World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT
	VACCINES ASSESSMENT TEAM

STANDARD OPERATION PROCEDURE

Reviewing an unsolicited test report for an IMD-PQS prequalified product (for the WHO PQS Team)

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Approved by:	For TL-VAX, date: 27 Mar 2025	ADG-MHP, date: 28 Mar 2025

1. OBJECTIVE

1.1. This SOP describes the procedure to evaluate the rigor of external unsolicited testing of IMD-PQS prequalified products.

2. SCOPE

2.1. This SOP is applicable when WHO IMD-PQS assesses any external unsolicited testing of IMD-PQS prequalified products or devices which involves a laboratory, whether that laboratory is IMD-PQS accredited or not.

2.2. All IMD-PQS prequalified products have been put through rigorous verification in order to be granted IMD-PQS prequalified status by the WHO. 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. External bodies wishing to test IMD-PQS prequalified products must do so according to the relevant WHO IMD-PQS standards and procedures. They must ensure that:

2.2.1. the testing process is equally rigorous and equivalent to WHO IMD-PQS independent type-testing procedures according to the appropriate verification protocol, and

2.2.2. the laboratory that tests the product is demonstrated to be competent and accredited to the standards required by WHO IMD-PQS.

2.3. WHO IMD-PQS verifies, from the documentation submitted by the test commissioner, that the testing laboratory demonstrates these competencies.

2.4. WHO IMD-PQS verifies that the testing laborator(y)ies conform(s) 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.*

3. CROSS-REFERENCES

Relevant KPI(s):	Nil
Background:	• https://extranet.who.int/pqweb/immunization-devices/guides-and-resources • ILAC-G15 Guidance for Accreditation to ISO/IEC 17025 • ILAC-G17 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025. • ILAC-G18:04 Guideline for the Formulation of Scopes of Accreditation for Laboratories • ISO 9001 Quality management systems — Requirements • ISO/IEC GUIDE 98-3 Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995) • ISO/IEC 17025 incl. COR 1: 2005 General requirements for the competence of testing and calibration laboratories • List of ILAC Mutual Recognition Arrangement Signatories • WHO/BCT/03.09: Procedure for assessing the acceptability, in principle, of single-use injection devices for procurement by United Nations agencies.
Under this SOP:	• IMD-TP-015a Provisions for evaluators of product dossiers within the scope of the evaluation procedure for IMD-PQS products • IMD-TP-015b Evaluation checklist
Other QMS documents:	• IMD/SOP/01: Developing and publishing an IMD-PQS product performance specification. • IMD/SOP/02: Reviewing and revising an IMD-PQS product performance specification. • IMD/SOP/03: Withdrawing an IMD-PQS product performance specification. • IMD/SOP/04: Developing and publishing an IMD-PQS product verification protocol.

	• IMD/SOP/05: Reviewing and revising an IMD-PQS product verification protocol. • IMD/SOP/06: Withdrawing an IMD-PQS product performance specification. • IMD/SOP/08 Re-evaluating a WHO IMD-PQS accredited test laboratory. • IMD/SOP/10: Re-evaluating a prequalified IMD-PQS product. • IMD/SOP/11: Removing a prequalified product from the IMD-PQS database. • Relevant IMD-PQS Product Specification and Verification Protocol for the specific product tested.

4. DEFINITIONS

Correspondence	Includes mail, fax and email.
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 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.
The IMD-PQS Working Group (WG)	The IMD-PQS Working Group 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 themself 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.
Verification protocol	An IMD-PQS product verification protocol describes in detail how the performance of a class of immunization-related products will be tested or otherwise evaluated as part of the IMD-PQS product prequalification procedure See IMD/SOP/04: Development and publishing an IMD-PQS product verification protocol.

5. RESPONSIBILITIES

IMD-PQS-required field studies are the responsibility of manufacturers. The *IMD-PQS* Secretariat (Secretariat) and/or individual members of the *IMD-PQS Working Group* (WG) may, in specific circumstances, fund studies.

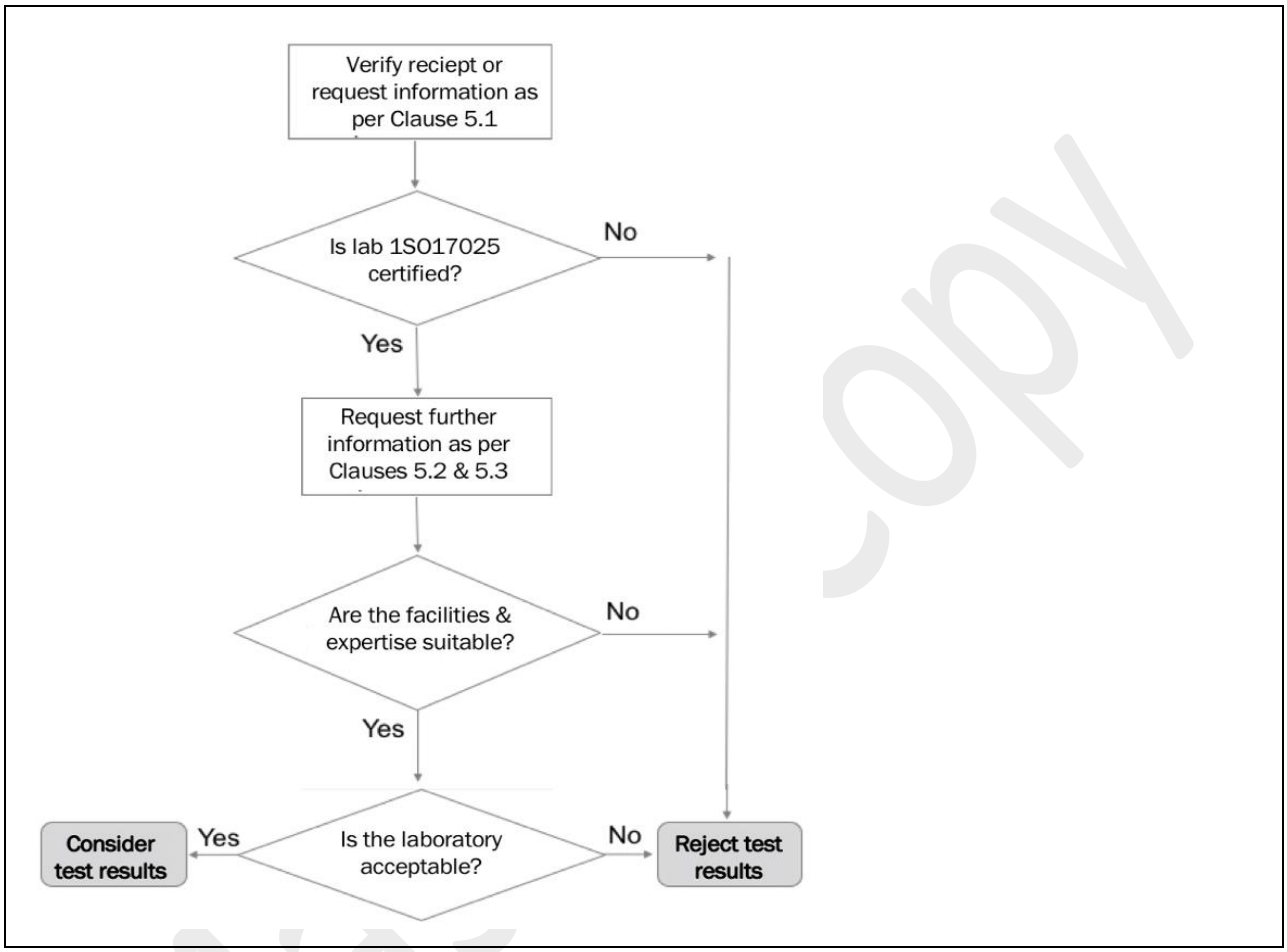
The IMD-PQS Working Group	• Members may be assigned the task of reviewing the external testing body's accreditations and technical capacities, and • Members or Technical Specialists (TS) may be requested by the Secretariat to prepare a report of the review.
IMD-PQS Secretariat	• Decides whether to consider the unsolicited test report. • If it proceeds to consideration of the test report, decides whether the unsolicited external testing results should be taken into consideration regarding consideration of the maintenance or withdrawal of prequalified status of a product or device; • Notifies the external testing body whether the test results will be taken into consideration by the WHO IMD-PQS or not; • Notifies the product manufacturer of the testing results and their implications of the prequalified status of the product where relevant, and

	• Makes amendments to the website to take account of the decisions.

6. HIGH LEVEL FLOW CHART SUMMARY

Each of the task headings below includes (in brackets) a description of the person or group responsible for the task. Figure 1 summarizes the evaluation process for unsolicited external testing of a WHO IMD-PQS prequalified product.

Figure 1 – Procedure for evaluation of unsolicited test reports



7. PROCESS STEPS

7.1. Detailed information

7.1.1. WHO IMD-PQS requests and reviews the following documentation from the external testing body:

7.1.1.1. The precise E00 categories and subcategories of the product that has been tested.

7.1.1.2. Whether the laboratory has carried out, as per the relevant published IMD-PQS protocols:

(a) Type-examination,

(b) Type testing, and/or

(c) Quality assessment.

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

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

7.1.1.4. A copy of laboratory quality manual.

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

7.1.1.6. The CVs of key staff who will oversaw or led specified areas of testing.

7.1.1.7. 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.

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

7.1.1.9. A full and unredacted copy of the complete set of raw data of all tests carried out.

7.1.1.10. A summary of the key test results and conclusions.

7.1.1.11. Calibration certification for test equipment used.

7.1.1.12. Copy of test protocols.

7.2. Information dossier evaluation

7.2.1. WHO IMD-PQS follows these procedures to verify the that the testing laboratory complies with WHO IMD-PQS standards (IMD/TP/15b). Initial checks are as follows:

7.2.1.1.1. ISO/IEC 17025 certification: Verification of valid ISO/IEC 17025 certification, ideally with an ILAC registered authority. Verification that certification is valid, either via the issuing authority's website or directly with the issuing authority.

7.2.1.1.2. Quality System: Verification that the laboratory has a quality system that meets ISO 9001 requirements. This may be done by checking particular aspects of the laboratory's Quality Manual, including those aspects referenced in clause 7.3 of this SOP.

7.2.1.1.3. Facilities: Verification that the laboratory has adequate facilities to perform the tests shown in the product verification protocol(s) of the proposed E00 categories.

7.2.1.1.4. 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.

7.3. Laboratory requirements

7.3.1. WHO IMD-PQS Secretariat verifies the presence of the following requirements for an acceptable laboratory, which are those identified as being the optimum. However, failure to fully comply does not preclude consideration.

7.3.2. The laboratory:

7.3.2.1. Has 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);

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

7.3.2.3. Uses laboratory equipment required for testing against the appropriate IMD-PQS verification protocol and which is properly installed, maintained and pre-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);

7.3.2.4. Submits uncertainty budgets for all major parameters measured in accordance with IEC 17025, Clause 7.6. For example, for temperature and energy measurements. (The laboratory may reference ISO/IEC GUIDE 98 Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement.)

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

7.3.2.6. Employs laboratory practices that are demonstrable and meet WHO requirements, such as:

7.3.2.6.1. Sample identification (IEC 17025, Clause 5.7 – Sampling)

7.3.2.6.2. Test methods and procedures (IEC 17025, Clause 5.4)

7.3.2.6.3. Checking of results and calculations (IEC 17025, Clause 4.12.2 1 to 3);

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

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

7.4. **Confidentiality** (Secretariat, WG, Evaluators)

7.4.1. WHO treats all information to which they gain access during the review, or otherwise in connection with the discharge of their responsibilities in regard to the prequalification of IMD-PQS products, as confidential.

7.4.2. WHO requires evaluators of product dossiers to likewise treat all information as confidential.

7.4.3. In addition, the evaluators of product dossiers results are required to sign a Declaration of Interest. A sample of the confidentiality and Declaration of Interests (WHO Expert) is available.

7.4.4. Only if, based on this Declaration of Interest, it is felt that there is no risk of real or perceived conflict of interest and it is thus deemed appropriate for evaluators to undertake this work, they conduct their functions exclusively as advisers to WHO.

7.5. **Evaluation Outcome** (Secretariat)

7.5.1. WHO IMD-PQS Secretariat conducts an evaluation and, if the outcomes and findings are unsatisfactory, does not take the external unsolicited test results into consideration. In such cases, the external testing body is notified in writing of the outcome of the evaluation.

7.5.2. If the outcomes are satisfactory, the Secretariat communicates this to the external testing body in writing.

7.6. **Approval process** (Secretariat, WG)

7.6.1. The Secretariat alone takes the (final) decision whether to accept the unsolicited external testing results as significant for the prequalified status of products or devices, or not.

7.7. **Publication** (Secretariat)

7.7.1. If the Secretariat accepts or otherwise finds value in the non-IMD-PQS testing results, the manufacturer is notified in writing of the outcome of the testing and, where relevant, they are informed of any consequences for the prequalified status of their product or device. UNICEF Supply Division is notified.

7.8. **DISTRIBUTION** (Secretariat)

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

- IMD-PQS Secretariat,
- IMD-PQS WG,
- WHO Expanded Programme on Immunization (EPI),
- UNICEF Supply Division and UNICEF Programme Division,
- Each Technical Specialist commissioned to work on any aspect of the product prequalification process,
- All relevant manufacturers,
- IMD-PQS and TechNet-21 websites

8. RECORDS

8.1. N/A

9. REVISION HISTORY

Version	Reason for revision	Author	Drafted
2	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	Approved by: R. Gaspar	01/2024

	7. PQS updated to IMD-PQS (Immunization Devices Performance, Quality and Safety)		