PERFORMANCE, QUALITY & SAFETY (PQS) STANDARD OPERATING PROCEDURE		
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HOW TO ASSESS A LABORATORY FOR PQS ACCREDITATION.		
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Prequalification Team (PQT)		

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1. Purpose

This SOP describes how to assess a laboratory for PQS accreditation. Before a product or device can be added to the PQS database, it must be verified whether it meets all the requirements of the published specification for that product, which often includes testing in accordance with the PQS verification protocol appropriate to the product. Depending on the type of product, there can be three separate processes:

1. Type-examination;
2. Independent type-testing according to the appropriate verification protocol; or
3. Full Quality Assurance.

Independent type-testing of a manufacturer's product for PQS approval must be carried out by a PQS accredited laboratory. In addition, accredited testing laboratories may sometimes be contracted to carry out *type examination* or *full quality assurance* of PQS products.

A PQS accredited laboratory is commissioned by the product manufacturer or supplier to carry out tests that will form part of their dossier (see Clause 7 of any product specification) submitted to WHO PQS for approval.

The PQS accredited laboratory should demonstrate its competency by conforming to internationally accepted standards or codes of practice as witnessed by a competent third-party accreditation body. These include quality standards such as ISO 9001 *Quality management systems — Requirements* and IEC 17025 *General requirements for the competence of testing and calibration laboratories*

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 when a laboratory applies or re-applies for PQS accreditation. Laboratories that demonstrate relevant facilities and competencies through the assessment process may then be accredited by PQS to test specific categories of products.

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 reviewing the application; and
- Members or Technical Specialists (TS) will be requested by the Secretariat to prepare a report of the review.

The PQS Secretariat (Secretariat)[2]:

- Decides whether a test laboratory should be accredited or rejects the application;
- Notifies the test laboratory whether they are accredited or rejected; 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 incl. COR 1: 2005 General requirements for the competence of testing and calibration laboratories
- List of ILAC Mutual Recognition Arrangement Signatories
- SOP No MHP/RPQ/PQT/VAX/PQS/008 Version 1.6

[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 support the development, introduction and advancement of technologies that will meet countries' EPI needs for high-quality cold chain equipment and devices.

[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. The Secretariat holds ultimate responsibility for the PQS process and takes all final PQS decisions, including the decision to award prequalified status to a product or device.

5. Procedure

It is anticipated the following exchanges will be carried out via email.

5.1 Initial inquiries

A prospective laboratory applies to WHO for assessment. In some cases, the PQS Secretariat may invite a laboratory to apply.

In their initial enquiry, a laboratory should:

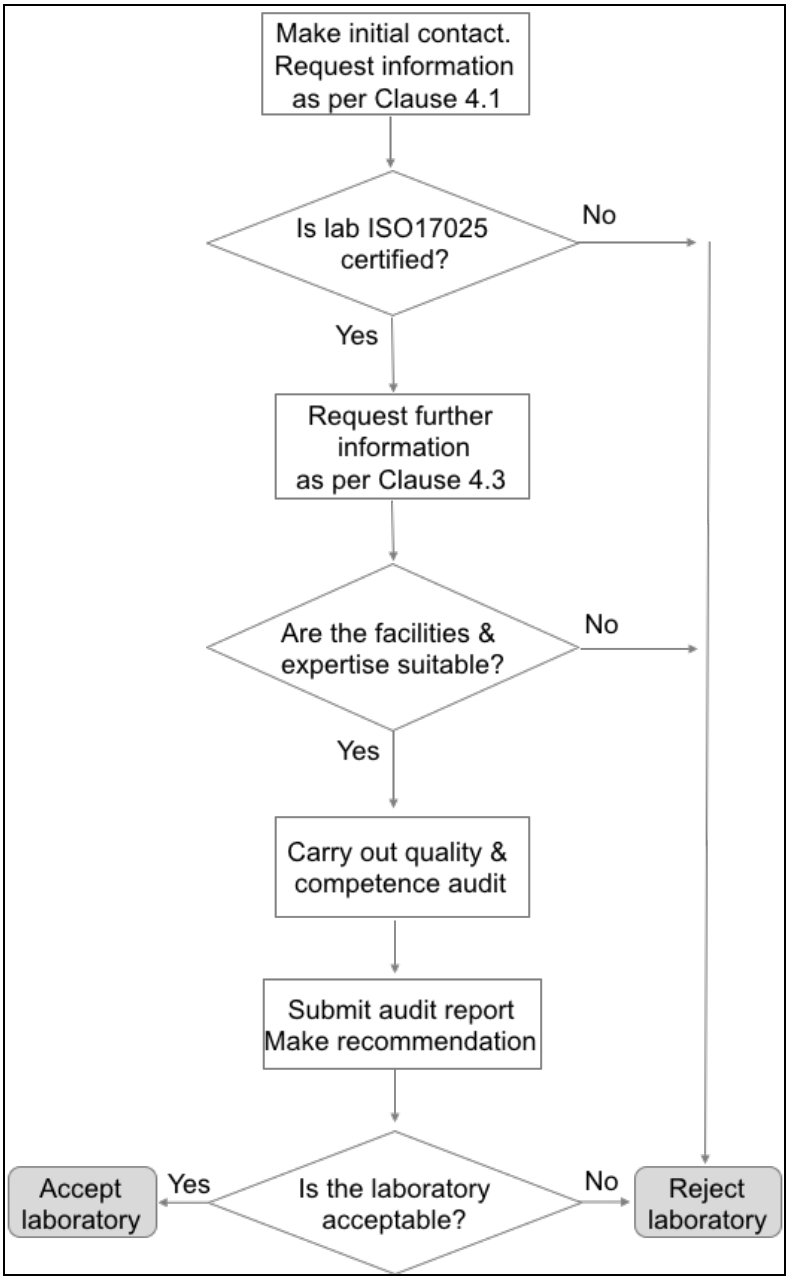
- Outline the categories they wish to be accredited for (E001 – E0013) as listed on: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorylist.aspx?cat_type=device
- State their current laboratory accreditation and general area of expertise[3].
- Have written quality procedures (a quality manual) based on ISO 9001.

5.2 Summary outline

Figure 1 provides a schematic for the laboratory accreditation procedure.

[3] Except under special circumstances, for a laboratory to be accepted to carry out type-examination, independent type-testing or full quality assurance, it should be already accredited in accordance with ISO/IEC 17025:2005/COR1:2006 General *requirements for the competence of testing and calibration laboratories.*

Figure 1: Laboratory accreditation procedure



5.3 Detailed information

Following the above initial enquiry, the PQS Secretariat or its representative can ask the laboratory to forward a detailed dossier to include the following information:

- The precise E00 categories and subcategories the laboratory wishes to test. (Note: It is acceptable for laboratory to exclude some of the sub-categories within an E00 group. This should be listed by references to protocols.)

- Whether the laboratory wishes to carry out:
  - Type-examination,
  - Type testing, and/or
  - Quality assessment

  (Not all of the above are applicable to each subcategory.)

- A copy of the laboratory's IEC 17025 and quality certification, including whether the certifying authority is ILAC registered.

- A copy of laboratory quality manual.

- A list of the laboratory's main test facilities. e.g. environmental chambers, drop test equipment etc.

- The CVs of key staff who will oversee or lead specified areas of testing.

- The names and contact details of at least three well-established organizations (referees) that have used the laboratory’s expert services during the past three years.

- Examples of recent testing in the past three years that is similar to the tests for which they wish to be accredited. (Clients need not be named if this is confidential.)

- A copy of one test report similar to the tests for which they wish to be accredited. (Client's name and details can be redacted.)

5.4 Information dossier evaluation

Completed information dossiers to be evaluated either by the PQS Secretariat or their representative. See Annex 3. Initial checks will be as follows:

5.4.1 ISO/IEC 17025 accreditation

Verification of valid ISO/IEC 17025 accreditation, ideally with an ILAC registered authority.

5.4.2 Quality System

Verification that the laboratory has a quality system that could stand up to ISO 9001 scrutiny?

5.4.3 Facilities

Verification that the laboratory has adequate facilities to perform the tests shown in the product verification protocol(s) of the proposed E00 categories? (It is possible that the laboratory may have to make an investment once accreditation is granted.)

5.4.4 CVs

Verification that the laboratory has suitably qualified personnel to perform the tests shown in the product verification protocol(s) of the proposed E00 categories?

5.5 Laboratory requirements

The following requirements for an acceptable laboratory are those identified as being the optimum. However, failure to fully comply will not preclude consideration. The Secretariat will contact the laboratory about the requirement for an audit (see Clause 4.6).

The laboratory will:

- Have a quality management system that is clearly defined and which is organized in such a way that the integrity of its staff and operation can be judged. (IEC 17025 Clause 4 – Management requirements);

- Employ suitably qualified laboratory staff, experienced and technically competent for the work to be undertaken. (IEC 17025 Clause 5.2 – Personnel);

- Use laboratory equipment required for testing against the appropriate PQS verification protocol and which is properly installed, maintained and calibrated. Adequate records of calibration and servicing must be maintained. and documentation provided in the dossier (IEC 17025 Clause 5.4 – Test and calibration methods and method validation);

- Have a testing environment and laboratory suitable for the tests undertaken. (IEC 17025 Clause 5.3 – Accommodation and environmental conditions);

- Employ laboratory practices that are demonstrable and meet WHO requirements, such as:
  - Sample identification (IEC 17025 Clause 5.7 – Sampling)
  - Test methods and procedures (IEC 17025 Clause 5.4)
  - Checking of results and calculations (IEC 17025 Clause 4.12.2 1 to 3);

- Operate a secure laboratory record system containing full details of all tests undertaken. (IEC 17025 Clause 4.3 – Document control); and

- Supply test reports and documents which are accurate, clear and unambiguous and contain all the relevant information. (IEC 17025 Clause 5.10 – Reporting the results).

5.6 Laboratory audit

Laboratories that are accredited by ILAC signatories should receive a surveillance visit by that signatory every 12 to 18 months and a full audit every four to five years. Other accreditation bodies may have different arrangements.

In the case of ILAC signatory-laboratories, if there is test urgency and if all certification, documentations and quality manuals are up to date and if comprehensive knowledge of the relevant type of testing can be readily demonstrated, then accreditation may be granted rapidly (i.e. without a full audit). In all other cases an audit will take place.

The audit should take one to two days and can cover all aspects of the laboratory's operation. Key personnel will be interviewed during the audit which will examine the E00 category testing and quality procedures

The Secretariat will arrange for a suitably qualified member of staff or a consultant to visit the laboratory to carry out an audit. Before the audit is carried out, the auditor needs to make direct contact with key persons at the laboratory to make it clear that both quality and testing aspects of the laboratory will be audited. Key personnel must be on site at the time of audit and a test mock-up of applicable testing must be observed.

The auditor will prepare a report for the secretariat setting out their observations including any non-compliances, recommendations and conclusions.

5.7 Audit evaluation

The secretariat or its representative will prepare a report which recommends whether to adopt the laboratory for PQS accreditation or not.

Towards the end of the audit, the auditor will normally provide their draft evaluation to the laboratory (e.g. in the form of a short, written summary). This is good ISO 9001 practice and can help to avoid misunderstandings. The report itself is the property of the Secretariat because the auditor is commissioned by PQS. The report may be later forwarded to the laboratory.

The audit may not be an immediate pass or fail. Audits often reveal non-compliances that can be addressed within a set time frame. Once there is evidence that non-compliances have been correctly addressed, the laboratory may become accredited.

The Secretariat may discuss accreditation with the auditor and/or PQS members, but the final decision is taken by Secretariat.

5.8 Accreditation

The laboratory will be notified of the Secretariat's final decision. If accepted, a copy of this notification will also be sent to UNICEF-SD.

Relevant details of every accepted laboratory will be published electronically in .pdf format on the PQS website, in the format shown in Annex 4. In addition, notification of publication will be posted on the TechNet-21 forum.

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: WHO PQS accredited laboratory terms and conditions

1.	The Secretariat will evaluate the application and contact the laboratory acknowledging the application and that the Secretariat wishes to make an audit of the laboratory.
2.	A PQS-accredited laboratory is one that the Secretariat considers to be competent to carry out specified work which can then form part of a manufacturer's dossier when submitting a product for inclusion in the PQS Catalogue. It should be clear to the laboratory that such work is not commissioned by the PQS Secretariat.
3.	*Payment for testing services:* The Secretariat does not itself undertake to pay for testing services. In most instances testing fees will be paid by the manufacturer of the product under test.
4.	*Re-evaluation:* The laboratory will be subjected to a PQS review every year. The laboratory will be required to submit evidence of periodic surveillance or reassessment of any relevant accreditations or certifications, including ISO/IEC 17025 and quality certification, together with details of any changes in facilities or key personnel[4]. The laboratory will be required to submit a list of test reports for products submitted for PQS approval during the year.
5.	*Periodic audits:* Laboratories may be subject to periodical audit visits by the PQS to determine whether a laboratory is continuing to comply with requirement for PQS accreditation. Such visits will be undertaken and completed within one to two days depending on the size of the facility and the amount of PQS work undertaken since the previous PQS audit. It is anticipated that this will occur every three to five years.
6.	If PQS accreditation is withdrawn, the PQS Secretariat will communicate the reason for the withdrawal to the laboratory. After this, it will be necessary to make a new application for PQS accreditation.
7.	*Confidentiality undertaking:* PQS, their staff, and those representing PQS will treat all information provided by the laboratory during the evaluation as confidential. In addition, those evaluating information dossiers will be required to sign a Declaration of Interest (DOI). A sample of the confidentiality and DOI undertaking for evaluators of information dossiers can be obtained on request.

[4] See ILAC-G10:1996 Harmonized Procedures for Surveillance and Reassessment of Accredited Laboratories. www.ilac.org

Annex 2: Standard email request for reference

Dear <name of referee>,

The PQS Secretariat is evaluating <name of laboratory> for its suitability to carry out independent testing of the following types of products for PQS approval.

The laboratory has given the name of your organization as a reference. Please complete the attached questionnaire and return it to us within two weeks. Your reply will be treated as confidential and will be used solely for our own internal evaluation of the named laboratory.

Please use the "other comments" section to highlight any issues that are not covered elsewhere by the questionnaire. We recognise some responses can be subjective. If you would like to forward additional material to support your observations and conclusions, we would be grateful to receive it.

Yours sincerely,

<name>

For and on behalf of the WHO PQS Secretariat

Reference questionnaire for: <name of laboratory>

Questionnaire completed by…….....

Position in company / organization…….....

Date.....…….....

1. How many times have you used the laboratory over the past three years?
……times.

2. Will you continue to use the laboratory? Whether your answer is Yes or No, please state why:

…..
.....

.....……
….....

3. What types of product have been tested for you and for what purpose?

Type of product	Purpose of test
……	……
……	……

Other comments:

……

Annex 3: Evaluation checklist

Evaluation checklist for: <name of laboratory>

Checklist completed by: <name>

Date: <dd.mm.yy>

#	Question	Response
1	Is laboratory ISO/IEC 17025 accredited?	<Yes/No>
2	Date of next ISO 17025 re-assessment	<dd.mm.yyyy>
3	Name of accreditation body	<name>
4	Is accreditation body an ILAC signatory?	<Yes/No>
5	If the answer to Q4 is 'no', is the accreditation body acceptable?	<Yes/No>
6	References: Have five references been received. Have these been followed-up?	<Yes/No>
7	Target date for laboratory audit?	<Yes/No>
8	Target date for an audit report to be submitted to the secretariat?	<Yes/No>
9	General comments	<summarize results of audit>
10	Is acceptance of this laboratory recommended?	<Yes/No>
11	For which E00 categories have services been accepted?	<Yes/No>

Annex 4: Example format for a PQS-accredited test laboratory data sheet

PERFORMANCE QUALITY SAFETY

Test laboratory data sheet

Name:

Country:

Address:

Telephone:

Fax:

Email:

Web address:

Contact:

PQS cat.	Equipment type	Type-examination	Type-testing	QA inspection	The following equipment types are excluded
E001	Cold rooms, freezer rooms	No	n/a	No	
	Standby generators	No	n/a	n/a	
	Large voltage regulators	No	n/a	n/a	
E003	Refrigerators and freezers	**Yes**	**Yes**	n/a	
	Solar power systems	**Yes**	**Yes**	**Yes**	
E004	Insulated containers	**Yes**	**Yes**	n/a	
E005	Water packs	**Yes**	**Yes**	n/a	
E006	Temperature monitoring Electronic	**Yes**	**Yes**	n/a	IN05 - VVMs
	Temperature monitoring Chemical	No	No	n/a	
E007	Cold chain accessories	No	No	n/a	
	Small voltage regulators	No	No	n/a	
E008	Single-use injection devices	No	No	n/a	
	Jet injectors	No	No	n/a	
E010	Safety boxes	**Yes**	**Yes**	n/a	
	Needle cutters	**Yes**	**Yes**	n/a	
E011	Specimen collection equipment	**Yes**	**Yes**	n/a	
E013	Therapeutic injection devices	No	No	n/a	
	Nasal atomizer	No	No	n/a	

Shipping contact name:	Shipping telephone:
Shipping address:	Shipping fax:
Email address:	Mobile phone:
ISO/IEC 17025 accreditation body: UKAS	**Next reassessment date:** 4/1/2010 12:00:00 AM
WHO accreditation date:	

Check shipping arrangements with the laboratory to avoid problems with customs and to ensure safe delivery of test samples.

Annex 5: 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[5]. 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.
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.*

[5] 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. • Reworking/restructuring of Clause 5. • Deletion of annexes containing 'standard letters' with the exception of the	Drafted by P. Mallins Approved by I. Gobina

	'standard email to request a reference'. • Addition of annex 'WHO PQS accredited laboratory terms and conditions'. • Addition of annex 'Example format for a PQS accredited Test laboratory data sheet'.	
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