# Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment

**Amended and restated on 15 November 2023***

* As per Board Decision GF/B50/DP06. Replaces the Global Fund Quality Assurance Policy for Diagnostics Products, originally issued on 15 December 2010 (Board decision GF/B22/DP10) and amended on 4 May 2017 (Board decision GF/B36/DP12)

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## BASIC PRINCIPLE

1. Global Fund resources and Grant Funds may only be used to procure Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment in accordance with the standards prescribed in this Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment (the "Policy").

## DEFINITIONS

2. Capitalized terms and acronyms used in this Policy shall have the meaning given to them below unless the context requires otherwise.

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| **Core Personal Protective Equipment (Core PPE)** | means equipment or an interchangeable component to be worn or held by a person for protection against harmful biological agents to that person's health or safety. Depending on their intended purpose, such equipment can be classified as a Medical Device or as personal protective equipment or both.[1] |
| **Expert Review Panel (ERP)** | means a panel of technical experts independent of the Global Fund which, in accordance with its terms of reference and under the oversight of WHO, analyzes the potential risks and benefits of Medical Device (including IVDs) and Core PPE and advises the Global Fund on use of Global Fund resources and Grant Funds for procurement of Medical Devices (including IVDs) for a time-limited period. |
| **External Quality Assessment** | means a program that assesses the performance of laboratories and/or testing sites by demonstrating the reliability and accuracy of testing results. External Quality Assessment may include proficiency testing (otherwise known as an External Quality Assessment scheme), or on-site visits to assess the laboratory practices and procedures, or a combination of the above.[2] |
| **Grant Funds** | means the funds specified in a Grant Confirmation, which the Global Fund, subject to the terms and conditions set forth in the Grant Agreement, agrees to make available to the Grantee (or to its Principal Recipient designated in the Grant Confirmation) in the form of a grant for the implementation of the relevant program. |
| **HIV Self-Testing** | is a process in which a person collects their own specimen (oral fluid or blood) using a simple rapid HIV test and then performs the test and interprets their result, when and where they want.[3] |
| **International Health regulations (IHR)** | means the Regulations to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which |

[1] For the purpose of this Policy, Core Personal Protective Equipment includes such items as apron protection, gloves, face shields, masks, respirators, gowns and protective goggles.
[2] Adapted from: ISO 17043. Conformity assessment – General requirements for proficiency testing.
[3] WHO recommends HIV self-testing – evidence update and considerations for success https://www.who.int/publications/i/item/WHO-CDS-HIV-19.36

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| | avoid unnecessary interference with international traffic and trade. |
| **International Organization for Standardization (ISO)** | means the non-governmental organization, including national standards institutes of 167 countries, which sets standards, including generic standards (e.g., ISO 9000 series) or product-specific requirements for implementing a quality management system (e.g., ISO 13485 for medical devices). |
| **In Vitro Diagnostic (IVD)** | means a Medical Device, whether used alone or in combination with other devices, intended by the Manufacturer for *in vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes including, reagents, calibrators, control materials, specimen receptacles, software, and related instruments, apparatus, and other articles.[4] |
| **Lot** | means a defined quantity of products, manufactured in a single process or series of processes, and therefore expected to be homogeneous. Interchangeable with 'batch'. |
| **Lot Testing** | means quality control testing of a lot or batch of a Medical Device including an IVD or a Core PPE after manufacture and release from the manufacturing site. |
| **Malaria Rapid Diagnostic Test** | means immunochromatographic lateral flow devices for the detection of malaria parasite antigen, and designed to provides a result timely enough to inform immediate treatment (e.g. within 60 minutes). |
| **Manufacturer** | means any natural or legal person with responsibility for design and/or manufacture of Medical Device (including an IVD) or a core PPE product with the intention of making it available for use, under the Manufacturer's name; whether or not such a Medical Device (including IVD) or Core PPE product is designed and/or manufactured by the Manufacturer itself or on its behalf by another person(s) or entit(y)ies. |
| **Medical Device** | means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the Manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:<br>(i) diagnosis, prevention, monitoring, treatment, or alleviation of disease,<br>(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury,<br>(iii) investigation, replacement, modification, or support of the anatomy or of a physiological process,<br>(iv) supporting or sustaining life, |

[4] Global Harmonization Task Force Document SG1/N045:2008.

(v) control of conception,

(vi) disinfection of medical devices,

(vii) providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.[5]

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| **National Regulatory Authority (NRA)** | means the official regulatory authority of a country designated to administer the regulatory activities related to Medical Devices including IVDs. |
| **Public Health Emergency of International Concern (PHEIC)** | means a formal declaration by the World Health Organization of an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response.[6] |
| **Recipient** | means any legal entity that receives Grant Funds and/or Global Fund resources. |
| **Regional regulatory system (RRS)** | means a system composed of individual regulatory authorities, or a regional body composed of individual regulatory authorities, operating under a common regulatory framework including or excluding a common legal framework. The common regulatory framework must at least ensure equivalence between the members in terms of regulatory requirements, practices and quality assurance policies. |
| **Regulatory Authorities of the Founding Members of the Global Harmonization Task Force (GHTF)** | means the regulatory authorities of the United States, the European Union,[7] Japan, Canada and Australia. |
| **Quality Assurance** | refers to all measures taken from manufacturing processes, to selection and the use of a Medical Device (including an IVD) or a Core PPE, including Quality Monitoring, to ensure that the products are of the quality required for the Manufacturer's intended use. |
| **Quality Management System** | a management system to direct and control an organization with regard to quality[8] (for quality system essentials for: facilities and safety, organization, personnel, equipment, purchasing and inventory, process control (QC), information management, document and records, customer |

[5] GHTF SG1 N071:2012 - Definition of Terms Medical Device and In Vitro Diagnostic Medical Device - May 2012: https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf

[6] WHO International Health Regulations (2005): https://www.who.int/publications/i/item/9789241580496

[7] Including United Kingdom as member of GHTF prior to October 2011

[8] Adapted from: ISO 9001 Quality management systems – requirements.

service, external quality assessment).

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| **Quality Monitoring** | means all activities undertaken to ensure that the products continue to conform with the Manufacturer's established quality specifications during the storage, distribution, and use of such product, including but not limited to Lot Testing, reporting of deficient product and surveillance, as part of a Quality Assurance system. |
| **Total Cost of Ownership** | means the total amount of all direct and indirect monetary costs related to the procurement, storage and distribution of a product by a Recipient, including the price of the product itself, any reagents and other consumables, transportation, customs clearance, insurance, in-country distribution and storage, Quality Assurance and Quality Monitoring, training, and validation of new diagnostic algorithms, and, as applicable, operating costs including cost of installing, servicing, commissioning, warranty for and maintaining equipment. |
| **WHO** | means the World Health Organization. |
| **WHO Emergency Use Listing (EUL)** | means WHO's risk-based procedure for assessing and listing unlicensed vaccines, therapeutics, and in vitro diagnostics with the ultimate aim of expediting the availability of these products to people affected by a public health emergency.[9] |
| **WHO Listed Authority[10] (WLA)** | means a regulatory authority or a regional regulatory system (RRS) which has been documented by WHO to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process. |
| **WHO Prequalification** | means the program managed by WHO which prequalifies health products that are considered to be acceptable for procurement by the United Nations and specialized agencies. |

## INTERPRETATION

3. In this Policy, unless the context otherwise requires:

   (i) headings do not affect the interpretation of the Policy;

   (ii) the singular shall include the plural and vice versa;

   (iii) any phrase introduced by the terms "including", "include", "in particular", "such as", or any other similar expression shall be illustrative only and shall not limit the sense of the words preceding those terms; and

   (iv) reference to an undated ISO standard designates the latest version of that standard.

[9] Regulatory Authorities of the Founding Members of GHTF or WLAs may also implement similar procedures for the same purpose, cf. Section 25 (ii).

[10] Evaluating and publicly designating regulatory authorities as WHO listed authorities WHO Policy document – Geneva 2021: https://apps.who.int/iris/rest/bitstreams/1351058/retrieve

## APPLICABLE LAWS AND REGULATIONS

4. Each Recipient shall ensure that the procurement of Medical Devices (including IVDs) and Core PPE with Grant Funds and Global Fund resources is undertaken in compliance with all applicable national laws and regulations.

## CLINICAL STANDARDS

5. Global Fund resources and Grant Funds may only be used to procure Medical Devices (including IVDs) and Core PPE that are consistent with WHO guidance (including a WHO Rapid Communication[11]) or comply with applicable national guidelines.

   Funding requests submitted by Recipients shall include the following:

   (i) A description of the Medical Devices (including IVDs) or Core PPE to be procured with Grant Funds in line with grant making guidance. Upon request by the Global Fund, applicants shall provide a copy of, or refer to, the relevant WHO guidance or national guidelines supporting the use of the Medical Devices (including IVDs) or Core PPE to be procured; and

   (ii) A technical justification, satisfactory to the Global Fund, for the procurement of Medical Devices (including IVDs) or Core PPE that is consistent with WHO guidance but may not be consistent with national guidelines or vice versa. The Global Fund may, at its sole discretion, refer the technical justification provided to the relevant WHO disease program for review and advice.

6. If a Recipient proposes to use Grant Funds to procure Medical Devices (including IVDs) or Core PPE other than the ones already approved by the Global Fund, it shall provide the Global Fund with a brief description of the Medical Devices (including IVDs) or Core PPE and, if applicable, the technical justification described in Paragraph 5 (ii) above, for approval by the Global Fund.

## QUALITY STANDARDS

7. For the purpose of this Policy, Medical Devices (including IVDs) are classified per the globally harmonized principles of the medical devices classification consisting of four regulatory classes A, B, C and D, where Class A represents the lowest risk and Class D the highest.[12]

8. Global Fund resources and Grant Funds may only be used to procure Medical Devices (including IVDs) of the four classes that meet, at minimum, the following standards:[13] all Medical Devices (including IVDs) shall be manufactured at a site compliant with the requirements of ISO 13485 or an equivalent Quality Management System recognized by one of the Regulatory Authorities of the Founding Members of the GHTF or by a WLA.[14]

9. In addition to the requirements of Section 8, Global Fund resources and Grant Funds may only be used to procure Medical Devices (excluding IVDs) which are categorized as Class C or Class

[11] WHO may issue a Rapid Communication to indicate an update in progress to WHO treatment guidelines which may take additional time before finalization.

[12] GHTF/SG1/N77 Principles of Medical Devices Classification-November 2012: https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf

[13] Recipients may request the inclusion of higher standards or requirements for the purchase of IVDs. However, any request must be accompanied by a justification/rationale as to why these should be included and is subject to the approval of the Global Fund.

[14] By a WLA with the regulatory inspection function within its scope of listing, as published and regularly updated on the WHO website.

D that meet either one of the following standards, such as:

(i) Prequalified by the WHO Prequalification of medical products; or

(ii) Authorized for use by one of the Regulatory Authorities of the Founding Members of the GHTF; or

(iii) Authorized for use by a WLA within their scope of listing;[15] or

(iv) Recommended for use by the ERP.

10. In addition to the requirements of Section 8, IVDs with respect to HIV, tuberculosis and malaria and to Hepatitis B, hepatitis C and syphilis co-infections, as well as IVDs providing information that is critical for patient management of these diseases, must meet any one of the following standards:

(i) Prequalification by the WHO Prequalification of IVDs; or

(ii) For tuberculosis: recommendation by relevant WHO programme or WHO Rapid Communication;[16] or

(iii) Authorization for use by one of the Regulatory Authorities of the Founding Members of the GHTF when stringently assessed (as Class C or D);[17] or

(iv) Authorized for use by a WLA within their scope of listing;[18] or

(v) Approved for procurement using Global Fund resources and Grant Funds, as determined by the Global Fund,[19] based on the recommendation of the ERP.

11. In addition to the requirements of Section 8, condoms (male and female) and lubricants must meet any of the following standards:

(i) Prequalification by the United Nations Population Fund (UNFPA Prequalification Programme); or

(ii) Authorization for use by one of the Regulatory Authorities of the Founding Members of the GHTF when stringently assessed (as Class C or D);[20] or

(iii) Authorized for use by a WLA within their scope of listing;[21] or

(iv) Approved for procurement using Global Fund resources and Grant Funds, as determined by the Global Fund,[22] based on the recommendation of the ERP.

12. Global Fund resources and Grant Funds may only be used to procure Core PPE[23] that meet any of the following standards:

[15] By a WLA with the registration and marketing authorization, regulatory inspection and vigilance functions within its scope of listing, as published and regularly updated on the WHO website.

[16] As published and regularly updated on the WHO website.

[17] This option is not applicable to RDTs for HIV-Self-Testing

[18] By a WLA with the registration and marketing authorization, regulatory inspection and vigilance functions within its scope of listing as published and regularly updated on the WHO website.

[19] Notwithstanding a determination made by the Global Fund that a relevant product is acceptable or not-acceptable for procurement by a Recipient using Grant Funds, the Global Fund shall not be responsible or liable for any loss or damage arising out of or in connection with the manufacture, distribution, use or non-use of such product. The Global Fund may revoke or amend such determination in its sole discretion at any time.

[20] This option is not applicable to RDTs for HIV-Self-Testing

[21] By a WLA with the registration and marketing authorization, regulatory inspection and vigilance functions within its scope of listing as published and regularly updated on the WHO website.

[22] Notwithstanding a determination made by the Global Fund that a relevant product is acceptable or not-acceptable for procurement by a Recipient using Grant Funds, the Global Fund shall not be responsible or liable for any loss or damage arising out of or in connection with the manufacture, distribution, use or non-use of such product. The Global Fund may revoke or amend such determination in its sole discretion at any time.

[23] With or without medical purpose

(i) Prequalified under the WHO Prequalification Programme; or

(ii) Compliant with the regulatory requirements and standards of one of the Founding Members of the GHTF; or

(iii) Authorized for use by a WLA within their scope of listing.[24]

## Expert Review Panel

13. The Global Fund may at its discretion, request advice from the ERP to determine the acceptability for procurement for Medical Devices (including IVDs) for which there is a public health need and which are not yet compliant with Section 9, 10 or 11 for a time-limited period as recommended by the ERP but no more than 12 months (the "ERP Recommendation Period"), pending full assessment by one of the processes listed in Section 9, 10 or 11.

14. The Global Fund may, at its sole discretion, request the ERP to consider extending the ERP Recommendation Period for up to an additional 12 months if the Medical Device (including IVDs) is not yet WHO-prequalified or WLA-authorized[25] or approved by one of the Regulatory Authorities of the Founding members of the GHTF within the ERP Recommendation Period. The Global Fund may refer more than one request for such an extension to the ERP.

15. Manufacturers of Medical Devices (including IVDs) approved through ERP referred to in Section 9, 10 and 11 are encouraged to submit their applications for full product review to the WHO Prequalification or to a WLA[26] or, for stringently regulated product types, to one of the Regulatory Authorities of the Founding Members of GHTF.

## Quality of Use of In-Vitro Diagnostics

16. Recipients shall implement a Quality Assurance System for the procurement, supply management and intended use of all IVDs products procured with Grant Funds in accordance with the guidelines specified in this Policy and on the Global Fund website,[27] so as to ensure the quality of diagnostic results.

17. A Quality Assurance System defines a systematic approach to ensuring quality testing through use of standard operating procedures, management of documents and records, implementation of quality control and external quality assessment, including proficiency testing and on-site supervisory visits. The quality system extends to appropriate physical infrastructure, procedures for purchasing and inventory, equipment maintenance, customer service, human resource management and review, and continual process improvement.[28]

18. Each Recipient shall ensure that IVDs are only used by appropriately trained and suitably qualified persons in settings for which the products are intended. Recipients shall also implement appropriate information management and record-keeping, use best efforts to support and participate in External Quality Assessment programs, and ensure good facility management, safe and efficient operations with appropriate process controls, and calibration and maintenance of relevant equipment, as specified in relevant WHO guidance.

[24] By a WLA with the registration and marketing authorization, regulatory inspection and vigilance functions within its scope of listing, as published and regularly updated on the WHO website.
[25] By a WLA with the registration and marketing authorization, regulatory inspection and vigilance functions within its scope of listing, as published and regularly updated on the WHO website.
[26] By a WLA with the registration and marketing authorization, regulatory inspection and vigilance functions within its scope of listing, as published and regularly updated on the WHO website.
[27] https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/
[28] Adapted from: ISO 15189 Medical laboratories — Particular requirements for quality and competence. CLSI GP26-A4 Application of a Quality Management System Model for Laboratory Services; Approved Guideline-Third Edition

### Calibration and preventive maintenance

19. Each Recipient shall ensure that the requirements needed for proper calibration, maintenance, repair and other services for instruments and equipment of Classes C and D are identified and are adequately fulfilled. This may be budgeted for in Global Fund grants.

### Transportation, Storage and Distribution

20. Each Recipient shall comply or ensure compliance with WHO or internationally recognized guidance for good transportation, storage, and distribution practices applicable to Medical Devices (including IVDs) or Core PPE.

### Post-Market Surveillance

21. Recipients shall arrange for the monitoring of the quality of Medical Devices (including IVDs) and Core PPE procured with Grant Funds in line with relevant WHO or internationally recognized guidelines on post-market surveillance of Medical Devices (including IVDs) and Core PPE. The cost of conducting quality control activities may be budgeted for in Global Fund grants. Recipients must submit the results of quality control testing to the Global Fund.

22. Recipients shall use best efforts to develop and maintain a mechanism to report defects relating to Medical Devices (including IVDs) and Core PPE to the appropriate regulatory authorities and to the Global Fund and facilitate appropriate communication with Manufacturers, procurement agents, distributors, and end users.

23. The costs for conducting any relevant Quality Assurance and capacity building measures related to the procurement, supply management and use of Medical Devices (including IVDs) or Core PPE with Grant Funds, as far as they are not covered from other funding sources, may be included in the relevant Global Fund grant budget, which is subject to approval by the Global Fund.

## PROCUREMENT PRACTICES

24. In addition to the requirements set out in this Policy, each Recipient must also comply with the following:

    (i) All other Global Fund procurement policies and principles that may be applicable to Medical Devices (including IVDs) or Core PPE, as published on the Global Fund website; and

    (ii) The standard terms and conditions of Global Fund Grant Agreements, Grant Regulations, including the requirement for a competitive process to be undertaken to obtain the best value for money for relevant Medical Devices (including IVDs) and Core PPE, taking into account Total Cost of Ownership, and ensuring that the Manufacturer and manufacturing site of the Medical Devices (including IVDs) or Core PPE are disclosed in all applicable solicitation and procurement-related documentation.

## EMERGENCIES

25. To provide support to countries facing Public Health Emergency of International Concern (PHEIC), as declared by WHO Director General per International Health Regulations,[29] the Global Fund Board may approve the use of Global Fund resources and Grant Funds to procure Medical Devices (including IVDs) and Core PPE that are:

[29] https://apps.who.int/iris/rest/bitstreams/1031116/retrieve

(i) Approved pursuant to the WHO Emergency Use Listing (EUL) procedures; or

(ii) Approved pursuant to any other emergency procedure set up by one of the Regulatory Authorities of the Founding Members of GHTF or WLA.[30]

## MONITORING POLICY IMPLEMENTATION

26. The Global Fund's Strategy Committee oversees the implementation of this Policy.

27. In order to ensure implementation of this Policy, the Global Fund will provide guidance, training and a reporting mechanism to enable monitoring and oversight.

28. During implementation, the Global Fund Secretariat may need to review and address issues identified related to the quality of health products on an order-by-order basis (e.g., non-conformities with product specifications or non-compliance with product authorizations). The Secretariat will investigate, conduct a risk-based assessment and implement appropriate measures in consideration of patient safety, supply security and programmatic implications.

## TRANSITIONAL ARRANGEMENTS

29. If, before the entry into force of this amended and restated Policy, a Recipient has directly or indirectly through a procurement agent entered into a legally binding contract with a Manufacturer or supplier to procure Medical Devices (including IVDs) and Core PPE with Grant Funds which do not comply with this Policy, the Recipient must promptly notify the Global Fund and provide reasonable details about the terms of that contract and procurement. The Global Fund may, after consultation with the Recipient, decide not to authorize the use of Grant Funds for the procurement of the Medical Devices (including IVDs) and Core PPE that are non-compliant with this Policy. The Recipient shall manage its relevant contractual relationship with suppliers as it deems suitable.

30. Authorization given by Regulatory Authorities of the Founding Members of the GHTF becomes not relevant for the purposes of this Policy when the regulator becomes WLA listed.[31] In that instance, implementation of Sections 8, 9, 10, 11, 12, 14, 15 and 25 of this Policy will only be on the basis of the regulator's WLA status going forward.

[30] By a WLA with the registration and marketing authorization, regulatory inspection and vigilance functions within its scope of listing, as published and regularly updated on the WHO website.

[31] By a WLA with the registration and marketing authorization, regulatory inspection and vigilance functions within its scope of listing, as published and regularly updated on the WHO website.