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National Agency for Food & Drug Administration & Control (NAFDAC)

Vaccines, Biologics, and Medical Devices Registration & Regulatory Affairs Directorate

NAFDAC Guidelines for Conformity Assessment of In Vitro Diagnostic (IVD) Medical Devices

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1.0 Acknowledgement

NAFDAC acknowledges the adoption of IMDRF document No. **GHTF/SG1/N046:2008** and the technical support of the International Medical Device Regulators Forum (IMDRF) in the development of these guidelines.

2.0 Rationale, Purpose, and Scope

2.1 Rationale

Regulatory systems are intended to ensure a high level of protection of public health and safety.

Public trust and confidence in IVD medical devices, and in the administrative systems by which they are regulated, are based on the safety and performance of such products throughout their life cycle.

Conformity assessment, conducted before and after an IVD medical device is placed on the market, and post-marketing surveillance of IVD medical devices in use are complementary elements of the Agency's regulatory model. These complementary elements are intended to provide objective evidence of safety, performance, benefits, and risks, to maintain public confidence.

Conformity assessment is primarily the responsibility of the IVD medical device manufacturer. However, it is done in the context of the established regulatory requirements and both the process and conclusions are subject to further review by NAFDAC.

In general, the degree of involvement of the Agency in such reviews is proportional to the risks associated with a particular category of devices.

2.2 Purpose

To describe:

- An overview of the available conformity assessment elements to demonstrate conformity to the Essential Principles of Safety and Performance of Medical Devices;
- The conformity assessment elements that should apply to each class of device such that the regulatory demands are proportional to the risk class of the IVD medical device;
- The manufacturer's responsibility to provide evidence that the IVD medical device is safe and performs as intended by the manufacturer;
- The responsibility of the Agency to confirm that the conformity assessment elements are properly applied by the manufacturer.

2.3 Scope

This document applies to all products that fall within the definition of an IVD medical device that appears in the GHTF document *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification*.

3.0 References

GHTF final documents

GHTF/SG1/N044:2008 *Role of Standards in the Assessment of Medical Devices.*

GHTF/SG1/N041:2005 *Essential Principles of Safety and Performance of Medical Devices.*

GHTF/SG1/N043:2005 *Labelling for Medical Devices.*

GHTF/SG2/N054:2006 *Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices.*

GHTF/SG3/N010:2004 *Quality Management Systems – Process Validation Guidance.*

GHTF/SG4/N024:2002 *Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General Requirements – Supplement No. 4 – Compilation of Audit Documentation (Clause 5.7)*

GHTF/SG4/N028:1999 *Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements.*

GHTF/SG1/N045:2008 *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification*.

4.0 Definitions

Audit: a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
(Source – GHTF/SG4/N028:1999).

Authorized Representative: means any natural or legal person established within a country or jurisdiction who has received a mandate from the manufacturer to act on his behalf for specified tasks with regards to the latter's obligations under that country or jurisdiction's legislation.

Conformity Assessment: the systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the *Essential Principles of Safety and Performance of Medical Devices (SG1/N041)*.

Recognised Standards: standards deemed to offer the presumption of conformity to specific essential principles of safety and performance

Technical Documentation: the documented evidence, normally an output of the quality management system, that demonstrates compliance of a device to the *Essential Principles of Safety and Performance of Medical Devices (SG1/N041)*.

5.0 Conformity Assessment Elements

The conformity assessment elements that the Agency has included in its conformity assessment system are:

- A quality management system
- A system for post-market surveillance
- Technical documentation
- A declaration of conformity
- Recognition of manufacturers and registration of their IVD medical devices by the Agency.

All five elements apply to each of the device classes. Where there are alternatives within a conformity assessment element, the manufacturer may choose the one that it believes to be most suitable.

The conformity assessment elements that appear in this Section describe the tasks of the manufacturer and, where appropriate, the responsibilities of the Agency. Specific guidance on the conformity assessment elements for each device class is provided in the tables in Section 6.2.

Although the Agency's responsibilities for Class C and Class D IVD medical devices are the same, it needs to be understood that the ToC for a Class C IVD medical device will contain less elaborate information than the ToC for a Class D device. The main difference for a Class D ToC would be in the level of detail in the clinical/performance data and details of the manufacturer's QC release program. The Agency in its review process would not normally require more elaborate information for a Class C device however this does not preclude the Agency from requesting such information in specific cases.

5.1 Quality Management System (QMS)

The requirements for a quality management system that is accepted by the Agency for regulatory purposes and based on internationally recognised standards[1] for medical devices, combined with the other conformity assessment elements, are intended to ensure that IVD medical devices will be safe and perform as intended by the manufacturer.

A manufacturer needs to demonstrate its ability to provide IVD medical devices that consistently meet both customer and regulatory requirements. Manufacturers demonstrate compliance through an established and effectively implemented quality management system that meets the regulatory requirements.

The scope and complexity of the quality management system that a manufacturer needs to establish is influenced by varying needs, objectives, the products provided, processes employed, the size and structure of the organisation, and the specific regulatory requirements.

Processes required by the quality management system but carried out on the manufacturer's behalf by third parties remain the responsibility of the manufacturer and are subject to control under the manufacturer's quality management system. The Agency would assess the adequacy of this control as part of the conformity assessment process.

The extent of the Agency's assessment of the manufacturer's quality management system is influenced by the class of the IVD medical device.

[1] SG1/N044 *Role of Standards in the Assessment of Medical Devices*

For Class B, C and D devices, the Agency needs to be satisfied that the manufacturer has an effective quality management system in place, appropriate for the device under assessment. In doing this, the Agency will carry out an on-site audit of the manufacturer's facility.

Manufacturers of Class C and D devices should have a full quality management system[2] that includes design and development. Manufacturers of Class B devices should have a quality management system also; however, the procedures incorporated within it may not necessarily include design and development activities. Manufacturers of Class A devices are expected to have the basic elements of a QMS in place but need not include design and development activities.

The QMS for manufacturers of Class A devices will be subject to premarket on-site audit by the Agency.

5.2 System for post-market surveillance

Before placing the product on the market, the manufacturer will put in place, as part of its quality management system, a process to assess the continued conformity of the device to the *Essential Principles of Safety and Performance* throughout the IVD medical device lifecycle. This process will include, at a minimum, complaint handling, vigilance reporting, and corrective and preventive action[3].

The Agency would confirm that such a process is in place, usually at the time of the quality management system audit[4].

5.3 Technical documentation

The technical documentation provides evidence that the IVD medical device meets the Essential Principles of Safety and Performance.

For conformity assessment, the manufacturer will establish a subset of technical documentation to be submitted, as required by the class of the device. A description of that subset is provided in the Agency's **Guidelines for Compilation of a Product Dossier for Registration of In Vitro Diagnostics - IMDRF ToC**. The extent of evidence in that ToC is likely to increase with the class of the IVD medical device and its complexity.

The Agency would determine the adequacy of the documented evidence in support of the manufacturer's Declaration of Conformity to the Essential Principles through a review of the ToC. The depth and the timing of the review will be influenced by the risk class of the IVD medical device and its complexity.

5.4 Declaration of Conformity

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[2] See GHTF/SG3 guidance documents
[3] See GHTF/SG2 guidance documents
[4] Further details are provided in the GHTF guidance documents issued by Study Groups 3 and 4

One element of the Agency's regulatory model for IVD medical devices requires that the manufacturer attest that its IVD medical device complies fully with all applicable *Essential Principles for Safety and Performance* as documented in a written 'Declaration of Conformity' (DOC).

At a minimum, this declaration should contain the following information:

- A statement that each device that is the subject of the declaration:
  - complies with the applicable *Essential Principles for Safety and Performance*,
  - has been classified according to the classification rules[5], and
  - has met all the applicable conformity assessment elements.
- Information sufficient to identify the device/s to which the Declaration of Conformity applies.
- A Global Medical Device code and term for the device/s.
- The risk class allocated to the device/s after following the guidance found in *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification*[6].
- Which of the conformity assessment procedures described in Section 6.2 have been applied.
- The date from which the Declaration of Conformity is valid.
- The name and address of the device manufacturer.
- The name, position and signature of the responsible person who has been authorised to complete the Declaration of Conformity upon the manufacturer's behalf.

The Agency may review and confirm the adequacy of the Declaration of Conformity, if required, by examining the supporting documents or other evidence.

[5] See GHTF/SG1/N045;2008 *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification.*

5.5 Recognition of manufacturers and registration of their IVD medical devices by the Agency

The Agency will register the IVD medical device(s) and recognize the party responsible for the manufacture of the IVD medical device as well as the party responsible for the IVD medical device/s in Nigeria (where this is a different entity) as part of the regulatory control of devices in the market and, thereby facilitating any regulatory activity.

Prior to placing an IVD medical device on the market, the manufacturer, its local distributor, or its Authorized Representative should provide the Agency with the required information.

6.0 Harmonized Conformity Assessment System

6.1 The relationship between conformity assessment and device classification

The Agency recommends that each IVD medical device be allocated to one of four classes, using a set of rules as defined in the GHTF document *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification*.

Class A devices are the lowest risk devices, Class B devices are moderate to low risk, Class C devices are moderate to high risk and Class D devices present the highest risk. The level of scrutiny and evidence needed to demonstrate that the IVD medical device meets the *Essential Principles of Safety and Performance* and conformity assessment procedures should be proportional to the risk class of the IVD medical device.

This principle is illustrated in the tables that follow. The tables identify available conformity assessment elements and propose a combination of those elements that would be applied to different classes of IVD medical devices to construct a harmonized conformity assessment system that would be adopted as part of the regulatory model for IVD medical devices. Where there are alternatives within conformity assessment elements, e.g. the quality management system for a Class A or Class B device may be either a full quality management system or one without design and development control, the manufacturer may choose the one that it believes to be most suitable.

6.2 Conformity assessment system

The four tables below summarise conformity assessment elements that apply to Class A, B, C and D devices.

CLASS "A" DEVICE

Conformity Assessment Element	Manufacturer Responsibility	NAFDAC Responsibility	Section
Quality	Establish and maintain a	Premarket regulatory audit	5.1

Management System (QMS)	full QMS or a QMS without design and development controls.	required.	
Post Market Surveillance	Establish and maintain an adverse event reporting procedure according to GHTF SG2 guidance.	May audit post-market to investigate specific safety or regulatory concerns.	5.2
Technical Documentation	Upon request prepare ToC.	Premarket submission of ToC not required. May be requested to investigate specific safety or regulatory concerns.	5.3
Declaration of Conformity	Prepare, sign and maintain.	On file with the manufacturer; available upon request.	5.4
Registration of manufacturers and their devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.	5.5

CLASS "B" DEVICE

Conformity Assessment Element	Manufacturer Responsibility	NAFDAC Responsibility	Section
Quality Management System (QMS)	Establish and maintain a full QMS or a QMS without design and development controls.	Be satisfied that a current and appropriate QMS is in place and conduct a QMS audit prior to marketing authorization.	5.1
Post Market Surveillance	Establish and maintain an adverse event reporting procedure according to GHTF SG2 guidance.	Be satisfied that a current and appropriate adverse event reporting procedure is in place as part of the QMS.	5.2
Technical Documentation	Upon request prepare ToC.	Premarket submission is normally not required but if requested, receive and conduct a review of the ToC to determine conformity to Essential Principles.	5.3
Declaration of Conformity	Prepare, sign and submit.	Review and verify compliance with requirements.	5.4
Registration of manufacturers and their devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.	5.5

CLASS "C" DEVICE

Conformity Assessment Element	Manufacturer Responsibility	NAFDAC Responsibility	Section
Quality Management System (QMS)	Establish and maintain a full QMS.	Be satisfied that a current and appropriate QMS is in place and conduct a QMS audit prior to marketing authorization.	5.1
Post Market Surveillance	Establish and maintain an adverse event reporting procedure according to GHTF SG2 guidance.	Be satisfied that a current and appropriate adverse event reporting procedure is in place as part of the QMS.	5.2
Technical Documentation	Prepare and submit ToC for review.	Receive and conduct a premarket review of the ToC to determine conformity to Essential Principles.	5.3
Declaration of Conformity	Prepare, sign, and submit.	Review and verify compliance with requirements.	5.4
Registration of manufacturers and their devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.	5.5

Note: Although the Agency's responsibilities for Class C and Class D IVD medical devices are the same, it needs to be understood that the ToC for a Class C IVD medical device will contain less elaborate information than the ToC for a Class D device. The main difference for a Class D ToC would be in the level of detail in the clinical/performance data and details of the manufacturer's QC release program. The Agency would in the review process not normally require more elaborate information for a Class C device however this does not preclude the Agency from requesting such information in specific cases.

CLASS "D" DEVICE

Conformity Assessment Element	Manufacturer Responsibility	RA / CAB Responsibility	Section
Quality Management System (QMS)	Establish and maintain a full QMS.	Be satisfied that a current and appropriate QMS is in place and conduct a QMS audit prior to marketing authorization.	5.1
Post Market Surveillance	Establish and maintain an adverse event reporting procedure according to GHTF SG2 guidance.	Be satisfied that a current and appropriate adverse event reporting procedure is in place as part of the QMS.	5.2
Technical Documentation	Prepare and submit ToC for review. A ToC for this class should contain more extended information such as full performance evaluation reports.	Receive and conduct a premarket review of the ToC to determine conformity to Essential Principles.	5.3
Declaration of Conformity	Prepare, sign, and submit.	Review and verify compliance with requirements.	5.4
Registration of manufacturers and their devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.	5.5

Note: Although the Agency's responsibilities for Class C and Class D IVD medical devices are the same, it needs to be understood that the ToC for a Class C IVD medical device will contain less elaborate information than the ToC for a Class D device. The main difference for a Class D ToC would be in the level of detail in the clinical/performance data and details of the manufacturer's QC release program. The Agency would in the review process not normally require more elaborate information for a Class C device however this does not preclude the Agency from requesting such information in specific cases.

6.3 Conformity Assessment Considerations

There are situations when characteristics of the device and/or its manufacturer may cause the Agency, by exception, to modify particular requirements of the elements of conformity assessment. For example:

- This may include deferring the review of the ToC for Class C devices until a subsequent regulatory audit.

- The Agency may exempt the manufacturer from making a complete premarket submission and/or conduct an audit that is more limited in scope than would normally apply to a device of that class when:

  - the device incorporates well-established technology that is already present in the market;
  - The agency is familiar with the manufacturer's capabilities and its products;
  - the device is an updated version of a compliant device from the same manufacturer and it contains no substantive change;
  - The agency has particular experience with a comparable device;
  - internationally recognized standards[6] are available to cover the main aspects of the device and have been used by the manufacturer.

Similarly, the Agency may require a more detailed premarket submission and/or a more rigorous audit and/or the provision of more performance evaluation data than would normally apply to a device of that risk class when:

- The device incorporates innovative technology;
- An existing compliant device is being proposed for a new intended use;
- The manufacturer's experience level with the type of IVD medical device is limited;
- The device type tends to be associated with an excessive number of adverse events, including use errors;
- The device incorporates innovative or potentially hazardous materials;
- The device type raises specific public health concerns.

It should be emphasized that there must be a fully justified and documented case before the Agency modifies in any way the relationship between the device class and the associated conformity assessment procedure. Where there is justification for variation to the conformity assessment procedures normally applicable to a particular device class, a statement in this regard should be included in the ToC.

[6] SG1/N044 *Role of Standards in the Assessment of Medical Devices*