 World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT	
	VACCINES ASSESSMENT TEAM	
STANDARD OPERATION PROCEDURE		
ASSESSING A LABORATORY FOR IMD-PQS ACCREDITATION		
Doc No: IMD/SOP/07	Version No: 2	Revise before: 15 Jun 2027
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1. OBJECTIVE

To describe the processes to assess a laboratory for IMD-PQS accreditation.

2. SCOPE AND BACKGROUND

- 2.1. This [SOP](#) is applicable when a laboratory applies or re-applies for IMD-PQS accreditation.
- 2.2. Laboratories that demonstrate relevant facilities and competencies through the assessment process may then be accredited by IMD-PQS to test specific categories of products.
Before a [product](#) or [device](#) can be added to the IMD-PQS database, it is verified whether it meets all the requirements of the published [specification](#) for that product, which often includes testing in accordance with the IMD-PQS [verification protocol](#) appropriate to the [product](#).
- 2.3. Depending on the type of [product](#), there can be three separate processes:
 - 2.3. Type-examination;
 - 2.3. Independent type-testing according to the appropriate verification protocol; or
 - 2.3. Full Quality Assurance.
- 2.4. *Independent type-testing* of a [manufacturer's](#) product for IMD-PQS approval is carried out by an IMD-PQS accredited laboratory. In addition, accredited testing laboratories may sometimes be contracted to carry out *type examination* or *full quality assurance* of IMD-PQS products.
- 2.5. An IMD-PQS accredited laboratory is commissioned by the [product manufacturer](#) or supplier to carry out tests that will form part of their dossier (see Clause 4 “Verification” of any product specification) submitted to WHO IMD-PQS for approval.
- 2.6. The IMD-PQS accredited laboratory demonstrates its competency by conforming to internationally accepted standards or codes of practice as witnessed by a competent third-party accreditation body.
- 2.7. 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](#)
- 2.8. The [IMD-PQS Secretariat](#) (Secretariat), the [IMD-PQS Working Group](#) (WG) and by all *Technical Specialists* (TS) commissioned by the [Secretariat](#) follow these procedures for assessing a laboratory for accreditation.



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3. CROSS-REFERENCES

Relevant KPI(s):	Nil
Background:	<ul style="list-style-type: none"> • https://extranet.who.int/pqweb/immunization-devices/accreditation-process • 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
Under this SOP:	<ul style="list-style-type: none"> • IMD/Annex/07a: WHO IMD-PQS accredited laboratory terms and conditions • IMD/TP/07a: Standard email request for reference • IMD/TP/07b: Evaluation checklist • IMD/TP/07c: Example format for an IMD-PQS-accredited test laboratory data sheet
Other QMS documents:	<ul style="list-style-type: none"> • IMD/SOP/08: Re-evaluating a IMD-PQS testing laboratory

4. DEFINITIONS

Device	A medical device such as a syringe or temperature monitor for example.
IEC	International Electro-technical Commission.
ILAC	International Laboratory Accreditation Cooperation.
IMD-PQS Secretariat	The WHO IMD-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



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	product feedback reports and learnings from product field monitoring. The Secretariat holds ultimate responsibility for the IMD-PQS process and takes all final IMD-PQS decisions, including the decision to award prequalified status to a product or device.
IMD-PQS Working Group (WG)	IMD-PQS Working Group (WG) is comprised of the WHO (IMD-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.
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 their own name, regardless of whether these operations are carried out by that person themselves or on their behalf by a third party (Definition derived from Article 1 2.(f) of the EU Medical Device Directives). 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.



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Verification protocol	An IMD-PQS product verification protocol describes in detail how the performance of an immunization-related products or device will be tested or otherwise evaluated as part of the IMD-PQS product prequalification procedure. See IMD/SOP/04: Developing and publishing an IMD-PQS product verification protocol.
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5. RESPONSIBILITIES

IMD-PQS Working Group (WG)	<ul style="list-style-type: none"> • 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.
IMD-PQS Secretariat	<ul style="list-style-type: none"> • 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.

6. HIGH LEVEL FLOW CHART SUMMARY

Figure 1: Laboratory accreditation procedure



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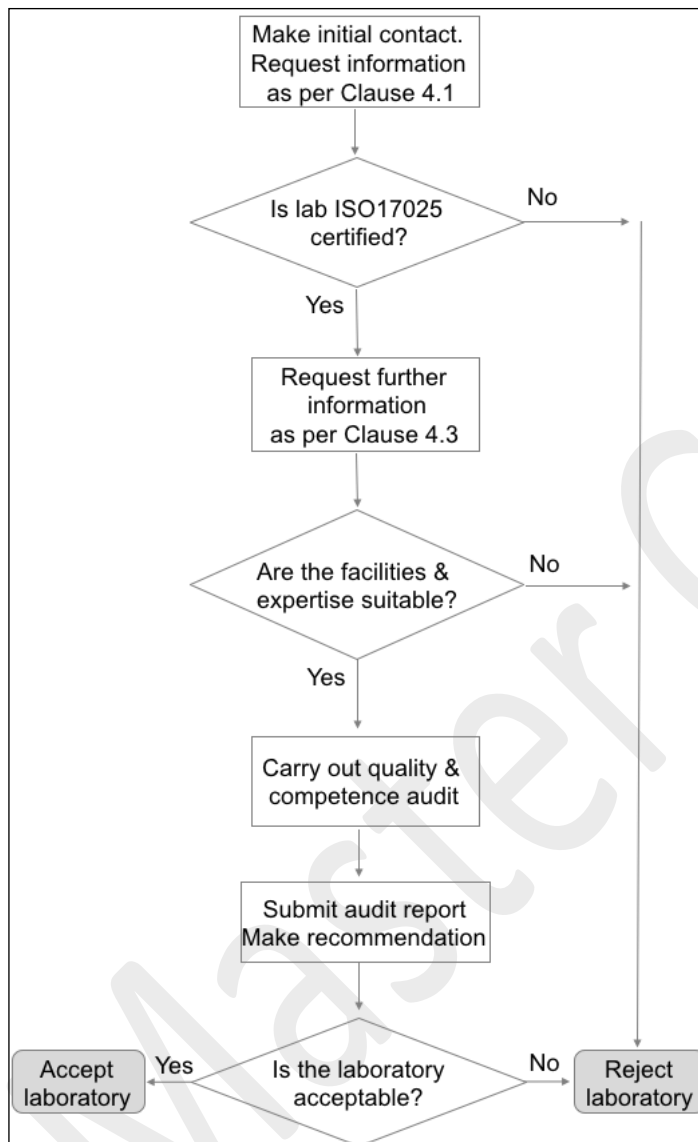
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7. PROCESS STEPS

It is anticipated the following exchanges are carried out via email.

7.1. Initial inquiries

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7.1. A prospective laboratory applies to WHO for assessment. In some cases, the [IMD-PQS Secretariat](#) may invite a laboratory to apply.

7.1. In their initial enquiry, a laboratory must:

7.1.2.1. Outline the categories they wish to be accredited for (E001 – E0013) as listed on: <https://extranet.who.int/pregual/immunization-devices/product-categories>

7.1.2.2. State their current laboratory accreditation and general area of expertise. (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.*)

7.1.2.3. Have written quality procedures (a quality manual) based on ISO 9001.

7.2. Summary outline

7.2. Figure 1 in 6 above provides a schematic for the laboratory accreditation procedure.

7.3. Detailed information

7.3. Following the initial enquiry, the [IMD-PQS Secretariat](#) or its representative asks the laboratory to submit a detailed dossier which includes the following information:

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

7.3.1.2. 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.)

7.3.1.3. A copy of the laboratory's IEC 17025 and quality certification, including whether the certifying authority is [ILAC](#) registered.

7.3.1.4. A copy of laboratory quality manual.

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

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

7.3.1.7. 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. These may be used to validate the labs performance if required.

7.3.1.8. 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.)

7.3.1.9. 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.)

7.4. Information dossier evaluation

7.4. Completed information dossiers to be evaluated either by the [IMD-PQS Secretariat](#) or their representative. See IMD/TP/07b Initial checks are as follows:

7.4.1.1. ISO/IEC 17025 accreditation

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

7.4.1.2. Quality System

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

7.4.1.3. 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.)

7.4.1.4. 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.

7.5. Laboratory requirements

7.5. The following requirements for an acceptable laboratory are those identified as being the optimum. However, failure to fully comply does not preclude consideration.

7.5. The [Secretariat](#) contacts the laboratory about the requirement for an audit (see IEC 17025 Clause 4.6).


7.5. The laboratory is required to:

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- 7.5.3.1. 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);
- 7.5.3.2. Employ suitably qualified laboratory staff, experienced and technically competent for the work to be undertaken. (IEC 17025 Clause 5.2 – Personnel);
- 7.5.3.3. Use laboratory equipment required for testing against the appropriate IMD-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);
- 7.5.3.4. Have a testing environment and laboratory suitable for the tests undertaken. (IEC 17025 Clause 5.3 – Accommodation and environmental conditions);
- 7.5.3.5. 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);
- 7.5.3.6. Operate a secure laboratory record system containing full details of all tests undertaken. (IEC 17025 Clause 4.3 – Document control); and
- 7.5.3.7. 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).

7.6. Laboratory audit

- 7.6. Laboratories that are accredited by [ILAC](#) signatories are required to 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.
- 7.6. 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 takes place.

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- 7.6. The audit takes one to two days and can cover all aspects of the laboratory's operation. Key personnel are interviewed during the audit which examines the E00 category testing and quality procedures.
- 7.6. The [Secretariat](#) arranges 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 are required on site at the time of audit and a test mock-up of applicable testing is observed.
- 7.6. The auditor prepares a report for the [Secretariat](#) setting out their observations including any non-compliances, recommendations and conclusions.

7.7. Audit evaluation

- 7.7. The [Secretariat](#) or its representative prepares a report which recommends whether to adopt the laboratory for IMD-PQS accreditation or not.
- 7.7. Towards the end of the audit, the auditor normally provides 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 IMD-PQS. The report may be later forwarded to the laboratory.
- 7.7. The audit may not be an immediate pass or fail. Audits often reveal non-compliances that can be addressed within a set time frame. In the case that a Corrective and Preventive Action plan (CAPA) is required, refer to INS/SOP/09 *Reviewing CAPAs and Closing out of Inspections*. Once there is evidence that non-compliances have been correctly addressed, the laboratory may become accredited.
- 7.7. The [Secretariat](#) may discuss accreditation with the auditor and/or IMD-PQS members, but the final decision is taken by [Secretariat](#).

7.8. Accreditation

- 7.8. The laboratory is notified of the [Secretariat's](#) final decision. If accepted, a copy of this notification is also sent to UNICEF-SD.
- 7.8. The [Secretariat](#) publishes relevant details of every accepted laboratory electronically in .pdf format on the IMD-PQS website, in the format shown in IMD/TP/07c. In addition, a notification of publication is posted on the TechNet-21 forum.

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7.9. DISTRIBUTION (Secretariat)

This SOP is distributed to the following individuals and groups:

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

8. RECORDS

8.1. The [Secretariat](#) saves laboratory applications for accreditation in WHO ePQS-Box / Sharepoint: Folder “Labs”.

1. REVISION HISTORY

Version	Reason for revision	Author	Drafted
01	<ul style="list-style-type: none"> • 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	06/01/2007
01	<ul style="list-style-type: none"> • Footnotes defining the IMD-PQS Working Group and the IMD-PQS Secretariat added in Clause 5. • IMD-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 7.9 ‘Distribution’ edited to reflect new IMD-PQS system. • ‘Terms & definitions’ moved to annex, revised, definitions updated in line with WG reviews of IMD-PQS glossary Feb 2018. 	Drafted by P. Mallins Approved by I. Gobina	27/01/2017



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	<ul style="list-style-type: none"> • Reworking/restructuring of Clause 7. • Deletion of annexes containing 'standard letters' with the exception of the 'standard email to request a reference'. • Addition of annex 'WHO IMD-PQS accredited laboratory terms and conditions'. • Addition of annex 'Example format for a IMD-PQS accredited Test laboratory data sheet'. 		
02	<ol style="list-style-type: none"> 1. Updating to new RPQ format 2. New department, unit and team names 3. Changed supervisors name from Group Lead to Team Lead 4. Assignment of IMD as code for the product stream on PQ of immunization devices and equipment and used for numbering of QMS documents 5. Inclusion of KPIs and their targets where applicable 6. Transforming some annexes into templates related to the SOP 7. PQS updated to IMD-PQS (Immunization Devices Performance, Quality and Safety) 	Approved by I. Gobina	01/2024