2025 Joint UNICEF-UNFPA-WHO Meeting with Manufacturers and Suppliers

Updates on in vitro diagnostics: Prequalification and Emergency Use Listing

30 September 2025

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Session outline

1. Highlights – Irena Prat
2. Product dossier and CRP – Susie Braniff
3. Technical specifications series – Ute Ströher
4. Performance evaluation – Anne-Laure Page
5. Changes – Fatima Gruszka
6. Emergency Use Listing – Ute Ströher
7. Capacity building – Susie Braniff
8. ePQS – Helena Ardura
9. Q&A – moderated by Irena Prat

Housekeeping rules

- Mute microphone
- The speakers will answer all questions at the end of the session during an interactive Q and A session
    - Submit your questions to the Q and A chat function and they will be answered directly in the chat or live during the Q and A session.

If we do not answer all questions, we will follow up after the meeting

- Session will be recorded and available on our website in the weeks following this meeting.

2025 Highlights

Irena Prat

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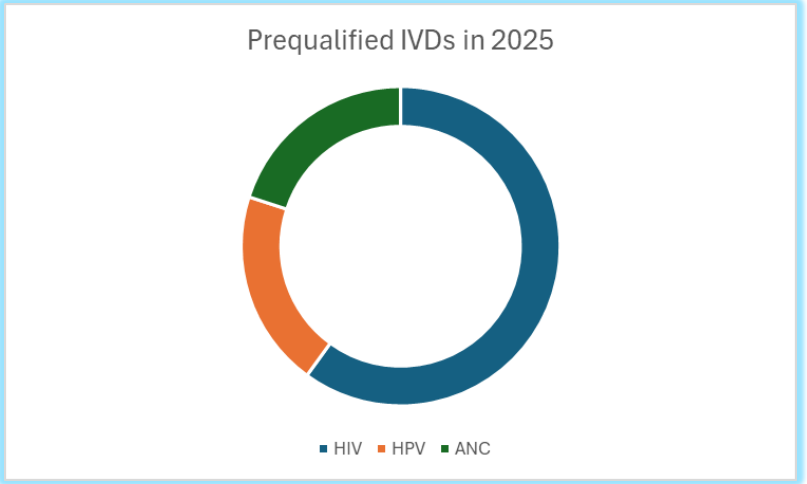
PQ listings and scope expansion

PQ listing of the first HIV ST by urine

PQ listing of the first triple diagnostic test for ANC



PQ expansion to haemoglobin point-of-care analysers intended for

- Screening for/diagnosis of anaemia;
- Aid in the diagnosis of anaemia;
- Aid in diagnosis of severe anaemia in patients with malaria; or
- Monitoring of haemoglobin levels

Launch of pilot project for parallel PQ assessment and policy development
WHO launches a pilot parallel WHO Prequalification and TB policy assessment process for new TB IVDs | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

Addendum to TSS-17: 250827 TSS 17 Addendum.pdf

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Launch of pilot project for parallel PQ assessment and policy development

WHO launches a pilot parallel WHO Prequalification and TB policy assessment process for new TB IVDs | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

- PQ/HTH partnership to pilot a novel parallel assessment process : streamline and optimize WHO assessment of new in vitro diagnostics
- HTH is assessing evidence on a new, near point-of-care class of tuberculosis (TB) diagnostic technologies that will inform updated TB policy guidance
- PQT will simultaneously assess individual near point-of-care testing class products for PQ
- Focus on tongue swabs and sputum swabs that are used with near PoC nucleic acid amplification tests (NAATs) and low-complexity automated NAATs (LC-NAATs) for Mycobacterium tuberculosis complex (MTBC) with or without drug resistance detection
- Manufacturers of eligible products are invited to contact the WHO Prequalification Unit at diagnostics@who.int to schedule a pre-submission call
- Addendum to TSS-17: 250827 TSS 17 Addendum.pdf

New changes guidance

A new guidance document supporting the post PQ and EUL change request process has been published and came into force on 1 June 2025

webinar recording Passcode: 7YK=s?3=

FAQ: PQDx 463_Q_and_A Change Request for WHO PQ and EUL IVDs.pdf

2025 Assessment sessions

- 6 fully virtual sessions in 2025
- PQ submissions and change requests

1. 10 to 14 February
2. 7 to 11 April
3. 16 to 20 June
4. 25 to 29 August
5. **13 to 17 October**
6. **1 to 5 December**

- Different model in 2026

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PQDx process revision

- Consultation held in 2024
- Revision aiming at streamlining processes and increasing efficiencies
- Performance evaluation:
  - Standalone activity / no longer part of PQ assessment
  - Pre-requisite for PQ listing
  - Initiated before PQ, run either in parallel to PQ or finalized prior to PQ assessment
  - Risk-based approach: full PE, analytical part PE or no PE depending on product type

- Updated abridged assessment process with additional RRAs and recognized approvals
- Enhanced use of reliance in dossier reviews (already in place for change reviews)

Product dossier & CRP

Susie Braniff

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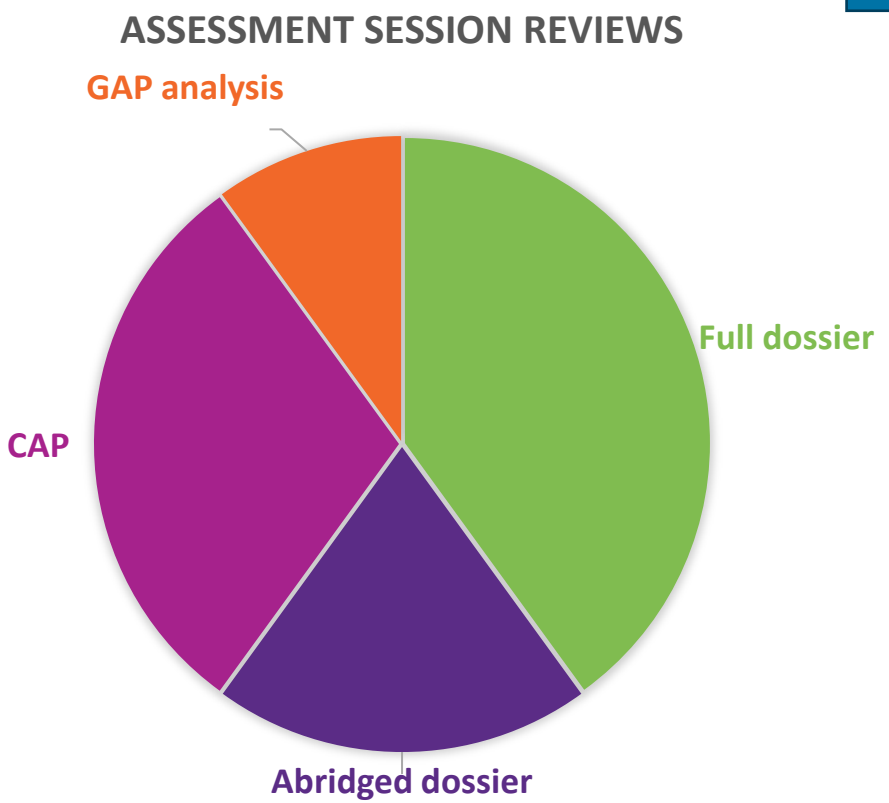
Product dossier updates

- 4 Assessment Sessions completed in 2025
  - 20 reviews completed
- 2 more Assessment Sessions this year
  - 13 – 17 October
  - 1 – 5 December
- **Complete submissions received 14 days prior to a session can be included for review**
- Training for new assessors conducted in August & September, next training scheduled for October
- 18 pre-submission calls held with manufacturers
- 11 new dossiers submitted so far in 2025



2026 Assessment Session dates to be announced soon

Planning for 9 sessions

Preparing for PQ Assessment

- Check eligibility criteria
- Request access to **ePQS portal**
- Complete and submit pre-submission form through the **ePQS portal**
- WHO Team will arrange a pre-submission call to explain the assessment process
- WHO will inform the Mx in writing if the product is prioritized

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Collaborative Registration Procedure (CRP)

The Manufacturer

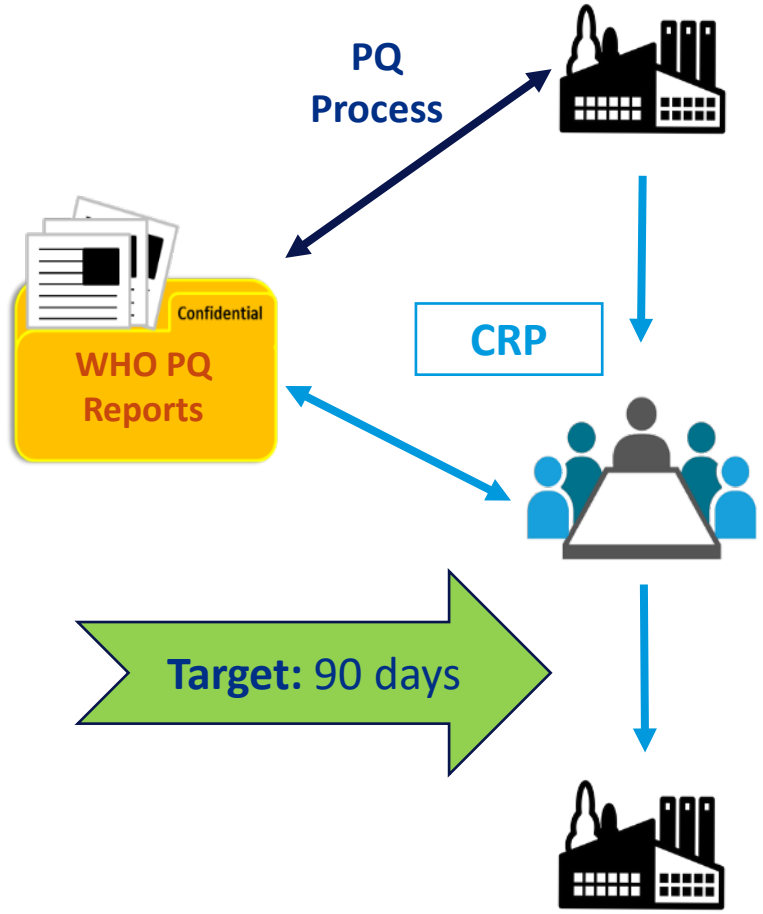
- Submit an expression of interest to the NRA
- Provide consent for WHO to share PQ reports
- Submit product dossier to NRA

WHO

- Make reports available to NRA via secure transfer

The NRA

- Treat WHO PQ reports as confidential
- Review the WHO assessment and use the information to support their regulatory decision
- Issue a decision in 90 days or less



- NRAs from **37** countries have signed CRP agreement
- **25** CRP registrations by CRP in Jan-June 2025
  - 33 CRP registrations in 2024
- PQ assessment reports have been shared for **41** prequalified products
  - 15 manufacturers participating
- PQ reports for approved changes are shared with NRAs that have registered products using the CRP

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Technical Specification Series - Update

Dr. Ute Ströher

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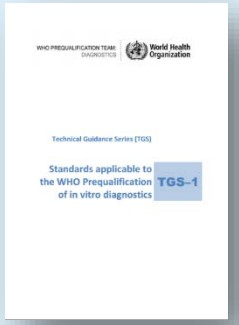
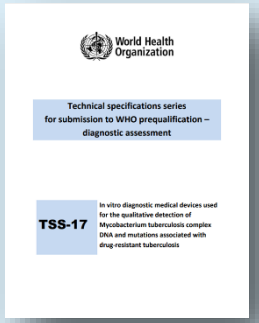
PQ IVD Guidance documents





Technical Guidance Series (TGS)

- Applicable to all IVDs
- Focus on the needs of WHO Member States
- Each TGS provides detailed guidance on a specific aspect related to IVD performance

Technical Specifications Series (TSS)

- Written for a specific analyte/pathogen/IVD
- Summarize minimum performance requirements for WHO prequalification
- Specific requirements tailored to types of infections, conditions, etc.
- Requirements that address needs of Member States incl resource limited settings

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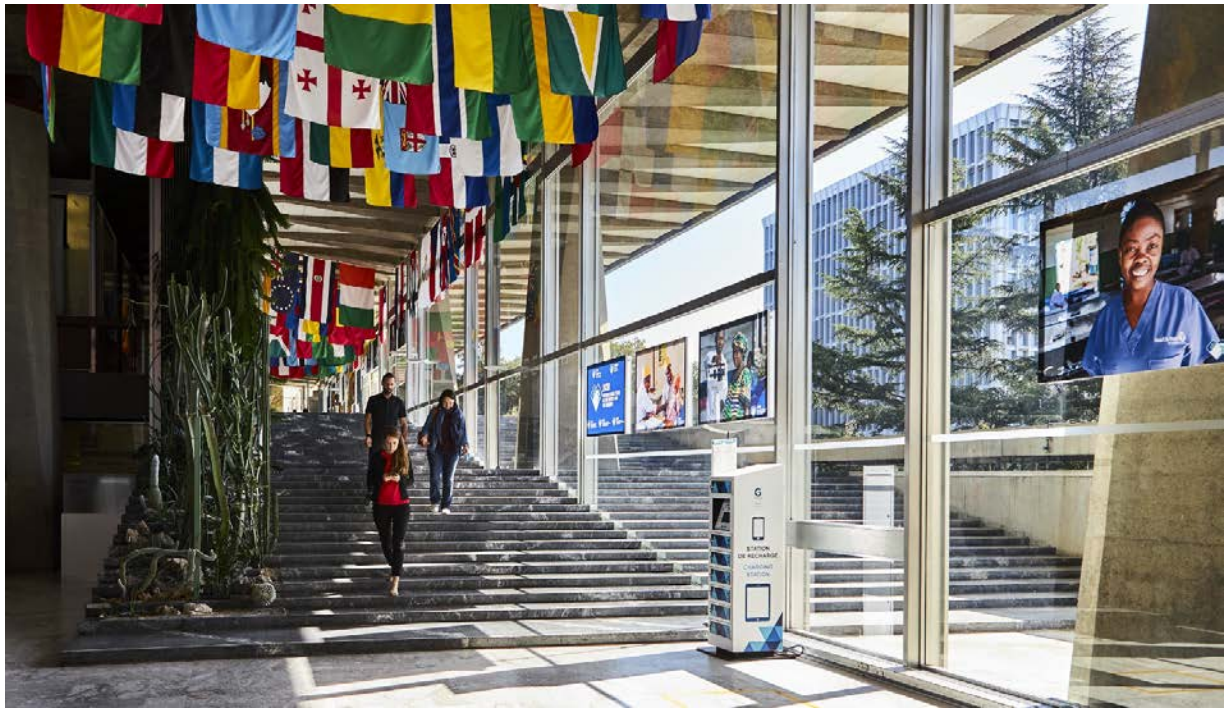
https://extranet.who.int/prequal/vitro-diagnostics/guidance-documents

Outline

- Overview of PQ-IVD technical specifications series (TSS) documents published in 2025
- PQ-IVD TSS in development
- PQ-IVD TSS under revision
- PQ-IVD TSS planned for 2026/2027



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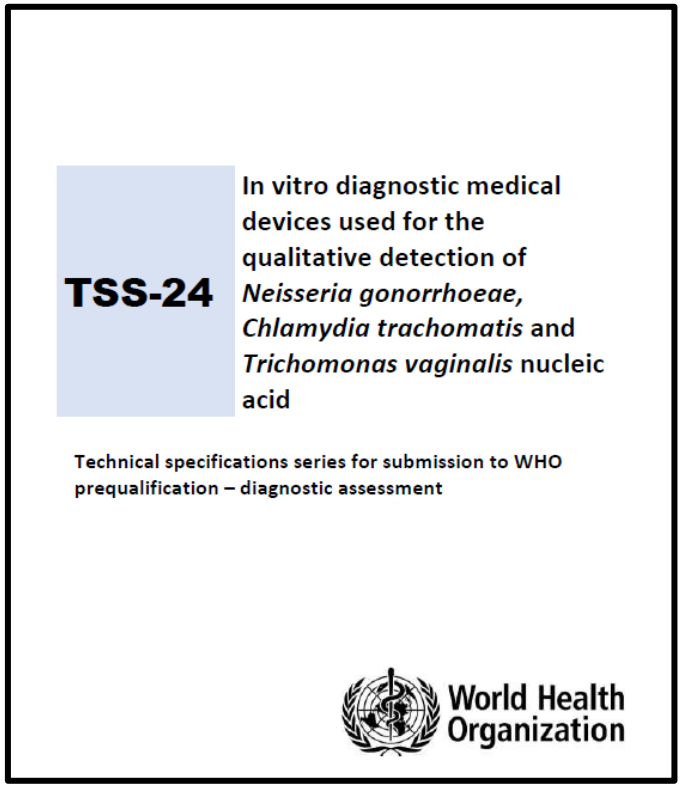
TSS (IVD) published in 2025

https://extranet.who.int/prequal/vitro-diagnostics/technical-specifications-series-ivds

TSS-24: In vitro diagnostic medical devices used for the qualitative detection of *Neisseria gonorrhoeae, Chlamydia trachomatis* and *Trichomonas vaginalis* nucleic acid



Intended Use
DNA or rRNA of NG/CT/TV
qualitative
professional use
screening, diagnosis, or aid to diagnosis
sexually active population, pregnant people, symptomatic and asymptomatic individuals
urine, vaginal swabs, endocervical swabs, anorectal swabs, penile meatal swab and oropharyngeal swabs
professional collected, self-collected (vaginal swabs)

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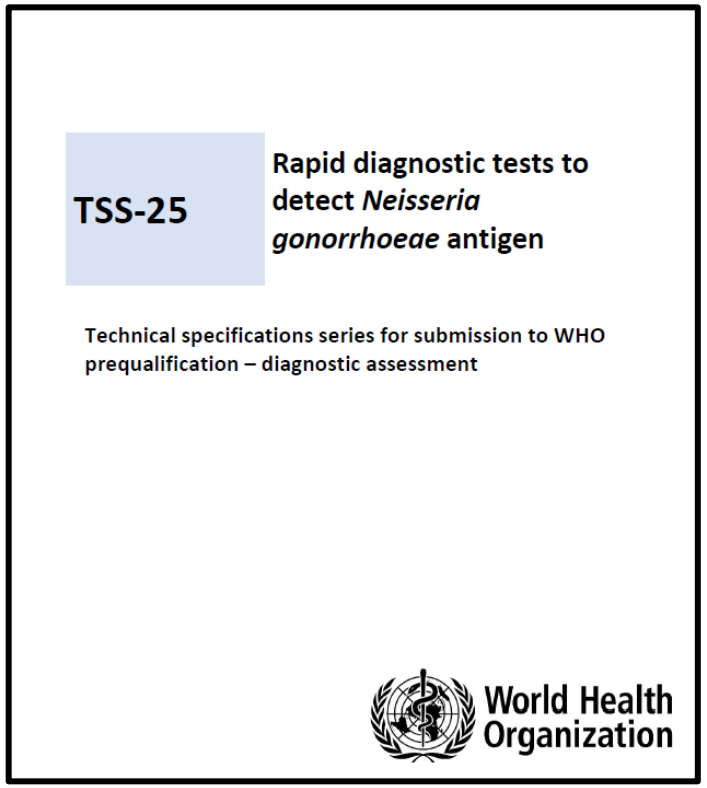
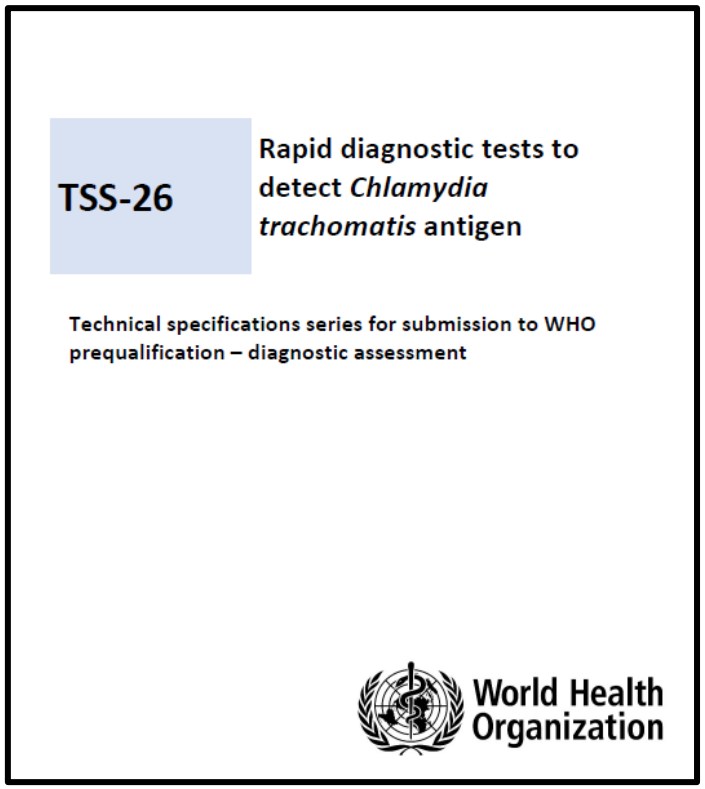
TSS-25: Rapid diagnostic tests to detect *Neisseria gonorrhoeae* antigen



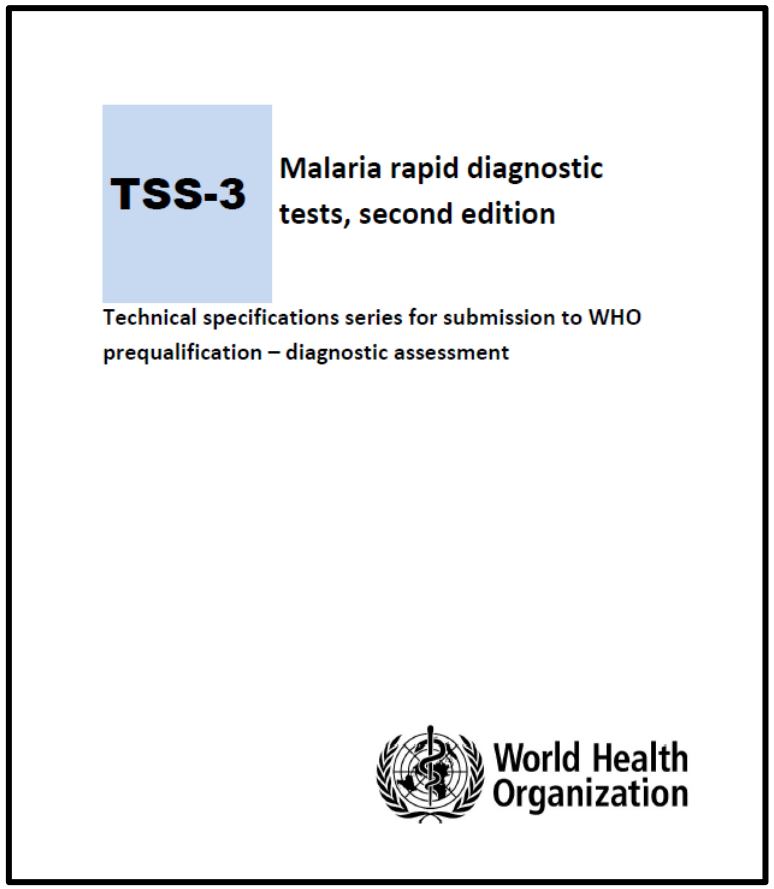
Intended Use
NG antigen
qualitative
professional use
diagnosis of NG infection, aid to diagnosis, screening of population subgroups at increased risk of STIs
symptomatic individuals, population subgroups at increased risk of STIs and attendees of clinics or service for STIs (including adolescents within these groups)
urine, vaginal swabs, endocervical swabs, penile meatal swabs
health care provider-collected, self-collected in a clinical setting

TSS-26: Rapid diagnostic tests to detect *Chlamydia trachomatis* antigen



Intended Use
CT antigen
qualitative
professional use
diagnosis of CT infection, aid in the diagnosis
symptomatic individuals, population subgroups at increased risk of STIs and attendees of clinics or service for STIs (including adolescents within these groups)
urine, vaginal swabs, endocervical swabs, penile meatal swabs
health care provider-collected, self-collected in a clinical setting

TSS-3: Malaria rapid diagnostic tests, second edition



Scope of the revision:

- Format changes → align with IMDRF ToC chapter numbering
- Availability of WHO International Standard for Pf & Pv (analytical studies)
- Clinical evidence to support claim for the detection of parasites with HRP2/3 deletions (applicable to all IVDs that detect Pf non-HRP antigens, e.g. LDH)

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TSS-17: In vitro diagnostic medical devices used for the qualitative detection of Mycobacterium tuberculosis complex DNA and mutations associated with drug-resistant tuberculosis
ADDENDUM (interim document)

- intended to support manufacturers applying for PQ assessment as part of the parallel, coordinated process of WHO Guideline development and the PQ process.
- the upcoming WHO GTB Guideline Development process aims to establish evidence-based recommendations on the use of tongue swabs and sputum swabs that are used with NPOC molecular tests
- validation requirements for generating supporting evidence
- the current TSS-17 document will be revised accordingly once relevant WHO GTB guidelines are published. If no WHO TB guidelines are issued on this topic, the addendum will be removed.

https://extranet.who.int/prequal/sites/default/files/document_files/250827%20TSS%2017%20Addendum.pdf

TSS (IVD) in revision

TSS-27: Syphilis rapid diagnostic tests for professional use and/or self-testing

Public comment phase completed (Q4 2024)

Scope of the revision:

- Format changes → align with IMDRF ToC chapter numbering
- Add Usability Studies to support claim for **self-testing**
- Address unavailability of WHO International Standard

TSS-4: In vitro diagnostic medical devices (IVDs) used for the detection of high-risk human papillomavirus (HPV) genotypes in cervical cancer screening

Scope of the revision:

- Format changes → align with IMDRF ToC chapter numbering
- self-collection
- mRNA tests
- genotype spectrum related studies

Ensure alignment with TPP (2024)

https://iris.who.int/server/api/core/bitstreams/544db89c-fb23-49e7-b27d-6ee0e625fb05/content

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TSS (IVD) in development

PQ-IVD TSSs in development

- TSS xx1: **Interferon-gamma release assay** in vitro-diagnostic medical devices for the detection of tuberculosis infection
- TSS xx2: **CD4 enumeration** technologies
- TSS xx3: **Targeted next-generation sequencing** based in vitro diagnostic medical devices used for the detection of **drug-resistant tuberculosis**

Performance evaluations

Anne-Laure Page

Performance evaluations- summary of activities in 2025

- Evaluations finalized in 2025 (final report issued by 25 September 2025): 7
  - HIV serology: 3
  - HIV- syphilis serology: 1
  - Syphilis serology: 1
  - TB NAT (drug-resistance): 1
  - SARS-Cov-2 antigen RDT: 1
- Highlights
  - First evaluation of HIV serology test on urine
  - First evaluation of NAT for TB drug resistance
  - First evaluation of SARS-CoV-2 rapid test

Updates

- Evaluation of malaria RDTs
  - Historically conducted at US-CDC
  - New PEL listed for evaluation of malaria RDTs
  - Transfer of malaria panel ongoing

- Serology panels
  - Introduced annual re-testing for long-term storage of serology panels
    - 10 specimens (6 positive and 4 negative) representing variety of reactivity levels
  - Full re-testing of HBsAg panel ongoing
  - HIV panel – additional testing with prequalified RDTs ongoing

Protocols

- New protocols
  - Protocol for TB-LAM tests finalized
  - Protocol for STI NAT (*N. gonorrhoeae, C. trachomatis, T. vaginalis*) finalized
  - Protocols for STI RDT (*N. gonorrhoeae* and *C. trachomatis)* – review by external experts

- Protocol revision
  - All protocols to be updated for new procedure
  - Protocol TB NAT under revision to include sputum and tongue swabs
  - Malaria protocol under revision to update PEL, and additional analytical sensitivity testing with WHO International Standards

Performance Evaluation Laboratories

- New PEL listed in 2025
  - ACPCC, Australia listed for HPV NAT
- Scope extension
  - NRL, Australia had scope extended to malaria RDT, STI NAT and STI RDT
  - NICD, South Africa had scope extended to TB LAM
- Remote PEL meeting
  - 1st session in May to introduce PQ process revision
  - 2nd session to be scheduled in coming months on technical aspects

Assessment of changes to PQ-ed and EUL-ed IVDs

Fatima Gruszka

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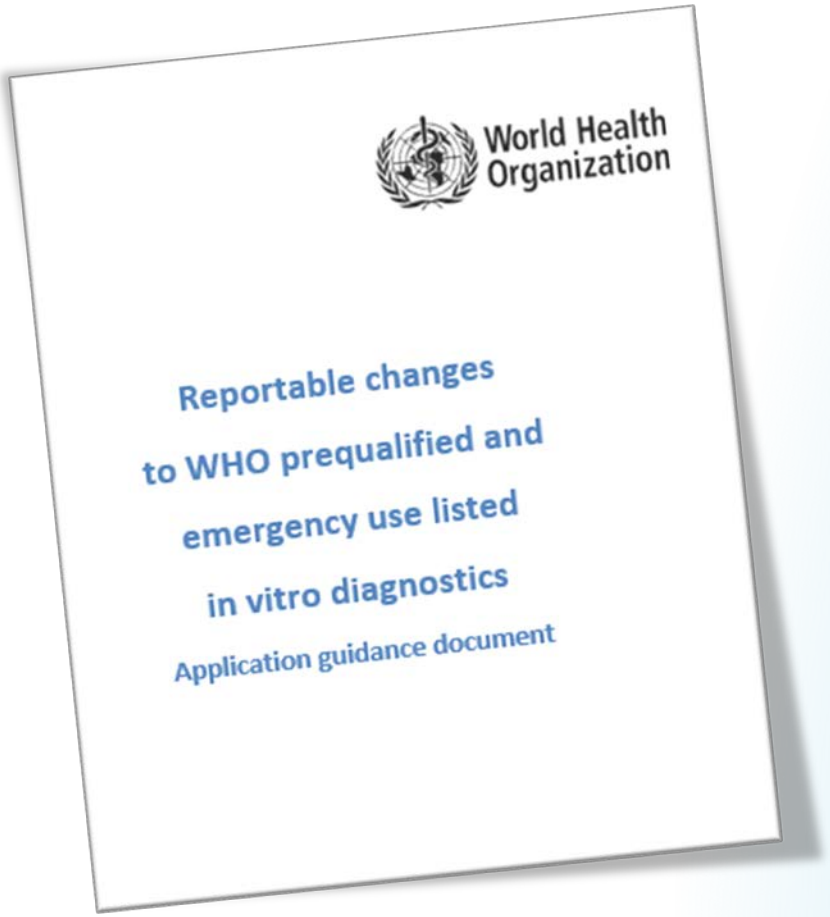
Purpose and Scope



- **Purpose**

1. Introduce the new process for reporting changes to WHO.
2. Integrate a risk-based methodology.
3. Align with international best practices.
4. Strengthen regulatory reliance and improve process efficiency.

- **Scope**

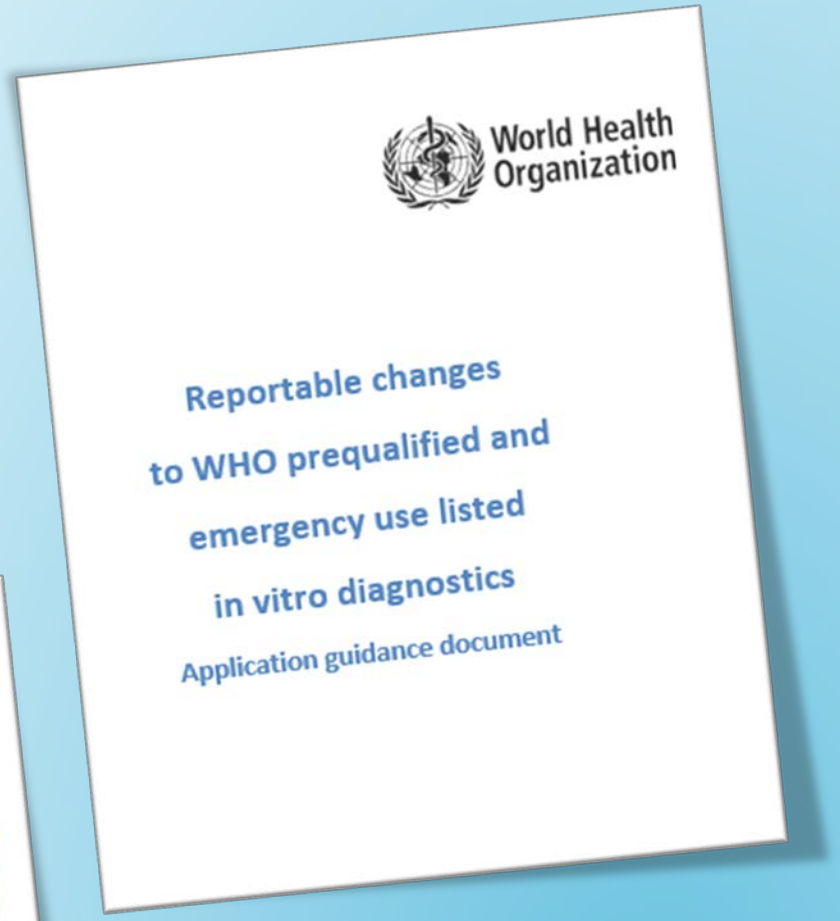
1. Types of changes that need to be reported
2. What to report
3. WHO assessment
4. What causes delays
5. New submission process

NEW GUIDANCE

Reportable Changes to WHO Prequalified & Emergency Use Listed IVD

NEW

Overview of 2025
New guidance
Post PQ
EUL listed products



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01

REPORTABLE CHANGES

The new guidance details the
Criteria for **Determining if the change needs to be reported to WHO**

02

NEW

REPORTABLE CHANGES CATEGORIES

The new guidance introduces definitions and
Criteria for determining **Changes Categories**

03

NEW

CHANGE APPLICATION

The new guidance details the
a list of information requested to support the
Change application.

Post-PQ Changes of PQ and EUL products throughout the Product Lifecycle

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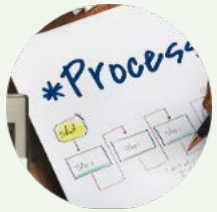
NEW GUIDANCE

Non Reportable Changes

PQ and EUL listed IVD

Administrative updates

Administrative updates, that do not need to be reflected in the WHO Public Report.



Changes impacting QMS

Routine changes to the QMS, manufacturing, or quality control and release processes to maintain compliance with standards and support continuous improvement in line with quality policy objectives.

Changes impacting Risk Assessment

Changes involving updates to the risk file made in accordance with applicable procedures and PMS policies, with no impact on the product's quality, safety, or performance.

Changes impacting Design

No examples found of changes impacting the design that would be non-reportable.

NEW GUIDANCE

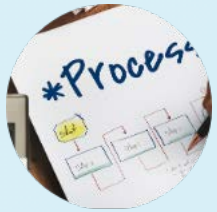
Reportable Changes

PQ and EUL listed IVD

Update of the WHO Public Report

Administrative updates, changes to product information, or new product codes, new product presentation (e.g., labeling, indications for use) that need to be reflected in the WHOPAR.

Changes impacting QMS



Change in the QMS, manufacturing or quality control and release processes or technologies with a potential impact on the quality, safety, or performance of the product.

Changes impacting Risk Assessment

Changes that introduce new risks, modify probability of existing hazardous situations or require updating or extending the scope of mitigation measures impacting the quality, safety, or performance of the product.

Changes impacting Design

Change in the design, nature, quality, attributes or specifications of critical components or reference materials with a potential impact on the quality, safety, or performance of the product.

NEW GUIDANCE

Change Category & Review

PQ and EUL listed IVD

Reportable Low Impact Changes

A change that has no potential impact or a limited potential impact on the function, quality, 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 WHOPAR.

Approval Decision upon screening

Quicker response

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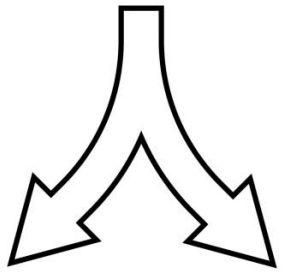
NEW GUIDANCE

Change Category & Review

PQ and EUL listed IVD

Moderate/High Impact Changes

A change with the potential to affect the function, quality, performance, usability, and/or safety of an IVD product, associated with risks that have been determined to be high or mod



Regulatory Reliance

The change has previously undergone stringent assessment and approval by a recognized National Regulatory Authority (NRA) : **Approval decision upon screening**

Full Change Application Review

Desk Review of submitted data by the WHO. Depending on the type of change, the assessment may also necessitate : **Site inspection**(s) and/or a **Performance evaluation**.

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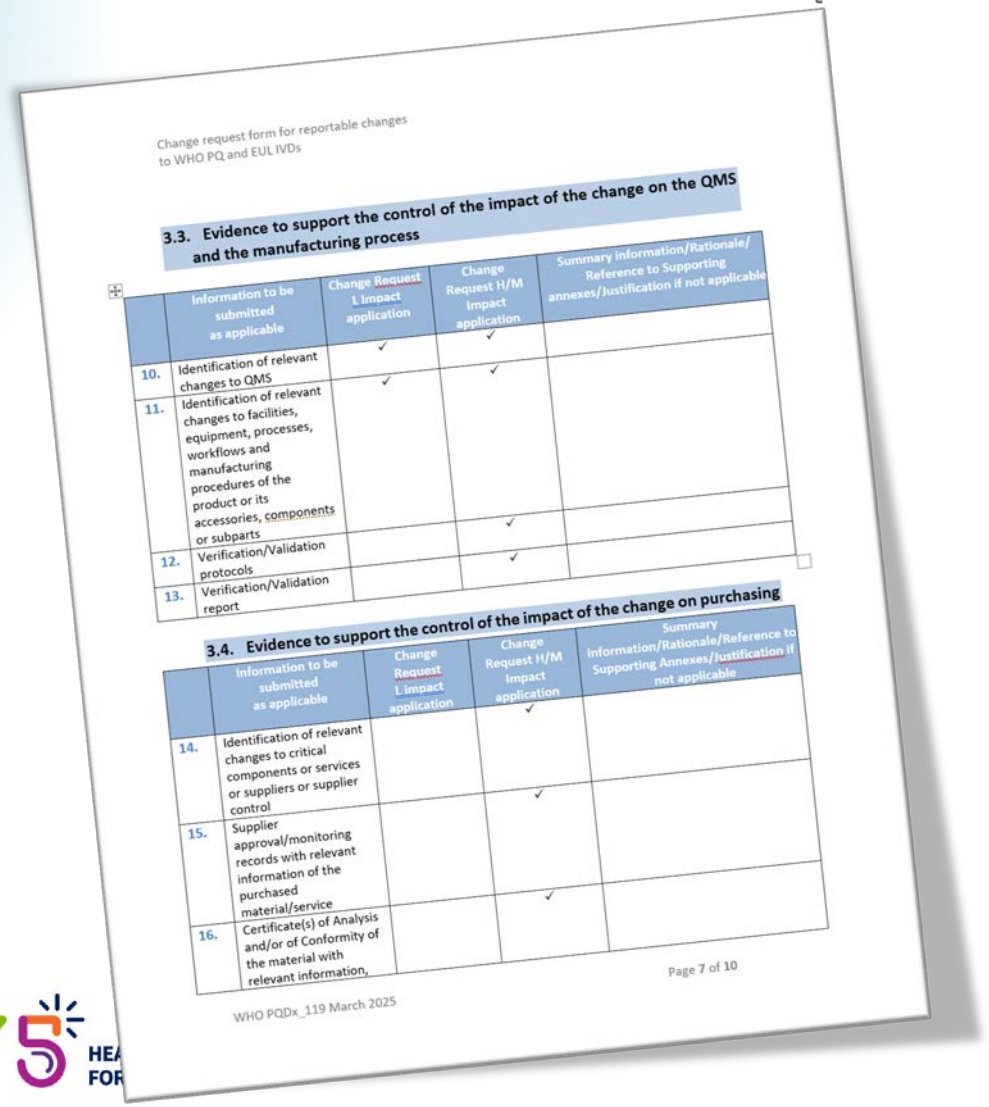
Example of Changes Categories

PQ and EUL listed IVD



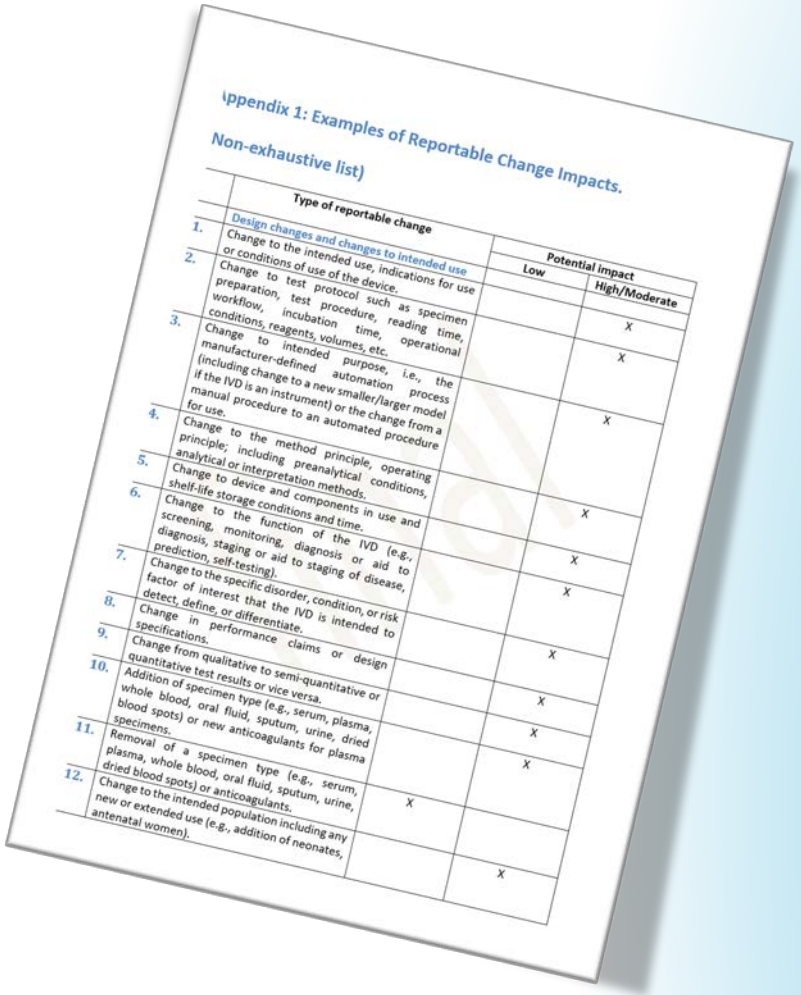
Change request form for reportable changes to WHO PQ and EUL IVDs

3.3. Evidence to support the control of the impact of the change on the QMS and the manufacturing process

	Information to be submitted as applicable	Change Request L impact application	Change Request H/M Impact application	Summary information/Rationale/ Reference to Supporting annexes/Justification if not applicable
10.	Identification of relevant changes to QMS	✓	✓	
11.	Identification of relevant changes to facilities, equipment, processes, workflows and manufacturing procedures of the product or its accessories, components or subparts	✓	✓	
12.	Verification/Validation protocols		✓	
13.	Verification/Validation report		✓	

3.4. Evidence to support the control of the impact of the change on purchasing

	Information to be submitted as applicable	Change Request L impact application	Change Request H/M Impact application	Summary Information/Rationale/Reference to Supporting Annexes/Justification if not applicable
14.	Identification of relevant changes to critical components or services or suppliers or supplier control		✓	
15.	Supplier approval/monitoring records with relevant information of the purchased material/service		✓	
16.	Certificate(s) of Analysis and/or of Conformity of the material with relevant information,		✓	



ppendix 1: Examples of Reportable Change Impacts.

Non-exhaustive list)

	Type of reportable change	Potential impact	
		Low	High/Moderate
1.	Design changes and changes to intended use 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, 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 IVD (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

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NEW GUIDANCE

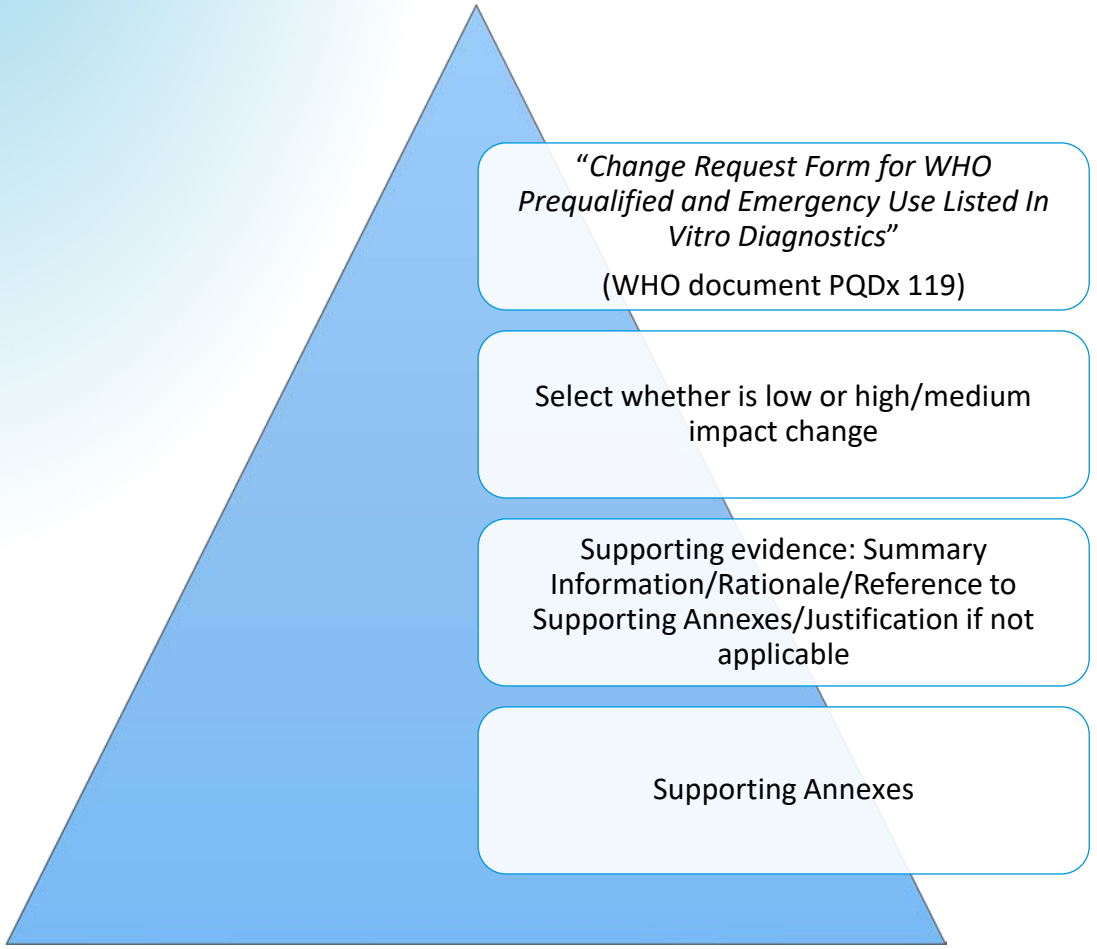
Change Process Overview

PQ and EUL listed IVD

NEW GUIDANCE

Required documentation

PQ and EUL listed IVD



⚠️ **WHO will not accept any changes without justification/rationale on their impact assessment and supporting documentation.**

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NEW

NEW GUIDANCE

Submission Process via WHO ePQS portal

PQ and EUL listed IVD

Reporting Changes via ePQS portal

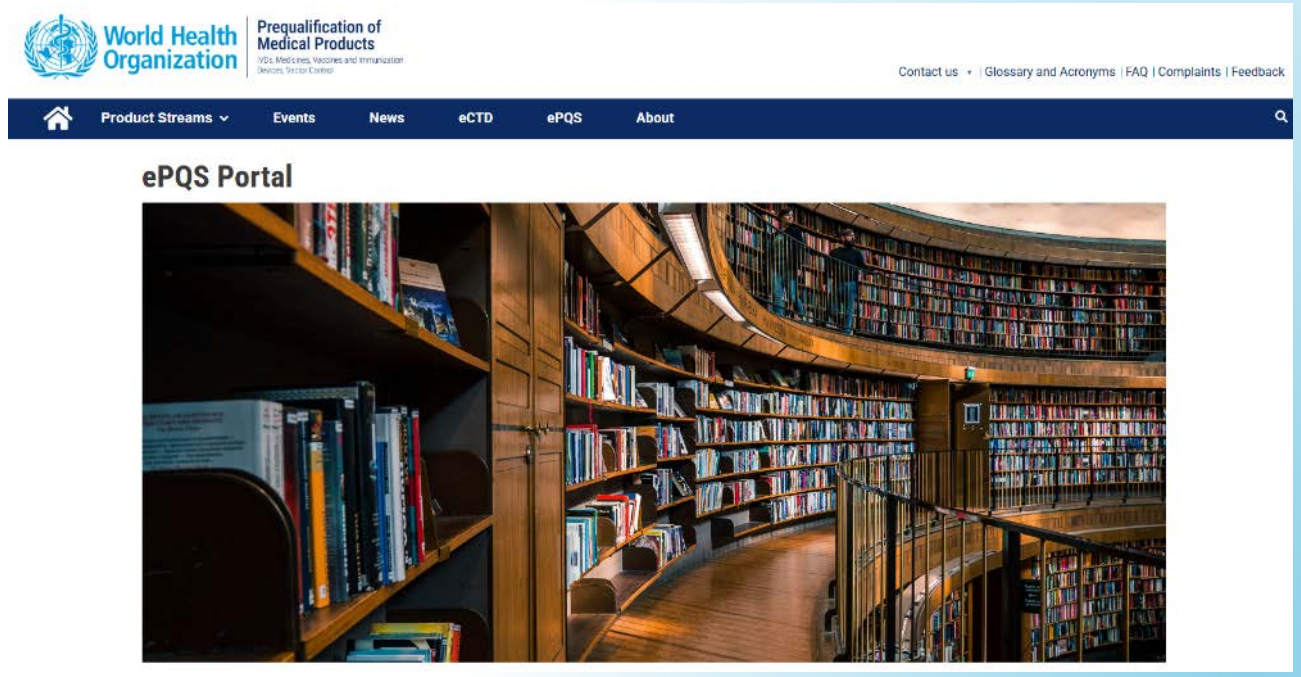
https://extranet.who.int/prequal/epqs-portal

General Portal Information

ePQS - Accounts Contacts Users and Record Visibility
ePQS - Creating or editing a Contact or Account
ePQS - Portal Features, Uploading and Downloading Documents
ePQS - Terms and Conditions of use (4 October 2023)
ePQS - User Registration and accessing the ePQS Portal

Pre-requisites

Register on ePQS : Creating or editing registered users



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2025 in numbers

102 Cases
171 decisions
(Jan–Sep 2025)

- 3 rejections: 1.8%

- Rejection Reasons

2 cases: Shelf life not supported by data

1 case: Misleading description

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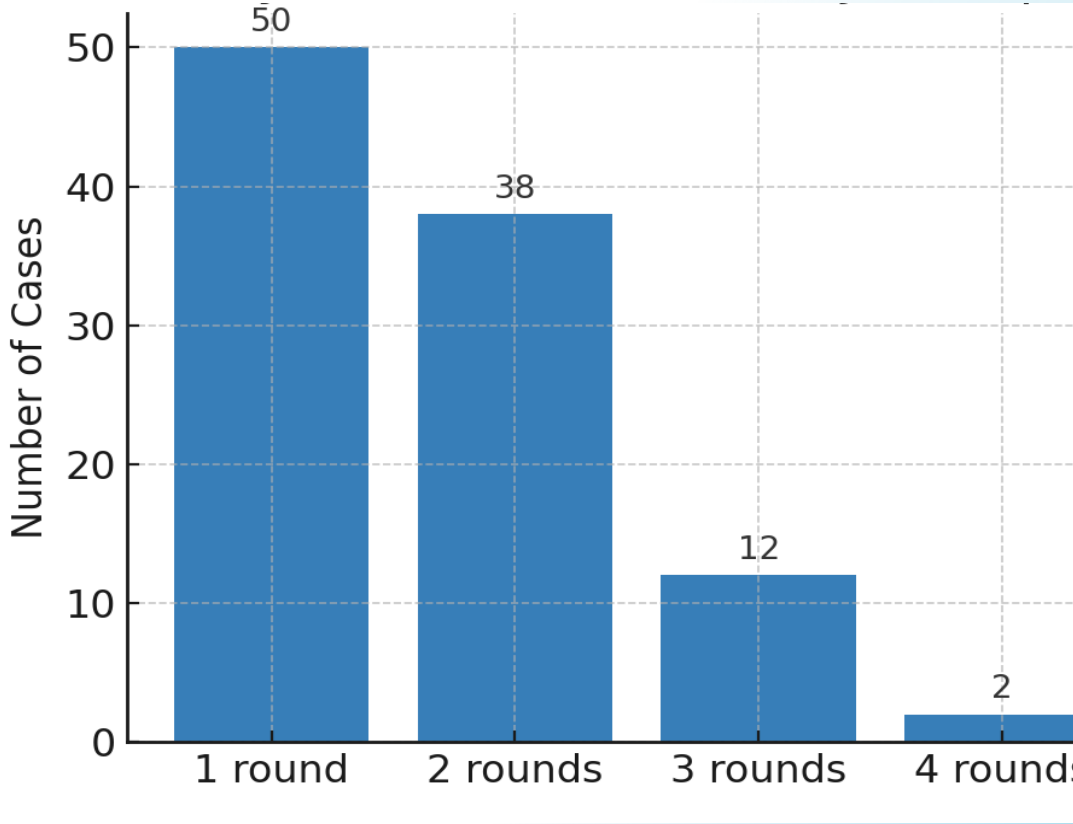
2025 in numbers

WHO Cases Decisions per round (Jan–Sep 2025)

- **1 Round (50 cases):** Clear description of the changes with a complete set of supporting evidence.
- **2 Rounds (38 cases):** Inaccurate or incomplete description of the change; missing, inadequate, or insufficient evidence; limited impact assessment; or process coverage only partial.
- **3 Rounds (12 cases):** Inadequate risk management and weak mitigation measures to demonstrate maintained performance.
- **4 Rounds (exceptional rounds):** Evidence provided to support regulatory status was insufficient or inaccurate.



What causes delays

01 **Description of the change**

Lack of clarity in the scope or rationale of the change
Missing descriptions and **Non-disclosed Changes**

02 **Generic Risk Assessment**

Failure to address impact of the particular Change on processes and on safety, performance, or intended use/ risk mitigation strategies or not relevant to the particular change

03 **Incomplete or Inadequate Documentation**

Missing technical justifications, validation data, or regulatory references or V&V data not relevant to the particular change

04 **Poor Traceability**

Inability to link test data, validation reports, or risk assessments to specific product versions and lack documents control across the submission

05 **Lack of Clarity on Timelines**

No Change control plan
Unclear implementation dates or phased rollout plans

06 **Highlighting of Changes in Labeling & IFU**

Changes not clearly marked and detailed

07 **Gaps in PMS Plans**

PMS activities not documented or addressed

Emergency Use Listing

Dr. Ute Ströher

World Health Organization

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EUL for IVDs in context of the mpox PHEIC

- 23 Jul 2022 – Jul 2023: the WHO DG declared that the outbreak of mpox (clade II) constitutes a PHEIC
- 14 Aug 2024: the WHO DG declared that the outbreak of mpox (clade I) constitutes a PHEIC
- 28 Aug 2024: manufacturers of IVDs for the detection of **MPXV nucleic acid** are invited to submit an EOI for assessment of candidate IVDs under the EUL procedure

Scope

  - IVDs for the detection of mpox nucleic acid (multiplex assays, detecting more than one non-variola Orthopox virus targets, at least one target must be Monkeypox virus specific)
  - Differentiation of Monkeypox virus clades I and II is preferred but not required.
  - Not eligible: single target tests, multi pathogen test

- 9 Sep 2024: WHO publishes 'Emergency Use Listing of IVDs **Instructions for Submission Requirements**: In vitro diagnostics detecting Monkeypox virus nucleic acid' (version 1)
- 5 Sep 2025: WHO declares end of mpox PHEIC, **BUT extends** EUL for IVDs and vaccines

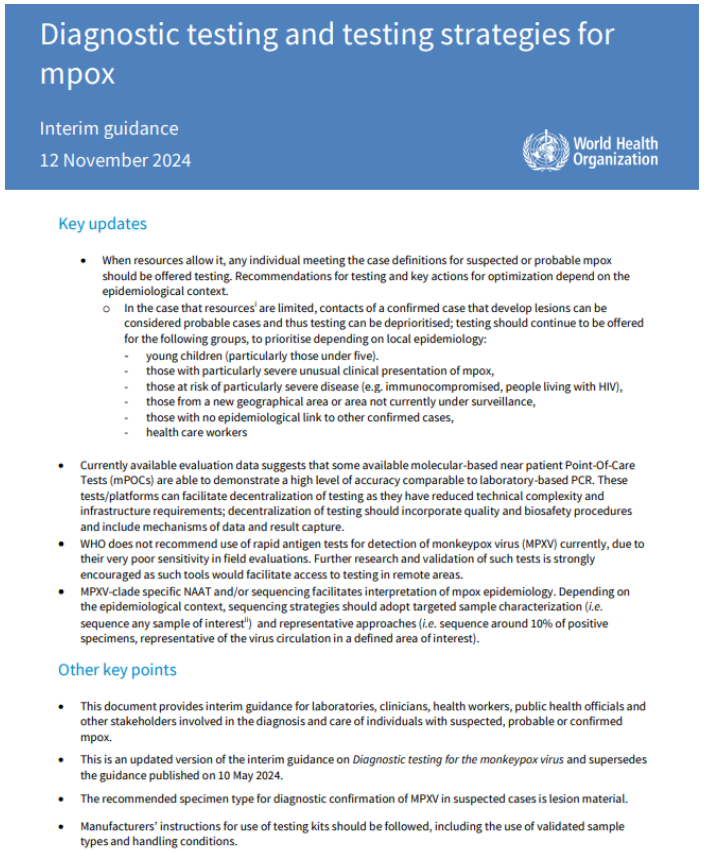
EUL MPXV IVD: Application status

- 72 contacts
- 43 pre-submission calls
    - 14 letters of applications
    - 16 dossiers received
        - 8 products listed
        - 3 application closed
        - 5 assessments ongoing

https://extranet.who.int/prequal/vitro-diagnostics/mpox-disease-pheic-emergency-use-listing-procedure-eul-ivds

Will MPXV antigen RDTs be eligible for EUL? (I)

- WHO EUL is aligned with WHO testing recommendations



Diagnostic testing and testing strategies for mpox

Interim guidance

12 November 2024

World Health Organization

Key updates

- When resources allow it, any individual meeting the case definitions for suspected or probable mpox should be offered testing. Recommendations for testing and key actions for optimization depend on the epidemiological context.
  - In the case that resources' are limited, contacts of a confirmed case that develop lesions can be considered probable cases and thus testing can be deprioritised; testing should continue to be offered for the following groups, to prioritise depending on local epidemiology:
    - young children (particularly those under five).
    - those with particularly severe unusual clinical presentation of mpox,
    - those at risk of particularly severe disease (e.g. immunocompromised, people living with HIV),
    - those from a new geographical area or area not currently under surveillance,
    - those with no epidemiological link to other confirmed cases,
    - health care workers
- Currently available evaluation data suggests that some available molecular-based near patient Point-Of-Care Tests (mPOCs) are able to demonstrate a high level of accuracy comparable to laboratory-based PCR. These tests/platforms can facilitate decentralization of testing as they have reduced technical complexity and infrastructure requirements; decentralization of testing should incorporate quality and biosafety procedures and include mechanisms of data and result capture.
- WHO does not recommend use of rapid antigen tests for detection of monkeypox virus (MPXV) currently, due to their very poor sensitivity in field evaluations. Further research and validation of such tests is strongly encouraged as such tools would facilitate access to testing in remote areas.
- MPXV-clade specific NAAT and/or sequencing facilitates interpretation of mpox epidemiology. Depending on the epidemiological context, sequencing strategies should adopt targeted sample characterization (*i.e.* sequence any sample of interest[i]) and representative approaches (*i.e.* sequence around 10% of positive specimens, representative of the virus circulation in a defined area of interest).

Other key points

- This document provides interim guidance for laboratories, clinicians, health workers, public health officials and other stakeholders involved in the diagnosis and care of individuals with suspected, probable or confirmed mpox.
- This is an updated version of the interim guidance on *Diagnostic testing for the monkeypox virus* and supersedes the guidance published on 10 May 2024.
- The recommended specimen type for diagnostic confirmation of MPXV in suspected cases is lesion material.
- Manufacturers' instructions for use of testing kits should be followed, including the use of validated sample types and handling conditions.

WHO **does not recommend** use of rapid antigen tests for detection of monkeypox virus (MPXV) currently, due to their very **poor sensitivity** in **field evaluations**.

Further research and validation of such tests is strongly encouraged as such tools would facilitate access to testing in remote areas

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Will MPXV antigen RDTs be eligible for EUL? (II)

- Only a limited number of field evaluations have been conducted
- Performance of most products does not meet WHO TPP2
  (Tests used as an aid to diagnosis by detecting OPXV antigens, which are amenable to decentralized use, including in the community)
- WHO plans to convene Guideline Development Group to assess the available data and consider revision of the current testing recommendation for MPXV antigen tests

	Minimal	Preferred
Clinical sensitivity	≥ 80% when using lesion material compared to a reference molecular method.	≥ 90% when using lesion material compared to a reference molecular method.
Clinical specificity	≥ 97% when using lesion material compared to a reference molecular method.	≥ 99% when using lesion material compared to a reference molecular method.

https://iris.who.int/bitstream/handle/10665/371297/9789240076464-eng.pdf?sequence=1

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Capacity Building

Susie Braniff

World Health Organization

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Capacity Building

- Workshops for IVD Manufacturers
  - Held in Jakarta 20-22 January
    - Over 150 participants from 8 Asian countries
    - PQ procedure and case studies
    - Donor perspective: access, QA & local manufacturing
    - Support available from partners
  - **Upcoming** workshop for IVD Manufacturers based in China
    - 9 – 11 December in Guangzhou
    - Focus on PQ assessment process

Registration OPEN

- Webinars
  - Change Request reporting webinar recording is available here
  - **Upcoming** webinar on RDT Accessibility 7 October 2pm
    - Details and registration at this link

Staff from NRAs participating in PQ Assessment Sessions

Training for new assessors on dossier review & change requests

Expansion of the roster of subject-matter experts working with PQ

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ePQS update

Helena Ardura

World Health Organization

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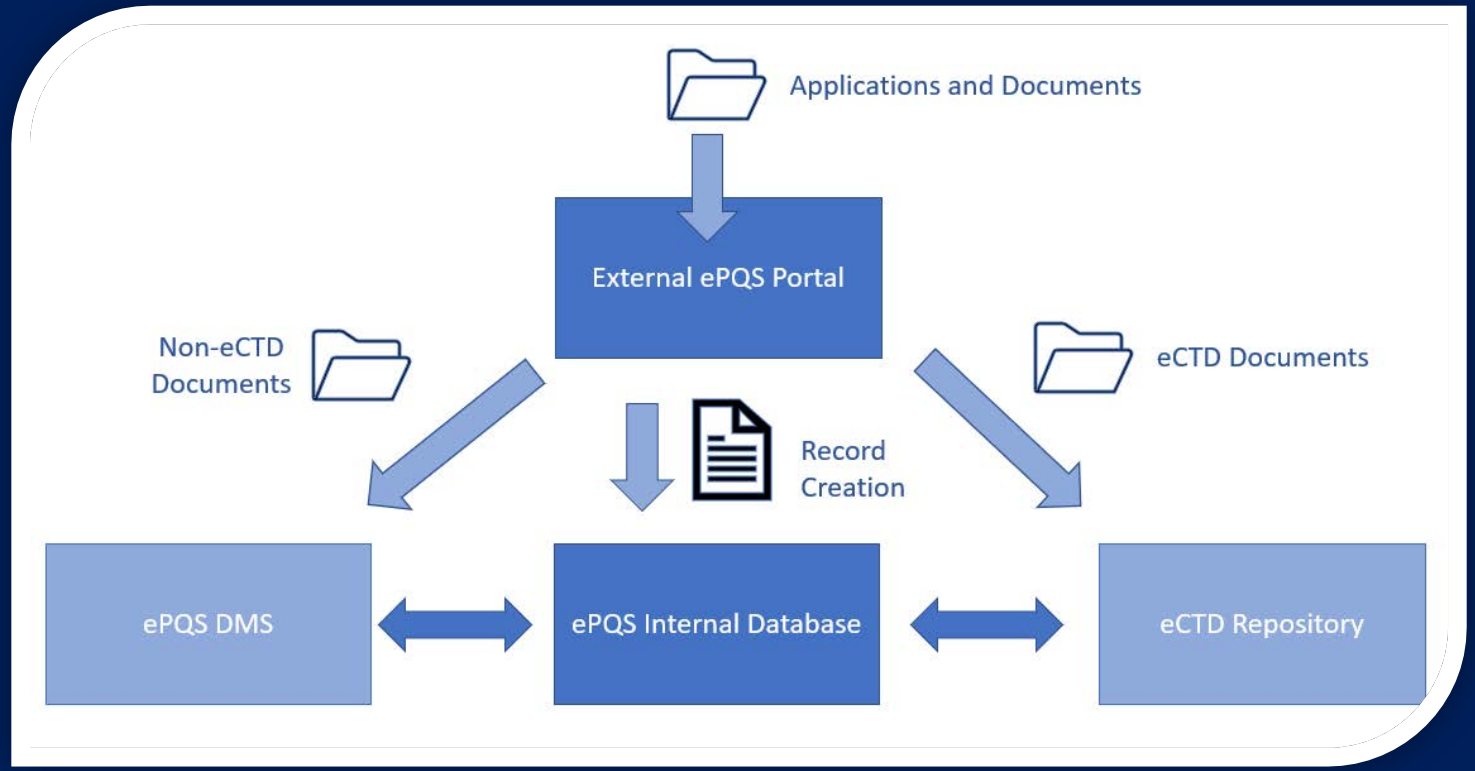
ePQS Portal Update – September 2025

- The ePQS portal is the outward facing portion of a larger IT system.

It permits applicants to file applications, upload and download documents.

It permits the submission of dossiers in eCTD format



ePQS Portal Update – September 2025

- The ePQS portal went live for applicants in May 2025 and feedback from applicants is positive.
- There is a steady flow of registrants for the portal.
- The use of the ePQS portal to file applications will become compulsory early 2026. Currently, some cases we still accept applications via dbinbox\diagnostics.

ePQS Portal Update – Submissions

Dossiers:

- 14 new applications made online using ePQS since February 2025.
- Manufacturers can drop documentation in ePQS.
- For commitments to PQ, applicants need to use dbinbox\diagnostics.

Change requests:

- 51 initial applications + responses

WPEL:

- 4 applications

Registered portal users:

- >100 from ~30 organizations

Bugs, Tips and Observations #1

When an initial application is submitted, internal staff are alerted.

But when further documents are submitted for the same application, the notification does not occur.

It is important for PQT and applicants that additional submissions are not missed.

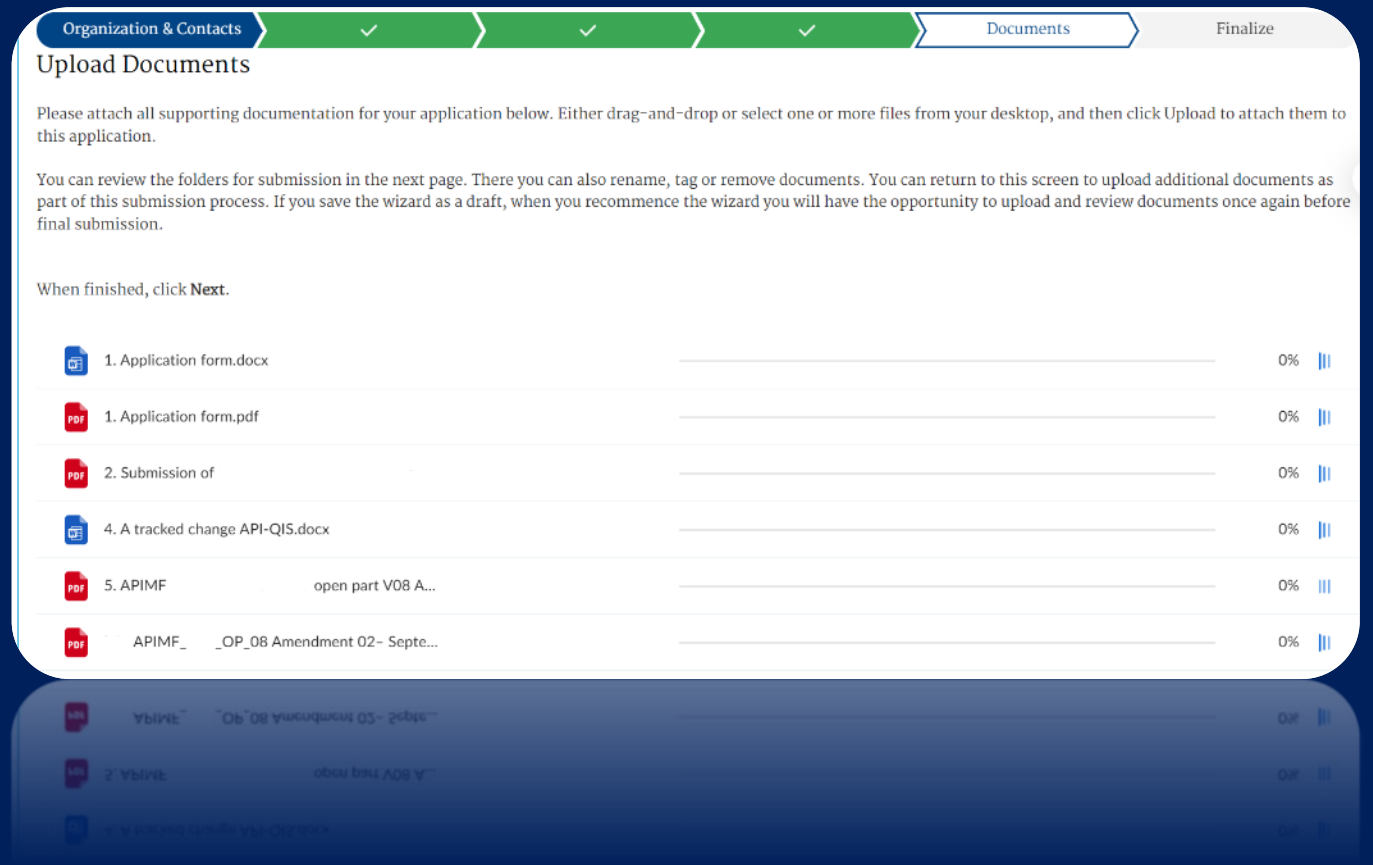
Please always send an email to diagnostics@who.int and copy the focal point for your application, after you have uploaded documents to the corresponding case on ePQS.

Bugs, Tips and Observations #2

In some cases, when trying to upload documents for the first time the upload process stays at 0% (files are not uploaded).

The issue appears to be caused by the local firewall blocking access to BOX, the document management system integrated within the ePQS portal

See Q&A document on the ePQS website for advice



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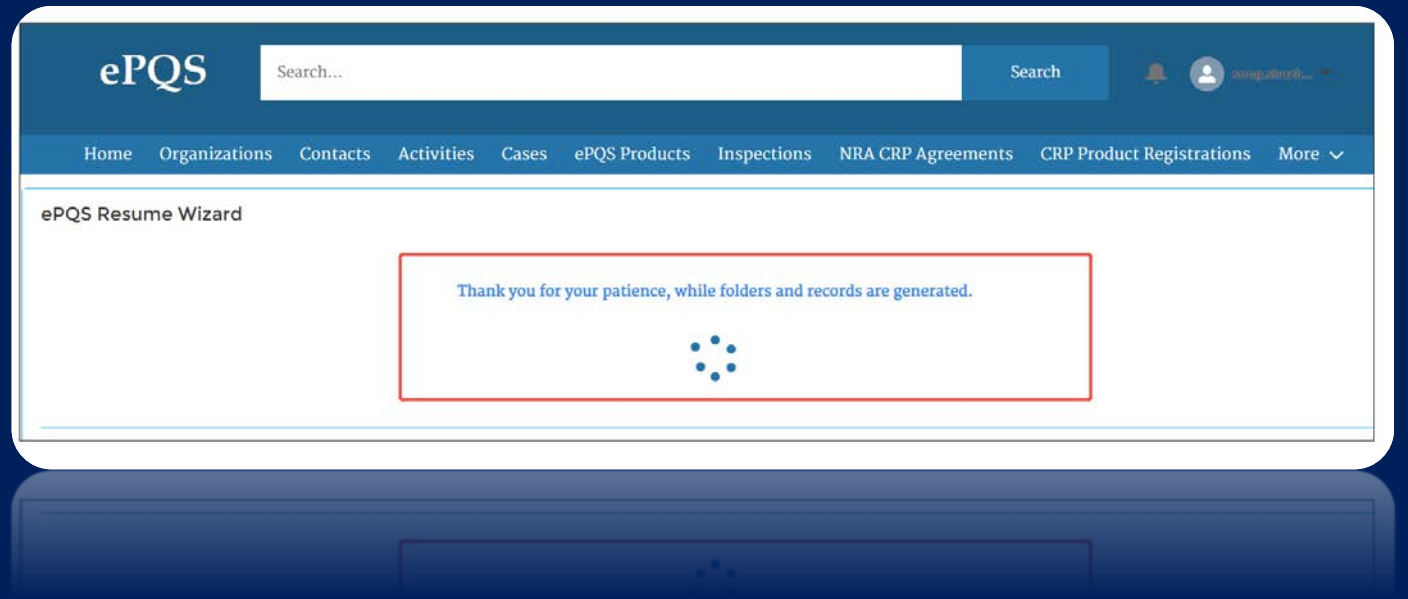
Bugs, Tips and Observations #3

When trying to upload documents for a Post-PQ change applications the system starts to loop.

This is almost always because no Product record was earlier associated with the change application.



ePQS Portal Information

- Information relating to the ePQS portal can be found at this link: https://extranet.who.int/prequal/epqs/epqs-portal

- This include several guidance documents, training information, and guidance on the use of submission wizards for various applicant types.

- If applicants encounter technical issues, please contact the ePQS manager at **epqs@who.int**

Q&A