PERFORMANCE, QUALITY & SAFETY (PQS) STANDARD OPERATING PROCEDURE		
SOP N°: MHP/RPQ/PQT/VAX/PQS/008	**Version n°:** 01.06	**Page:** 1 of 16

HOW TO RE-EVALUATE A WHO PQS ACCREDITED TEST LABORATORY.

	Effective date	**Revision date**
1st edition: 08/07/2004 *(For details see revision table)*	08/07/2004	06/01/2007; 27/01/2017
2nd edition: 06/04/2018 *Authorised by:* *Reviewed by:*	06/04/2018 I. Gobina P. Mallins	01/04/2020

Prequalification Team (PQT)

Contents

1. Purpose

This SOP describes how to re-evaluate a PQS accredited laboratory that has previously been accepted in accordance with the procedures set out in SOP No MHP/RPQ/PQT/VAX/PQS/007: *How to assess a laboratory for PQS accreditation.* It describes the procedure for re-approving a laboratory. Any laboratory that has failed to perform adequately risks losing its PQS accreditation status.

A PQS Review will take place every year. This review verifies that ISO and other certification is up to date, whether changes have occurred in key personnel and summarises product testing for PQS approval that has been carried out in the 12 months prior.

A *surveillance* audit visit should take place every three to five years depending on the amount of PQS verification carried out. It is expected that these audit visits should only take one day unless the laboratory has carried out a lot of PQS verification or the laboratory has more than one site.

The procedures set out in this SOP will be followed by the *PQS Secretariat* (Secretariat), the *PQS Working Group* (WG) and by all *Technical Specialists* (TS) commissioned by the Secretariat.

2. Scope

This SOP is applicable whenever a testing laboratory is being considered for requalification.

3. Responsibility

Responsibilities and tasks will be assigned as follows.

The *PQS Working Group* (WG)[1] (at the direction or request of the PQS Secretariat):

- Members may be assigned the task of conducting the annual review; and
- Members or Technical Specialists (TS) will prepare a report of the review.

[1] The PQS Working Group (WG) is comprised of the WHO (PQS and Expanded Programme on Immunization), the United Nations Children's Fund (UNICEF) Supply and Programme Divisions, the Gavi, the Vaccine Alliance Secretariat, specialist agencies, partner organizations and other key stakeholders. In an advisory capacity through the WG structure, these actors offer a wide range of programmatic and technical expertise that supports the development, introduction and advancement of technologies that will meet countries' EPI needs for high-quality cold chain equipment and devices.

The *PQS Secretariat* (Secretariat)[2]:

- Commissions an annual review of the performance of each PQS testing laboratory;
- Takes the decision to disqualify a test laboratory, to amend the list of assessed services, or to maintain the assessment status unaltered based on the report of the annual review;
- Notifies the test laboratory of a decision to continue or suspend[3] accreditation; and
- Makes amendments to the website to take account of the decisions.

4. Associated reference documentation

- ILAC-G15:2001 Guidance for Accreditation to ISO/IEC 17025
- ILAC-G17:2002 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025
- ILAC-G18:04/2010 Guideline for the Formulation of Scopes of Accreditation for Laboratories
- ISO 9001:2015 Quality management systems — Requirements
- ISO/IEC 17025 inc COR 1: 2005 General requirements for the competence of testing and calibration laboratories.
- List of ILAC Mutual Recognition Arrangement Signatories
- ISO 9001:2015 Quality management systems — Requirements
- ISO/IEC 17025 inc COR 1: 2005 General requirements for the competence of testing and calibration laboratories.
- SOP No MMHP/RPQ/PQT/VAX/PQS/007 How to assess a PQS testing laboratory New Version: 1.6

[2] The WHO PQS Secretariat is responsible for sharing up-to-date information on prequalified immunization devices and products, as well as product alerts. It ensures that the standards that apply to equipment maintenance, manufacturing and product testing are current. The Secretariat also coordinates product feedback reports and learnings from product field monitoring.

[3] Suspension may be temporary subject to certain conditions being met.

5. Procedure

5.1 Assessment of accredited laboratories

(Secretariat or its representative)

The Secretariat will contact the accredited laboratory to request up-to-date information. It will do so by email with the wording provided in Annex 1, attaching the *Re-accreditation checklist* provided in Annex 2 and the *Evaluation log* provided in Annex 3, to request the following information:

- Copies of IEC 17025 and other certification. If an expiry date is within six months, laboratory must state the anticipated date of next audit;
- An up-to-date .pdf web page of the complete *laboratory data sheet*. This is required to facilitate a comparison with the current PQS-accredited laboratory web page in order to check for any changes such as categories of testing, contact information etc.;
- Indication of whether the laboratory wish to continue to test their products to maintain PQS-prequalified status and/or to change their current PQS categories;
- Up-to-date copies of the CVs of key personnel, stating their role and responsibilities in regard to PQS testing and/or verification or other responsibilities within the organization, to demonstrate if there has been any change in key personnel;
- An up-to-date copy of the laboratory quality manual, highlighting any changes that have taken place in the previous 12 months;
- Up-to-date copies of any SOPs, TWI or similar documents that are maintained in regard to PQS testing and/or verification, and highlighting any changes that have taken place in the previous 12 months;
- A list of all tests of products PQS approval carried out in the past year, including dates and with manufacturer and/or suppliers named in each case; and
- Details of complaints from clients and the actions carried out in accordance with their quality procedures (CAPA). This information will be kept confidential and does not automatically affect a laboratory's PQS accreditation.

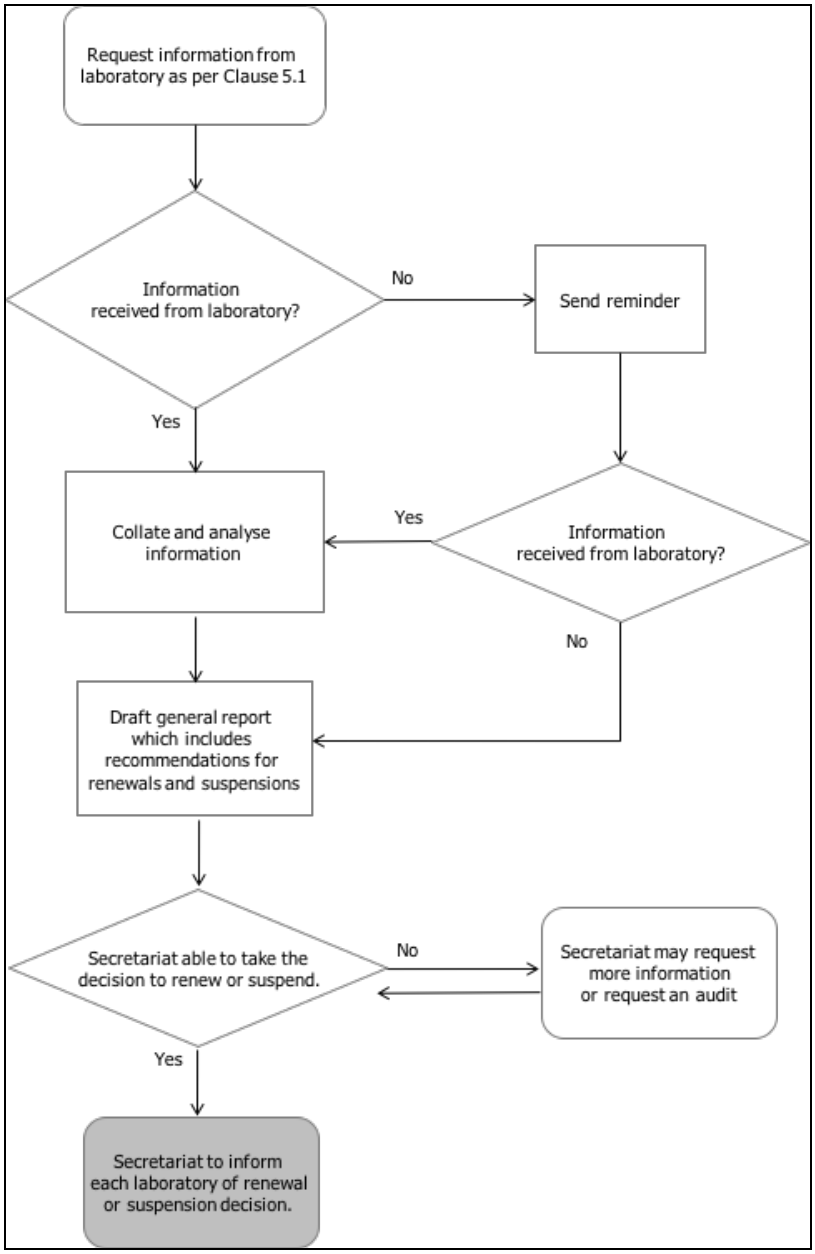
Ideally the above information should be requested from the laboratory towards the end of each February, with the deadline for replies set at mid-March so that the information is available to PQS for analysis in early April.

The above information must be transcribed to a spreadsheet by the accredited lab in accordance with the formats in Annexes B & C.

5.2 Laboratory re-accreditation summary overview

Figure 1 provides an overview of the laboratory re-accreditation procedure.

Figure 1: Laboratory annual re-accreditation procedure



5.3 Assessment

(Secretariat or its representative)

The Secretariat will collate all of the information collected in Clause 5.1 for each laboratory onto one spreadsheet, in order to conduct a general assessment.

This assessment should also check whether certificates are in order, whether there is suitable staff in place, whether there are any changes to the category of products being tested (this can be permitted on request), and any other changes.

5.4 Reporting

(Secretariat or its representative)

The information collected in Clause 5.1 and analysed in Clause 5.3 should be summarized in one report that recommends which laboratories should retain PQS-accredited status and which should be disqualified. Any matters arising from the assessment should be highlighted; including unsatisfactory and/or adverse reports from manufacturers, suppliers or users of equipment in the field that might imply a testing issue with a need for further action by a laboratory or the Secretariat.

This report should highlight:

- Loss of ISO/IEC 17025 accreditation;
- Loss of other certification;
- Bankruptcy, receivership, corruption or other financial irregularity;
- Change to product categories;
- Evidence of collusion between testing laboratory and product manufacturer(s);
- Loss of key testing facilities;
- Loss of key personnel;
- Unsatisfactory service (reported by users);
- Unsatisfactory test reports; or
- Any need for further action by a laboratory or the secretariat.

5.5 Laboratory audit

(Secretariat or its representative):

If the report suggests an audit is required, the Secretariat will arrange for a suitably qualified member of staff or a consultant to carry out an audit and submit a report setting out their observations and conclusions.

All laboratories should have an audit every three to five years, depending on the turnover of PQS verification and/or testing.

5.6 Accreditation

(Secretariat)

The Secretariat will review the annual report and any audits to decide which laboratories should retain or lose PQS accreditation. The Secretariat will email each laboratory to inform them of the decision. In general, laboratories will be encouraged to retain their accreditation status by taking appropriate action to improve their practices or facilities within an agreed time frame. If no improvements are made in the agreed time frame the laboratory accreditation may be terminated.

5.7 Publication

(Secretariat)

If the laboratory retains its PQS accreditation status, the current (or a revised) web page must be published each year. It must be dated to demonstrate that it is up to date.

If the laboratory loses its PQS accreditation status, the current web page will be withdrawn and information published below the list of accredited laboratories to make it clear that this particular laboratory is no longer PQS accredited, including a disqualification date. After this date, any testing carried out at this laboratory will not be valid.

It is anticipated that the web site that lists PQS accredited laboratories will be up to date by 1st June of each year, pending any audits and/or time for corrective actions by a laboratory.

6. Distribution

(Secretariat)

This SOP is to be distributed to the following individuals and groups:

- PQS Secretariat;
- All members of the PQS Working Group;
- Any WHO employee or consultant who is appointed to inspect a testing laboratory.

Annex 1: Email to request up-to-date information from a PQS accredited laboratory

To be sent via email in February. Check for replies in March with some follow-up if necessary. Formal review in April.

Dear <Contact name from web page>,

WHO PQS is conducting its annual review of accredited laboratories. In order to ensure the retention of your current accreditation, it is very important that you provide us with the following information, within two weeks of receipt of this letter.

The WHO PQS is conducting its annual review of accredited laboratories. To retain your accreditation, it is very important that you respond to the following requests.

In the first instance, please *immediately acknowledge* receipt of this questionnaire by email. Then return the information as requested below in English within two weeks please. Failure to comply with these requests may affect your WHO PQS accreditation.

- Please forward a copy of your IEC 17025 certification. If the original copy is not in English, also include a notarised copy in English. State whether the certifying authority is ILAC registered. Please state the **web site** where this certification can be verified. If the expiry date is within 6 months, laboratory to state date for their next IEC 17025 audit.

- Copies of all other certification (e.g. ISO 9001) in English.

- An up-to-date copy of your quality manual, listing all the changes that have occurred in the last year.

- A list of complaints and corresponding following actions in the past year (CAPA).

- Up-to-date copies of SOPs[4] or TWIs[5] or similar documents in regard to the PQS verification / testing highlighting the changes. These may relate to setting up of environmental chambers and logging equipment etc.

[4] SOP: Standard Operating Procedure
[5] TWI: Test Work Instruction

- Up-to-date copies of the CVs of key personnel, stating their role and responsibilities in regard to PQS testing / verification or other responsibilities within the organization. This includes the Quality Manager and senior staff who have line manager responsibilities for test engineers and sign test reports.

- A list of PQS published testing carried out with dates and the name of the product manufacturer / supplier carried out in the past year. (See Annex C.)

- An up-to-date "Test laboratory data sheet" .pdf for publication on the PQS web page confirming the PQS categories for test / verification and contact details etc.

- List the PQS categories / sub-categories you are currently testing and/or wishing to amend.

- Any feedback you would to forward to PQS. e.g. suggestions for improvements or complaints.

Please see Annex 2 for a checklist to help forward all information.

Yours sincerely,

<Name>

For and on behalf of WHO PQS.

Annex 2: Laboratory re-accreditation checklist

Please verify that the following items and information are included with your email response. Please complete this checklist and include it in your reply.

All information will be treated in confidence.

Item	**Check**
Laboratory name	
Laboratory address	
Laboratory email address for general inquiries	
Laboratory phone number for general inquiries	
Best two contact persons for PQS work	
Contact person # 1 email address	
Contact person # 1 phone number	
Contact person # 2 email address or general “info address”	
Contact person # 2 phone number or general contact number	
Laboratory web page pdf with up-to-date details	
Copy of IEC 17025 Certificate	
Notarised copy of IEC 17025 Certificate in English, if necessary	
Copies of all other certificates (in English)	
CVs of key personnel	
Up-to-date copy of your laboratory’s Quality Manual	
Current E00 categories, with proposed amendments if applicable	
Up-to-date copies of SOPs, TWI or similar	
A list of PQS testing carried out with dates and manufacturer / suppliers (See next page)	

Annex 3: Testing log - all PQS testing and/or evaluation carried out since 1st March of last year

Enter one line for each product tested.

Date of Report	E00 Category	Type-testing or Type-exam or QA?	Verification Protocol Reference ID	Name of manufacturer and/or reseller

Annex 4: Terms and definitions

Device	A medical device such as a syringe or temperature monitor for example.
IEC	International Electro-technical Commission.
ILAC	International Laboratory Accreditation Cooperation.
ISO	International Standards Organization.
Legal manufacturer	The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party[6]. A legal manufacturer may commonly contract another company to manufacture products or devices sold under the legal manufacturer's name. A manufacturer that is contracted in this way is typically known as an Original Equipment Manufacturer, or OEM.
Manufacturer	In the context of this SOP the word manufacturer includes both legal manufacturers and resellers.
Product	In this document, where the word 'product' is used on its own, it includes device.
QA	Quality Assurance.
Reseller	A commercial entity, licensed to act on behalf of a legal manufacturer and which carries product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.
SOP	Standard Operating Procedure.
TWI	Test Work Instruction.
Verification protocol	Describes in detail how the performance of a product or device will be tested or otherwise evaluated as part of the PQS product prequalification procedure. See SOP No. MHP/RPQ/PQT/VAX/PQS/004: *How to develop and publish a PQS product verification protocol.*

[6] Definition derived from Article 1 2.(f) of the EU Medical Device Directives.

Revision history

(form number MHP/RPQ/PQT/VAX/PQS/GEN/F002)

SOP Number:	MHP/RPQ/PQT/VAX/PQS/010	
Date of issue 1st edition:	08/07/2004	
Date of issue 2nd edition:	06/04/2018	
Revisions		
Date	**Change and reason**	**Authorised by (Signature and Name)**
06/01/2007	• ATT team was changed to QSS team due to the reorganization in the IVB Department. • The code VML was changed to PQS in the SOP No.s for easy reference. • The person responsible for giving no-objection clearance for the specifications was identified as the QSS Coordinator.	Drafted by O. Afsar Approved by U. Kartoğlu
27/01/2017	• Footnotes defining the PQS Working Group and the PQS Secretariat added in Clause 3. • PQS system structure simplified, removing FMWG, Steering Group. IVB/QSS is also renamed EMP/PQT. Revisions to this SOP reflect these changes (text and figures). • 'Responsibilities' clause revised to separate out specific responsibilities of key actors and to remove process elements. • Clause 6 'Distribution' edited to reflect new PQS system. • 'Terms & definitions' moved to annex, revised, definitions updated in line with WG reviews of PQS glossary Feb 2018. • Clause 5.2 'Laboratory re-accreditation summary overview' added plus corresponding diagram. • Substantial rewriting/restructuring of Clause 5 `Procedure`, in particular reporting. • Removal of 'Standard Letter' annexes, of 'Website entry' annexes and of 'Model	Drafted by P. Mallins Approved by I. Gobina

	Checklist for a lab reassessment visit'. • Addition of Annexes: 'Email to request up to date information', 'Lab accreditation checklist', and 'Testing Log' template.	
01/04/2020	• MVP/EMP/PQT is renamed MHP/RPQ/PQT/VAX throughout to reflect structural changes: (Vaccines & Immunization Devices Assessment Team (VAX), Prequalification Unit (PQT), Regulation and Prequalification Department (RPQ), Access to Medicines and Health Products Division (MHP)	Drafted by P. Mallins Approved by I. Gobina