In Vitro Diagnostics Assessment Team
Prequalification Unit – Regulation and Prequalification Department

REPORTABLE CHANGES TO WHO PREQUALIFIED & EMERGENCY USE LISTED IN VITRO DIAGNOSTICS

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Contents

1 Purpose of this document

1.1 Intended audience

This document aims at providing manufacturers with information on the reporting of changes applied to in vitro diagnostic (IVD) products that have been either WHO prequalified or listed as part of the WHO Emergency Use Listing Procedure (EUL).

Manufacturers of WHO prequalified or EUL-listed IVDs must be aware of and fully comply with the obligations outlined in this document.

Note: For the purpose of this document the following definition of "manufacturer" applies: *Any natural or legal person with responsibility for design and/or manufacture of a diagnostic product with the intention of making the diagnostic product available for use, under his/her name; whether or not such a diagnostic product is designed and/or manufactured by that person himself/herself or on his/her behalf by another person(s)* **[1].**

> *This document does not address the required response to changes made during the prequalification assessment. For changes implemented during the assessment process, manufacturers should contact the PQT/IVD team to seek guidance.*

1.2 Scope

This document describes when and how a manufacturer is required to report to WHO a change to a prequalified or EUL listed IVD, including, but not limited to:

- changes to the product design
- changes to its manufacture
- changes to the Quality Management System (QMS) that the product was designed and/or manufactured under; and/or
- other reportable "administrative" changes.

1.3 Background

As part of the life cycle of an IVD, changes to the product, its components, its manufacture (e.g., processes, location), and/or the QMS under which it is produced may become necessary. Such changes[1] can present little potential to impact the quality, safety and/or performance of the IVD or be likely to significantly affect the quality, safety and/or performance of the product.

Changes applied to an IVD must be made in compliance with the requirements for control of design change and change control according to ISO 13485:2016 **[2].** One critical step in this process is to evaluate the potential impact of the change on the product.

[1] Some regulatory authorities refer to changes as "variations".

1.4 Terms and Definitions

1.4.1 **High/Moderate impact change:** A change with the potential to affect the function, performance, usability, and/or safety of an IVD product, associated with risks that have been determined to be high or moderate.

1.4.2 **Low-impact change:** A change that has a limited potential to affect the function, performance, usability, and/or safety of an IVD product, associated with risks that have been determined to be low. This includes administrative changes requiring an update to the WHO Public Assessment Report (WHOPAR).

1.4.3 **Reportable change:** A reportable change is one that is demonstrated, through risk analysis, to have a potential impact on the function, performance, usability, safety or the information provided with prequalified IVD. A reportable change may: introduce new hazards that have not been previously addressed. adversely affect risks associated with existing hazards.

1.4.4 **Screening:** Initial assessment of the change request submission by WHO for accuracy and completeness verification.

1.4.5 **WHOPAR:** World Health Organization Public Assessment Report, which summarizes the findings of the prequalification assessment, but excludes confidential and proprietary information.

1.4.6 **WHOPIR:** World Health Organization Public Inspection Report, which summarizes the findings made during the inspection of the manufacturing site(s) as well as corrective actions taken in respect of the site(s) but excludes confidential and proprietary information.

2 Reporting of changes to WHO

Changes associated with a prequalified or EUL-listed IVD, as exemplified in **Appendix 1** below, are considered as **reportable changes**. These must be reported via a change request by submitting a *"Change Request Form for WHO Prequalified & Emergency Use Listed In Vitro Diagnostics*" (WHO document PQDx 119) and supporting documentation to WHO Prequalification Team – Diagnostics. The rationale for determining whether a change is reportable or not must be documented under the QMS change control process.

A **reportable change** may:

- introduce a new risk not previously identified;
- change the probability of existing hazardous situations occurring; and/or
- alter the presentation to the user of existing or new risks (this can involve labelling changes or new indications for use).
- demand the update or extension of the scope of mitigation measures.

A **reportable change** can be categorized as having a low potential impact or a high/moderate potential impact according to its nature and extent (see definition in 1.4 above and how to determine the impact in section 5).

Submission of reportable changes should occur prior to their implementation. The manufacturer takes responsibility for evaluating and managing the risks associated with changes, while being subject to appropriate change request assessment:

- **High/Moderate-impact changes** will undergo a comprehensive assessment by WHO. In case the manufacturing of changed product batches is needed within the change control process (e.g., process validation pilot batches), they should only be released to the market after the change is accepted.
- **Low-impact changes** will be approved by WHO upon screening and will not require a full review before implementation in most cases.

The change request form and supporting documentation will be subject to desk review prior to acceptance of the change and some aspects may be reviewed and verified during post-prequalification periodical inspections.

3 Non-Reportable Changes

Non-reportable changes are those that do not need to be reported according to the provisions outlined in this guidance document. Examples of non-reportable changes include, but are not limited to the following, provided they are not specified in the **Appendix 1**:

- QMS-controlled changes for maintenance and continuous improvement of the QMS.
- Routine updates of procedures and processes necessary for maintaining ISO 13485 or Recognized QMS certifications.
- Changes to non-critical suppliers and non-critical components.

- Changes to non-critical processes.
- Updates of design files or batch records to improve the completeness of information.
- Improvements in post-market surveillance activities or regular updates of controlled QMS procedures with no impact on product performance or safety.

The rationale for determining whether a change is reportable or not must be documented under the manufacturer's QMS.

Manufacturers are encouraged to contact WHO when in doubt whether a change is reportable or not.

4 Changes requiring a new prequalification or EUL application

In cases where a change results in a product or application information that substantially differ from what was originally accepted, a new prequalification or EUL application will be required. This applies when changes result in a product or application information that substantially differs from what was originally accepted.

In these cases, WHO will notify the manufacturer that a new application is required. This application will undergo prequalification or EUL assessment, according to WHO applicable guidance.

The changes listed below are examples of changes that would require submission of a new application for prequalification/EUL:

- a change in what is detected (i.e., the biomarker, analyte or measurand);
- changes replacing antigens, antibodies, primers or solid phase.
- a change to the specific disorder, condition, or risk factor of interest that it is intended to detect, measure or differentiate.
- a change replacing the test result format from a qualitative or quantitative or vice versa.
- a change in biological or chemical principle of the test;
- a change in design of test technology or test automation.

The combination of several changes that, in isolation, would not require submission of a new application, can also result in the need for a new prequalification/EUL application. Manufacturers should seek advice from WHO when planning to introduce several changes at the same time.

5 Determining the impact of a change

The reporting requirements related to changes to a prequalified or EUL listed IVD will depend on the potential impact of the change to WHO set criteria. The assessment pathway will depend on whether the change is classified as low or high/moderate impact, based on the severity of the associated risks, including but not limited to the following factors:

- Changes to the design or composition of the IVD
- Redevelopment including state-of-the-art product improvements;
- changes to the critical components or products parts

- changes to a manufacturing process, facility, or equipment;
- changes to the organization of the manufacturer;
- changes to the manufacturing, QC and release workflow
- changes to the intended use and /or test procedure; and/or
- changes that raise new issues of safety and performance necessitating new clinical and/or analytical studies.

Consideration shall be given to the potential impact of the change on the overall residual benefit/risk evaluation of the IVD as per **ISO 14971:2019** [3]. This includes a determination of whether the change:

- introduces new hazardous situations that have not been previously addressed;
- adversely affects the risk associated with existing hazards;
- alters the details of any of the information submitted for prequalification (related to the dossier, manufacturing site(s) inspection, or performance evaluation), such as the intended use and/or compliance with the Essential Principles of safety and performance of medical devices and in vitro diagnostic products [4]**;** and/or
- affects the continued compliance of the QMS with the relevant standards.

A critical part of a manufacturer's QMS change management is a documented, controlled, and accepted process to assess, plan, review, verify, validate, approve, and implement changes. Relevant change control processes shall be applied, and design change documented (if applicable), to ensure that design outputs are still traceable to design inputs after the change implementation. This will also facilitate risk mitigation and provide evidence of maintenance of device's safety and performance.

Risk assessment process should follow the applicable ISO 14971 standard. Additional information regarding the risk assessment process can be found in the WHO guidance "TGS 7 Risk management for manufacturers of in vitro diagnostic medical devices" [5]**.**

A list of examples of changes and their impact categorization is provided in **Appendix 1**. These are only examples, and each case must be assessed within its specific context. It remains the sole responsibility of the manufacturer to evaluate and categorize the impact of any changes accordingly.

6 Submitting to WHO

6.1 Change request submission

Submissions should be done **only electronically.** Please contact diagnostics@who.int for the latest instructions on how to proceed. The documents to be submitted are described in the *Change request form for WHO Prequalified and Emergency Use Listed In Vitro Diagnostics* (PQDx 119).

WHO will not accept any changes without assessment.

Depending on the type of change, the assessment may also include site inspection(s) and/or a performance evaluation. Manufacturers should seek advice from WHO when planning to introduce a change.

6.2 Administrative changes

For administrative changes, the following information should be provided with the *Change request form for WHO Prequalified and Emergency Use Listed In Vitro Diagnostics (*PQDx 119*):*

- a declaration that the change only affects the product name, product code(s) and/or manufacturer name and has no impact on the quality, safety and/or performance, as supported in the submitted prequalification documentation, and the reason(s) for making the changes; and
- the new product labelling (labels, instructions for use, and any other printed or electronic labelling material) reflecting the changes.

6.3 Formatting requirements for submissions

- Electronic copies of the PQDx 119 and supporting documentation must be submitted as per the most up-to-date instructions provided by WHO. Searchable, unprotected PDF file format is preferred.
- The layout and order of this documentation must be easy to follow, and documents must be appropriately identified. Attachments to the Change Request Form must be clearly identified and divided into sections as indicated in the *Change request form for WHO Prequalified and Emergency Use Listed In Vitro Diagnostics* (PQDx 119).
- A separate cover letter is not required.
- File names should be descriptive of their content and meaningful to the assessors. File names can be up to 125 characters-long and can have spaces, dashes (not elongated dashes), underscores, and periods. However, the name of the file must not contain any of the following special characters or it will fail the loading process:

  - tilde (~)
  - vertical bar (|)
  - asterisk (*)
  - forward slash (/)
  - elongated dash (–)
  - backward slash (\)
  - apostrophe (’)
  - greater than sign (>)
  - single quotation mark (‘)
  - less than sign (<)
  - double quotation marks (“)
  - question mark (?)
  - colon (:)
  - pound sign (#)
  - various other symbols (e.g., →,*,β,α,∞,±,™)

- When capturing data or creating a PDF from a source document (e.g., Microsoft Word document) using Adobe® plug-ins, please consider there is a risk that information may not display correctly because assessors may not have access to the required plug-ins.
- All PDF files should be created directly from the source documents whenever feasible rather than creating them by scanning. PDF documents produced by scanning paper documents are far inferior to those produced directly from the source document, such as

a Microsoft Word document, and thus should be avoided if at all possible. Scanned documents, particularly tables and graphs, are more difficult to read.

- For any scanned document, it is highly recommended that optical character recognition (OCR) is applied so that the text is searchable. Check that the content has been correctly converted by: (1) highlighting an area of text and (2) searching for a word or phrase. If the word or phrase is not returned in the search, then the OCR did not recognize the text.
- WHO recognizes that the use of OCR may not be feasible in some cases for documents with figures and images. Hence, there may be cases in which it is appropriate to include scanned documents in the electronic submission.
- Submit all documents presented in the change request in English (unless other arrangements have been made with WHO prior to submission of the documentation).
- Any translations of documents must be carried out by a certified translator. Provide an official document attesting to the accuracy of the translation and details on the credentials of the translator.
- Provide both the original and the translated documents.
- All measurement units used must be expressed in the International System of Units (SI).

Submissions not meeting the above formatting requirements will not be considered for assessment.

An overview of the Process for initiating, categorizing and reporting a change is presented in Figure 1.

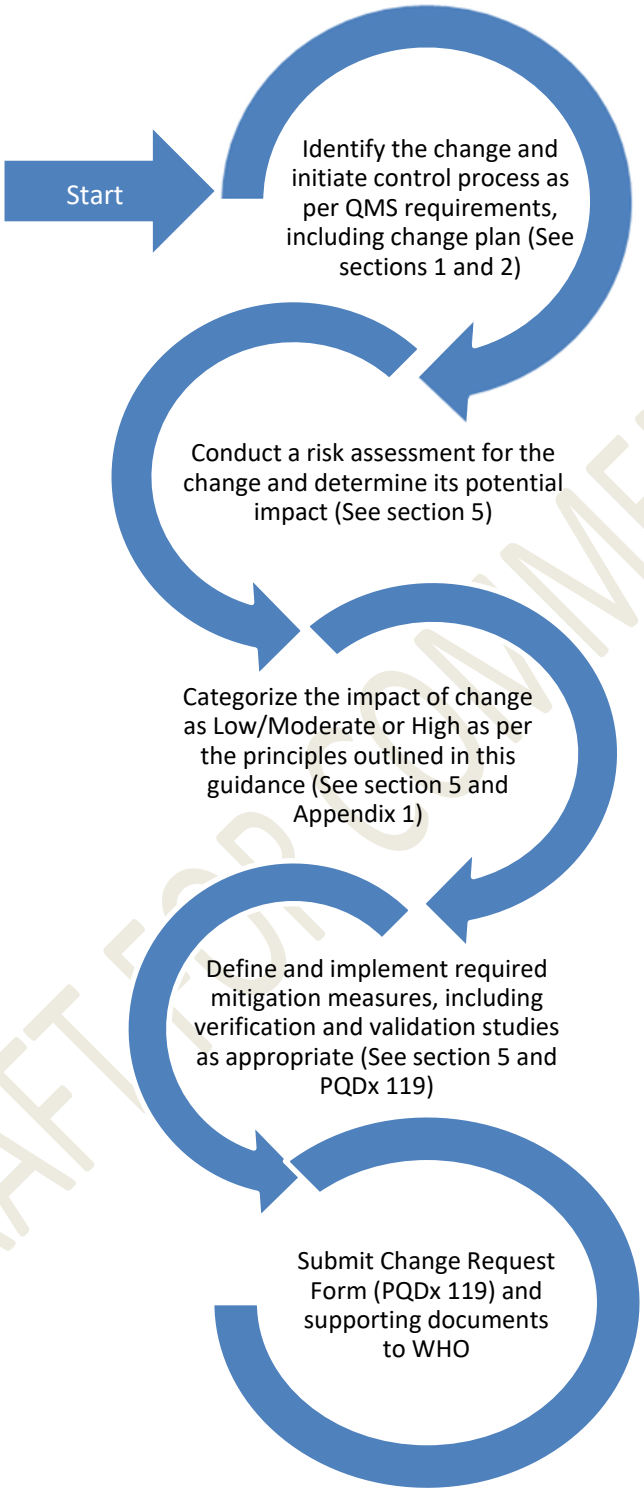

Figure 1. Flow diagram for initiating, categorizing and reporting a change.

7 Assessment of Change Request by WHO

Once WHO receives the PQDx 119 and supporting evidence, the completeness of the submission will be verified, as well as the correctness of the risk categorization, in order to determine the assessment pathway.

If the provided documentation is incomplete, the manufacturer will be informed and requested to provide the missing documentation within a specified time period set by WHO. The manufacturer will be given two opportunities to provide additional information prior to the change request assessment.

High/Moderate impact changes will undergo a full review as per the WHO document *Overview of the prequalification of in vitro diagnostics assessment* (PQDx 007). **Low-impact changes** may be accepted by WHO upon screening and a full technical review will not be conducted in these situations.

Changes pertaining to technical aspects of the product will be managed by WHO PQ IVD Assessment team. The review of changes pertaining to QMS aspects will be managed by the WHO PQ Inspection Services team.

Any change request, including those already accepted by WHO, may be followed up during post prequalification monitoring activities (e.g., verification of records and related activities auditing during post prequalification inspections).

An overview of the assessment process is presented in Figure 2.

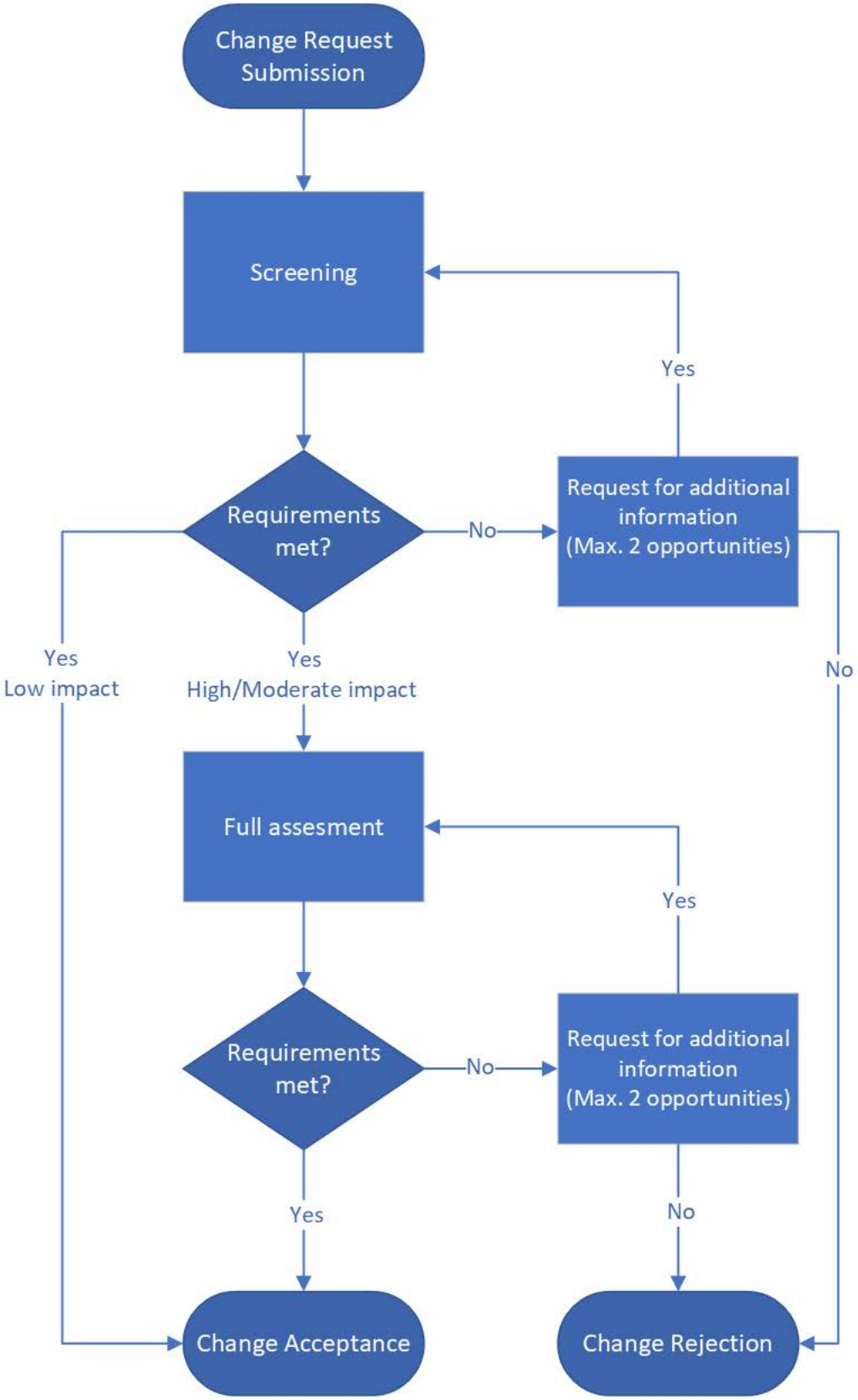
Change Request Submission
Screening
Yes
Requirements met?
No
Request for additional information (Max. 2 opportunities)
Yes
Low impact
Yes
High/Moderate impact
No
Full assesment
Yes
Requirements met?
No
Request for additional information (Max. 2 opportunities)
Yes
No
Change Acceptance
Change Rejection

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Figure 2. Overview of the change request assessment process.

7.1 Abridged assessment

If the manufacturer can provide objective evidence that the exact same proposed high/moderate impact change has previously undergone stringent assessment and approval by a Recognized National Regulatory Authority (NRA) as defined in the WHO document *Abridged prequalification assessment: prequalification of in vitro diagnostics* (PQDx_173), the change request may be accepted upon screening. In this case, the submission requirements for low impact change would apply (See PQDx 119).

8 Outcome of assessment of the change request

WHO will inform the manufacturer of the outcome of the assessment of the change and supporting documentation in writing. The manufacturer will be notified of the decision and if WHO deems that a manufacturing site inspection and/or a laboratory evaluation is required. The need to perform a manufacturing site(s) inspection and/or a laboratory evaluation will be established based on the nature of the change and its potential impact on the quality, safety and/or performance.

The manufacturer will be given two opportunities to resubmit additional data or evidence to address any deficiencies identified in the submitted documentation.

If the submitted documentation supporting the change does not meet WHO prequalification requirements or the requested information is not provided by the manufacturer within the specified time period, WHO will not accept the change. In this case, the manufacturer may resubmit a new change request application, provided they have all the necessary elements or updated information.

The impact of such a decision on the status of the IVD product will be communicated to the manufacturer.

Where a change is found acceptable, it will be notified to the manufacturer who may implement the proposed change. As needed, WHO may update the public report and its lists of prequalified or EUL products to reflect the change. Information on the change may be included in the updated WHO prequalification public reports (WHOPAR and WHOPIR).

9 Monitoring of change reporting and failure to report

As described in this guidance document, reporting of changes is mandatory for all prequalified and EUL-listed IVDs. It is the manufacturer's responsibility to notify WHO of changes, as described

in this guidance document, in order to keep the prequalification or EUL status of the product up to date.

As part of routine post-prequalification activities, WHO inspection services may review the compliance of the manufacturer processes to the requirements of this document.

Failure to submit reportable change in accordance with the requirements set in this document or non-fulfilment of one or more of these requirements will result in the assignment of a non-conformity against the manufacturer's QMS and may lead to the publication of a notice of concern or delisting of the product.

10 Change assessment fee

The cost of the activities required to assess the change will be covered in part by the manufacturer. A non-refundable change request fee (please refer to WHO document *PQDx 299 Prequalification fees: WHO prequalification of in vitro diagnostics*) will contribute to the costs associated with change documentation review and dissemination of change information. The assessment of the change will commence upon fee payment.

WHO reserves the right to decide, based on the change assessment findings, whether a product meets the change requirements. Therefore, payment of the change assessment fee does not guarantee that the change will be accepted. WHO also reserves the right to reject the proposed change(s) at any stage if the manufacturer is not able to, or fails to, provide the required information in a specified time period, or when the information supplied is inadequate to complete the change assessment effectively.

11 Relevant documents

- WHO. Overview of the prequalification of in vitro diagnostics assessment. PQDx_007. Geneva, Switzerland. World Health Organisation; 2021

- ISO 13485:2016. Medical devices – Quality management systems – Requirements for regulatory purposes. Geneva, Switzerland: International Organization for Standardization; 2016.

- ISO 14971:2019. Medical devices – Application of risk management to medical IVDs. International Organization for Standardization; Geneva, Switzerland: 2019.

- IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices. International Medical Devices Regulators Forum (IMDRF) Management Committee; 2018

- CLSI. Evaluation of Stability of *In Vitro* Medical Laboratory Test Reagents. 2nd ed. CLSI guideline EP25. Clinical and Laboratory Standards Institute; 2023.

- NB-MED/2.5.2/Rec2. Reporting of design changes and changes of the quality system. Co-ordination of Notified Bodies Medical devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC; 2008

- FDA: Deciding When to Submit a 510(k) for a Change to an Existing Device. Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER), MD, USA; 2017

- FDA: Guidance for Industry and Food and Drug Administration Staff. 30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75- Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes. Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER), MD, USA; 2019

- FDA: Guidance for Industry and Food and Drug Administration Staff. Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process. Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER), MD, USA; 2008

- FDA: Guidance for Industry and Food and Drug Administration Staff. Manufacturing Site Change Supplements: Content and Submission. Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER), MD, USA; 2018

- FDA: General Principles of Software Validation; Final Guidance for Industry and FDA Staff. Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER), MD, USA; USA; 2002

- FDA: PMA Supplements and Amendments | FDA Accessed 21 June 2024

- FDA: Real-Time Premarket Approval Application (PMA) Supplements. Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER), MD, USA; 2019

- MDCG 2022-6 - Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR. Medical Device Coordination Group (MDCG), Directorate-General for Health and Food Safety, 2022

- Health Sciences Authority of Singapore. GN-21: Guidance on Change Notification for Registered Medical Devices. Revision 5. Singapore; 2023

- TGA: Varying entries in the ARTG: medical devices and IVDs. Therapeutic Goods Administration (TGA). ACT, Australia; 2023

- Health Canada: Guidance for the Interpretation of Significant Change of a Medical Device. Health Products and Food Branch, Ottawa, Ontario; 2011

12 Contact information

Any inquiries regarding changes to in vitro diagnostics should be addressed to: diagnostics@who.int

Appendix 1: EXAMPLES OF POTENTIAL IMPACT OF REPORTABLE CHANGES (Non-exhaustive)

	Type of reportable change	Potential impact	
		Low	High/Moderate
	Design changes and changes to intended use		
1.	Change to the intended use, indications for use or conditions of use of the device.		X
2.	Change to test protocol such as specimen preparation procedure, test procedure, reading time, workflow, incubation time, operational conditions, reagents, volumes, etc.		X
3.	Change to intended purpose, i.e., the manufacturer-defined automation process (including change to a new smaller/larger model if the IVD is an instrument) or the change from a manual procedure to an automated procedure for use.		X
4.	Change to the method principle, operating principle; including preanalytical conditions, analytical or interpretation methods.		X
5.	Change to device and components in use and shelf-life storage conditions and time.		X
6.	Change to the function of the product (e.g., screening, monitoring, diagnosis or aid to diagnosis, staging or aid to staging of disease, prediction, self-testing).		X
7.	Change to the specific disorder, condition, or risk factor of interest that the IVD is intended to detect, define, or differentiate.		X
8.	Change in performance claims or design specifications.		X
9.	Change from qualitative to semi quantitative or quantitative test results or vice versa.		X
10.	Addition of specimen type (e.g., serum, plasma, whole blood, oral fluid, sputum, urine, dried blood spots) or new anticoagulants for plasma specimens.		X
11.	Removal of a specimen type (e.g., serum, plasma, whole blood, oral fluid, sputum, urine, dried blood spots) or anticoagulants.	X	
12.	Change to the intended population including any new or extended use (e.g. addition of neonates, antenatal women).		X
13.	An addition of a contraindication, precaution, or warning for the device.	X	

14.	A deletion of a contraindication, precaution, or warning for the device.		X
15.	Change in the stability data resulting in an extension of the claimed shipping, in use, and/or shelf-life stability of the IVD product.		X
16.	Change in the stability data resulting in a shortening of the claimed shipping, in use, and/or shelf-life stability of the IVD product.	X	
17.	Physical changes to the outer packaging (e.g. change of pack size).	X	
18.	Change to Interpretation algorithm(s) or software or modification of the assay cut off that can impact the performance or safety characteristics or the intended purpose of the device.		X
19.	Change to quality control panel members' specifications for cut off control or release.		X
20.	Changes to biological materials (e.g., changes to the supplier; source, method of preparation, purification, etc.).		X
21.	Software change that impacts critical steps of the assay protocol and/or result interpretation.		X
	Changes in materials/components		
22.	Changes to the formulation of reagents in the assay that may result in a change of performance (either increase or decrease) such as: • Changes in the conjugate or substrates; • Changes in specimen preparation such as a nucleic acid extraction method; • Change of preservatives; • Changes from liquid to lyophilized reagents or vice versa; • Changes in ingredient concentration.		X
23.	Changes to reagents supplied with the IVD (e.g., quality control reagents, calibrators, buffer, etc.).		X
24.	Changes to accessory products supplied with the IVD (e.g., lancet; specimen transfer device).		X
25.	Changes to accessory components supplied with the IVD (other accessories, with no impact on the protocol or performance of the devices; etc.).	X	
26.	Changes to the test protocol of an IVD such as specimen pretreatment, incubation time,		X

	operating temperatures, calibration, etc.		
	Changes to the manufacturing process		
27.	Move/relocation of finished product manufacturing, assembling or other processing equipment from one location to a different location within the same site.	X	
28.	Move/relocation of finished product manufacturing, assembling or other processing equipment to a different site.		X
29.	Addition of new manufacturing lines applying the same technology, within the same site.	X	
30.	Inclusion of a new facility (manufacturing facility, warehouse, etc.)		X
31.	Move of manufacturing, processing or packaging from a supplier to the manufacturer's facility.		X
32.	Move of manufacturing, processing or packaging from the manufacturer's facility to a supplier or subcontractor.		X
33.	Relocation or introduction of a new warehouse.		X
34.	Change in the manufacturing process such as the introduction of new equipment for capacity increasing, change in workflow or manufacturing technology.		X
35.	Change to in process quality control method, reference material, specifications and/or protocols that reduces sampling or testing and/or relaxes acceptance criteria.		X
36.	Changes in Lot calibration/adjustment protocols and metrological traceability		X
	Changes to the QMS		
37.	Changes in the certification body, changes in the QMS certificates or change in the scope of certification.	X	
38.	Changes to the legal manufacturer including: • Change of ownership; • Change of legal entity status (e.g., Ltd, SA, etc.); • Changes in the name and/or address with no change in activities location.	X X X X	
39.	Changes to the lot release procedures, changes in the reference method, recognized standard, change in the responsibility, or change in the procedure for lot release by a third party or reference laboratory.	X	

	Change to the regulatory status		
40.	Change to the regulatory version of product.	X	X[2]
	Administrative or Labeling changes		
41.	Changes only to the product name.	X	
42.	Changes only to the product code(s).	X	
43.	Changes only to the manufacturer name.	X	
44.	Changes to the labelling and IFU of products that involve addition, removal and/or revision of warnings, precautions and/or contraindications arising due to safety and/or performance concerns.		X
45.	Changes in the IFU other than the ones originated from high/moderate impact changes (e.g., administrative, revision for clarity, typos, etc.) that only requires update of the public report.	X	
46.	Addition of languages.	X	
47.			
48.			

[2] Changes to regulatory version of products prequalified under the abridged pathway are considered as to have a high potential impact.

463
464 WHO reserves the right to ask for additional documents during the review of the submission as
465 needed.

466 ## References

1 GHTF/SG1/N071:2012 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'. Global Harmonization Task Force (GHTF) Steering Committee; 2012 .

2 ISO 13485:2016. Medical devices – Quality management systems – Requirements for regulatory purposes. Geneva, Switzerland: International Organization for Standardization; 2016.

3 ISO 14971:2019. Medical devices – Application of risk management to medical IVDs. International Organization for Standardization; Geneva, Switzerland: 2019.

4 IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices. International Medical Devices Regulators Forum (IMDRF) Management Committee; 2018

5 Technical Guidance Series for WHO Prequalification – Risk management for manufacturers of in vitro diagnostic medical devices. Geneva: World Health Organization; 2018.