1. OBJECTIVE

1.1. This standard operating procedure (SOP) describes how to re-evaluate an IMD-PQS accredited laboratory that has previously been accepted in accordance with the procedures set out in IMD/SOP/07: *Assessing a laboratory for IMD-PQS accreditation*.

2. SCOPE

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

2.2. It describes the procedure for re-approving a laboratory. Any laboratory that has failed to perform adequately, risks losing its IMD-PQS accreditation status.

2.3. An IMD-PQS Review takes place every year. This review verifies that ISO and other certifications are up to date, whether changes have occurred in key personnel and summarises product testing for IMD-PQS approval that has been carried out in the 12 months prior.

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

2.5. 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 re-evaluating an accredited test laboratory.

3. CROSS-REFERENCES

Relevant KPI(s):	Nil
Background:	• 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
Under this SOP:	• IMD/TP/08a: Email to request up-to-date information from a PQSIMD-PQS accredited laboratory • IMD/TP/08b: Laboratory re-accreditation checklist • IMD/TP/08c: Testing log - all PQSIMD-PQS testing and/or evaluation carried out since 1st March of last year I
Other QMS documents:	IMD/SOP/07: Assessing a laboratory for IMD-PQS accreditation

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 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)	The IMD-PQS 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,

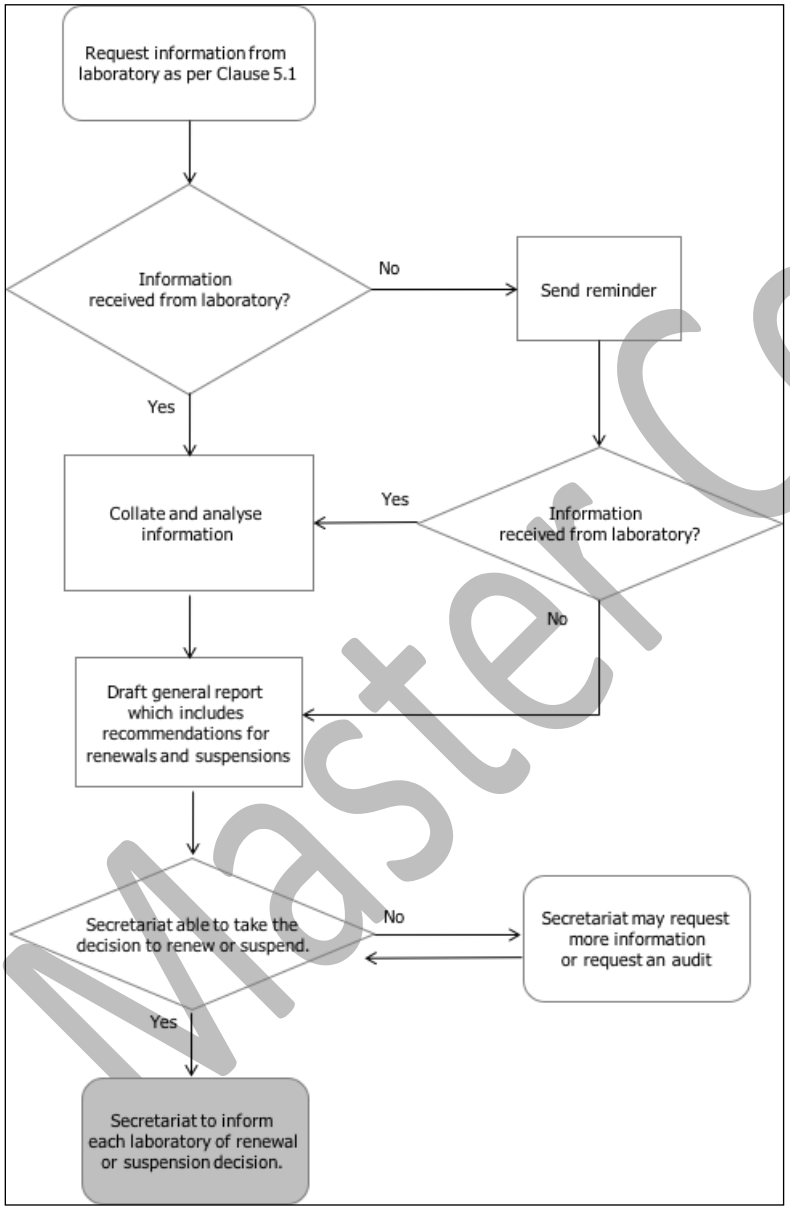
	introduction and advancement of technologies that will meet countries' EPI needs for high-quality cold chain equipment and devices.
ISO	International Standards Organization.
Legal manufacturer	The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under their own name, regardless of whether these operations are carried out by that person 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: Developing and publishing an IMD-PQS product verification protocol.*

5. RESPONSIBILITIES

IMD-PQS Working Group (WG)	• Members may be assigned the task of conducting the annual review; and • Members or Technical Specialists (TS) will prepare a report of the review
IMD-PQS Secretariat (IMD)	• Commissions an annual review of the performance of each IMD-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 accreditation (*Suspension may be temporary subject to certain conditions being met*); and • Makes amendments to the website to take account of the decisions

6. HIGH LEVEL FLOW CHART SUMMARY

Figure 1: Laboratory annual re-accreditation procedure



7. PROCESS INSTRUCTIONS

7.1. **Assessment of accredited laboratories** (Secretariat or its representative)

7.1.1. The Secretariat contacts the accredited laboratory to request up-to-date information. It does so by email with the wording provided in IMD/TP/08a, attaching the *Re-accreditation checklist* provided in IMD/TP/08b and the *Evaluation log* provided in IMD/TP/08c, to request the following information:

7.1.1.1. Copies of IEC 17025 and other certification. If an expiry date is within six months, laboratory must state the anticipated date of next audit;

7.1.1.2. An up-to-date .pdf web page of the complete *laboratory data sheet*. This is required to facilitate a comparison with the current IMD-PQS-accredited laboratory web page in order to check for any changes such as categories of testing, contact information etc.;

7.1.1.3. Indication of whether the laboratory wish to continue to test their products to maintain IMD-PQS-prequalified status and/or to change their current IMD-PQS categories;

7.1.1.4. Up-to-date copies of the CVs of key personnel, stating their role and responsibilities in regard to IMD-PQS testing and/or verification or other responsibilities within the organization, to demonstrate if there has been any change in key personnel;

7.1.1.5. An up-to-date copy of the laboratory quality manual, highlighting any changes that have taken place in the previous 12 months;

7.1.1.6. Up-to-date copies of any SOPs, TWI or similar documents that are maintained in regard to IMD-PQS testing and/or verification, and highlighting any changes that have taken place in the previous 12 months;

7.1.1.7. A list of all tests of products IMD-PQS approval carried out in the past year, including dates and with manufacturer and/or suppliers named in each case; and

7.1.1.8. Details of complaints from clients and the actions carried out in accordance with their quality procedures (CAPA). This information is kept confidential and does not automatically affect a laboratory's IMD-PQS accreditation.

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

7.1.3. The requested information is transcribed to a spreadsheet by the accredited laboratory in accordance with the formats in IMD/TP/08a and IMD/TP/08b.

7.2. Assessment (Secretariat or its representative)

7.2.1. The Secretariat collates all information collected in Clause 7.1 for each laboratory onto one spreadsheet, and subsequently conducts a general assessment.

7.2.2. This assessment also checks 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.

7.3. Reporting (Secretariat or its representative)

7.3.1. The Secretariat summarizes the information collected in Clause 7.1 and analysed in Clause 7.2 in one report that recommends which laboratories retain IMD-PQS-accredited status and which ones are disqualified.

7.3.2. Any matters arising from the assessment are 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.

7.3.3. This report highlights:

7.3.3.1. Loss of ISO/IEC 17025 accreditation;

7.3.3.2. Loss of other certification;

7.3.3.3. Bankruptcy, receivership, corruption or other financial irregularity;

7.3.3.4. Change to product categories;

7.3.3.5. Evidence of collusion between testing laboratory and product manufacturer(s);

7.3.3.6. Loss of key testing facilities;

7.3.3.7. Loss of key personnel;

7.3.3.8. Unsatisfactory service (reported by users);

7.3.3.9. Unsatisfactory test reports; or

7.3.3.10. Any need for further action by a laboratory or the secretariat.

7.4. Laboratory audit (Secretariat or its representative)

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

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

7.5. Accreditation (Secretariat)

7.5.1. The Secretariat reviews the annual report and any audits to decide which laboratories retain or lose IMD-PQS accreditation.

7.5.2. The Secretariat emails each laboratory to inform them of the decision. In general, laboratories are encouraged to retain their accreditation status by taking appropriate action to improve their practices or facilities within an agreed time frame.

7.5.3. If no improvements are made in the agreed time frame the laboratory accreditation may be terminated.

7.6. Publication (Secretariat)

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

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

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

7.7. 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

8. RECORDS

8.1. The Secretariat saves laboratory audit reports in WHO ePQS-Box / Sharepoint: Folder "Labs".

8.2. The Secretariat saves laboratory applications for accreditation in WHO ePQS-Box / Sharepoint: Folder "Labs.

9. REVISION HISTORY

Version	Reason for revision	Author	Drafted
01	1. ATT team was changed to QSS team due to the reorganization in the IVB Department. 2. The code VML was changed to PQS in the SOP No.s for easy reference. 3. 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	1. Footnotes defining the IMD-PQS Working Group and the IMD-PQS Secretariat added in Clause 5. 2. 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). 3. 'Responsibilities' clause revised to separate out specific responsibilities of key actors and to remove process elements. 4. Clause 7.7 'Distribution' edited to reflect new IMD-PQS system. 5. '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

	6. Clause 'Laboratory re-accreditation summary overview' added plus corresponding diagram. 7. Substantial rewriting/restructuring of Clause 7 `Procedure`, in particular reporting. 8. Removal of 'Standard Letter' annexes, of 'Website entry' annexes and of 'Model Checklist for a lab reassessment visit'. 9. Addition of Annexes: 'Email to request up to date information', 'Lab accreditation checklist', and 'Testing Log' template.		
02	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	April 2024