerial posts filled?	Yes=4 Yes=3 Yes=2 Yes=1 Yes=0
			b. Are the approved technical posts filled?	Yes=4 Yes=3 Yes=2 Yes=1 Yes=0
			c. Are the skill sets, responsibilities, and key performance indicators (KPIs) of each of the managers in (a) formally defined and applied?	Not for all posts=2 Skill sets and responsibilities yes, KPIs no=1 No=0
			d. Are the skill sets, responsibilities, and key performance indicators (KPIs) of each of the technical posts in (b) formally defined and applied?	Yes=4 Not for all posts=2 Skill sets and responsibilities yes, KPIs no=1 No=0
12) Premises	<ul style="list-style-type: none"> Review of certification body accommodation in the light of defined requirements. 	The system certification body occupies premises accessible to its customers, with minimum environmental disturbances and facilitating optimum service delivery.	Aggregate score: Management and personnel (a+b+c+d)/4	
			0.0	
			a. Is the system certification body housed in appropriate premises, i.e., it is easily accessible by clients (e.g., not in the middle of town with traffic problems) and has adequate parking (e.g., not haphazardly all over the sidewalk)?	Yes=4 Partially=2 No=0
			b. Is the system certification body housed in premises that allow for acceptable working conditions for employees (light, ventilation, temperature, space available, furniture, and so on)?	Needs upgrading=1 No=0 Yes=4 Inadequate=1 No=0
		Do the premises have adequate meeting rooms for discussions with customers?	Aggregate score: Premises (a+b+c)/3	
			0.0	

13) Equipment	<ul style="list-style-type: none"> Consideration of effectiveness and efficiency of the IT system Consideration of access control of the IT system 	An effective and efficient intranet is available, and IT equipment (servers, computers, printers, digital projectors, and so on) is installed and maintained.	Yes=4 Must be upgraded=2 Partially=1 No=0		
		a. Is the appropriate IT system equipment available for administration of the system certification work and effective communication within the organization (e.g., desktop computers, digital projectors for meeting rooms, and so on)?	Yes=4 Must be upgraded=1 No=0		
		b. Is an IT network available and operational for effective electronic communication to and from the outside world, especially through the internet?	Yes=4 Must be upgraded=1 No=0		
		c. Is the appropriate internet presence in place, with an up-to-date website containing all relevant system certification scheme documentation and details of the certified companies?	Yes=4 Must be upgraded=2 Partially=1 No=0		
		Aggregate score: Equipment (a+b+c)/3		0.0	
Pillar 3: Service delivery and technical competency					
14) System certification scopes	<ul style="list-style-type: none"> Quality management system documentation Internal audit results Certification body website Management review records and brochures Accreditation records 	The scope of system certification services provided by the system certification body is clearly defined and based on market needs.	Yes=4 Not defined in detail but generally indicated=2 No=0		
		a. Is the scope of system certification services offered by the system certification body clearly and formally defined?	Yes=4 Not defined in detail but generally indicated=2 No=0		
		b. Is the scope of certification based on demonstrable market needs?	Yes=4 Parts thereof, yes=2 Not known=0 No=0		
		c. Are the standards, national or international, on which the system certification schemes are based clearly defined?	Yes=4 Not defined in detail but generally indicated=2 No=0		
		Aggregate score: system certification scopes (a+b+c)/3		0.0	
15) Quality management system documentation	<ul style="list-style-type: none"> Quality management documentation Internal audit results Management review records Accreditation records 	An appropriate quality management system (e.g., ISO/IEC 17021 or similar) formalized in relevant quality system documentation is in place.	Yes, externally evaluated=4 Yes, not externally evaluated=3 Being implemented=2 Being developed=1 No=0		
		a. Does the system certification body have a formal quality management system, as required for accreditation (e.g., ISO/IEC 17021 or similar), implemented?	Yes, externally evaluated=4 Yes, not externally evaluated=3 Being implemented=2 Being developed=1 No=0		
		Aggregate score: Quality management system documentation (a)		0.0	
		The system certification body has been preassessed, subjected to the initial assessment, and accredited to ISO/IEC 17021.	Yes, and all nonconformities have been addressed=4 Yes, but nonconformities are still being addressed=2 No=0		
		a. Has the system certification body been preassessed to determine whether a formal quality management system is in place?	Yes, and all nonconformities have been addressed=4 Yes, but nonconformities are still being addressed=2 No=0		
16) Accreditation	<ul style="list-style-type: none"> Accreditation application Assessment result of the quality management system documentation Preassessment record Initial assessment reports and records List of identified nonconformities Records of closure of nonconformities Accreditation certificate Public records of accreditation body 	Has an initial assessment been conducted by the accreditation body regarding the implementation of the quality management system documentation and the operations of the system certification body?	Yes, and all the nonconformities have been addressed=4 Yes, but nonconformities are still being addressed=2 No=0		
		b. Has an initial assessment been conducted by the accreditation body regarding the implementation of the quality management system documentation and the operations of the system certification body?	Yes, and all the nonconformities have been addressed=4 Yes, but nonconformities are still being addressed=2 No=0		
		c. Has the system certification body been accredited to ISO/IEC 17021?	Yes, for all its scopes=4 Yes, for some of its scopes=3 Waiting for the accreditation body decision=1 No=0		
		Aggregate score: Accreditation (a+b+c)/3		0.0	
		The processes the system certification body follows to certify a system comply with the requirements of ISO/IEC 17021 (or similar) and IAF guidance documents.	Yes=4 Audit and prototype testing arranged before the adequacy audit=1 No=0		
17) Certification process	<ul style="list-style-type: none"> Certification body quality management and process documentation Application records Audit reports and records Certification committee records Certification body website 	a. Stage 1 audit: Does the system certification body evaluate the company's quality management system documentation for adequacy before arranging for an audit?	Yes=4 Audit and prototype testing arranged before the adequacy audit=1 No=0		
		b. Stage 2 audit: Does the system certification body conduct a full audit on-site to determine whether the applicant's quality management system has been implemented and is fully effective?	Yes=4 Partially=2 No=0		
		c. Certification: Do authorized persons or a committee totally independent of the audit team review the audit and test reports and decide whether to grant certification or not?	Yes=4 Decision made by team leader=1 No=0		
		Aggregate score: Certification process (a+b+c)/3		0.0	
		Aggregate score: Certification process (a+b+c)/3		0.0	

18) Surveillance process		The process the system certification body follows after certification (e.g., surveillance and recertification) complies with the requirements of ISO/IEC 17021 (or similar) and IAF guidance documents.	a. Does the system certification body provide its certified companies details on a publicly accessible website that is up-to-date?	Yes, up-to-date=4		
				Yes, but information needs updating=2		
				Information available on request=1		
				No=0		
				Yes=4		
		b. Surveillance audits: Does the system certification body conduct surveillance audits at least twice a year to determine continued compliance with requirements?	Some surveillance audits done once a year=3			
			Ad hoc surveillance audits=2			
			Only when complaints are received=1			
			No=0			
			Yes, always=4			
		c. Recertification audit: Does the system certification body conduct a recertification audit similar to the Stage 2 audit in the third year after certification to renew the certificate for another three years?	Only after the first cycle=2			
			Depend on surveillance audit results for recertification=1			
			No=0			
			Aggregate score: Surveillance process (a+b+c)/3			0.0
Pillar 4: External relations and recognition						
19) Recognition at national level	<ul style="list-style-type: none">Official lists of accredited certification bodiesOfficial lists of regulatory authorities regarding designated certification bodies	The system certification body is recognized at the national level through accreditation and designation where relevant.	a. Has the system certification body been accredited to ISO/IEC 17021?	Yes, for all of its scopes=4		
				Yes, for a few of its scopes=2		
				No, but has applied for accreditation=1		
				No=0		
				Yes=4		
		b. Has the system certification body been designated by a regulatory authority for rendering services in specific regulatory domains?	No, but designation has been applied for=1			
			No=0			
			Aggregate score: Recognition at national level (a+b)/2			0.0
20) Recognition at international level	<ul style="list-style-type: none">System certification strategy and its implementation plansIAF membership dataOther international recognition systems relevant to the country	The system certification body is recognized at the international level through accreditation to ISO/IEC 17021 and arrangements with private sector certification schemes such as Fairtrade, FSC, MSC, and others as relevant for the country's export sector.	a. Has the system certification body been accredited to ISO/IEC 17021 by an internationally recognized accreditation body?	Yes=4		
				No, but has applied for accreditation=1		
				No=0		
				Yes=4		
				No, but is in the process of doing so=1		
		b. Has the system certification body negotiated cooperative ventures to conduct audits on behalf of private sector certification schemes such as Fairtrade, FSC, MSC, and others as needed by the local industry?	No=0			
			Aggregate score: International recognition (a+b)/2			0.0
21) Coordination within the QI	<ul style="list-style-type: none">Regulatory authority policies, pronouncements, and documentationCertification body association documentation and minutes of meetingsTechnical regulation coordination office mandate and pronouncements	Coordination between the system certification bodies of the country is based on activities managed through voluntary associations.	a. Is a system certification body association established in the country with the following attributes?	o Voluntary membership		
				o Coordination of practical training among members		
				o Lobbying of government		
				o Communication strategy to highlight value of technically competent system certification services		
				Yes=1		
		b. Is a technical regulation coordination office or similar actively coordinating the activities of system certification bodies within the regulatory domain?	Yes=4			
			Technical regulation office being established=1			
			No formal coordination takes place=0			
			Aggregate score: Coordination within the QI (a+b)/2			0.0



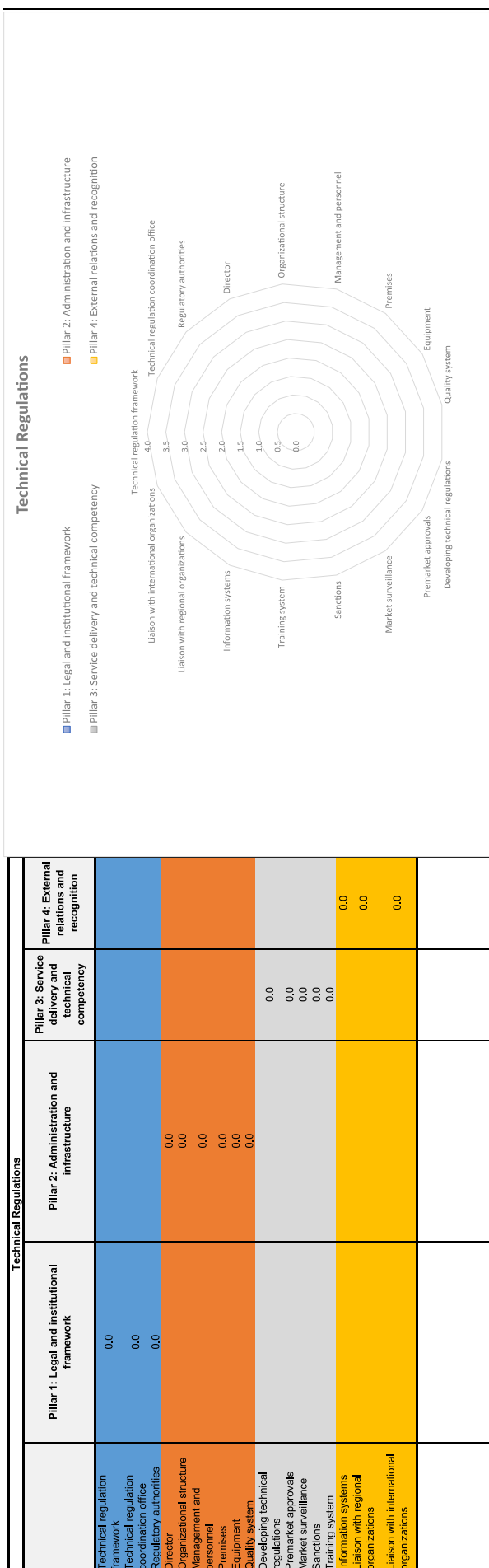
Technical Regulations					
Element	Information sources	Benchmark and questions	Scoring	Score	Comments: What is your score based on? Please provide information and links.
Pillar 1: Legal and institutional framework					
1) Technical regulation framework	<ul style="list-style-type: none"> Relevant legislative instruments, e.g., Acts of Parliament WTO TBT notifications of the country Relevant ministry papers <p>NOTE: Compulsory or mandatory standards are considered to be technical regulations under the WTO TBT Agreement and should be fully considered when completing this questionnaire.</p>	A technical regulation framework enshrined in legislation provides guidance for all the modalities of the development and implementation of technical regulations across all ministries and regulatory authorities at the national, provincial, or local levels.	Yes=4 Applicable only to some authorities=2 Developed, but not yet promulgated=2 Being developed=1 No=0		
		a. Is a technical regulation framework (however named) applicable to all authorities developing and implementing technical regulations on the statute books? NOTE: If your answer is No, please indicate "No" for all responses of question (b) below.			
		b. Does the technical regulation framework include all the necessary elements, namely: o Conducting an appropriate regulatory impact assessment (RIA) before promulgation of a technical regulation o The use of international, regional, or national standards as the basis of technical regulation o The utilization of technically competent and designated conformity assessment service providers o The responsibilities of regulatory authorities regarding premarket approvals, in-market surveillance, and the imposition of sanctions	Yes=1 Yes=1 Yes=1 Yes=1		
		c. Does the technical regulation framework comply with WTO TBT Agreement requirements, and has it been notified to the WTO TBT Secretariat?	Yes on both counts=4 If on both counts but has not been notified=2 Unknown=1 No=0 Aggregate score: Technical regulation framework (a+b+c)/3	0.0	
2) Technical regulation coordination office	<ul style="list-style-type: none"> Technical Regulation Framework Act or similar Technical regulation coordination office records 	A technical regulation coordination office (however named) is established at the highest political level to coordinate technical regulation activities of the regulatory authorities among each other and with the QI service providers.	Yes, and placed above a ministry level=4 Yes, but placed in a ministry=2 Establishment being planned=1 No=0		
		a. Has a technical regulation coordination office (however named) been established and been placed in the highest possible administrative level in government?	Yes=1 Yes=1 Yes=1 Yes=1		
		b. Do the responsibilities of the technical regulation coordinating office include the following? o Coordination of the responsibilities or regulatory authorities to minimize overlaps and gaps o Coordination between the regulatory authorities and the QI institutions o Review of draft technical regulation for compliance with the technical regulation framework before they are promulgated o Oversight of a program to review all current technical regulations on the statute books for compliance with the technical regulation framework	Yes=1 Yes=1 Yes=1 Yes=1		
		The regulatory authorities are recognized and known entities, and their sphere of responsibility is clearly defined to minimize regulatory overlaps and gaps.	Aggregate score: Technical regulation coordination office (a+b)/2	0.0	
3) Regulatory authorities	<ul style="list-style-type: none"> Technical regulation legislation Official ministerial decisions National TBT Enquiry Point information 	a. Are all the regulatory authorities known, and is their detail publicly accessible?	A comprehensive list is available on a government website=4 They are known within each ministry, but no comprehensive list is available=1 No publicly available information is available=0		
		b. Does the government have a formal process in place to ensure that there is no overlap in responsibilities among the various regulatory authorities regarding the products and services they are responsible for?	A continuous coordination function ensures no overlap=4 Coordination within relevant ministries only=1 No=0		
		c. Are the responsibilities of every regulatory authority clearly articulated in the relevant legislative instruments regarding premarket and in-market surveillance activities (e.g., premarket approval, market surveillance, and imposition of sanctions) without institutional overlaps?	Yes=4 Mostly with some gaps=2 Not known =1 No=0		
		Aggregate score: Regulatory authorities (a+b+c)/3		0.0	

Pillar 2: Administration and infrastructure						
4) Director	<ul style="list-style-type: none"> Relevant technical regulation legislation Official ministerial decisions Agreed-upon director's key performance indicators 	<p>The regulatory authority is managed by a responsible individual (director or other title) who has the authority to ensure compliance of products in the marketplace falling within the scope of the technical regulations for which the regulatory authority is responsible.</p> <p>a. Does the regulatory authority have a responsible individual (director or other title) dedicated to managing the affairs of the regulatory authority?</p> <p>b. Is the responsible individual (director or other title) of the regulatory authority responsible for the following without undue interference from outside?</p> <ul style="list-style-type: none"> Operates as the link between the regulatory authority and the relevant line ministry Oversees the development, delivery, and quality of regulatory activities Recommends the annual budget for approval and manages the regulatory authority resources within the approved budget Keeps track of potential and actual problem areas in the marketplace in relation to the technical regulations and ensures their speedy resolution 	<p>Yes=4 Part of a bigger organization without its own responsible individual or director=2 No=0</p> <p>Yes=1 Yes=1 Yes=1 Yes=1</p> <p>Aggregate score: Director (a+b)/2</p> <p>0.0</p>			
5) Organizational structure	<ul style="list-style-type: none"> Approved organizational structure Ministry decisions Ministerial decisions Financial system documentation 	<p>The organizational structure of the regulatory authority facilitates the effective and efficient execution of all technical regulations it is responsible for, and it has divisions that optimally support the regulatory subject fields.</p> <p>a. Has the regulatory authority established divisions in accordance with the product categories and their service requirements such as premarket approval, market surveillance, and imposition of sanctions?</p> <p>b. Has the regulatory authority established a presence close to the marketplace (e.g., provincial or local inspection offices) for optimum market surveillance activities?</p> <p>c. Has the regulatory authority the following relevant support functions?</p> <ul style="list-style-type: none"> Financial services Human resources function Trading function Legal function with resident lawyers 	<p>Yes=4 Partially=2 No=0</p> <p>Yes, throughout the country=4 Partially, some areas still to be established=2 Only the head office is operational=1</p> <p>No=0 Yes=1 Yes=1 Yes=1 Yes=1</p> <p>Aggregate score: Organizational structure (a+b+c)/3</p> <p>0.0</p>			
6) Management and personnel	<ul style="list-style-type: none"> Approved organizational structure Training records of staff Appointment and withdrawal records of inspector certificates Actual staffing levels Staff turnover figures 	<p>Management and personnel are employed with the appropriate skill sets assured by appropriate training, qualifications, and experience for the management and technical knowledge required by the technical regulation scopes with specific emphasis on inspectors.</p> <p>a. Are the approved managerial posts filled?</p> <ul style="list-style-type: none"> 90–100% 80–89% 70–79% 60–69% 50–59% 40–39% 30–29% 20–19% 10–9% 0–9% <p>b. Are the approved technical posts filled?</p> <ul style="list-style-type: none"> 90–100% 80–89% 70–79% 60–69% 50–59% 40–39% 30–29% 20–19% 10–9% 0–9% <p>c. Are the skill sets, responsibilities, and key performance indicators (KPIs) of each of the managers in (a) formally defined and applied?</p> <p>d. Are the skill sets, responsibilities, and key performance indicators (KPIs) of each of the technical posts in (b), with specific emphasis on inspectors, formally defined and applied?</p>	<p>Yes=4 Yes=3 Yes=2 Yes=1 Yes=0 Yes=4 Yes=3 Yes=2 Yes=1 Yes=0 Yes=4 Not for all posts=2 Skill sets and responsibilities yes, KPIs no=1 No=0</p> <p>Yes=4 Not for all posts=2 Skill sets and responsibilities yes, KPIs no=1 No=0</p> <p>Aggregate score: Management and personnel (a+b+c+d)/4</p> <p>0.0</p>			
7) Premises	<ul style="list-style-type: none"> Consideration of the regulatory authority premises in relation to design, environmental controls, access, and maintenance Review of laboratories and environmental controls Review of office space and meeting rooms Technical requirements as advised by experts in specific technical regulation fields 	<p>Appropriate accommodation for head office staff and technical activities is provided, as well as appropriate accommodation in provincial or local offices for inspectors and their inspection equipment.</p> <p>NOTE: Premises for testing activities are covered in the section on testing.</p> <p>a. Is the regulatory authority/head office housed in appropriate premises that allow for acceptable working conditions for employees (light, ventilation, temperature, space available, furniture, and so on)?</p> <p>b. Are the regulatory authority provincial or local offices housed in appropriate premises that allow for acceptable working conditions for employees (light, ventilation, temperature, space available, furniture, and so on)?</p> <p>c. Is appropriate space available for the following?</p> <ul style="list-style-type: none"> Storage for inspection equipment where it maintains its integrity Storage space for storing product samples for a specific time without deterioration 	<p>Yes=4 Needs upgrading=1 No=0</p> <p>Yes, all of them=4 Yes, but some need upgrading=2 No=0</p> <p>Yes=2 Needs upgrading=1 No=0 Needs upgrading=1 No=0</p> <p>Aggregate score: Premises (a+b+c)/3</p> <p>0.0</p>			

8) Equipment	<ul style="list-style-type: none">Consideration of the technical regulation fields of activityDemonstrable equipment needs of the regulatory authorityReview of working standardsReview of inspection equipmentReview of maintenance measures for all measuring equipment	Inspection offices are issued with appropriate inspection equipment. Working standards, traceably calibrated to national measurement standards, are maintained against which inspection equipment is calibrated continuously.	NOTE: Testing equipment is covered in the section on testing.			
		a. Have the inspection offices been issued with all the inspection equipment as determined by the technical regulation they are responsible for?	Yes, all of it=4 Mostly, some equipment still missing=2 Partially, more than half the equipment still missing=1 No=0			
		b. Have working standards been established to calibrate all the inspection equipment? And are these working standards traceably calibrated to national measurement standards?	Yes, in all cases=4 Mostly, some standards still missing or not traceably calibrated=2 Partially, more than half the standards still missing or not traceably calibrated=1 No=0			
		c. Is all inspection equipment continuously calibrated against the working standards?	Yes, all of them=4 Mostly, some equipment lacking=2 More than half the equipment lacking=1 No=0			
		Aggregate score: Equipment (a+b+c)/3		0.0		
9) Quality system	<ul style="list-style-type: none">Consideration of the regulatory authority's formal quality management system and its compliance with relevant standards such as ISO/IEC 17020, ISO/IEC 17025, and ISO/IEC 17065.	A quality management system in accordance with ISO/IEC 17020 (inspection), ISO/IEC 17025 (test laboratory), and/or ISO/IEC 17065 (product certification), as relevant, has been implemented and is maintained.				
		a. Has the regulatory authority implemented a formal quality management system in accordance with ISO/IEC 17020, ISO/IEC 17025, and/or ISO/IEC 17065 as relevant?	Yes=4 Being implemented=1 No=0			
		b. Has the quality management system of the regulatory authority been independently assessed and accredited?	Yes=4 Independently assessed, but not certified=2 Internally assessed=1 No=0			
		Aggregate score: Quality system (a+b)/2		0.0		
		Pillar 3: Service delivery and technical competency				
10) Developing technical regulations	<ul style="list-style-type: none">Relevant technical regulation legislationRecords of RIAs conductedRecords of all the ministries regarding the development of technical regulationsNotification records of the WTO TBT SecretariatPublished implementation transition periods	The process of developing technical regulations complies with WTO TBT Agreement requirements and follows good regulatory practices.				
		a. Does the regulatory authority have a regulatory impact assessment (RIA)—including (i) the need to regulate, (ii) assessment of state intervention options, and (iii) choosing the least burdensome one—conducted before a new technical regulation is developed and implemented?	Yes, always=4 Some, others not=2 Not in the past, but planning to do so in future=1 No=0			
		b. Are draft technical regulations published for public comment for a reasonable amount of time?	Always=4 Mostly, comments received have been considered and, if relevant, incorporated=2 Less than half are consulted=1 No=0			
		c. Are technical regulations based on international, regional, or national standards (e.g., by referencing them)?	Always=4 Mostly, but changes have been incorporated=2 Less than half are based on these=1 No=0			
		d. Are draft technical regulations notified to the WTO TBT Secretariat 60 days in advance of their implementation?	Yes, always=4 Mostly=2 No=0			
Aggregate score: Developing technical regulations (a+b+c+d)/4						

	For specific <i>high-risk</i> products, a consignment inspection regime is in place to ensure products meet technical regulation requirements before they are released to the market.				
	a. Has the regulatory authority made a formal decision based on risk assessment, on whether or not premarket inspections and approvals will be conducted for these <i>high-risk</i> products?	Yes=4 All products are <i>pre-market</i> approved=2 No=0			
11) Premarket approvals	b. Does the regulatory authority inspect such <i>high-risk</i> products, or have them inspected, at the ports of entry, at premises of manufacturers or producers, and in local warehouses based on an appropriate risk assessment?	Yes: all consignments=4 Audit samples only=2 Ad hoc inspections=1 No=0			
	c. Does the regulatory authority keep appropriate records, which can stand the scrutiny of a court of law, of all consignment inspections?	Yes=4 Yes, but there are some gaps=2 Partially=1 No=0			
		Aggregate score: Premarket approvals (a+b+c)/3	0.0		
	A market surveillance system in place covering all products for which the regulatory authority is responsible, and it is based on the appropriate risk assessments.				
	a. Has the regulatory authority established a market surveillance system covering all products for which it is responsible?	Yes=4 Partially=2 No=0			
12) Market surveillance	b. Is the market surveillance regime based on a continuous risk assessment of the impact that a nonconforming product could have and of the possibility of such an impact happening?	Yes, in all cases=4 Mostly, some not=2 All products are treated the same=1 No=0			
	c. In planning market surveillance, does the regulatory authority follow the principles of proportionality, i.e., the action taken is in accordance with the level of risk or nonconformity and is not more onerous on the economic entity than necessary?	Yes, in all cases=4 Mostly, some not=2 All products are treated identically=1 No=0			
	d. Does the regulatory authority plan for scheduled market surveillance as well as off-schedule surveillance based on dealing with an immediate threat or at the request of a court of law?	Yes=4 Off-schedule inspections are squeezed in=2 Inspections are implemented in an ad hoc way=1 No=0			
		Aggregate score: Market surveillance (a+b+c+d)/4	0.0		
	The regulatory authority implements administrative sanctions to remove nonconforming products from the marketplace and institutes legal proceedings against suppliers if they fail to heed administrative sanctions.				
13) Sanctions	a. Has the regulatory authority been given the legal mandate to impose administrative sanctions with regard to nonconforming products in the marketplace, if applicable?	Yes, legally sound=4 Yes, but could be challenged legally=2 No, but do it anyway=1 No=0			
	b. Do the administrative sanctions include the following?	Yes=1 No=0			
	o Recall from the market	Yes=1			
	o Rework to full compliance	Yes=1			
	o Destruction of nonconforming products	Yes=1			
	o Reexport in the case of imported products	Yes=1			
	c. Has the regulatory authority been given the legal mandate to take economic operators to court if they do not heed the administrative sanctions?	Yes=4 Not clearly defined=2 No=0			
		Aggregate score: Sanctions (a+b+c)/3	0.0		
	Trained and skilled inspectors are employed by the regulatory authority.				
	a. Does the regulatory authority operate a training scheme specifically designed for the inspectors?	Yes, all are trained=4 Yes, but there are some gaps=2 Trained only by example on the job=1 No=0			
14) Training system	b. Does the training scheme include training the inspectors on their legal rights, responsibilities, and obligations regarding their inspection function?	Yes=4 Could be enhanced=2 No=0			
	c. Are the inspectors issued with an inspector's identification card or similar upon passing the required examinations, and are their names made publicly known?	Yes, on all counts=4 Yes, but not made publicly known=2 Yes, but not subject to passing the examination=1 No=0			
	d. Are the inspectors' identification cards formally withdrawn when the inspectors leave the employment of the regulatory authority?	Yes=4 Most of the time=2 No=0			
		Aggregate score: Training system (a+b+c+d)/4	0.0		

Pillar 4: External relations and recognition				
		Information on nonconforming products found in the marketplace is readily available to other regulatory authorities, the customs and excise entities, and the general public.		
15) Information systems	<ul style="list-style-type: none"> • Official websites • Government gazette • Communication channel information between regulatory authorities 	a. Does the country operate an IT-based system regarding information on nonconforming products in the marketplace, and is the regulatory authority properly connected to it?	Yes, fully operational=4 National system fully operational but authority not connected=2 National system in process of being established=1 No=0	
		b. Is information on technical regulation developments published promptly in official government publications?	Yes=4 Mostly=2 No=0	
		c. Do official rapid communication channels exist between the regulatory authorities and the customs and excise entities?	Yes=4 Depends mostly on the relevant staff=2 No=0	
		d. Is official information on nonconforming products publicly available (e.g., on the internet) to interested parties?	Yes=4 Partially=2 No or is outdated=0	
		Aggregate score: Information systems (a+b+c+d)/4		0.0
16) Liaison with regional organizations	<ul style="list-style-type: none"> • Membership of regional common markets • Regional TBT protocols, agreements, or similar • Regional common market technical regulation forums • Reports of attendance of regional technical regulation discussions 	The country participates in the relevant regional forums established to harmonize technical regulations across all members of the region or free trade area.		
		a. Does the country participate in relevant forums established to harmonize technical regulations and their implementation across members of the region or free trade area?	Yes, always=4 Yes, but selected domains only=2 At least participation=1 No=0	
		b. Does the country have mechanisms in place for the following?	Yes=1	
		<ul style="list-style-type: none"> o Promulgation of regional technical regulations that all member states must implement o Regional harmonization of standards, metrology, accreditation, and conformity assessment modalities to support technical regulations o Recognition of technical regulation premarket approvals of other members of the region o Regional recognition agreements on elements of conformity assessment 	Yes=1	
		Aggregate score: Liaison with regional organizations (a+b)/2		0.0
17) Liaison with international organizations	<ul style="list-style-type: none"> • Notification authority records • WTO TBT Agreement records of notifications 	As a member of the WTO, the country complies fully with the requirements of the WTO TBT Agreement regarding notifications and information about standards, conformity assessment, and technical regulations.		
		o Statements on implementation and administration of the WTO TBT Agreement (Article 15.2)	Yes, fully=1 Yes, partially=0.5 No=0	
		a. As a WTO member, does the country comply with the following notification requirements?	Yes, fully=1 Yes, half the articles=0.5 Yes, less than half the articles=0.1 No=0	
		o Notification of bilateral or multilateral agreements (Article 10.7)	Yes, fully=1 Yes, partially=0.5 No=0	
		o Notification under paragraphs C and J of the Code of Good Practice on the Preparation, Adoption and Application of Standards (Annex 3 to the Agreement)	Yes, fully=1 Yes, only one paragraph=0.5 No=0	
		Aggregate score: Liaison with international organizations (a)		0.0





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