1. OBJECTIVE

1.1. The purpose of this SOP is to describe the process of auditing a laboratory as a part of its assessment for IMD-PQS accreditation. This includes application as well as re-application.

2. SCOPE

2.1. Before a product or device can be added to the IMD-PQS database, verification of its conformity with all the requirements of the relevant product specification takes place.

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

2.3. In order to receive IMD-PQS-accreditation, a laboratory demonstrates its competence to carry out specific product tests by conforming to internationally-accepted standards or codes of practice, as witnessed by a competent third-party accreditation body.

2.4. These include current versions of quality standards such as ISO 9001 *Quality management systems — Requirements* and ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories.*

2.5. A laboratory's conformity with the required standards and codes is achieved by evaluation of a laboratory information dossier and examination of other requirements, described in full in described in IMD-PQS IMD/SOP/07 *Assessing a laboratory for IMD-PQS accreditation*.

2.6. In addition to presenting a satisfactory laboratory information dossier and demonstrating conformity with all requirements, a laboratory seeking IMD-PQS accreditation may be required to undergo a full or partial site audit.

2.7. The need for an audit is determined based on the arrangements of the accreditation body to which the laboratory is signatory and may be influenced by test urgency.

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 auditing a laboratory for accreditation.

2.9. Laboratories that successfully pass a required audit and demonstrate required competencies through the assessment process may then be accredited by IMD-PQS to test specific categories of products.

2.10. 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.

2.11. 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.

3. CROSS-REFERENCES

Relevant KPI(s):	Nil
Background:	• https://extranet.who.int/pqweb/immunization-devices/accreditation-process • https://extranet.who.int/pqweb/immunization-devices/re-accrediation • https://extranet.who.int/pqweb/immunization-devices/accredited-laboratories • ILAC-G15Guidance for Accreditation to ISO/IEC 17025 • ILAC-G17Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025 • ILAC-G18:04Guideline for the Formulation of Scopes of Accreditation for Laboratories • ISO 9001Quality management systems — Requirements • ISO/IEC 17025General requirements for the competence of testing and calibration laboratories • List of ILAC Mutual Recognition Arrangement Signatories
Under this SOP:	• IMD/TP/14a: Exemplar questionnaire • IMD/TP/14b: Exemplar timetable
Other QMS documents:	• IMD/SOP/07: Assessing a laboratory for IMD-PQS accreditation • IMD/SOP/08: Re-evaluating a prequalified IMD-PQS product

4. DEFINITIONS

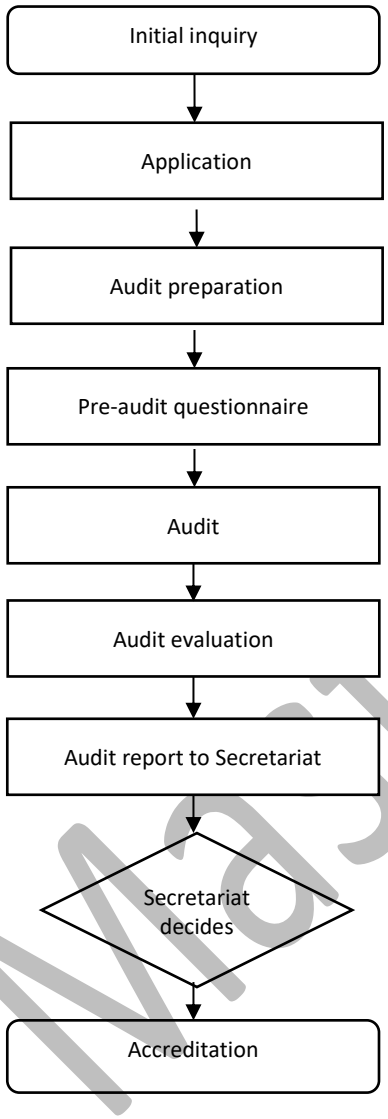
Device	A medical device such as a syringe or temperature monitor for example.
IEC	International Electro-technical Commission.
ILAC	International Laboratory Accreditation Cooperation.
IMD-PQS Secretariat	The WHO IMD-PQS Secretariat is responsible for sharing up-to-date information on prequalified immunization 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 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 *SOP No. 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 reviewing the original application
IMD-PQS Secretariat	• Requests the WG review(s) of the application if required; • Arranges for an audit of the laboratory by a TS if required; • Decides whether to accept or reject the application; • Notifies the test laboratory whether they are accredited or if their application has been rejected; and • Amends to the IMD-PQS website accordingly to reflect the decision.
Technical Specialists (TS)	• May be asked to audit the laboratory

6. HIGH LEVEL FLOW CHART SUMMARY



7. PROCESS STEPS

7.1. Initial inquiries

7.1.1. The following exchanges are carried out via email.

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

7.1.3. In their initial enquiry, a laboratory:

7.1.3.1. Outlines the categories they wish to be accredited for (E001 – E0013) as listed on the IMD-PQS website: https://extranet.who.int/prequal/immunization-devices/product-categories

7.1.3.2. States 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 is required to be already accredited in accordance with ISO/IEC 17025:2017: 2005/COR1:2006 General *requirements for the competence of testing and calibration laboratories.*

7.1.3.3. Has written quality procedures (a quality manual) in accordance with or based on ISO 9001. ISO 9001 accreditation is not a requirement for IMD-PQS accreditation.

7.1.4.

7.1.5. After the initial enquiry for IMD-PQS accreditation, the IMD-PQS Secretariat asks the laboratory to complete a detailed dossier in accordance with SOP No. IMD/SOP/07.

7.1.6. In the event that the laboratory is unfamiliar with the procedure, the IMD-PQS Secretariat provides additional support for application preparation via email exchange with the laboratory.

7.1.7. Once the application has been submitted and verified, the IMD-PQS Secretariat decides whether to request a full or partial audit visit as part of new applications for IMD-PQS accreditation or reaccreditation.

7.1.8. An audit visit may also be part of a routine surveillance visit, as described in SOP IMD/SOP/08.

7.2. Audit outline

7.2.1. Although ISO/IEC 17025 compliance requires a laboratory to have a quality management system in place, IMD-PQS requires additional information about quality procedures, test facilities and laboratory competences in order to evaluate an application for IMD-PQS accreditation.

7.2.2. The audit is a wide-ranging examination covering “horizontal” and “vertical” aspects of their procedures. For example, a horizontal audit could examine calibration or training, whereas a vertical audit follows testing from the moment

of a product's arrival at the laboratory to its departure and including customer follow-up.

7.2.3. The Secretariat assigns the audit to an audit team consisting of at least a lead auditor.

7.3. Communication

7.3.1. *Preliminary contact*

7.3.1.1. Several weeks before the proposed audit date(s), the IMD Secretariat and the lead auditor contact lead laboratory personnel; this may include the Head of the laboratory, but that is not a requirement.

7.3.1.2. Before the audit is carried out, the auditor makes direct contact with key persons at the laboratory to make it clear that:

7.3.1.2.1. both quality and testing aspects of the laboratory will be audited,

7.3.1.2.2. key personnel must attend the audit, and

7.3.1.2.3. a test mock-up of applicable testing must be observed.

7.3.1.3. Key personnel always include the Quality Manager (QM) or a manager whose remit includes quality.

7.3.1.4. Following initial contact, the lead auditor and laboratory key contact(s) establish and communicate:

7.3.1.4.1. The purpose of the audit visit

7.3.1.4.1.1. The auditor indicates that the audit is part of their new application or re-application for IMD-PQS accreditation.

7.3.1.4.2. Date(s) for the audit

7.3.1.4.2.1. The auditor is entitled to see any aspect of their quality and test procedures and since testing can take time to set up, this should be agreed in advance.

7.3.1.4.2.2. Depending on the size of the facility, number of sites and geographical location, it is reasonable to allow at least two to five days for the audit.

7.3.1.4.3. The approximate areas the auditor would like to examine

7.3.1.4.3.1. An audit may include horizontal test areas such as calibration and training (even if both are subcontracted externally), or vertical test areas such as following a

project from beginning to end (from agreed terms of reference to client satisfaction follow-up after completion).

7.3.1.4.4. The inclusion of test demonstrations relevant to the application

7.3.1.4.4.1. The laboratory must demonstrate testing capabilities for some or all of the IMD-PQS E00 categories for which the laboratory is applying.

7.3.1.4.4.2. Since some tests take more than one day, it may not be possible to see a test from beginning to end.

7.3.1.4.4.3. The auditor informs the laboratory that, in case an auditor observes a test in progress, it may be necessary for the auditor to interrupt the test (e.g. open the fridge door to examine thermocouple array) in order to fully evaluate the testing.

7.3.2. In many cases, English may not be the first language of laboratory personnel.

7.3.3. The auditor endeavours to communicate clearly and to avoid ambiguities and idiomatic expressions.

7.3.4. Replies and acknowledgements to emails are essential.

7.3.5. The auditor is responsible for all aspects of their travel to the laboratory, although they may request advice about travel routes and appropriate hotels from the laboratory.

7.4. Pre-audit checklist

7.4.1. At least three weeks prior to the visit, the auditor reviews the information obtained from the laboratory as a part of their application to be assessed for IMD-PQS accreditation (as described in **IMD/SOP/07**). All documents must be translated to English.

7.4.2. In case any of the following information or documentation is missing, the auditor requests it by email or telephone:

7.4.2.1. **The precise IMD-PQS categories (e.g. E003 or E004) and subcategories the laboratory wishes to test**. It is acceptable for laboratory to exclude some of the sub-categories within an E00 category. These exclusions should be listed by references to protocols.

7.4.2.2. **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.

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

7.4.2.4. **A copy of laboratory quality manual**. This is a large document and may not be in English. The auditor should obtain at least a copy of the contents page and a list of recent updates.

7.4.2.5. **Names and contact details of at least three referees.** That is, well-established organizations (referees) that have used the laboratory's expert services during the past three years.

7.4.2.6. **Examples of testing undertaken by the laboratory in the last three years that is similar to the tests for which they wish to be accredited.** Clients need not be named if this is confidential.

7.4.2.7. **A copy of one test report similar to the tests for which they wish to be accredited.** Client's name and details may be redacted.

7.5. Pre-audit laboratory questionnaire

7.5.1. Immediately after completing the pre-audit checklist described in section 7.4 at three weeks prior to the planned audit visit, the auditor asks the laboratory to complete a detailed questionnaire by written (electronic) correspondence. The questionnaire can take the form of a three-column spreadsheet which provides space to include: Question; Laboratory's response; Exemplar response or guidance. See an example questionnaire format in IMD/TP/14a.

7.5.2. The auditor tailors the questionnaire to the particular laboratory and to the nature of the specific audit to be carried out.

7.5.3. The questionnaire includes references to relevant ISO/IEC 17025:2017 clauses.

7.5.4. The auditor requests the laboratory to respond to the questionnaire within two weeks. In the case of any missing, incomplete or unclear responses in the questionnaire, the audit provides the opportunity to follow-up.

The following notes are intended to annotate the questionnaire in IMD/TP/14a and should be read in conjunction with it. The numeration of these notes corresponds to those in the questionnaire.

7.5.5. *General questions*

7.5.5.1. Requests background on the laboratory.

7.5.5.2. Helps identify the individual laboratory staff you may meet.

7.5.5.3. Requests the CVs of the Laboratory Manager, Quality Manager and Engineers who will oversee the testing. These CVs should be kept confidential by the auditor.

7.5.5.4. Enquires about the current accreditation status of the laboratory. The auditor should be able to verify accreditations and certifications with the issuing authority's web site. In case the appropriate web page is difficult to locate, the auditor may need to contact the issuing authority before the audit visit.

7.5.5.5. Asks for a brief description of the quality management system. The laboratory will have drafted a Quality Manual (QM). A QM can be hundreds of pages long so an auditor may not have time to read it in its entirety. Ideally a QM is much less than 100 pages. Better quality QMs have sub-sections for specialist areas Nevertheless, having reviewed at least the contents pages can prime certain questions at the time of audit. e.g. “Take me through the procedure for the checking-in of test samples.” If the QM is not written in English, request at least the contents pages in English.

7.5.5.6. Requests information about document control procedures in QMS. It is reasonable to print instructions or procedures, but any hard copy is technically only valid on the day of printing. “UNCONTROLLED COPY” should be stamped or written on the printed document with a signature and a date.

7.5.5.7. Asks for dates of previous audit visits. Note that the lab’s ISO/IEC 17025 certification requires keeping records of previous audit visits from other authorities.

7.5.5.8. Asks for information on the frequency and type of *internal* audits. Frequency of audits depends on the outcome of the previous audit. In general, auditing each department once per year is reasonable unless specific circumstances require a 3- or 6-month follow-up; including but not limited to the recurrence of the same issue(s). It is up to the lab whether internal auditors are senior or junior personnel, but they should be trained.

7.5.5.9. Concerns supplier auditing: the laboratory must not *assume* the quality of its suppliers. They must either ask for quality certification or carry out their own audit. This is mandatory for suppliers providing key test material,

whereas the laboratory may apply their judgement for suppliers of other materials.

7.5.5.10. Requests information about "ring testing" an ISO/IEC 17025 requirement and intra-laboratory comparisons (a good practice).

7.5.6. *Test experience*

7.5.6.1. Solicits details of current testing standards and protocols. Although the laboratory may be brand new to *IMD-PQS* testing, it is hoped that they have some similar experience.

7.5.6.2. Asks for information on participation in standard setting bodies. Note: participation in national or international standard committees is not compulsory however and relies on senior management to commit time and money.

7.5.6.3. Requests training records, which may be provided in hard copy or electronic.

7.5.7. *Test procedure*

7.5.7.1. Prompts a description of the sample handling procedure. Arriving samples should be unpacked and at least visually checked fairly soon after arrival, i.e. one to two working days. The laboratory shall define the time period during which the samples must be checked; the IMD-PQS Secretariat will review the rationale. A functional check may be carried out. Keeping the packaging for damage inspection may be useful. Damage should be photographed and reported to the client immediately for their decision. A dent in the body may look trivial but both the laboratory and the client should be mindful of hidden damage.

7.5.7.2. Asks for a list or description of environmental test chambers. This should include air speed which should be lower than 0.25 m/s for refrigerator testing.

7.5.7.3. Asks for a description of the procedure to follow a test protocol. It is not a requirement to have a "test manual". In fact, these can be unwieldy and inefficient. However, testing and procedures are usually complicated enough that reference to some sort of document like a "Test Work Instruction" (TWI) or a "Standard Operating Procedure" (SOP) about the instrumentation or the test set-up is probably useful. In case a laboratory

indicates that they only "follow the IMD-PQS protocol", the auditor requests the laboratory to demonstrate that procedure during audit. Often there are instructions for setting up instruments and other procedures not contained or covered in the IMD-PQS protocol.

7.5.8. *Measuring instruments and accuracy*

7.5.8.1. Requests detail on the measurement and logging of all relevant parameters. There is usually a dedicated chain: sensor – transducer – logger – PC/laptop to capture data. Temperature must be logged at least once per minute. Humidity capture is not stated. Since power is constantly varying, it is reasonable to log it every 10 seconds (although this is not stated as requirement).

7.5.8.2. Enquires about the type of temperature sensors and end "slugging" if applicable.

7.5.8.3. Solicits information on individual identification of all instruments, including every thermocouple, which must have a unique ID number.

7.5.8.4. Invites detail on instrument calibration. Temperature readings (if applicable) should be accurate to 0.5°C. This is from the tip of the temperature sensor to the value in the display or spreadsheet.

7.5.8.5. Invites detail on logged humidity accuracy. While there is no requirement for humidity accuracy (if applicable), 5% RH is reasonable.

7.5.8.6. Asks about the accuracy of power and energy measurements. If applicable, these should be accurate to 1%.

7.5.8.7. Asks if instruments are calibrated internally or externally. The laboratory may select either option; however, internal calibration of temperature sensors (for example) is not difficult and can offer more flexibility. Each instrument must have a calibration file, so a year-on-year history is available.

7.5.8.8. Enquires about the quarantine of out-of-calibration instruments. It must be obvious to the technician which instruments are "in-calibration", "out-of-calibration" or "quarantined". For significant instruments, it is usual to include instrument ID with calibration dates in the report.

7.5.8.9. Asks about laboratory treatment for uncertainty calculations. To assess this criterion the auditor should have experience of uncertainty budgets.

7.5.9. *Reporting*

7.5.9.1. Requests the laboratory to provide an example copy of a test report to the auditor in advance. The confidentiality of this report must be maintained.

7.5.9.2. Asks about the regularity of feedback on project progress; every week for example. Sometimes this is agreed in the terms of reference.

7.5.9.3. Enquires about the laboratory procedure for control of tested samples. Once testing is complete, test samples should not be released until the client is satisfied with the report. It is the client's decision whether the test sample is returned to them or disposed of; there are cost implications in either case.

7.5.9.4. Asks about client follow-up procedures. Assuming the client wishes to continue working with the laboratory, it is useful for the laboratory to solicit feedback on what could be improved in the supplier-client relationship.

7.5.10. *Corrective action*

7.5.10.1. Requests a description of the laboratory procedure for "complaints" with corrective action or preventative action (CAPA). The laboratory must have a documented CAPA procedure for both internal and external complaints and must be able to show examples to the auditor. No laboratory has zero complaints, and where applicable, the auditor reassures the laboratory that CAPA is a beneficial process when completed adequately. Assessing the laboratory's attitude towards CAPA is a key quality indicator.

7.6. <u>Laboratory practice</u>

7.6.1. The auditor assesses all information related to the laboratory practice (e.g. SOPs) and identifies good laboratory practice, including the items described in section 7.6.2 below, which is not an exhaustive list. However, failure to fully comply with these practices does not preclude IMD-PQS accreditation as long as necessary steps are made within an agreed timeframe to show eventual compliance with ISO/IEC 17025:2017 and with IMD-PQS requirements.

7.6.2. *The laboratory:*

7.6.2.1. Maintains a quality management system that is clearly defined and documented, and which is organized in such a way that the integrity of its staff and operations can be judged. (ISO/IEC 17025 Clause 4 – *Management requirements*.)

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

7.6.2.3. Has a testing environment and laboratory suitable for the tests undertaken. (ISO/IEC 17025 Clause 5.3 – *Accommodation and environmental conditions*.)

7.6.2.4. Uses laboratory equipment appropriate for the IMD-PQS verification protocol(s) which is properly installed, maintained and calibrated. Adequate records of calibration and servicing must be maintained. (ISO/IEC 17025 Clause 5.4 – *Test and calibration methods and method validation.)*

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

7.6.2.5.1. Sample identification (ISO/IEC 17025 Clause 5.7 – *Sampling*).

7.6.2.5.2. Test methods and procedures (ISO/IEC 17025 Clause 7.2 *Validation of methods*.

7.6.2.5.3. Checking of results and calculations (ISO/IEC 17025 Clause 7.7 - *Ensuring the validity of results*).

7.6.2.6. Operates a secure laboratory record system containing full details of all tests undertaken. (ISO/IEC 17025 Clause 4.3 – *Document control*.)

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

7.7. Laboratory audit

7.7.1. *Introduction*

7.7.1.1. The audit visit takes one to two days and can cover all aspects of the laboratory's operation.

7.7.1.2. An example schedule is provided in IMD/TP/14b and described in more detail below. The auditor(s) interview key personnel during the audit which examines the E00 category testing and quality procedures.

7.7.2. *General practice for behaviour with staff during the audit visit*

7.7.2.1. The auditor conducts the audit as a series of interviews with appropriate personnel. This includes those directly involved in the testing, although this is done with discretion and an appreciation for the extent of their experience. The audit is not conveyed as a "challenge" to laboratory staff as this is counter-productive and results in a non-realistic assessment of quality and performance.

7.7.2.2. The auditor requests the Quality Manager to be present, or on-call, for most of the audit visits because there may be questions that the technician cannot answer. Alternatively, and if necessary, these questions may be stored for later.

7.7.2.3. During audit, the auditor asks questions and encourages staff to explain what they do. The auditor ensures the auditee has sufficient opportunity to explain and justify their processes.

7.7.2.4. During the audit of the laboratory and its departments, at least one member of senior staff or their representative is expected to be present, for example the Quality Manager or a senior staff member concerned with IMD-PQS testing is required to be present. Presence of too many senior staff or managers *may* impact on the interviewees feeling of ease to freely communicate all aspects of required information in some situations.

7.7.3. *Documenting and resolving non-compliances*

7.7.3.1. The auditor communicates any issues identified during the audit to the laboratory key contact at the moment of identifying. This is good audit practice as it allows the auditee to respond before the end of the audit and confirms audit findings and therefore reduces any potential misunderstandings.

7.7.3.2. Issues identified are referenced as *non-compliances* with the relevant ISO/IEC 17025 clauses.

7.7.3.3. Likewise, any lack of competence in following a verification protocol (VP) is referenced as *non-compliance* with verification protocol clauses (although this may not be possible until the audit report stage).

7.7.3.4. Most often, the senior staff member involved in the audit agree about any conflicts with ISO/IEC 17025 requirements identified. Laboratories which seek to improve quality often welcome constructive criticism. On occasion, senior managers may disagree with the auditor (either about the details of the issue or a timetable for remedial action) in which case the auditor consults with the IMD-PQS Secretariat at the time of reporting.

7.7.3.5. Issues arising from the audit and a timetable to address them are agreed in writing at the latest during the summary meeting, if not straight away. This timetable may have to be discussed at the end of the full audit process to allow for a planned course of action. The timetable can be one week, one month or three months depending on the complexity of the issue. The timetable does not extend longer than three months so that required actions do not devalue over a time. If longer than three months is agreed, a progress update are submitted periodically.

7.7.4. *Audit visit*

7.7.4.1. Introductory meeting (day 1)

7.7.4.1.1. The introductory meeting is held with senior company staff and personnel concerned with IMD-PQS testing. This is to make introductions and explain the format of the visit. An approximate schedule is agreed in advance; though flexibility might be needed as staff address issues arising in the laboratory. During this introduction, the auditor seeks to put staff at ease and address any general concerns.

7.7.4.1.2. The auditor makes it clear that the audit is confidential, but that some aspects may have to be discussed with the IMD-PQS Secretariat, to whom the audit report is sent in the first instance. Laboratory managers often ask for the audit report to be sent to them, but the auditor may explain that **this usually happens after** IMD-PQS Secretariat **approval** and that there is a final summing up meeting where the audit is discussed (See Section 7.8) between the auditor and laboratory managers.

7.7.4.1.3. Though there is no specific restriction, it is not necessary for all staff to be present at the introductory meeting. At least one member of senior staff or their representative present, as well as

the Quality Manager and at least one member of senior staff concerned with IMD-PQS testing is present.

7.7.4.1.4. Having confirmed the schedule of the next one to two days, the auditor begins their audit. Sufficient time for summing-up by the auditor is planned for on the final day.

7.7.4.1.5. The auditor should be wary of "*deliberate* non-compliances" which may lead to spending undue time on comparatively trivial issues, leaving less time to potentially discover and investigate something more serious. Unless experienced, the auditor cannot know what is deliberate or not; they should simply record the non-compliance and move on in a professional manner.

7.7.4.1.6. The auditor should be wary of gifts; they must ensure that their objectivity and the integrity of the audit is maintained at all times.

7.7.4.2. Vertical audit

7.7.4.2.1. It is advisable to begin with a vertical audit, following a product through the full testing process. Following one 'project' can give a "whole view" of the laboratory's procedures and approach. A project manager should talk to the auditor through a project file (which may be electronic). For an existing IMD-PQS accredited laboratory, they should select an IMD-PQS test project. For a new laboratory, they should select a project which involves the testing of an appliance similar to that which may be found in the E00 category(s) for which they are seeking accreditation.

7.7.4.2.2. As noted in Section 7.1 above, the laboratory should have already provided the auditor with the report of this project at pre-audit stage, along with the audit questionnaire. The auditor should have therefore had time to examine that report and to review it with the laboratory.

7.7.4.2.3. A project normally begins with terms of reference and a contract signed by the client. There should be an agreed test programme or a verification protocol. Where there is deviation from the protocol, this must be agreed by the client in writing.

7.7.4.2.4. It should be clear from the project file when the test product arrived and left the laboratory. Even if testing is not due to begin immediately, it is good practice to visually inspect the appliance very soon after arrival so that any damage can be referred to the client for their decision. This includes a visual assessment of the packaging with photographs, if there is any damage. For example, accidental prodding with forklift-truck forks is sometimes apparent.

7.7.4.2.5. If possible, there should be a quick functional check of the appliance as some damage may be visible. A refrigerator can be cooled down overnight for example. In a few cases (not IMD-PQS protocols) unpacking, inspection and functional checking is part of the agreed test programme so this may not be carried out until that specific audit project actually begins.

7.7.4.2.6. The client should be informed of the arrival of their product and its apparent condition.

7.7.4.2.7. Ideally, the product in the test project should be set up for testing to be demonstrated by a technician, although a test demonstration of a similar appliance is acceptable in case the original product is no longer available.

The absence of a test demonstration altogether is not acceptable.

7.7.4.2.8. Reference may be made to the verification protocol and other documents necessary for setting-up. The technician should not be expected to remember everything by heart. Indeed, the use of checklists can be good laboratory practice.

7.7.4.2.9. Since many IMD-PQS tests take place over many days, running into weeks, it is often not possible to observe a full test from beginning to end; i.e. it is usually a fairly *static* demonstration. The auditor should see a test set-up and observe how data is captured.

7.7.4.2.10. Test manuals, SOPs and TWIs

7.7.4.2.10.1. Most laboratories will have test manuals, standard operating procedures (SOPs) or test work instructions (TWIs) as there are often procedures and test set-ups (including setting instrumentation, setting conditioned rooms) which are not specified in test protocols and similar instructions. Therefore, it *may* be an indicator of potential poor practice if a laboratory does not have any SOPs or TWIs or other test manuals. There will be a certain rate of staff turnover or absences due to illness etc., and up-to-date documents will be necessary to swiftly and adequately replace personnel of test procedures.

Since this is not a quality requirement, the absence of SOPs and TWIs would be an observation, not a non-compliance.

7.7.4.2.11. Uncontrolled documents

7.7.4.2.11.1. Nearly all quality documentation, standard operating procedures (SOPs) and test work instructions (TWIs) will be held electronically. However, it is reasonable to print part or all of these for working practices. For example, there may be a complicated test set-up or a diagram of thermocouple positions.

7.7.4.2.11.2. Owing to potential updates, each printed document is only valid on the day of printing and the following or similar must be stamped on every sheet, “UNCONTROLLED DOCUMENT” with a date and a signature.

7.7.4.2.11.3. After this date, the user should understand the risk of using this document. When documents are updated, it may be expected that relevant staff are informed but this is not a guarantee that the auditor will be informed of the update.

7.7.4.2.11.4. The use of “post-it notes” is generally not good practice. Prompts and reminders can be useful (e.g. Shut

the window!) but post-it notes with crucial instructions (e.g. Don't forget to re-calibrate!) can be lost.

7.7.4.2.12. Calibration

7.7.4.2.12.1. Data must be captured on calibrated instrumentation. (Calibration may be part of a horizontal audit though it will definitely be observed in vertical audits.) All instruments should have a reference number and a date of calibration which is recorded in the test report. There should be a calibration history for each instrument kept on file.

7.7.4.2.12.2. Ideally, instruments should be calibrated before the start of the test protocol. Applying a correction afterwards to achieve post-calibration can be not only very time consuming and subject to error, but even render the results void and should be avoided if at all possible.

7.7.4.2.12.3. Instrumentation includes temperature sensors, data logging systems and power meters. Even rulers should be calibrated though a yearly calibration may not be necessary. There is often a debate about retractable tape measures; some are calibrated while others can be verified before use against a fixed ruler. Such a verification should be recorded.

7.7.4.2.12.4. If an instrument is not calibrated, it should clearly state this on the instrument. (The instrument may be in-between calibrations or calibration may not be required.)

7.7.4.2.13. Recording test data

7.7.4.2.13.1. Often data is recorded electronically and automatically transferred to excel files or spreadsheets etc.

7.7.4.2.13.2. Data that is recorded by hand (e.g. linear measurements) and then transferred to an electronic file should be checked for transposition errors, preferably by

a different technician. The original paper document should be signed, dated and kept on file for later verification; it should not be discarded.

7.7.4.2.13.3. If there are automatic calculations, e.g. macros or just simple arithmetic operations, these should be checked periodically, at least until a reliable history is known. The checker should always sign and date this for the record; checking should not be assumed. Spreadsheets are sometimes updated, and "knock-on effects" are not always appreciated.

7.7.4.2.14. Laboratory report writing

7.7.4.2.14.1. According to ISO/IEC 17025:2017 Clause 7.8.2.1, a laboratory report shall include at least the following information (unless the laboratory has valid reasons for not doing so) thereby minimizing any possibility of misunderstanding or misuse:

a. a title and a unique reference,
b. the name and address of the laboratory,
c. the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities,
d. unique identification that all report sections are recognized as a portion of a complete report and a clear identification of the end,
e. the name and contact information of the customer,
f. identification of the method used,
g. a description, unambiguous identification and, when necessary, the condition of the item,
h. the date of receipt of the test or calibration item(s) and the date of sampling, where this is critical to the validity and application of the results,
i. the date(s) of performance of the laboratory activity,
j. the date of issue of the report,

k. reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results,
l. a statement to the effect that the results relate only to the items tested, calibrated or sampled,
m. the results with, where appropriate, the units of measurement,
n. additions to, deviations or exclusions from the method,
o. identification of the person(s) authorizing the report, and
p. clear identification when results are from external providers.

7.7.4.2.14.2. It is good to include a statement specifying that the report shall not be reproduced except in full without the approval of the laboratory. This can help provide assurance that parts of a report are not taken out of context.

7.7.4.2.14.3. It is also good to include the following statement: "The results in this report pertain only to the sample(s) tested and do not represent mean values if a larger number of samples were tested."

7.7.4.3. Horizontal audit

7.7.4.3.1. A horizontal audit reviews activities that spread across all aspects of laboratory functioning and practice. These include quality management, training, calibration and uncertainties. There may or may not be a separate department for these; indeed, separation into departments is increasingly outdated as horizontal-vertical integration becomes more common. Often a line manager or project manager will take responsibility or delegate all of these.

7.7.4.3.2. <u>Quality management system</u>

7.7.4.3.2.1. The laboratory must have a quality management system which complies with ISO/IEC 17025:2017 Clause 8 – Management system requirements.

7.7.4.3.2.2. As a minimum, the management system of the laboratory shall address the following:

a. management system documentation (Clause 8.2),
b. control of management system documents (Clause 8.3),
c. control of records (Clause 8.4),
d. actions to address risks and opportunities (Clause 8.5),
e. improvement (Clause 8.6),
f. corrective actions (Clause 8.7),
g. internal audits (Clause 8.8), and
h. management reviews (Clause 8.9).

7.7.4.3.3. Training

7.7.4.3.3.1. The auditor inspects the laboratory's staff training records and verify that the training is appropriate for the work they carry out. (ISO/IEC 17025:2017 Clause 6.2. - *Personnel*) If there are a large number of test staff, only a few sample training records may be inspected.

7.7.4.3.3.2. "All staff" must include temporary staff who, for example, must know procedures for leaving the building in an emergency from the first day of employment.

7.7.4.3.3.3. Training includes familiarization with quality procedures. Although it is not expected that each employee has memorized the quality manual, they should know how to search for items in it.

7.7.4.3.4. Calibration

7.7.4.3.4.1. The auditor should check that calibrated equipment is handled in accordance with ISO/IEC 17025 Clauses 7.4, 7.5 & 7.8.2.

7.7.4.3.4.2. Ideally instruments should be pre-calibrated as post-calibration can be very time consuming and subject to error. Post-calibration could even render the results void and should be avoided if at all possible.

7.7.4.3.4.3. There should be a file for each instrument though often a batch of thermocouples for example is kept within one file. This file means a year-on-year calibration history is retained which, for example, justifies the calibration interval e.g. 6 months, 1 year, 2 years etc.

7.7.4.3.4.4. There should be a calibration certificate which will identify and justify error, accuracy and any uncertainty for each instrument. Note error, accuracy and uncertainty are different entities. This certificate can be produced internally or externally as desired by the laboratory.

7.7.4.3.5. <u>Uncertainties</u>

7.7.4.3.5.1. Uncertainties are closely linked to calibration and each instrument will have an uncertainty value on its certificate.

7.7.4.3.5.2. For key parameters, e.g. energy consumption and volume, there will be an uncertainty calculation often in the form of a "budget" or spreadsheet calculated in accordance with ISO/IEC 17025 Clause 7.6.

7.7.4.3.5.3. This budget will isolate uncertainty contributors from measures and combine these uncertainty measures into one combined uncertainty for that parameter. This budget may be based on G.U.M (ISO/IEC Guide 98-3, Guide to the Expression of Uncertainty in Measurement (GUM), also ISO 21748 and the ISO 5725 series) or a similar guide. The auditor should check that the person in charge of developing these budgets has knowledge and training in uncertainty budgets.

7.7.4.3.5.4. The combined uncertainty can be expressed in the same units as the parameter or as a percentage. If the uncertainty is higher than a single figure percentage, the laboratory should be checking the cause by investigating

the instrumentation, the method. In some cases, it may be justified by the nature of the sample under test.

7.7.4.3.5.5. Uncertainties should be reported in accordance with ISO/IEC 17025Clause 7.8.3.1 C.

7.7.4.3.5.6. The laboratory should check the validity of their results in accordance with ISO/IEC 17025 Clause 7.7.1

7.8. Audit evaluation

7.8.1. Towards the end of the audit, the auditor convenes a summary meeting with laboratory staff. There should be senior staff present with some testing staff, as determined by the laboratory. Sufficient time for summing-up by the auditor should be allowed on the final day.

7.8.2. The auditor thanks the laboratory for their hospitality and state first their positive observations.

7.8.3. The auditor discusses a *draft* verbal evaluation along with a short, written summary. This discussion is good ISO 9001 practice and can help to avoid misunderstandings. The discussion should include a potential timetable to address concerns, although it may not be possible to have a firm schedule until certain items are checked (such as funding and the availability of new equipment). If it is not possible to have a draft written summary by the end of the audit this should be sent very soon afterwards and copied to IMD-PQS.

7.8.4. It should be noted that no laboratory has a complete pass nor a complete fail. There are always good practices but also areas which need addressing. The draft evaluation should list non-compliances, observations and the auditor's concerns. The draft evaluation is not final and there may be issues that require follow-up or checking, either by the auditor or by the laboratory. There may also be questions from the IMD-PQS Secretariat.

7.8.5. The auditor should ***not*** state whether the laboratory will be IMD-PQS accredited or have its accredited status renewed: that is the decision of the IMD-PQS Secretariat.

7.9. Audit report

7.9.1. The auditor prepares a report for the Secretariat setting out their observations; including any non-compliances, observations and conclusions. This report may make

a recommendation whether or not to IMD-PQS-accredit or renew accreditation of laboratory.

7.9.2. When drafting the report, the auditor may wish to re-contact the laboratory to check facts or fill in any missing information.

7.9.3. The headings in the questionnaire can be used as a basis for the report. Other recent audit reports may be a helpful guide for formatting and presentation.

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

7.9.5. The Secretariat may discuss accreditation with the auditor and/or IMD-PQS members, but the final decision is taken by the Secretariat. Accreditation may be conditional on certain non-compliances or observations from the audit being addressed within a set timeframe.

7.9.6. The laboratory will usually want to see the audit report. Technically the audit belongs to IMD-PQS but the IMD-PQS Secretariat will often send the report to the laboratory once it is satisfied with the accuracy and quality of the report.

7.10. Accreditation

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

7.10.2. WHO publishes relevant details of every accepted laboratory electronically in .pdf format on the IMD-PQS website, in the format shown in IMD/TP/14b. In addition, notification of publication will be posted on the TechNet-21 forum.

7.11. DISTRIBUTION (Secretariat)

This SOP is distributed to the following individuals and groups:

- IMD-PQS Secretariat,
- All members of the IMD-PQS Working Group, and
- Any WHO employee or consultant who is appointed to audit a testing laboratory.

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 - WHO ePQS-Box /

Sharepoint: Folder "Labs".

9. REVISION HISTORY

Version	Reason for revision	Approval	Drafted
01	New document	Approved by I. Gobina	Aug 2019
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 7. PQS updated to IMD-PQS (Immunization Devices Performance, Quality and Safety)	Approved by R. Gaspar	01/2024