Medical Laboratory Science Council of Nigeria

Guidelines for In-Vitro Diagnostics (IVDs) Regulation in Nigeria

Plot 1166, Muhammad N. Umar lane,
Durumi Phase II,
Garki, Abuja
Email – info@mlscn.gov.ng
Website – www.mlscn.gov.ng

This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

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Policy Statement	MLSCN in fulfillment of its statutory mandate is desirous to ensure compliance to production of quality of test results from all medical laboratories nationwide. MLSCN which regulates the profession and practice of medical laboratory science will ensure that only MLSCN approved In – Vitro Diagnostics (medical laboratory equipment, reagents, chemicals and consumables) are allowed to be produced, imported, distributed, stocked, marketed and used in medical laboratories in Nigeria.

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1. INTRODUCTION

Medical Laboratory Science is the bedrock of the 21st Century evidence-based medicine. This means accurate reproducible results are invaluable to providing quality health care services. There are several elements of quality in medical laboratory practice; this includes qualified and skilled personnel, regular supply and use of appropriate equipment, reagents and consumables, use of appropriate procedure and a preventive maintenance schedule.

Before now there has been no regulation or coordination on the types of equipment, reagents and consumables imported, distributed, marketed and used in the country with people with limited knowledge about these products dealing in such products. This has resulted in substandard, non-appropriate equipment, reagents and consumables being imported and used in the country which ultimately affects the quality of reports emanating from the laboratories.

In 2003, the MLSCN Act was passed which empowers MLSCN to, inter alia, regulate the production, importation, sales and stocking of diagnostic laboratory reagents and chemicals (*in-vitro* diagnostics (IVDs)). Subsequently on 5th September, 2013, the MLSCN Public Health IVDs control laboratory was commissioned by the President of Nigeria. The MLSCN Public Health IVDs control laboratory mandate is to ensure that only quality IVDs enter the Nigerian market, and stamp out all fake and adulterated IVDs in line with the international standard and the vision of the MLSCN; to be a world

acclaimed regulatory agency driving the culture of quality and efficient health laboratory care to the public.

Therefore, as part of efforts to contribute to improving the quality of health care services in the country and as part of its regulatory function over the profession and practice of medical laboratory science, the Medical Laboratory Science Council of Nigeria hereby formulate this guideline to ensure that only In – Vitro Diagnostics that meet the set standards are produced in or imported into Nigeria.

Definition of terms:

IVDs - any medical laboratory diagnostic reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for in-vitro use. It must be intended by the manufacturer to be used in vitro for the examination of specimens derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient, or to monitor therapeutic measures.

Equipment -A tool, device or machine used to perform an act in a medical laboratory at the end of which it is available in its original form and ready to perform another of the act.

Reagent - Chemicals, compounds, mixtures and other devices employed as reactants in laboratory analysis.

Consumable - Materials used in the laboratory to perform certain acts at the end of which they are not available for reuse. Consumable may include equipment, reagents but includes all other non-recoverable materials not classically defined as reagents.

Product - any equipment, reagent or consumable manufactured in or imported into and stocked or marketed in Nigeria.

Manufacture - fabrication and or production of goods from raw materials mostly in large quantities for commercial purposes.

Import - To bring something or cause something to be brought from another country for commercial, industrial and/or medical laboratory routine/research purposes.

Manufacturer – A person or company that produces goods in large quantities.

Importer - A person or company that buys goods from another country to sell in Nigeria.

Facility - Any place of business under one management at one general physical location where a product is manufactured, imported, assembled, compounded, stocked, distributed and marketed in Nigeria.

Owner - The corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registering Facility.

MLSCN - Medical Laboratory Science Council of Nigeria.

NGO - Non-Governmental Organization

Listing - Catalog or directory of products submitted by a Facility to MLSCN for purposes of commercial production, importation and marketing in Nigeria.

WHO - World Health Organization

WAHO - West African Health Organization

SAGE - Strategic Advisory Group of Experts (World Health Organization)

3. SCOPE

This document is to provide guidance for the Regulatory control of in- vitro diagnostics (IVDs) in the Nigerian market.

4. POLICY OBJECTIVES

MLSCN shall:

1) Register all the manufacturers, importers, distributors and marketers of medical laboratory equipment, reagents and other consumables.
2) Provide standards for equipment, reagents and consumables to be produced in or imported into Nigeria.
3) Give approval for equipment, reagents and consumable intended for use in medical laboratories in Nigeria before manufacture, importation, stocking, distribution and marketing can commence.
4) Inspect the facilities from time to time to ensure adherence.
5) Hold facility owners responsible for the on-time provision of details of the products to be imported or manufactured.
6) Evaluate or validate all equipment, reagents and consumables for medical laboratory use in Nigeria.
7) Ensure that all evaluated and validated reagents and equipment have MLSCN identification number.
8) Collaborate with relevant agencies, NGOs, government agencies and international organizations to ensure that sub-standard equipment, reagent and

consumables are not manufactured, imported, distributed and marketed in the country.

9) Ensure that all purchases and donations in kind conform to national standards under this policy.

10) Determine fees for the purpose of registration, inspection and any such other fees as may be necessary in furtherance of the implementation of this guideline.

11) Determine minimum standards for various establishments engaged in production, importation, stocking, distribution, marketing and storage of medical laboratory equipment, reagents and associated consumables. It shall also review such minimum standards from time to time.

12) Ensure that all registered facilities have Medical Laboratory Scientist in its employ, who shall see to strict compliance with standards and professional matters that shall be made from time to time by MLSCN.

13) Ensure that all registered facilities have or show capability to provide backup, maintenance and repair services for products and services they market.

14) At all times show commitment to ensuring that quality equipment, reagents and consumables are available and accessible to Nigerians.

15) By public enlightenment, bring to the knowledge of the consumers and the general public the contents of this policy with regards to their rights and privileges.

16) Ensure that all Service providers use equipment, reagents and consumables that comply with MLSCN guidelines.

17) Design appropriate forms and make such forms available for Facilities to provide relevant information for purposes of premarket evaluation or validation, facility registration, updates and annual registration.

5. PROCEDURES

The following steps applies to regulation of IVDs in Nigeria:

A. Manufacturers

i. The manufacturer shall register the premises, products and services with MLSCN.

ii. MLSCN shall provide the manufacturers with registration numbers.

iii. Medical laboratory reagents and consumables with less than two (2) years expiry dates, unless otherwise specified, shall not be manufactured in the country.

iv. The registration shall be renewed annually.

v. The manufacturer/ own brand labeler is responsible for their leaflet or labeling /branding and ensure appropriate conformity assessment procedures is correctly complied with by the manufacturer /or any sub-contractor involved.

vi. Manufacturer and any sub-contractor makes available to MLSCN compliance marking, appropriate documentation necessary for them to fulfill their respective responsibilities;

vii. Manufacturer makes a declaration of conformity for the products concerned, and retains them for future reference by MLSCN

viii. Manufacturer shall register its organization and devices with MLSCN

ix. Manufacturer shall ensure the compliance marking of conformity is properly applied;

x. Manufacturer shall ensure post-marketing obligations such as Surveillance/vigilance are implemented in-conjunction with MLSCN.

xi. Where any of the manufacturer's responsibilities are subcontracted to another party, the contract between the manufacturer and the subcontractor must assign the subcontracted responsibilities to the subcontractors.

xii. A distributor whose name appears on the packaging, labels or instructions for use is not considered to be its own brand labeler or a manufacturer if it is clear that the product is being placed on the market under the actual manufacturer's own name or that of the authorized representative.

xiii. The requirement for the control of IVDs imposes obligations on manufacturers with respect to:

a) Post production monitoring

b) The reporting of adverse incidents, and any malfunction or deterioration, which might lead to an adverse incident to MLSCN.

xiv. Manufacturers, including own brand labelers, should be familiar with the relevant obligations regarding use of the compliance mark of the respective originating country.

xv. All obligations to report IVDs incidents across the several own brand labelers to MLSCN should be taken seriously as there would be grave consequences for not reporting.

xvi. MLSCN considers that it is the responsibility of the own brand labeler to ensure that incidents or potential incidents with IVDs that is being placed on the market under his name should also be notified to the 'actual manufacturer'. It is also the responsibility of the actual manufacturer of the IVDs, if he is aware of a particular issue with his IVDs to ensure that own brand labelers are informed of the issue so that the appropriate corrective action can be implemented in the interest of public health.

B. Importers /Marketers

i. All importers of IVDs shall register all products and services with MLSCN.

ii. MLSCN shall provide the importers with IVDs registration numbers.

iii. The registration shall be renewed annually.

iv. IVDs with less than two (2) years expiry dates unless otherwise specified, shall not be imported into the country.

v. MLSCN shall ensure that reagents and consumables that are expired are appropriately destroyed.

vi. The manufacturer/ own brand labeler is responsible for their leaflet or labeling /branding and ensure that appropriate conformity assessment

procedures is correctly complied with by the manufacturer /or any sub-contractor involved.

vii. Manufacturer and any sub-contractor makes available to MLSCN compliance marking, appropriate documentation necessary for them to fulfill their respective responsibilities;

viii. Makes a declaration of conformity for the products concerned, and retains them for future reference by MLSCN

ix. Registers own organization and devices with the MLSCN

x. The compliance marking of conformity is properly applied;

xi. Post-marketing obligations such as Surveillance/vigilance are implemented.

xii. Where any of the manufacturer's responsibilities are subcontracted to another party, the contract between the manufacturer and the subcontractor must assign the subcontracted responsibilities to the subcontractors.

xiii. A distributor whose name appears on the packaging, labels or instructions for use is not considered to be an own brand labeler or a manufacturer if it is clear that the product is being placed on the market under the actual manufacturer's own name or that of the authorized representative.

xiv. The requirement for the control of IVDs imposes obligations on manufacturers with respect to:

a) Post production monitoring, and

b) The reporting of adverse incidents, and any malfunction or deterioration, which might lead to an adverse incident, to the MLSCN.

xv. Manufacturers, including own brand labelers, should be familiar with the relevant obligations regarding use of the compliance mark of the respective originating country.

xvi. All obligations to report IVDs incidents across the several own brand labelers to MLSCN should be taken seriously as there would be grave consequences for not reporting.

xvii. MLSCN considers that it is the responsibility of the own brand labeler to ensure that incidents or potential incidents with IVDs that is being placed on the market under his name should also be notified to the 'actual manufacturer'. It is also the responsibility of the actual manufacturer of the IVDs, if he is aware of a particular issue with his IVDs to ensure that own brand labelers are informed of the issue so that the appropriate corrective action can be implemented in the interest of public health.

(C) MLSCN

MLSCN functions as regulatory authority for IVDs are as outlined:

i. The maintenance of a register of IVDs manufacturers/importers /distributors /marketers and their respective IVDs placed in the Nigeria market.

ii. The establishment and administration of a vigilance system for incidents attributable to IVDs.

iii. The examination and approval (if acceptable) of applications for performance evaluation for IVDs.

iv. The monitoring of IVDs post market surveillance in Nigeria.

v. The maintenance of market surveillance systems, which may involve the inspection of IVDs manufacturers and their authorized representatives for compliance with the relevant national and international standard.

vi. Enforcement of compliance to the relevant national and international standard where necessary.

vii. Participation in international activities including various relevant working groups and committees e.g. WHO, WAHO, SAGE, etc.

viii. Issuance of product certificate to the manufacturers /Distributors /Marketers of IVDs

ix. Issuance of import permits to the importers of the IVDs

x. Ensuring the withdrawals of non-certified IVDs and substandard IVDs.

xi. Ensure that reagents and consumables that are expired are destroyed appropriately.

xii. Certify all IVDs produced or imported into the Nigerian market.

xiii. Ensure that all duly certified IVDs products carries the conformity mark of MLSCN

xiv. Carry out post production surveillance of the IVDs

xv. Ensure the establishment and administration of a vigilance system for incidents attributable to IVDs

xvi. Ensure compliance to field Safety Corrective Actions for In-vitro Diagnostics

xvii. Register and maintain register of all the manufacturers, importers, distributors and marketers of IVDs and their respective IVDs.

7. - Stocking of IVDs / Sales

MLSCN shall:

i. Carry out Post market surveillance on IVDs products

ii. Ensure appropriate storage facility

iii. Maintain Registers of organization and their respective IVDs

iv. Ensure Conformity marks as applicable

v. Conduct periodic Post-market surveillance/vigilance

8. Withdrawal of unfit products

MLSCN shall:

i. Ensure that unfit and fake IVDs are withdrawn from circulation

ii. Ensure withdrawal of IVDs products that are not in conformance with the stated standard/criteria on the manufacturer's leaflet

iii. Ensure withdrawal from circulation of IVDs that are not in compliance with the safety inspection checks

iv. Ensure withdrawal of IVDs product that are not certified by MLSCN.

9. CLASSIFICATION OF IVDS

IVDs are categorized by risk as follows:

i. Those that constitute a direct risk to patients

ii. Those that could constitute a serious risk to health and are essential to control e.g. AIDS and hepatitis, etc.

These categories are then subdivided into a further four classes dependent again on risk and the level of conformity assessment required. The following provides a summary of the class, perceived risk and conformity assessment requirement.

IVDs categories are

as follows:

Based on intended use; expectation of users, importation information; health impact of the regulation:

D – High Risk; A - Low risk

Rule 1:

Class D – Tests for blood, tissue, organ screening prior to transfusion or transplantation

Rule 2:

Class C/D – Tests of immunological compatibility classified by their criticality

Rule 3:

Class C - Moderate public health risk or high individual risk providing the critical or sole determinant for correct diagnosis.

Rule 4:

Class B/C - Self-testing devices classified by their criticality.

Rule 5:

Class B - IVD reagents, instruments and test receptacles

Rule 6:

Class A/B: Applies to all other devices

Rule 7:

Class A: IVD controls without an assigned value

10. CONFORMITY ASSESSMENT

Conformity assessment is the process of review that takes place by the Manufacturer/ Importer/ Marketer/ Distributors and MLSCN in order to ensure that safe and compliant products are placed in the Nigerian market.

MLSCN shall:

i. Upon completion of conformity assessment, issue product certificates to the manufacturer/ Importer/ Marketer/ Distributors respectively.
ii. Ensure that all IVDs placed in the market comply with this guideline.
iii. Ensure that a declaration of conformity (product certificate) is provided for all IVDs.
iv. Be solely responsible for issuing of product certificates.

11. MLSCN CONTACT WITH THE MANUFACTURER

i. MLSCN reserves the right to visit any facility upon receipt of any complaints to verify such reports.

ii. MLSCN shall from time to time have contact with manufacturers or their authorized representatives placing products in the Nigeria market.

iii. MLSCN may be in communication with the manufacturer or the authorized representative in relation to any other IVDs regulation.

12. PERFORMANCE EVALUATION

i. For purposes of performance evaluation by MLSCN's Public Health IVDs Laboratory, Registration is required.

ii. All IVDs require performance evaluation in order to ensure the attainment of intended performance.

iii. MLSCN is responsible for the monitoring of the quality, security and safety of IVDs including those for performance evaluation placed in the Nigerian market.

13. LABELLING AND LEAFLETS

MLSCN shall inspect each IVD for proper labeling to ensure it contains the following minimum basic information:

i. Label and instructions for use (IFUs)

ii. English language is required for information to be supplied with IVDs for users.

iii. User type must be considered for labels and IFUs

iv. Instructions for use must accompany the IVDs

v. Shelf life must be stated on the packaging

vi. Expiry date, date of manufacture, batch number and environmental requirement like temperature and humidity must be visibly stated. These Information must be on the IVDs itself or on the outer packaging or both.

vii. Use of electronic labeling and IFUs (Internet, CD-ROM, etc.) is allowed.

viii. Each IVDs must be accompanied by information on usage, safety and manufacturer identification taking into consideration the knowledge and training limitation of the potential user.

14 Registration

a) Facilities that manufacture, import, stock, distribute and market medical laboratory equipment, reagent and consumables are required to register with the Medical Laboratory Science Council of Nigeria (MLSCN).

b) The "owner" of the establishment is responsible for registration.

c) Registration is required by manufacturers, contract manufacturers and contract sterilizers if they put the product into commercial distribution, initial importers, specification developers, re-packagers or re-labelers, re-processors of single-use devices, remanufacturers, distributors, marketers, retailers, and manufacturers of components or accessories that are ready to be used for any intended medical laboratory related purpose and are packaged or labeled for commercial distribution for such medical laboratory related purpose.

d) All registration information (new, updates, or annual review) must be submitted through properly filled MLSCN appropriate forms.

e) A facility must finalize registration with MLSCN within 45 days of commencement of business in Nigeria.

f) Updates to registration information shall be submitted within 30 calendar days after any change occurs.

g) Registered facilities shall review and update its registration on an annual basis.

h) MLSCN shall register a foreign facility only through a registered Nigerian agent. Such Nigerian agent shall provide MLSCN with the telephone numbers, e-mail and physical addresses of their foreign manufacturers.

i) After submission of initial registration information, MLSCN will notify the registrant in writing of their newly assigned registration number once the information is verified and their registration approved.

j) Registration information submitted by a Facility and payment of registration fee is not enough. A Facility is only registered when a letter stating so is received by the Facility from MLSCN.

k) Registration shall be renewed annually and registration information must be reviewed and updated within the first quarter of the year i.e. January to March every year.

3) Fees

The MLSCN shall:

a) Charge Facility and annual business registration fees which shall be paid at the point of submission of completed forms.

b) Charge Premarket submission fees.

c) Charge Such other fees that may be necessary in furtherance of the provisions of this policy.

d) From time to time determine such fees to be paid according to the type of business and these will be publicized before it takes effect.

e) Failure to pay Facility registration fees means the Facility will not be registered and failure to pay annual business registration fees will lead to closure of the Facility and its premises.

15. Listing

a) Owners, who are required to register their Facilities, are also required to provide product listings to MLSCN.

b) Listings shall be submitted to MLSCN through the filling of appropriate forms.

c) Owners shall submit their listing information at the time of initial registration. In addition, owners must review and update their product listings on an annual basis.

d) Listing updates shall be made annually and at any time a new product is introduced into or withdrawn from a Facility's products.

e) Owners shall submit the following listing information:

(i) Current registration number and name of each Facility under their ownership and/or control that performs a regulated function to that product,

(ii) The proprietary/brand name(s) under which the product is marketed,

(iii) Information concerning any regulated activities that they perform on or to the product (e.g., manufacturing),

(iv) MLSCN identification names for each product. (Identification names include the classification name and number and common name),

(v) Labeling when they are unable to identify an appropriate MLSCN identification name.

(vi) For products under evaluation or validation, owners should include the MLSCN premarket submission number.

16 WHO TO CONTACT AT MLSCN:

This guide and associated documents can be found under the 'Publications and Forms' section of MLSCN website: www.mlscn.gov.ng

Alternatively, they can be obtained from the MLSCN directly as follows:

1. **Medical Laboratory Science Council of Nigeria (MLSCN)**

   Head office complex,

   Plot 1166 Mohammed N. Umar Lane, Durumi Phase 2

   Abuja

   info@mlscn.gov.ng

2. **Public Health In-vitro Diagnostics Control Laboratory**

   Medical Laboratory Science Council of Nigeria

Block D, 8, Harvey Road

Yaba – Lagos

Nigeria

Telephone: +2349021765416

Email: info@mlscn.gov.ng

ivds@mlscn.gov.ng

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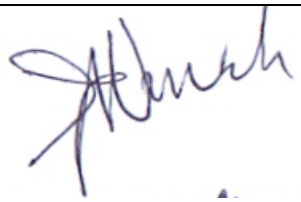
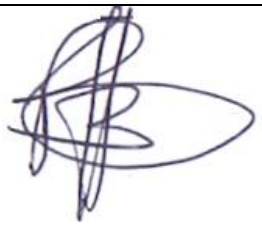
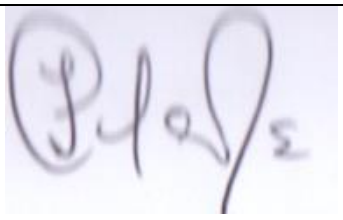
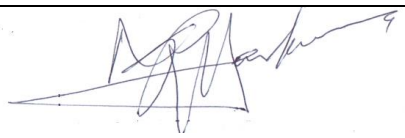
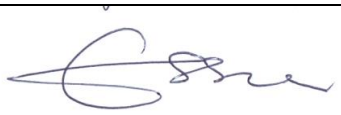
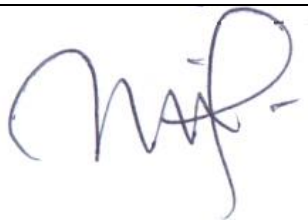
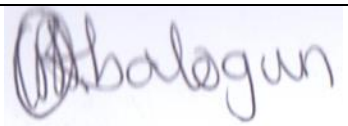
Contributors

S/N	Participant Name	Organization	Signature
1	ERHABOR, Tosan	Medical Laboratory Science Council of Nigeria	
2	AZEEZ, M. M.	Medical Laboratory Science Council of Nigeria	
3	UDO, Stella N.	Medical Laboratory Science Council of Nigeria	
4	NWOKAH, Easter G.	Rivers State University, Port Harcourt	
5	BARDE, Joshua B.	NEQAL Laboratory/ Medical Laboratory Science Council of Nigeria	
6	ADEOYE, Felix (Col.)	HIFASS	
7	UCHUNO, Gregory	Medical Laboratory Science Council of Nigeria	

8	AIKPITANYI- IDUITUA, G. A.	Medical Laboratory Science Council of Nigeria	
9	RUBAINU, Manason G.	Peak Medical Laboratories Ltd.	
10	ESSIEN, Victor	Medical Laboratory Science Council of Nigeria	
11	OFFUTALU, Paulinus N.	PHIVDS Laboratory, Medical Laboratory Science Council of Nigeria	
12	IFEANYI, CASMIR I. C. (Dr.)	University of Abuja	
13	IBANG, Livinus	Nigerian Biological Safety Association (NIBSA)	
14	BALAGUN. Oyebimpe	Institute of Human Virology, Nigerian	
15	ELENDU, Humphrey Ndubueze	Medical Laboratory Science Council of Nigeria	

16	AKINWALE, Abayomi Air Cdre (Rtd.)	USDOD Nigeria	
17	Tubi Abiola	NTBLCP