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Legal and Regulatory Frameworks Governing Science Laboratory Practice: A Global and Nigerian Perspective

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ABSTRACT

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Science laboratories are central to research, healthcare, industrial innovation, and education. Their operations must adhere to robust legal and regulatory frameworks to ensure safety, environmental protection, ethical compliance, and data integrity. This paper presents a narrative review of the global and Nigerian legal and regulatory environments governing science laboratory practice. It examines international standards such as those developed by the International Organization for Standardization (ISO), World Health Organization (WHO), and Organization for Economic Co-operation and Development (OECD), alongside Nigerian regulatory agencies including the National Institute of Science Laboratory Technology (NISLT), the Medical Laboratory Science Council of Nigeria (MLSCN), the National Agency for Food and Drug Administration and Control (NAFDAC), the National Environmental Standards and Regulations Enforcement Agency (NESREA), and the Standards Organization of Nigeria (SON). The review finds that while a relatively comprehensive regulatory architecture exists in Nigeria, persistent challenges — including inadequate infrastructure, poor enforcement, limited awareness, and corruption — undermine effective compliance. The paper underscores these challenges and proposes policy recommendations to bridge regulatory gaps and foster improved laboratory governance in Nigeria.

1. INTRODUCTION

A laboratory is a purpose-built facility used for specialized services, research, teaching, and learning. While laboratories are

indispensable to scientific advancement, they may also expose workers to health hazards — arising from chemicals, biological materials, radiation, and advanced apparatus — if not

properly managed. Due to the possibility of such hazards, laboratories are designed to operate under legal requirements that ensure and promote health and safety. A legal requirement, by definition, refers to a mandated law that compels certain preconditions to be met before the commencement of laboratory activities. When such conditions are provided for the wellbeing, welfare, and protection of employees, the regulatory system is striving to ensure their health and safety [1].

Laboratories in Nigeria operate within a complex framework of legal, ethical, and professional guidelines. These regulatory systems are essential for ensuring quality assurance, protecting the health and safety of laboratory personnel, and upholding public confidence in laboratory results. Nigerian laboratories, particularly in the health and academic sectors, face challenges such as inadequate infrastructure, poor enforcement of regulations, and ethical concerns. The current legal and regulatory framework in Nigeria is examined in this paper through relevant journal articles and statutory instruments to determine its efficacy and identify measures for improvement [2].

In Nigeria, the National Institute of Science Laboratory Technology (NISLT) plays a forerunner role in framing standards of practice in science laboratories, especially in non-medical laboratories such as academic and industrial settings. It holds a legislative mandate for controlling the training, registration, and professional practice of Science Laboratory Technologists. Beyond NISLT, other regulatory agencies — including the Medical Laboratory Science Council of Nigeria (MLSCN) and the National Agency for Food and Drug Administration and Control (NAFDAC) — issue specific directives to medical and research laboratories.

Globally, bodies such as the International Organization for Standardization (ISO) and the World Health Organization (WHO) offer universal standards — including ISO 15189 and ISO/IEC 17025 — to regulate laboratory work and ensure consistency, quality assurance, and safety worldwide³. Despite these institutional frameworks, many laboratories in developing countries continue to be plagued by deficiencies in equipment, staff training, infrastructure, and regulatory compliance — leading to substandard working conditions, unreliable results, and potential harm to individuals and the environment [4,5].

This paper examines the legal and regulatory frameworks guiding science laboratory practice globally and in Nigeria, their structures, enforcement mechanisms, and the extent to which they support scientific progress and public safety. Given the descriptive and analytical nature of this review, it is appropriately classified as a narrative review rather than a systematic review.

2. BACKGROUND TO STUDY

Science laboratories are indispensable in research, healthcare, industrialization, innovation, and education. The handling of chemicals, biological organisms, and advanced apparatus is accompanied by significant risks, necessitating strict regulatory management. Proper regulation ensures not only the safety of operators and the environment but also the precision and integrity of scientific data. Globally, regulatory frameworks have been developed to encompass safety regulations, ethical considerations, accreditation processes, and operating standards. Nigeria, as a member of the international scientific community, has enacted numerous regulations, albeit with persistent implementation challenges.

The importance of supervising laboratory work through regulation cannot be overemphasized. It has been established that compliance with international standards significantly reduces the incidence of laboratory accidents, reflecting the impact of relevant regulations [6]

Laboratories adhering to WHO guidelines experienced fewer safety infractions than poorly regulated ones. Similarly, [7] examined the implementation of regulatory systems in developing countries, identifying inadequate resources, poor infrastructure, and insufficient training as primary challenges. These findings suggest that even where global norms provide a useful model, their effectiveness depends on local capacity and enforcement practices.

3. IMPORTANCE OF REGULATIONS FOR SAFETY, ETHICS, LEGAL COMPLIANCE, AND DATA INTEGRITY

Laboratory regulations are not formalities; they are vital for the safety of life, for upholding the integrity of science, and for the responsible use of resources. They govern conduct in the laboratory to prevent accidents, uphold ethical behavior, ensure legal compliance, and produce reliable data.

3.1. Safety

Safety is one of the primary reasons laboratory regulations exist. In most laboratories, personnel work with chemicals, sharp instruments, open flames, electrical equipment, and sometimes infectious agents. Without safety rules, the risk of accidents — such as burns, chemical spills, fires, or infections — becomes very high. Laboratory safety protocols guide workers on how to store materials, wear protective gear, use equipment correctly, and respond to emergencies⁸. Adherence to these protocols saves lives and prevents injuries.

3.2. Ethics

Ethics in the laboratory refers to application of moral principles (honesty and integrity) to ensure professional conduct. Ethical regulations ensure that all experiments and procedures are carried out responsibly, with respect for human life, animals, and the environment. Examples include rules against falsifying results, mistreating animals in research, or using unapproved methods. Ethics also encompasses obtaining proper informed consent before collecting samples from human subjects. Laboratory ethics build public trust in science and protect the reputations of institutions [9].

3.3. Legal Compliance

Laboratories are subject to local, national, and sometimes international laws. Regulations ensure that laboratories do not violate these laws, especially when handling toxic substances, biological agents, or human samples. NISLT plays a major role in enforcing professional and legal standards for science laboratories across Nigeria. Failure to comply with legal standards can lead to sanctions, fines, or operational shutdowns. For example, the unauthorized disposal of chemical waste or the misuse of laboratory facilities for illegal activities are punishable offenses under environmental and public health legislation [10].

3.4. Data Integrity

Scientific work depends on accurate, reliable, and reproducible data. Regulations help ensure that laboratory results are not manipulated, exaggerated, or falsified. This is critically important in research, diagnostics, and product development. Following standard operating procedures (SOPs), maintaining proper records, and using validated methods are all part of regulatory requirements that protect data integrity

[3,11]. Trustworthy laboratory data leads to better decision-making in medicine, science, and public policy.

3.5. Levels of Laboratory Regulation

There are different levels at which laboratory regulations operate:

- **National Regulations:** In Nigeria, institutions such as NISLT and MLSCN oversee the regulation of science and medical laboratory practice respectively, while NAFDAC ensures the safety of food, drugs, and chemicals used in laboratories [10].
- **International Regulations:** Guidelines developed by the WHO and ISO promote uniformity and quality across laboratories internationally. ISO standards such as ISO 15189 (for medical laboratories) and ISO/IEC 17025 (for testing and calibration laboratories) serve as universal benchmarks for accreditation and quality assurance [3].
- **Institutional Policies:** Universities, hospitals, and research institutes maintain internal policies, standard operating procedures (SOPs), safety manuals, and waste disposal procedures that are aligned with national and international standards.

These layers collectively constitute a foundation ensuring that laboratory work is conducted safely, legally, and scientifically.

4. GLOBAL REGULATORY FRAMEWORKS GOVERNING LABORATORY PRACTICE

Laboratories globally are governed by regulatory frameworks designed to ensure the accuracy, safety, reliability, and ethical integrity of scientific work. These frameworks include international standards and national regulations that promote best practices and enhance global data comparability.

4.1. OSHA — Occupational Safety and Health Administration

OSHA, a US-based regulatory agency, is globally recognized for its comprehensive workplace safety guidelines. In laboratories, OSHA standards cover areas such as chemical hygiene, biological safety, radiation protection, and ergonomics. Although OSHA is an American institution, many of its safety models are adopted or adapted in Nigerian laboratories, particularly in institutions collaborating with international bodies [12].

4.2. WHO — World Health Organization

The WHO provides extensive guidance on laboratory biosafety, disease surveillance, and quality management. Its Laboratory Biosafety Manual is a widely used global reference, outlining how laboratories should handle infectious materials, respond to biological risks, and prepare for public health emergencies. The WHO also collaborates with countries like Nigeria to strengthen laboratory systems, especially in areas such as antimicrobial resistance (AMR) and outbreak response [13].

4.3. OECD Principles of Good Laboratory Practice

The OECD Principles of Good Laboratory Practice (GLP) provide a quality system for non-clinical safety studies related to health and environmental safety. GLP ensures that the planning, performance, monitoring, recording, archiving, and reporting of test data are consistent and of high quality, facilitating data acceptance among member countries and avoiding duplicative testing [14].

4.4. ISO/IEC 17025: General Requirements for Testing and Calibration Laboratories

ISO/IEC 17025 is an international standard specifying the general requirements for the competence of testing and calibration

laboratories. It addresses both technical and management requirements that influence the precision and accuracy of laboratory findings [15]. Accreditation to these standard signals that a laboratory is technically qualified to produce precise and reliable test and calibration data. It is extensively applied in industrial, academic, and regulatory laboratories and is often used as the basis for international recognition and collaboration [12].

4.5. ISO 15189: Medical Laboratories — Requirements for Quality and Competence

ISO 15189 is specifically designed for medical laboratories and combines technical and management system requirements to ensure consistent and accurate medical testing [3]. It assists laboratories in adopting a quality management system that supports diagnostic accuracy and patient safety.

4.6. WHO Laboratory Biosafety Manual

The WHO Laboratory Biosafety Manual outlines practices, procedures, and safety measures for the laboratory handling of infectious agents. It aims to minimize risks to laboratory staff, the community, and the environment, and is widely used as a reference in both developed and developing countries ¹⁶.

4.7. CDC - Centers for Disease Control and Prevention

The CDC provides practical resources and training for laboratory safety, especially in the handling of infectious agents. It provides protocols for biosafety levels (BSL 1–4), sample transportation, and laboratory response in public health emergencies. Nigerian laboratories often adopt CDC protocols when dealing with emerging diseases such as Lassa fever and Ebola [4]. Compliance with these international standards ensures that laboratory practices are not only locally compliant but globally trusted.

Table 1. Summary of Key Global Regulatory Frameworks for Laboratory Practice

Framework /Body	Scope	Key Document	Standard/ Relevance to Nigeria
WHO	Global	Laboratory Manual; Guidelines.	Biosafety Adopted in biosafety & outbreak QM response.
ISO	Global	ISO 15189; ISO/IEC 17025.	Basis for NiNAS accreditation.
OECD	Member states	GLP Principles	Applied in NAFDAC-regulated labs.
OSHA	USA (globally adapted)	Chemical Plan	Hygiene Adapted in international-partnership labs.
CDC	USA (globally adopted)	BSL 1–4 Protocols	Adopted for infectious disease management.

5. NIGERIA'S LEGAL AND REGULATORY FRAMEWORK GOVERNING LABORATORY PRACTICE

Laboratory practice in Nigeria is regulated by several legal instruments and institutions that impose requirements related to health, safety, ethics, and environmental protection. In addition to professional regulatory bodies the framework incorporates biosafety, bioethics, and biosecurity provisions to guarantee sound scientific practices. These organizations exist at national and institutional levels, and together they develop standards, enforce guidelines, and support the professional development of laboratory scientists and technologists.

5.1. Nigerian Institute of Science Laboratory Technology (NISLT)

NISLT, established by Act 12 of 2003, regulates the training and professional practice of Science Laboratory Technologists in Nigeria. The Institute ensures that laboratories are staffed by competent technologists and comply with safety and procedural standards [17]. Its functions include:

- Accrediting training institutions and Programmes for Laboratory Technology;
- Certifying and registering qualified Laboratory Technologists;
- Setting professional standards and codes of conduct for laboratory practice;
- Inspecting laboratories across institutions to assess compliance with safety standards, infrastructure requirements, and equipment maintenance;
- Promoting adherence to ethical and safety standards through a formal Code of Ethics covering confidentiality, sample handling, waste disposal, and reporting;

- Supporting research, conferences, and publications to advance laboratory practice;
- Collaborating with national and international agencies to remain aligned with global standards.

Through these activities, NISLT ensures that laboratory personnel are adequately trained and adhere to best practices in biosafety and biosecurity [18].

5.2. Medical Laboratory Science Council of Nigeria (MLSCN)

Established under Act 11 of 2003, the MLSCN is the primary regulatory body overseeing medical laboratory science practice in Nigeria. It ensures the accreditation of laboratories, registers practitioners, and oversees quality assurance [19]. In its 2023–2024 operational year, MLSCN inspected over 103 laboratories, sealed 23, and sanctioned six for operating illegally [20]. Its mandates include:

- Regulating the practice of medical laboratory science;
- Determining standards of knowledge and skill for practitioners;
- Accrediting training institutions for scientists, technicians, and assistants;
- Maintaining a register of qualified practitioners;
- Regulating the production, importation, and distribution of diagnostic laboratory reagents and chemicals.

5.3. Institute of Chartered Chemists of Nigeria

The Institute of Chartered Chemists of Nigeria (ICCON), established by Decree No. 91 of 1993 (now ICCON Act, CAP I.12 LFN 2004), regulates the teaching, learning, and professional practice of Chemistry in Nigeria.

Operating under the Federal Ministry of Education, ICCON ensures that chemical practices within laboratories adhere to professional standards. Its roles include:

- Ensuring that chemical laboratories adhere to safety standards and protocols;
- Promoting continuous professional development among Chemists;
- Collaborating with other regulatory bodies to enhance chemical safety and biosecurity.

5.4. National Biosafety Management Agency

The National Biosafety Management Agency (NBMA), established by the National Biosafety Management Agency Act 2015 (amended in 2019), regulates biotechnology activities to safeguard human health and the environment. The Agency develops biosafety protocols, oversees biosecurity measures, and ensures compliance with national standards in biotechnology practice. It provides protocols for Genetically Modified Organisms (GMOs) and ensures that laboratories handling such materials comply with biosafety guidelines. The NBMA also aligns with international frameworks such as the Cartagena Protocol on Biosafety, promoting the safe handling of genetically engineered materials [21]. Its key roles include:

- Formulating policy guidance on biosafety issues;
- Implementing provisions of international conventions and protocols relating to GMOs;
- Developing measures for biosafety risk assessment and management;
- Ensuring compliance with biosafety regulations through monitoring and enforcement.

In 2022, Nigeria launched the National Biosafety Policy and Action Plan (2022–2026), aiming to strengthen the country's biosafety framework and enhance biosecurity measures across the agriculture, health, and environment sectors.

5.5. Standards Organization of Nigeria

The Standards Organization of Nigeria (SON), established under Act No. 56 of 1971 (as subsequently amended), is responsible for standardizing and regulating the quality of all products in Nigeria, including laboratory equipment and materials. SON's functions encompass certifying products, assessing quality assurance activities, and enforcing standards to ensure the reliability of laboratory instruments and consumables [22]. In the context of laboratory practice, SON:

- Develops and promotes standards for laboratory equipment and procedures;
- Conducts conformity assessments and certifications for laboratories;
- Collaborates with international standardization bodies to align Nigerian standards with global best practices.

5.6. National Health Research Ethics Committee

The National Health Research Ethics Committee (NHREC), inaugurated in 2005, advises on ethical issues concerning health research in Nigeria. It sets norms and standards for conducting human and animal research, ensuring that laboratory-based research adheres to ethical guidelines and protects the rights and welfare of research subjects²³. Its key roles include:

- Reviewing and approving research protocols to ensure ethical compliance;
- Monitoring ongoing research for adherence to approved ethical standards;

- Providing guidance and training on research ethics to institutions and researchers.

5.7. National Agency for Food and Drug Administration and Control (NAFDAC)

NAFDAC plays a pivotal role in regulating laboratories involved in the testing of foods, drugs, and cosmetics. It mandates Good Laboratory Practice (GLP) compliance and monitors the use of reagents and chemicals to ensure public safety [24]. Laboratories under NAFDAC's purview must comply with strict guidelines for drug testing, chemical analysis, and reporting. The agency also mandates periodic re-certification of laboratories conducting regulated activities [4]. In the laboratory context, NAFDAC is responsible for:

- Ensuring that laboratories involved in the testing of regulated products adhere to GLP standards;
- Conducting inspections and audits of laboratories to verify compliance with regulatory requirements;
- Providing guidelines and training on laboratory quality management systems.

5.8. National Environmental Standards and Regulations Enforcement Agency (NESREA)

Established by Act No. 25 of 2007, NESREA oversees environmental compliance in laboratories. It ensures proper disposal of laboratory waste and enforces environmental safety standards to prevent pollution [25]. Laboratories are required to complete Environmental Impact Assessments (EIAs) before commencing operations. NESREA's roles in the context of laboratory practice include:

- Regulating the disposal of hazardous and biomedical waste generated by laboratories;

- Ensuring laboratories comply with environmental standards to prevent pollution and protect public health;
- Conducting inspections and monitoring laboratory activities for environmental compliance.

5.9. Federal Ministry of Environment (FMEnv)

The FMEnv creates and oversees national environmental policies, including those affecting laboratories operating in the oil and gas, agriculture, and healthcare sectors. This ministry ensures that laboratories in Nigeria align with national Environmental Impact Assessment (EIA) requirements and provides support for sustainable and green laboratory initiatives [18].

5.10. Legal Instruments and Policies

The regulatory framework for laboratory practice in Nigeria is underpinned by several key legal instruments:

- **Medical Laboratory Science Council of Nigeria Act Cap M25 LFN 2004:** Outlines the legal responsibilities of laboratory scientists and enforcement mechanisms for addressing professional misconduct [2].
- **NESREA Act:** Governs the safe disposal of laboratory waste and enforces environmental compliance measures.
- **Factories Act:** Provides health and safety standards applicable to laboratories operating within industrial premises.
- **Employees Compensation Act:** Mandates compensation for occupational injuries sustained in laboratory settings¹.
- **Animal Disease Control Act and National Code of Health Research Ethics:** Provide guidance on the use of animals in laboratory experiments,

ensuring humane treatment and minimising pain or distress [26].

Table 2. *Key Nigerian Regulatory Agencies for Laboratory Practice*

Agency	Establishing Instrument	Primary Focus
NISLT	Act 12 of 2003	Training & practice of science lab technologists.
MLSCN	Act 11 of 2003	Medical laboratory science regulation & accreditation.
NAFDAC	Decree 15 of 1993 (as amended)	Food, drug & chemical safety; GLP compliance.
NESREA	Act No. 25 of 2007	Environmental compliance & waste management.
SON	Act No. 56 of 1971 (as amended)	Product & equipment standardisation.
NBMA	NBMA Act 2015 (amended 2019)	Biosafety & biosecurity for biotechnology.
NHREC	Inaugurated 2005	Health research ethics.
ICCON	Decree 91 of 1993	Chemical laboratory standards & chemist regulation.
NiNAS	Established under SON framework	Laboratory accreditation (ISO 15189, ISO/IEC 17025).

6. ETHICAL CONSIDERATIONS AND PROFESSIONAL CONDUCT

Ethical issues in laboratory practice include data falsification, unauthorized testing, privacy breaches, and patient consent violations [2]. These issues can severely undermine public trust and the integrity of scientific findings.

The Code of Ethics for Medical Laboratory Scientists, enforced by MLSCN, requires practitioners to maintain objectivity, honesty, confidentiality, and respect for human dignity. In Nigeria, ethical approval from recognized Institutional Review Boards

(IRBs) is mandatory for research involving human and animal subjects. However, enforcement remains inconsistent due to weak institutional capacity [26]. Continuous ethics training is essential to ensure professionals remain aware of evolving ethical standards, particularly with regard to emerging technologies such as genetic testing and digital diagnostics.

6.1. *Ethical Guidelines Governing Laboratory Animal Use*

The use of animals in scientific research is guided by the ethical principles of the 3Rs: Replacement, Reduction, and Refinement. In Nigeria, the NHREC provides oversight for

animal use in research, requiring that studies minimize harm and employ alternatives wherever possible.

Researchers must obtain ethical clearance before using animals and must adhere to appropriate standards of care, housing, feeding, and humane euthanasia. The use of laboratory animals enables an understanding of disease mechanisms, drug efficacy and toxicity testing, and vaccine development. However, ethical concerns regarding animal suffering, the high cost of animal care, and the limited translatability of animal models to human outcomes present ongoing challenges.

6.2. Key Frameworks: Biosafety, Biosecurity, and Bioethics

Biosafety refers to the containment principles and practices used to prevent unintentional exposure to pathogens and toxins. It is institutionalized through NBMA and NAFDAC policies [16] and encompasses the use of personal protective equipment (PPE), secure sample containment, and biosafety cabinets [11]. NiBSA promotes biorisk management, develops training for laboratory professionals, and partners with government bodies to secure biological materials and influence, and support, and regulate modern biotechnology.

Biosecurity involves measures to prevent the loss, theft, or misuse of biological materials. Nigerian institutions have integrated biosecurity policies particularly in virology and research laboratories under NBMA and MLSCN [21]. This includes access control, surveillance, and secure documentation of biological materials [4]. NiBSA promotes biorisk management, develops training for laboratory professionals, and partners with government bodies to secure biological materials and influence, and support, and regulate modern biotechnology.

Bioethics governs the moral principles underlying scientific research, such as informed consent, justice, and beneficence. NHREC remains the foremost body ensuring that ethical standards are upheld across Nigerian research institutions [27].

7. QUALITY ASSURANCE AND ACCREDITATION SYSTEMS

A significant number of laboratories in Nigeria do not have formal Quality Management Systems (QMS). This results in inconsistent testing procedures, elevated rates of diagnostic errors, and poor patient outcomes [28]. External Quality Assessment (EQA) Programmes are designed to ensure that laboratories meet internationally accepted benchmarks. However, participation in such Programmes is limited due to cost and logistical barriers [29].

The Nigeria National Accreditation Service (NiNAS) is responsible for accrediting laboratories based on international standards such as ISO 15189. Despite its efforts, NiNAS faces challenges related to resource constraints and limited public awareness. Laboratories also struggle with the procurement of substandard reagents, the absence of calibration services, and poor maintenance culture — factors that collectively erode the credibility of laboratory results and discourage international collaboration [30].

8. IMPLEMENTATION AND MONITORING

Implementing laboratory regulations goes beyond drafting rules — it requires ensuring that those rules are actively practiced, monitored, and improved over time.

8.1. Institutional Safety Committees

Most well-structured laboratories — particularly in universities and research institutions — maintain Internal Safety Committees responsible for overseeing laboratory safety and compliance. These committees typically consist of senior technologists, safety officers, and academic staff who monitor adherence to safety guidelines, conduct regular risk assessments, provide training and orientation for laboratory users, and oversee emergency preparedness (e.g., fire drills, chemical spill response). They work closely with external regulators like NISLT, NAFDAC, and FMEnv, especially during inspections or when applying for operational licenses. Studies have shown that laboratories with active safety committees tend to perform better in maintaining compliance, reducing accidents, and protecting data integrity [10].

8.2. Standard Operating Procedures (SOPs)

SOPs are step-by-step instructions guiding how specific laboratory tasks should be carried out — from sample collection and chemical handling to equipment use and waste disposal. Every regulated laboratory is expected to have documented SOPs tailored to its operations. These are required by NISLT, ISO, and other standards, and serve as training guides, error-reduction tools, and consistency assurance mechanisms [12]. A well-written SOP for blood sample handling, for instance, will specify required PPE, steps for sample labelling and storage, biosafety precautions, and procedures for reporting incidents. Having SOPs that are readily available and regularly updated is a hallmark of a well-managed laboratory.

8.3. Safety Audits and Compliance Checklists

Routine safety audits help laboratories assess their level of compliance with national

and international standards. These audits may be conducted internally or by bodies such as NISLT or NAFDAC, and involve checklists covering fire safety, chemical storage, PPE availability, and biosafety practices [4]. They provide opportunities to detect risks early and implement corrective actions.

8.4. Laboratory Information Management Systems (LIMS)

LIMS help laboratories manage data, inventory, equipment logs, and personnel activity. By using digital systems, laboratories can reduce manual errors, improve traceability, and meet regulatory demands more efficiently. WHO and CDC recommend adopting LIMS to track specimen data, especially in public health laboratories¹². Some Nigerian laboratories are progressively adopting LIMS for quality control and record-keeping.

9. REGULATORY CHALLENGES IN NIGERIA

Despite the existence of regulatory guidelines and standards, enforcing laboratory regulations in Nigeria remains a significant challenge. A combination of financial, structural, and human limitations makes compliance inconsistent across institutions.

9.1. Inadequate Infrastructure and Underfunding

Many laboratories in Nigeria operate on tight budgets that barely cover consumables, let alone investments in safety equipment or modern infrastructure. Basic infrastructure such as fume hoods, autoclaves, chemical storage cabinets, and proper ventilation is absent in many facilities. Even where regulations exist, they cannot be effectively enforced if the physical environment does not support compliance. Some laboratories also lack backup power, clean water, and waste

treatment systems, making it difficult to meet environmental standards [5,18].

9.2. Limited Awareness and Poor Training

Many laboratory personnel, especially in smaller Institutions, are unaware of current regulations or lack the training to implement them. This is particularly concerning in the handling of infectious agents or hazardous chemicals. Studies such as that of [Halatoko et al⁴](#) in Togo identified limited biosafety knowledge among laboratory staff as a key driver of increased contamination and accident risk — a pattern similarly observed in parts of Nigeria.

9.3. Corruption and Weak Enforcement

Corruption within regulatory institutions impairs effective oversight. Some unregistered laboratories continue to operate illegally, often with the knowledge or connivance of corrupt officials. Additionally, bureaucratic bottlenecks in the accreditation and licensing processes delay laboratory development and create barriers for start-up and small facilities [31,32].

9.4. Resistance to Change

Staff members are sometimes unwilling to adopt new protocols or safety procedures, reverting instead to familiar but outdated practices. This resistance often stems from poor leadership, insufficient incentives, or fear of disciplinary measures. Without a supportive organizational culture, regulations are perceived as burdens rather than safety tools.

9.5. Limited Quality Management and EQA Participation

A large number of Nigerian laboratories lack formal Quality Management Systems (QMS), resulting in inconsistent testing procedures and elevated rates of diagnostic errors. Participation in External Quality

Assessment (EQA) Programmes is limited due to cost and logistical barriers, further compromising the reliability of laboratory results ^{29,33}.

10. POLICY RECOMMENDATIONS

To bridge existing regulatory gaps and strengthen laboratory governance in Nigeria, the following policy recommendations are proposed:

1. **Increase Government Funding:** Dedicated budgetary allocation for laboratory infrastructure, equipment, and reagents should be increased at both federal and state levels to enable compliance with ISO and WHO standards.
2. **Strengthen Regulatory Enforcement:** NISLT, MLSCN, NAFDAC, and allied agencies should intensify unannounced inspections and impose meaningful sanctions on non-compliant facilities. Corruption within regulatory bodies must be addressed through independent oversight and whistle-blower protection.
3. **Expand Training Programmes:** Mandatory, periodic biosafety and regulatory compliance training should be institutionalized for all laboratory personnel. Partnerships with international bodies (WHO, CDC, ISO) can facilitate capacity building.
4. **Promote ISO Accreditation:** Subsidized pathways and technical assistance for NiNAS accreditation should be developed to increase the number of ISO 15189 and ISO/IEC 17025-certified laboratories in Nigeria.
5. **Harmonize the Regulatory Framework:** A coordinating committee comprising NISLT, MLSCN, NAFDAC, SON, NESREA, NBMA, and NHREC should be established to reduce overlaps, streamline licensing, and present a

unified regulatory front to the laboratory community.

6. **Adopt Digital Tools:** Nationwide adoption of Laboratory Information Management Systems (LIMS) and electronic quality management platforms should be incentivized to improve data integrity, traceability, and regulatory reporting.
7. **Strengthen Ethics Oversight:** IRBs and NHREC should be adequately resourced and their decisions made more transparent. Ethics training should be embedded in the curricula of all laboratory science Programmes.

11. GENERAL LABORATORY SAFETY RULES

Safety rules are only effective when actively enforced. Strong laboratory management is essential for this purpose. While safety requirements vary according to the type of laboratory, the following general rules apply broadly:

1. Familiarize yourself with all alarms and safety signs and follow the indicated instructions in the event of an emergency.
2. Be aware of your facility's evacuation procedures and designated assembly points.
3. Know the location of all laboratory safety equipment, including first aid kits, fire extinguishers, eye wash stations, and safety showers.
4. Keep a list of local emergency contact numbers readily accessible.
5. Ensure that all areas containing dangerous substances and equipment are clearly labelled with appropriate warnings.
6. Always work in properly ventilated areas.
7. Do not eat, drink, or chew gum in the laboratory.

8. Never use laboratory glassware as food or beverage containers.
9. Do not operate laboratory equipment for which you have not received proper training and authorization.
10. Do not work alone in the laboratory.
11. Never leave operating equipment unattended.
12. Never raise glassware, solutions, or apparatus above eye level.

12. CONCLUSION

The legal and regulatory framework governing laboratory practice in Nigeria is evolving but remains burdened by implementation challenges, resource deficits, and ethical lapses. A comprehensive architecture of regulatory bodies exists — spanning NISLT, MLSCN, NAFDAC, NESREA, SON, NBMA, and NHREC — yet the translation of regulations into consistent, on-the-ground practice is frequently undermined by under-funding, weak enforcement, inadequate training, and institutional corruption.

Globally, frameworks developed by ISO, WHO, OECD, OSHA, and the CDC provide well-established benchmarks that Nigeria has partially adopted but not fully operationalized. Closing this gap requires a multi-stakeholder approach involving policymakers, regulatory agencies, academic institutions, professional bodies, and the private sector. Through sustained investment in infrastructure, robust enforcement of ethical and legal standards, and deliberate alignment with global best practices, Nigeria can build a laboratory regulatory system capable of supporting improved diagnostic outcomes, scientific integrity, research advancement, and international collaboration.

Conflict of Interest Declaration

The authors declare there is no conflict of interest in this publication. The authors are in agreement.

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