



**FEDERAL REPUBLIC OF SOMALIA**

**TERMS OF REFERENCE**

**FOR**

**FEASIBILITY ASSESSMENT FOR REFERENCE LABORATORY, BORDER POSTS  
LABORATORIES, RAPID TEST/KITS AND TESTING DEMAND**

**October 2024**

## 1. Background:

### Somali Bureau of Standards

The Somali Bureau of Standards (SoBS) is the mandated institution in Somalia, spearheading the nation's commitment to quality assurance, safety, and economic development. Established by the Somali Standards and Quality Control Act Lr27, SoBS officially commenced operations in 2020, marking a significant milestone in Somalia's pursuit of a robust quality infrastructure.

The Somali Bureau of Standards (SoBS) operates with a multifaceted mission tailored to the specific needs of Somalia. Key objectives include establishing a comprehensive quality infrastructure encompassing standards, metrology, accreditation, and conformity assessment. SoBS prioritizes consumer protection by preventing the consumption of harmful products. Additionally, the Bureau actively promotes export through standards harmonization, enhancing the global competitiveness of Somali goods. Supporting the standardization of local production, SoBS aims to elevate the quality of domestically manufactured goods, fostering growth in local and international markets. Affiliating with regional and international standard bodies ensures Somalia's alignment with global best practices.

The Quality Infrastructure System (QIS) championed by SoBS serves as a catalyst for elevating the quality of products and services at a national scale. Beyond regulatory functions, the QIS stimulates demand for quality products and services, thereby invigorating individual businesses and propelling economic growth. It is positioned as a transformative force that not only ensures compliance but also fuels a culture of excellence and innovation.

SOBS is a pivotal government institution established with the primary objective of promoting standardization, quality assurance, and conformity assessment across various industries within the Somali Republic. SOBS plays a crucial role in enhancing the competitiveness of Somali products and services both domestically and internationally. Specifically, the institution achieves this through the following key functions:

1. **Standardization:** SOBS is responsible for developing and adopting national standards across various sectors, including manufacturing, agriculture, healthcare, and other services. These standards are designed to enhance product quality, safety, and reliability.
2. **Quality Assurance:** The bureau is mandated to implement quality assurance programs and conformity assessment procedures to ensure that products and services comply with established standards. This includes certification processes, product testing, and inspection mechanisms.
3. **Regulatory Compliance:** SOBS collaborates with regulatory bodies to ensure that businesses and industries adhere to national and international standards. This collaboration is vital for maintaining a regulatory environment that fosters fair competition and protects consumers.
4. **Capacity Building:** SOBS is actively involved in capacity-building initiatives, providing training and technical assistance to businesses, government agencies, and other stakeholders. This helps improve the understanding and implementation of quality standards throughout the country.
5. **International Collaboration:** Recognizing the importance of global integration, SOBS engages in partnerships and collaborations with international standardization bodies and

other relevant organizations. This facilitates the adoption of best practices and ensures alignment with global standards.

SOBS plays a critical role in supporting economic development and trade by instilling confidence in Somali products and services. The bureau's efforts contribute to the creation of a favourable business environment, attracting investment, and facilitating international trade relationships.

### **DRIVE Project**

Under the Horn of Africa Initiative, the World Bank is financing the De-Risking, Inclusion and Value Enhancement of Pastoral Economies Project (DRIVE). DRIVE aims to protect pastoralists against drought shocks, using a package of financial services including drought insurance, payment, savings and possibly credit, and to connect pastoralists better to markets by upgrading the livestock value chains and facilitating the regional livestock trade. This project is regional and with Djibouti, Ethiopia, Kenya and Somalia participating. The development objective is to enhance de-risking, financial inclusion and value addition of pastoral economies in the HoA.

DRIVE project envisions to protect pastoral Economies from disaster brought about by drought and related natural calamities through De-risking and Livestock value chain enchantment by supporting private investment in the pastoral value chains to facilitate livestock trade to ensure pastoralists get more value for their livestock-rearing activities. The project has two components: Component 1- Package of financial services for climate resilience that will support the provision of an integrated package of financial services to build the climate resilience of pastoralists. Component 2 focuses on Livestock Value Chains and Trade Facilitation. In Somalia, the activities will have a strong focus on quality infrastructure which is incipient in the country. Somalia is developing its national quality infrastructure system and strengthening the national quality infrastructure system will support the private sector to export live animals and processed livestock products. SoBS faces some challenges including support for standards development in terms of procedural scope and operations, for implementing metrology, certification and testing services that are not yet operational. Similarly, there is need for a quality assurance system for livestock products. This sub-component will improve livestock product quality by supporting (i) technical assistance to SoBS covering standards, accreditation, metrology and conformity assessment. The technical assistance will also include testing, laboratory procedures, livestock quality and regulations, establishment of quality systems and operation of a traceability system; and (ii) goods and services including equipment and testing supplies.

Within this framework, the Federal Government of Somalia is seeking the services of a qualified firm(s) with relevant experience in undertaking a feasibility study for the establishment of a national reference test laboratory and lab test centers in key border points to facilitate trade in livestock products.

## **2. Objectives of the Feasibility Study:**

Comprehensively assess the feasibility and sustainability of establishing a national reference testing laboratory under the Somalia Bureau of Standards along with testing labs at key border points to support the livestock export industry. This will involve:

- Evaluating the practicality of setting up testing labs considering available resources, infrastructure needs, staffing requirements, technological capacity, operating costs and projected revenues.

- Identifying and analysing internal and external factors that are critical for the successful launch and sustainable functioning of the labs including infrastructure, equipment, human resources, training needs, regulatory requirements, market demand, private sector needs and potential challenges.
- Assessing financial viability through cost analysis, exploring funding options and developing a self-sustaining operational model.
- Map the current laboratory landscape in Somalia covering public and private sector capabilities, gaps compared to international best practices and specific conformity testing needs of the livestock export sector that require support.
- Recommend a roadmap for establishing the laboratories including sequential activities, reasonable timeframes and key implementation milestones aligned to DRIVE project goals.
- Suggest measures to manage risks and harness opportunities related to effective operationalization of the labs, quality assurance, regulatory compliance and engagement with stakeholders.
- Evaluate how new laboratory infrastructure could facilitate greater participation of pastoral communities in the livestock export value chain and contribute to higher income realization aligned to the strategic objectives of the DRIVE project.
- Ensure testing facilities and services meet the targeted requirements of the regional livestock trade corridors and demands of the private sector while also recommending strategies for continued alignment with evolving needs.

### 3. Scope of Work

#### *3.1. Inception Phase*

In the Inception Phase of the feasibility study, the appointed firm is tasked with conducting a comprehensive situational analysis. This phase involves a review of Somalia's current quality infrastructure, including any existing laboratory facilities, related policies, and the needs of the livestock export market, aligning with the broader objectives of the DRIVE Project. The firm will evaluate international best practices in quality infrastructure and laboratory management, particularly in the context of developing economies, and adapt these insights to the Somali context. The analysis will also incorporate a climate perspective, recognizing the interplay between quality infrastructure, livestock trade, and climate resilience. This initial phase sets the stage for a detailed understanding of the requirements and challenges in establishing the labs, ensuring that the feasibility study is grounded in current realities and geared towards sustainable, climate-smart solutions.

#### *3.2. Technical, Situational, and Needs Analysis for Establishing National Test Reference Lab and Test Centers in Key Border Points*

This stage will involve a detailed evaluation of existing laboratory capabilities within Somalia, focusing on both public and private sectors, especially as they pertain to the nation's trade in the vital livestock sector and related industries. It includes an in-depth analysis of the current state of laboratory services, identifying gaps, and determining specific needs for testing capabilities, equipment, personnel, and technology. The analysis also covers the existing regulatory framework, exploring how it supports or hinders the development of laboratory infrastructure. This part also evaluates the infrastructure, technology, equipment, and human resources required for establishing and operating a reference laboratory.

Moreover, this stage examines the market demand for laboratory services, delving into aspects like conformity assessment necessary for trade facilitation. By understanding the technical needs and market dynamics, this phase aims to establish a solid foundation for developing reference and border testing laboratories, aligning them with Somalia's trade objectives and economic development goals. This comprehensive approach ensures that the proposed laboratories are technically feasible, meet market needs, and align with the broader objectives of enhancing Somalia's quality infrastructure for sustainable economic growth.

In the subsequent part of the analysis, the focus will be on the technical requirements essential for the establishment of the laboratories. This will encompass a detailed assessment of the specific types of tests, analyses, and associated technologies required, with special attention to those relevant to Somalia's key exports like livestock products. A critical deliverable from this phase will be a detailed list of equipment, technology, systems, and their precise specifications that are necessary for setting up the lab. Additionally, the study will specify the technical skills and training needs of staff required to proficiently operate these labs, ensuring they meet international testing standards and the demands of modern laboratory operations. This comprehensive approach guarantees that the laboratories are equipped with the most suitable and advanced resources for their intended functions. The evaluation extends to understanding how these technical requirements align with the existing and potential market needs. It should involve identifying the types of tests that are in high demand by the industry and required for compliance with international trade standards. This understanding is crucial for ensuring that the laboratory services are not only technically sound but also relevant and beneficial to Somalia's trade and economic sectors.

### *3.3. Financial Viability and Sustainability Analysis*

This stage of the scope involves conducting a detailed financial feasibility study for the establishment and operation of the national test reference lab and border testing centers. The analysis will start with a thorough estimation of the costs associated with setting up the laboratories, including expenses for construction, procurement of equipment and technology, hiring and training of personnel, and ongoing operational costs. The estimated costs involved in setting up and operating the laboratory should include the initial capital investment, operational expenses, and potential revenue sources (e.g., government funding, fees for services).

Alongside the cost estimation, a comprehensive financial model will be developed to ensure the sustainable operation of the laboratories. This model will include projections of operating costs, revenue streams, and financial performance indicators. It will also evaluate the economic impact of the laboratories on the local and national economy, particularly in terms of job creation, trade enhancement, and contribution to the GDP. The goal of this financial analysis is to establish a viable and sustainable financial framework that supports the long-term success and impact of the laboratories in enhancing Somalia's quality infrastructure and trade capabilities.

### *3.4. Regulatory Framework Review and Accreditation Requirements*

This stage involves a thorough review and analysis of the national and international regulatory frameworks that are pertinent to laboratory operations. The primary goal is to ensure that the proposed national test reference lab and border testing centers in Somalia are in compliance with international quality and safety standards. This includes examining existing Somali regulations governing laboratory practices and benchmarking them against global standards, such as those set by ISO, WTO, WHO etc. The review will also consider regulations related to trade, environment, and health to ensure comprehensive compliance. The outcome will be a detailed

report outlining the regulatory requirements and recommendations for aligning the proposed laboratories with these standards, thus facilitating their recognition and efficacy in international trade.

### *3.5. Risk Assessment and Mitigation Planning*

This critical stage focuses on identifying and assessing potential risks associated with establishing and operating the national test reference lab and border testing centers. The assessment will cover various aspects, including technical, operational, financial, and environmental risks. This comprehensive risk profiling will help in understanding the challenges and vulnerabilities of the project. Based on this assessment, the task will involve formulating robust mitigation strategies and contingency plans. These strategies will aim to minimize the identified risks, ensuring the resilience and sustainable operation of the laboratories. This planning is crucial for maintaining the integrity and reliability of the laboratory services and for safeguarding the investment against unforeseen challenges.

**3.6 Sustainability and Governance:** Propose sustainable models for the governance, management, and funding of the laboratory. This includes partnership opportunities with governmental, academic, and international organizations.

**3.7 Recommendations:** Provide actionable recommendations on the establishment, design, and operation of the reference laboratory.

## **FINAL REPORT**

The final report should present:

- a thorough assessment of the strengths, weaknesses, opportunities and challenges of the overall food safety and national quality infrastructure before considering any major investment in laboratories.
- Identify if appropriate initiate actions necessary to effect institutional and regulatory reforms so that laboratories will have a clear mandate and responsibilities, as well as a process for setting priorities that takes into account all relevant factors.
- Include in the report that decisions on any significant investment in laboratories include plans for regular funding of operational, maintenance, and upgrade costs.
- Present a business plan for new investment in the reference laboratory based on the assessment of capacities, and assessment of demand under various policy and investment alternatives;
- Present a benefit and risk analysis, supported by financial and economic analysis, and this analysis should be used as the basis for priority setting in the formulation of investment plans.

The final report will include a business plan and investment plan.

The business plan should include the following topics;

- general and specific policies and regulations
- description of the existing laboratory facilities and their quality

- assessment of the laboratory for which investment is proposed, including its capacities and operational performance
- assessment of trends in demand for laboratory services
- design of the investment proposal, including proposals for changes in policies, governance and administration, quality management
- prioritization and financial and economic feasibility of the investment
- making the case for investment
- monitoring and evaluation (how the laboratory will be assessed)

In addition, the consulting firm could also develop actionable recommendations.

#### 4. Deliverables:

#	Deliverable Title	Description	Weeks from Signature Date	% of Payment
1.	Inception Report	A report outlining the initial findings, methodology, and work plan for the feasibility study.	3	10%
2.	Situational Analysis and Technical Needs Report including market analysis report	Detailed analysis of current laboratory capabilities and technical needs for the proposed labs. Conduct interviews and workshops with key stakeholders	12	10%
3.	Technical and Financial Feasibility report and Compliance Report	A detailed report covering financial feasibility, regulatory framework compliance, and risk assessment and mitigation strategies for the labs. This includes accreditation processes, such as ISO certification. Develop a detailed budget, including capital expenditure, operating costs, and revenue projections. Identify potential funding sources, including government grants, international donors, and private sector contributions.	18	10

	Risk Assessment and Mitigation Strategy.	Conduct a risk analysis to identify potential challenges and threats (technical, financial, operational), and provide recommendations for mitigation. Propose sustainable governance structures to ensure long-term operational viability.		10%
6.	Draft Feasibility Study and Implementation Roadmap	Initial draft of the feasibility study, including recommendation and an implementation roadmap for the laboratories.	20	10%
7.	Validation Workshop	Present, discuss, and validate the findings with stakeholders.	21	10%
8.	Final Feasibility Study Report	The final comprehensive feasibility study report, incorporating feedback and revisions.	23	40%

## 5. Firm and Key Experts Qualifications

The firm selected for this project should exhibit an exceptional understanding and proven experience in developing and managing quality infrastructure, with a particular focus on laboratory services and testing capabilities in a developing country context. Essential qualifications include:

- **Proven Experience:** Minimum of 10 years of business operation and specific experience in establishing and operating laboratories, emphasizing quality infrastructure, compliance, and risk management.
- **Technical Expertise:** experience providing/designing/installing services in metrology, standardization, and laboratory accreditation processes.
- **Regional Knowledge:** Familiarity with sub-Saharan Africa's specific challenges and opportunities, especially in trade and quality infrastructure development.
- **Multidisciplinary Team:** A team comprising laboratory specialists, financial analysts, regulatory experts, and risk management consultants.
- **Successful Track Record:** Demonstrable experience in delivering comprehensive feasibility studies and actionable recommendations.

### Key Experts Qualifications and Experience

The key experts for this assignment are integral to the feasibility study's success, each bringing vital skills and experience aligned with the scope of services. The firm(s) should ensure that the Key Experts below are available within the technical team:

#### 1. Team Leader



- Academic Qualifications: Master’s Degree in Industrial Engineering, Chemical Engineering, or Biomedical Engineering; or in a related field.
- Experience: At least 12 years in managing large-scale laboratory setup projects or operations, with a strong emphasis on project coordination and team leadership.
- Specific Experience: Experience in overseeing laboratory establishment, ensuring alignment with quality standards and operational efficiency.

## **2. Financial Analyst**

- Academic Qualifications: Master’s Degree in Finance, Economics, or Accounting; or in a related field.
- Experience: Minimum of 10 years in financial analysis and modeling, specifically in infrastructure or laboratory projects.
- Specific Experience: Expertise in conducting cost-benefit analyses and developing sustainable financial models for similar projects.

## **3. Technical Expert**

- Academic Qualifications: Ph.D. or Master’s Degree in Laboratory Sciences, Biochemistry, or Microbiology; or in a related field.
- Experience: At least 10 years in laboratory operations and technology implementation.
- Specific Experience: Experience in setting up and accrediting laboratories in accordance with international standards, preferably in a developing country context.

## **4. Regulatory Specialist**

- Academic Qualifications: Master’s Degree in Biotechnology, Clinical Laboratory Sciences, or Environmental Sciences; or in a related field.
- Experience: Minimum of 10 years in laboratory regulatory compliance and procedure development.
- Specific Experience: Deep understanding of laboratory manuals, regulations, and operating procedures, with an emphasis on compliance with international standards.

## **5. Risk Management Consultant**

- Academic Qualifications: Master’s Degree in Risk Management, Environmental Health, or Industrial Safety; or in a related field.
- Experience: At least 10 years in risk analysis and mitigation, specifically in laboratory or infrastructure projects.
- Specific Experience: Proven ability to conduct risk assessments and develop mitigation strategies for complex laboratory projects, focusing on operational and safety risks.

## **6. Timeline:**

The consultant/firm should provide a detailed timeline for the completion of the Feasibility Study, including key milestones and deliverable submission dates. The duration of the Feasibility Study is six (6) months.

## **7. Reporting Arrangements**

The selected consultancy firm(s) will operate under the direct supervision of the Director General of the Somali Bureau of Standards. Regular reporting is essential for maintaining transparency and alignment with the project's objectives. The firm is required to provide bi-weekly progress reports, highlighting achievements, challenges, and any critical issues needing attention. Coordination with the Project Implementation Unit (PIU) of the DRIVE project and the World

Bank is essential, while ensuring inputs from relevant ministries and agencies, including the Ministry of Commerce and Industry, the Ministry of Livestock, Forestry and Range, Ministry of Agriculture etc. are integrated. This collaborative approach ensures that the development of the laboratory infrastructure is harmonized with national regulations and standards. Regular stakeholder meetings and workshops should be incorporated, and a final validation workshop will be conducted to ensure inclusivity and comprehensive stakeholder consultation. The reporting structure is designed to facilitate effective communication and decision-making, ensuring the feasibility study's success and alignment with Somalia's quality infrastructure objectives.

## **7. Evaluation Criteria**

The success of the feasibility study will be measured by:

- The thoroughness and accuracy of the needs assessment.
- The clarity and practicality of recommendations.
- The viability of the proposed technical and financial solutions.
- The level of stakeholder engagement and support.