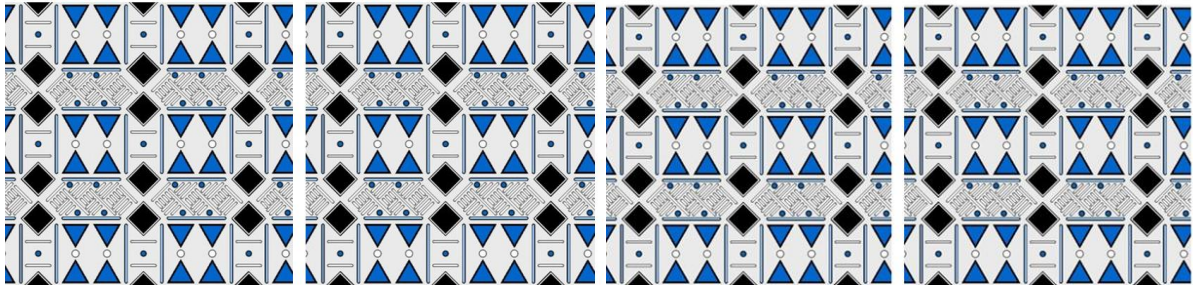




MINISTRY OF INVESTMENTS, TRADE AND INDUSTRY



REGULATORY IMPACT ASSESSMENT

FOR THE STANDARDS (SCIENTIFIC AND INDUSTRIAL METROLOGY) REGULATIONS, 2026

MAY 2026

This Regulatory Impact Assessment (RIA) has been prepared by the Cabinet Secretary - Ministry of Investments, Trade & Industry in line with Section 6 and 7 of the Statutory Instruments Act (No.23 of 2013)



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CHAPTER 1: INTRODUCTION

1.1 : Regulatory-Making Authority and the Legal Mandate

The Standards Act, Cap 496 of the Laws of Kenya (hereinafter ‘the Act’) mandates Kenya Bureau of Standards (KEBS) to provide or make arrangements for calibration of precision instruments, gauges and scientific apparatus. Calibration entails ensuring metrological traceability of measurements to the International System of Units.

Calibration assures the accuracy, consistency and metrological traceability of measurements to national and international standards (SI). In industry, calibrated instruments prevent measurement errors that lead to defective products, rework, waste, equipment damage and disputes in trade; they also support compliance with quality management and conformity assessment requirements. In the health sector, calibration safeguards patient safety by ensuring that diagnostic and therapeutic equipment such as laboratory analysers, imaging devices, infusion systems and imaging equipment perform within specified tolerances. This reduces the risk of misdiagnosis, incorrect dosing and ineffective treatment. Accuracy in measurement strengthens confidence in test results across sectors, supports regulation and enforcement, and enables acceptance of Kenyan measurement results in regional and international markets.

The Act empowers KEBS to establish calibration facilities by itself or through designated laboratories. The Act further mandates KEBS to regulate calibration service providers to enhance standardization in the industry. Regulations need to be formulated to provide a framework to support provision of calibration services by the Bureau; designation of calibration laboratories by the Bureau and licensing of calibration service providers.

Section 20 of the Standards Act empowers the Cabinet Secretary (CS), upon consultation with the Council, to make regulations generally for the better carrying out of the provisions and purposes of the Standard Act. The CS, in consultation with KEBS, has therefore developed proposed **Standards (Scientific and Industrial Metrology) Regulations, 2026** (Proposed Regulations) to govern the implementation of Section 12B and 12C of the Act. This is a statutory instrument which seeks to boost the practice in metrology services and regulate provision of calibration services across the county. It is likely to impose costs on calibration service providers to whom it will apply hence the need for this Regulatory Impact Assessment.

1.2 : Requirements of the Statutory Instruments Act

The Statutory Instruments Act, No. 23 of 2013 is the legal framework governing the conduct of RIA in Kenya. Sections 6 and 7 require that if a proposed statutory instrument is likely to impose significant costs on the community or a part of the community, the regulation-making authority shall, prior to making the statutory instrument, prepare a RIA about the instrument. The Act further sets out certain key elements that must be contained in the RIA namely:



- (a) a statement of the objectives of the proposed legislation and the reasons;
- (b) a statement explaining the effect of the proposed legislation;
- (c) a statement of other practicable means of achieving those objectives, including other regulatory as well as non-regulatory options;
- (d) an assessment of the costs and benefits of the proposed statutory rule and of any other practicable means of achieving the same objectives; and
- (e) the reasons why the other means are not appropriate.

Section 5 of the Act requires a regulation-making authority to conduct public consultations drawing on the knowledge of persons having expertise in fields relevant to the proposed statutory instrument and ensuring that persons likely to be affected by the proposed statutory instrument are given an adequate opportunity to comment on its proposed content. The Cabinet Secretary now undertakes public consultations and prepares this Regulatory Impact Assessment (RIA) in partial fulfilment of the requirements of the Statutory Instruments Act.

1.3 : What is a Regulatory Impact Assessment?

RIA is a systematic policy tool used to examine and measure the likely benefits, costs and effects of new or existing regulation. It is an analytical report to assist decision makers. As an aid to decision making RIA includes an evaluation of possible alternative regulatory and non-regulatory approaches with the overall aim of ensuring that the final selected regulatory approach provides the greatest net public benefit. Typically, the structure of a RIA should contain the following elements: title of the proposal, the objective and intended effect of the regulatory policy, an evaluation of the policy problem, consideration of alternative options, assessment of all their impacts distribution, results of public consultation, compliance strategies, and processes for monitoring and evaluation¹.

RIA is usually conducted before a new government regulation is introduced to provide a detailed and systematic appraisal of the potential impact of a new regulation in order to assess whether the regulation is likely to achieve the desired objectives. RIA promotes evidence-based policy making as new regulations typically lead to numerous impacts that are often difficult to foresee.

From a societal viewpoint, RIA should confirm whether or not a proposed regulation is welfare-enhancing, in that, the benefits will surpass costs. RIA therefore has objectives of improving understanding of the real-world impact of regulatory action, including both the benefits and the costs of action, integrating multiple policy objectives, improving transparency and consultation; and enhancing governmental accountability.

¹ Regulatory Policy Division Directorate for Public Governance and Territorial Development: Building an Institutional Framework for Regulatory Impact Analysis (RIA): Guidance for Policy Makers. OECD, 2008



CHAPTER 2: PURPOSE AND OBJECTS OF PROPOSED STANDARDS (SCIENTIFIC AND INDUSTRIAL METROLOGY) REGULATIONS, 2026

2.1 : Scope

The scope of the Regulations is to:

- (a) provide for the designation of KEBS as the National Metrology Institute
- (b) prescribe the functions of the National Metrology Institute
- (c) provide for designation of calibration service providers
- (d) create an obligation for persons operating precision equipment to ensure the equipment are calibrated.
- (e) provide for calibration of equipment by the Bureau
- (f) define calibration procedures
- (g) define categories of equipment subject to mandatory calibration
- (h) provide for licensing of calibration service providers
- (i) create offences on persons who violate the Regulations.

2.2 : Objective

The Proposed Regulations aims to enumerate provisions to give effect to Sections 12B and 12C of the Standards Act.

2.3 : Specific objectives

Specifically, the implementation of the Proposed Regulations is intended to:

- (a) Ensure metrological traceability of measurements to the International System of Units through national measurement standards;
- (b) Ensure accuracy of precision instruments, gauges and scientific apparatus through calibration; and
- (c) Regulate calibration service providers to enhance standardization.

2.4 : An Overview of the Proposed Order: Salient Features

This overview is intended to assess whether the Proposed Regulations is clear, consistent, comprehensible, and comprehensive enough to address the identified problem. The rules should be understood by persons likely to be affected by the Proposed Regulations, and to that end KEBS has taken steps to ensure that the text and structure of Proposed Regulations are as clear as possible.

An overview of the Proposed Regulations is as follows:

1. **Citation**- This section provides for the reference/name of the Regulations.
2. **Interpretation** - This section provides the definition and the meaning of different terms and words used in the Regulations.



3. **Object of the regulations**- This section defines the purpose for the regulations drawn from Sections 12B and 12C of the Standards Act.
4. **Application** - This section provides limits the application of the Regulations to scientific and industrial metrology.
5. **Designation of National Metrology Institute** - This section defines the Bureau as the National Metrology Institute.
6. **Functions of the National Metrology Institute** – The section enumerates the role of the Bureau as the National Metrology Institute.
7. **Designation of Institutes** – The Regulations empower the Bureau to designate other institutes to provide metrological traceability.
8. **Eligibility for designation** – The section enumerates requirements to make a calibration library eligible for designation by the Bureau.
9. **Responsibilities of Designated Institutes** – The section defines responsibilities of designated laboratories.
10. **Issuance of Designation Certificate** – The Bureau shall issue designated institutes with designation certificates
11. **Peer Review Assessment** - The Bureau shall verify compliance of designated institutes through peer reviews
12. **Register of Designated Institutes** – The Bureau shall maintain a register of its designated institutes
13. **Liability of the Designated Institute** – The Bureau is not liable for any misdeeds of designated institutes.
14. **Suspension and revocation of designation** – The section empowers the Bureau to suspend or revoke designation for non-compliance with the Regulations.
15. **National measurement standards** – The section provides for development of national measurement standards
16. **Primary standards** –The Bureau shall be the custodian of primary standards.
17. **Secondary standards** – The Bureau shall maintain secondary standards
18. **Working standards** – The Bureau and calibration service providers shall maintain working standards.
19. **Units of measurement** – The section defines base units of measurement.
20. **Metrological traceability** – The section mandates the Bureau to ensure traceability of national measurement standards to international system of units
21. **Responsibility to calibrate** – The section requires persons operating measuring equipment used in industrial and medical measurements to ensure calibration.
22. **Calibration services by the Bureau** –The section provides for calibration by the Bureau and its designated institutes.
23. **Calibration procedures** – The section provides for calibration according to applicable standards
24. **Mandatory calibration** – The section provides for mandatory calibration of defined categories of instruments
25. **Calibration certificate for equipment** –the section provides for issuance of calibration certificate



26. **Voiding of calibration validity** – The section provides for circumstances for voiding of calibration
27. **Licensing of calibration service providers** – The section requires all calibration service providers to be licensed by the Bureau
28. **Eligibility for licensing** –the section provides eligibility requirements for licensing.
29. **Application and grant of a calibration licence**–the section provides for application requirements for licensing of calibration service providers
30. **Conditions for licensing** –the section spells out licensing conditions for calibration service providers.
31. **Participation in inter-laboratory comparison** – The Bureau shall provide inter-laboratory comparisons.
32. **Suspension and Revocation of calibration licence** – The section empowers the Bureau to revoke or suspend calibration licences.
33. **Disputes** –any person aggrieved with a decision of the Bureau under the Regulations may appeal to the Standards Tribunal.
34. **Offence of operating without valid licence** –the section makes it an offence to offer calibration services without a valid licence.
35. **Enforcement**–the section mandates the Bureau to enforce the Regulations.

First Schedule- Equipment Requiring Mandatory Calibration

Second Schedule- Calibration Licence Application Form

Third Schedule- License Fee Schedule

Fourth schedule - Calibration Licence



CHAPTER 3: BACKGROUND AND CONTEXT

POLICY FRAMEWORK

3.1 International context

a) *Bureau International des Poids et Mesures (BIPM)*

The Bureau International des Poids et Mesures (BIPM) is the intergovernmental organization established under the Metre Convention to ensure worldwide uniformity of measurements and their traceability to the International System of Units (SI). Through its coordination of international comparisons and the CIPM Mutual Recognition Arrangement (CIPM MRA), BIPM supports mutual acceptance of national measurement standards and calibration and measurement certificates. This international framework boosts confidence in measurement results across borders, supporting trade, public health and safety, and the credibility of national metrology systems across countries and regions.

Kenya is a signatory to the Metre Convention. Kenya participates in the BIPM through KEBS.

b) *United Nation Sustainable Development Goals (SDGs)*

Goal 8 addresses decent work and economic growth. It entails achieving higher levels of economic productivity through diversification, technological upgrading and innovation and increasing aid for trade support for developing countries through the Enhanced Integrated Framework for Trade-Related Technical Assistance. Further **Goal 9** provides for building of resilient infrastructure, promoting sustainable industrialization and fostering innovation. In Kenya, increasing industrialization, growth of medical services, environmental monitoring obligations, and participation in regional and international trade have significantly expanded reliance on calibrated precision instruments and scientific measurements. The Proposed Regulations support accuracy and reliability of measurement which underpin public health, industrial production, environmental protection, safety, trade facilitation, and consumer protection.

3.2 Regional context

a) *Africa Agenda 2063*

One of the key aspirations of Africa Agenda 2063 is “A Prosperous Africa, based on Inclusive Growth and Sustainable Development”. One of the goals under this aspiration is Transformed Economies whose priority areas are: sustainable and inclusive economic growth; Science Technology and Innovation (STI) driven Manufacturing / Industrialization and Value Addition; and economic diversification and resilience. Technology and innovation is considered a key driver of the manufacturing sector. KEBS will need to continuously develop standards in line with developing technologies. The Proposed Regulations support development and utilization of measurement standards to promote accuracy and reliability of



measurement which is critical for quality manufacturing.

b) African Regional Organization for Standardization (ARSO)

Among the fundamental mandates of ARSO is to develop tools for standards development, standards harmonization and implementation of these systems to enhance Africa's internal trading capacity, increased Africa's product and service competitiveness globally, and uplift of the welfare of African consumers as well as standardization forum for future prospects in international trade referencing. KEBS is Kenya's National Standardization Body mandated to develop standards for utilization by the industry. KEBS further plays the role of National Metrology Institute developing, maintaining and being a custodian of measurement standards. Accuracy of measurement supports implementation of standards for quality production.

c) The East African Community Standardisation, Quality Assurance, Metrology And Testing (SQMT) Act

The Act ensures standardisation, quality assurance, metrology and testing of products produced or traded in the Community in order to facilitate industrial development and trade; to make provision for ensuring the protection of the health and safety of society and the environment in the Community and to establish the East African Standards Committee and the East African Accreditation Board.

Pursuant to Section 6, KEBS is the designated National Metrology Institute. These Regulations are intended to support the mandate of KEBS as the National Metrology Institute,

3.3 Domestic context

a) Kenya's Vision 2030

The Vision identifies manufacturing as being a key enabler for driving the country to a globally competitive and prosperous country with a high quality of life by the year 2030. The goal is to generate an additional KES. 30billion to GDP by producing consumer goods that compete with imports. The Proposed Regulations facilitate accuracy and reliability of measurement which is critical for quality manufacturing.

b) The Kenya National Trade Policy, 2016

The Policy outlines its mission as to facilitate Kenya's transformation into a competitive export led economy, enhance regional integration and widen participation in both domestic and international trade. It enumerates one of its objectives as creation of an enabling environment for trade and investment to thrive. KEBS plays a critical role in facilitating trade through development of standards that are used by the industry to support production of quality products that can compete effectively in the local and international market. The Proposed Regulations support development and utilization of measurement standards to promote accuracy and reliability of measurement which is critical for quality manufacturing.



c) The Kenya Quality Policy, 2024

The Policy recognizes that quality infrastructure is required for the effective operation of domestic markets, and quality infrastructure's international recognition is important to enable access to foreign markets. Further, it is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing. The National Quality Infrastructure (NQI) system comprise of Standardization, Metrology, Accreditation, Conformity Assessment and Market Surveillance. In addition, to overcome technical barriers to trade, Kenya needs to adopt and implement the internationally recognized and accepted quality standards of international markets. The specific objectives of this policy are to: enhance capacity within NQI, strengthen the NQI skills and technical expertise, create understanding and awareness on NQI, provide a conducive legal and regulatory framework. The Policy designates KEBS as the designated National Standards Body as well as National Metrology Institute. The Proposed Regulations enable execution of KEBS mandate as the National Metrology Institute.

d) Bottom-Up Economic Transformation Agenda (BETA)

The Fourth Medium Term Plan (MTP IV) 2023-2027 implements the Bottom-Up Economic Transformation Agenda (BETA), which is geared towards economic turnaround and inclusive growth through a value chain approach. BETA targets sectors with high impact to drive economic recovery. The BETA objectives are: bringing down the cost of living, eradicating hunger, creating jobs, expanding the tax base, improving foreign exchange balances and inclusive growth. This will be achieved through targeted investments in five core pillars, namely: Agriculture; Micro, Small and Medium Enterprise (MSME) Economy; Housing and Settlement; Healthcare; Digital Superhighway and Creative Economy. BETA will be implemented through five MTP IV sectors, namely: Finance and Production; Infrastructure; Social; Environment and Natural Resources; and Governance and Public Administration. The Proposed Regulations align with BETA as intended to promote quality manufacturing through reliable measurements. They further support provision of quality healthcare by requiring mandatory calibration of medical equipment.

LEGAL FRAMEWORK

An evaluation of the legal framework related to the Proposed Regulations provides a legal basis for developing the Proposed Regulations. It is also intended to bring out the context and legal environment within which the Proposed Regulations are being developed.

3.1. The Constitution

Article 46 of the Constitution of Kenya, 2010 has robust provisions on consumer protection. All consumers have a right to quality goods and services, access all information necessary to derive full benefit of the goods and services; and protection of their health, safety as well as that of the environment.

Integrity of equipment used in manufacturing is critical to the overall quality of manufactured products.



The Proposed Regulations intend to make it mandatory for persons operating precision equipment used for health, safety and environmental purposes.

3.2. Standards Act, Chapter 496

Section 4 (1)(b) of the Standards Act mandates KEBS to provide facilities or make arrangements for calibration of precision equipment, scientific apparatus and measurement gauges to determine their degree accuracy against applicable standards.

Section 12B provides for establishment of calibration facilities by KEBS and designation of other laboratories to provide calibration services. The calibration facilities of KEBS shall be the custodian of the national measurement standards; develop and maintain national measurement standards and disseminate their exactitude to industry and users in the country; provide metrological traceability to the national measurement standards and through it to the International System of Units; exercise oversight authority over entities that offer scientific and industrial metrology; offer technical support to industry in matters related to metrology; and offer inter-laboratory comparisons for calibration service providers and other national metrology institutes; and maintenance & dissemination of International System of Units (SI) of measurements.

Section 12C of the Act obligates every calibration service provider to reference their measurements with the national measurement standards maintained by KEBS. The CS may make regulations identifying specific categories of equipment used for health, safety and environmental purposes that should be subject to mandatory calibration. The regulations may further prescribe the timeline after which it becomes an offence to use equipment that is not calibrated.

The Proposed Regulations are intended to enable implementation of Sections 12B and 12C.

3.3. Statutory Instruments Act, No.23 of 2013

The Act defines a statutory instrument to mean any rule, order, regulation, direction, form, tariff of costs or fees, letters patent, commission, warrant, proclamation, by-law, resolution, guideline or other statutory instrument issued, made or established in the execution of a power conferred by or under an Act of Parliament under which that statutory instrument or subsidiary legislation is expressly authorized to be issued. The Standards (Scientific and Industrial Metrology) Regulations, 2024 is therefore a statutory instrument under the Standards Act, cap 496.

Where the proposed statutory instrument is likely to impose significant costs on the community or a part of the community, Section 6 of the Act requires the regulation making authority to prepare a regulatory impact statement about the instrument prior to the enactment of the instrument.



3.4 Constitutional Basis

Article 46 of the Constitution of Kenya, 2010 has robust provisions on consumer protection. All consumers have a right to quality goods and services, access all information necessary to derive full benefit of the goods and services; and protection of their health, safety as well as that of the environment.

KEBS plays a central role in ensuring consumer safety by promoting use of reliable measurements by industry and medical establishments.



CHAPTER 4: EVALUATION OF THE PROBLEM

This chapter identifies the pain points, problems and challenges presented by the absence of Metrology Regulations in Kenya by giving evidence of its nature and magnitude and explaining why these challenges have arisen.

4.1 : Absence of a legal obligation to calibrate

Measuring equipment are used in the industries for manufacturing, health facilities, trade and other fields. The integrity of measurement is critical to the output sought to be achieved. It is therefore necessary to make it obligatory upon persons operating certain categories of equipment in sensitive fields to mandatorily have the same calibrated.

4.2 Absence of a framework to support traceability of measurement by KEBS

Calibration services are not an exclusive mandate of KEBS. Section 12C (1) of the Act requires that all calibration service providers reference their measurements with the national measurement standards maintained by KEBS.

There is need for a framework to support KEBS function of establishing, maintaining national measurement standards and providing traceability of measurements to national measurement standards. There is a further need to create sanctions to compel calibration service providers to reference their standards to the SI system through national measurement standards established and maintained by KEBS.

4.3 : Designation of laboratories to offer calibration services

KEBS is mandated to provide facilities or make arrangements for provision of calibration services. This addresses the possibility that KEBS may not have adequate capacity to offer calibration services for all equipment. KEBS is empowered by law to recognize traceability of measurement done by other laboratories. This however necessitates the creation of a framework for this recognition and subsequent designation; identifying clear terms and conditions for operation of designated laboratories.

4.4 Licensing framework for calibration service providers

With various laboratories offering calibration services, it is important to regulate the process to ensure integrity of disseminated measurements.

In summary, this highlights a range of challenges presented by the absence of a regulatory framework to support uptake of calibration services in the country thereby leading to unreliable measurements effectively undermining the quality of manufacturing, compromising trade and compromising quality healthcare. These necessitate a comprehensive regulation to effectively address them.



CHAPTER 5: PUBLIC CONSULTATIONS

The Constitution of Kenya 2010 has embedded Public Participation in its tenets under Articles:1,10,27,33,35,201 and 232. The Statutory Instruments Act requires that the regulation making authority shall make consultations before enacting the Regulations in question in particular where there is likely to have a direct, or a substantial indirect effect on business or restrict competition.

Public Notice and awareness

The Proposed Regulations will be circulated on **MyGov** publication and further posted in the KEBS website through a public notice inviting views and comments from members of public.

Public participation fora

The Proposed Regulations will be subjected to stakeholders' engagement through physical meetings held in Nairobi, Eldoret, Kisumu, Nakuru, Mombasa, Garissa, Kakamega, Nyeri and Embu. The public participation fora will be open to all members of the public. Sector specific engagements will also be conducted on identified categories of stakeholders directly affected by the Regulations.

Additionally, stakeholders and all members of the public are encouraged to submit written memoranda through a prescribed email address as per the public invitation notice.

Conclusion of the Public Participation Process

KEBS will consider all stakeholder comments and make necessary amendments to the regulations prior to submission to the Cabinet Secretary. A virtual validation forum will thereafter be conducted to inform the public of how their feedback was treated as to inform any changes to the Proposed Regulations.



CHAPTER 6: COST-BENEFIT ANALYSIS

Introduction

The analysis of the expected costs and benefits of the Proposed Regulations in this part seeks to answer the question whether the benefits justify the projected costs. This would enable KEBS to estimate the total expected cost and benefit of every aspect of the regulations. This will inform the government on whether the Proposed Regulations are justified by its benefits. The task of comparing the benefits and costs associated with the Proposed Regulations and determining whether, and to what extent, there would be a net benefit associated with its adoption is a difficult one.

The approach taken in this section is to draw together the discussion of benefits and costs, indicate the relative magnitude of these where possible and draw conclusions as to the likely overall impact of the draft consolidation regulations where possible.

Problem	Proposed solution in the proposed Regulation	Benefit	Cost
Absence of a legal obligation to calibrate	-The Regulations: 1. obligate persons operating equipment for industrial and medical measurement to have the equipment calibrated; 2. mandatory calibration of all precision instruments, gauges and scientific apparatus used for health, safety and environmental measurements including medical and industrial equipment	-ensure reliability of equipment used in manufacturing and provision of health care products and services	Cost of calibration of equipment incurred by owners or operators of equipment
Absence of a framework to support traceability of measurement by KEBS	All calibration service providers to ensure traceability of measurement to national measurement standards maintained by KEBS	-Promote reliability of measurement in the country	-Cost of calibration borne by calibration service providers -Cost of developing and maintaining measurement standards borne by the Bureau
Designation of laboratories	KEBS is empowered to	Enhanced KEBS	-cost of organizing peer



Problem	Proposed solution in the proposed Regulation	Benefit	Cost
to offer calibration services	designate other laboratories to provide metrological traceability	capacity in providing calibration services	reviews and inter-comparisons borne by the Bureau -Cost of participating in peer review and inter-comparisons incurred by designated institutes and calibration service providers
Licensing framework for calibration service providers	KEBS to licence all persons offering calibration services	Ensure integrity of measurement	Cost of licensing borne by calibration service providers

Conclusion on how the benefits outweigh the cost.

In conclusion, the Proposed Regulations offer a comprehensive and proactive approach to ensuring reliability of measurement in the country. Accurate and reliable measurement support public health, industrial production, environmental protection, safety, trade facilitation, and consumer protection. In Kenya, increasing industrialization, growth of medical services, environmental monitoring obligations, and participation in regional and international trade have significantly expanded reliance on calibrated precision instruments and scientific measurements.

Prior to these Regulations, the metrology framework was fragmented. Calibration practices were largely voluntary in many sectors, oversight of calibration service providers was limited, and metrological traceability to the International System of Units (SI) was inconsistent. This resulted in: variability in measurement accuracy across sectors; increased risks to health, safety, and the environment; reduced confidence in industrial measurements and test results; barriers to international acceptance of Kenyan measurement results; and limited enforcement mechanisms for non-compliance.

These challenges necessitate a comprehensive regulatory framework to operationalize scientific and industrial metrology under the Standards Act, Cap 496.

The benefits of the proposed solutions in the regulations are evident. The Proposed Regulations seek to:

- a) prescribe the functions of KEBS as the National Metrology Institute
- b) empower KEBS to designate institutes to provide metrological traceability
- c) create an obligation for persons operating precision equipment to ensure the equipment are calibrated.
- d) define categories of equipment subject to mandatory calibration



- e) provide for licensing of calibration service providers
- f) create offences on persons who violate the Regulations.

In summary, these Proposed Regulations offer a comprehensive framework to address the identified challenges and are expected to bring about numerous benefits.

Consideration of Alternatives to The Standards (Scientific and Industrial Metrology) Regulations, 2026

This Part considers the question whether the making of the Proposed Regulations is the best form of government action to address the identified problem. The options considered under this part are the following:

Option 1: Maintain the Status Quo – Effects of not having regulations

While Section 12B and 12C of the Act set out a framework for calibration and regulation of calibration service providers, there is need for supporting Regulations to enable implementation of the same. The Regulations cure the following aspects not catered for in the Act;

- a) prescribe the functions of KEBS as the National Metrology Institute
- b) provide for designation of calibration service providers
- c) create an obligation for persons operating precision equipment to ensure the equipment are calibrated.
- d) define calibration procedures
- e) define categories of equipment subject to mandatory calibration
- f) provide for licensing of calibration service providers
- g) create offences on persons who violate the Regulations.

Option 2: Non- regulatory measures (Use of policies and procedures)

Policies and internal procedures have no capacity to compel compliance. Presently, KEBS provides calibration services on voluntary basis. This has presented challenges as below:

- (a) inability to regulate calibration service providers
- (b) inability to compel owners or operators of measuring equipment to safeguard integrity of measurement thereby risking dissemination of inaccurate results
- (c) Inadequate protection of public health and safety.
- (d) Undermined product quality and difficulty in accessing markets

Option 3: Self-Regulation

Section 12B (3) of the Standards Act provides for licensing of calibration service providers. This is a regulatory role that must be supported by Regulations to enable implementation. Consequently, this option cannot be considered.

Option 4: Developing the Regulations.

It is anticipated that once the intended Regulations are formally adopted, the following benefits will accrue:

- a) Established framework for designation of institutes to provide metrological traceability



- b) Make it an obligation for persons operating certain categories of precision equipment to ensure the equipment are calibrated.
- c) define categories of equipment subject to mandatory calibration
- d) provide for licensing of calibration service providers
- e) create offences on persons who violate the Regulations.
- f) Provide for enforcement powers by the Bureau

In view of the above, the development of Regulations presents the most viable option to address the identified problem.

ASSESSMENT OF IMPACT

This section examines other impacts that the Proposed Regulations may present as follows:

Economic impact

The Proposed Regulations present impact to the economy as follows: reduced measurement-related errors and rework; improved product quality and industrial efficiency; enhanced competitiveness of Kenyan exports; and growth of accredited calibration services sector.

Environmental impact

The Proposed Regulations present impact to the environment by requiring mandatory calibration of equipment used in environmental measurements. This protects the environment as well as consumers right to a healthy environment advancing realization of Article 42 of the Constitution.

Impact on Human Rights

Article 46 of the Constitution of Kenya, 2010 has robust provisions on consumer protection. All consumers have a right to quality goods and services, access all information necessary to derive full benefit of the goods and services; and protection of their health, safety as well as that of the environment. Reliability of measurement is a critical pillar of quality manufacturing leading to enhanced quality of manufactured goods while protecting economic interests of traders.

Social impact

If the Proposed Regulations are enacted, there will be improved social welfare as quality of healthcare, traded goods and environment improves.

Political impact

The Proposed Regulations provide opportunity to safeguard citizen welfare.



CHAPTER 7: COMPLIANCE AND IMPLEMENTATION

As different aspects of the Proposed Regulations are evaluated and analyzed, it is important to determine how compliance and implementation of the actual provisions will be achieved. It is the duty of the regulator to assess the adequacy of the institutional framework and other incentives through which the regulation will take effect, and design responsive implementation strategies that make the best use of them.

Section 20 of the Act enables formulation of regulations for the better carrying out of the provisions and purposes of the Act. These Regulations are intended to enable the implementation of Section 12B and 12C of the Act. The implementation and enforcement of the Regulations will be undertaken through the existing legal and institutional framework at various levels.



CHAPTER 8: CONCLUSION AND RECOMMENDATION

In view of the above, the Regulatory Impact Assessment concludes that the Proposed Regulations are necessary for the proper implementation of Section 12B and 12C of the Act. It is therefore recommended that the Proposed **Standards (Scientific and Industrial Metrology) Regulations, 2026** be adopted.



CHAPTER 9: ANNEXURES

1. The Standards (Scientific and Industrial Metrology) Regulations, 2026