 World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT	
	VACCINES ASSESSMENT TEAM	
STANDARD OPERATION PROCEDURE		
DEVELOPING AND PUBLISHING AN IMD-PQS PRODUCT VERIFICATION PROTOCOL		
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1. OBJECTIVE


- 1.1. This SOP provides the procedures for the [IMD-PQS Secretariat](#) (Secretariat), the [IMD-PQS Working Group](#) (WG) and all *Technical Specialists* (TS) commissioned by the [Secretariat](#) to follow when developing and publishing [product verification protocols](#).
- 1.2. [Manufacturers](#) may offer products for assessment that they believe will meet the performance standards set out in the [performance specification](#). [Products](#) that are demonstrated to meet these standards via the testing procedures set out in the relevant [verification protocol\(s\)](#) will be granted prequalified status and are included on the IMD-PQS database. This database enables national immunization to identify appropriate products.

2. SCOPE

- 2.1. This SOP is applicable to all product verification protocols prepared under the IMD-PQS initiative, with the exception of syringes.
- 2.2. All IMD-PQS performance specifications in the following product categories require an IMD-PQS [verification protocol](#), with the exception of syringes (Syringes are prequalified on the basis of ISO standards, as described in the World Health Organization document: "*Prequalification of single-use injection devices under the IMD-PQS system: Guidelines for manufacturers*"):
 - E001: [Cold rooms, freezer rooms, and related equipment](#)
 - E002: [Refrigerated vehicles](#)
 - E003: [Refrigerators and freezers](#)
 - E004: [Cold boxes and vaccine carriers](#)
 - E005: [Coolant-packs](#)
 - E006: [Temperature monitoring devices](#)
 - E007: [Cold chain accessories](#)
 - E010: [Waste management equipment](#)

3. CROSS-REFERENCES


Relevant KPI(s):	Nil
Background:	https://extranet.who.int/pgweb/immunization-devices

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Under this SOP:	<ul style="list-style-type: none"> • IMD/TP/04a: Standard format for a type-examination protocol • IMD/TP/04b: Standard format for a type-testing protocol • IMD/TP/04c: Standard format for a quality assurance protocol
Other QMS documents:	<ul style="list-style-type: none"> • IMD/SOP/01: Development 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/05: Reviewing and revising an IMD-PQS product verification protocol. • IMD/SOP/06: Withdrawing an IMD-PQS product verification protocol.

4. DEFINITIONS

Approved installer	A person or organization approved by the legal manufacturer or reseller as a competent installer of the system components and who has been appointed by the Employer to carry out the installation of the System.
Device	A medical device such as a syringe or temperature monitor.
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,

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	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
Manufacturer	In the context of this SOP, the word manufacturer includes both legal manufacturers and resellers.
Legal manufacturer	<p>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.</p> <p>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.</p>
Product	In this document, where the word 'product' is used on its own, it includes device.
Production-run product	"Samples" of the product submitted for IMD-PQS prequalification that are commercial-run / production-run products, NOT prototypes or models of products.
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
Universal design	The design of products and services that address the needs of the widest possible audience, irrespective of age or ability. Also called <i>Inclusive Design</i> or <i>Design for all</i> .
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..

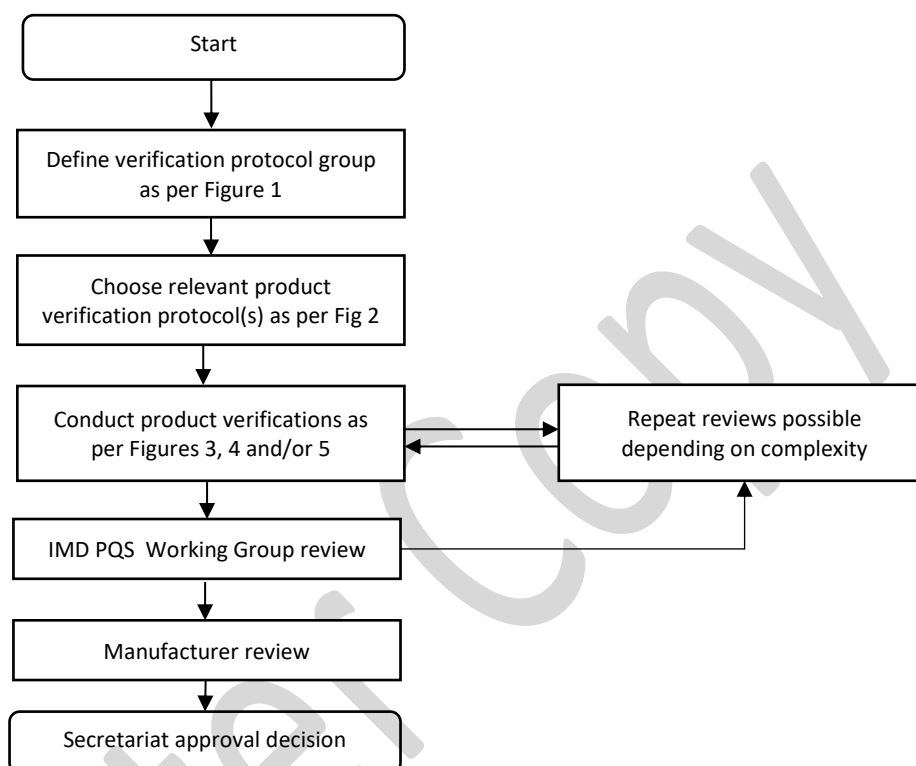
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5. RESPONSIBILITIES

A Technical Specialist (TS)	<ul style="list-style-type: none"> • Drafts the verification protocol in consultation with the WG; and • Revises the draft verification protocol based on the WG, peer and manufacturer reviews and submits a final draft to the Secretariat.
IMD-PQS Working Group (WG)	<ul style="list-style-type: none"> • Documents the need for a new verification protocol; • May prepare draft design criteria for the required product or device; • Sends the proposal to the IMD-PQS Secretariat (this may take place at any time); • Where requested by the Secretariat, solicits information and input from country EPI to inform prioritisation of protocol development; and • Reviews draft verification protocol and provides input to TS.
IMD-PQS Secretariat	<ul style="list-style-type: none"> • Examines the proposal and, if satisfied of the need, directs that a new verification protocol be commissioned; • Commissions a Technical Specialist to develop the draft verification protocol; • Reviews draft verification protocol and provides input to TS; • Requests WG review(s) of draft verification protocol; • Arranges for as peer review and manufacturer review of draft verification protocol; • Takes the decision for final approval of the document; and • Publishes the final verification protocol to the IMD-PQS website and circulates it to the relevant members of staff of WHO, UNICEF and manufacturers.

6. HIGH LEVEL FLOW CHART SUMMARY


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7. PROCESS STEPS

7.1. Introduction

- 7.1.1. A [verification protocol](#) is comprehensive, unambiguous and written in a consistent manner, in a 'neutral' style. This helps to avoid favouring [products](#) from a particular [manufacturer](#) or from a particular country or geographical region.
- 7.1.2. Wherever possible it cites any relevant ISO or other published normative references that are directly applicable to the specified [product](#) or to its component parts.
- 7.1.3. Finally, it complies fully with WHO immunization policies and guidelines current at the time of publication.
- 7.1.4. Figures 1 to 5 in this document provide an overview of the various stages in the development of a [verification protocol](#) and other associated protocols in the process. These protocols are described in more detail in the following paragraphs.

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7.1.5. Each of the task headings below includes (in brackets) a description of the person or group responsible for the task.

7.1.6. The IMD-PQS [Secretariat](#) reviews and signs off a [verification protocol](#) and all its subsequent revisions. All revisions are accurately recorded in the verification protocol's *revision history form*.

7.2. Product verification (IMD-PQS Secretariat, WG and TS)

7.2.1. [IMD-PQS Secretariat](#), [WG](#) and TS verify a [product](#) before it can be added to the list of prequalified [products](#) in the IMD-PQS database.

7.2.2. *Verification* establishes whether a specific [product](#) from a specific [manufacturer](#) satisfies the requirements of the relevant IMD-PQS [performance specification](#). There are three distinct methods:

7.2.2.1. Type-examination,

7.2.2.2. Independent type-testing, and

7.2.2.3. Full quality assurance.

7.2.3. Effective quality control (QC) throughout the [manufacturing](#) process is an essential prerequisite for consistent [product](#) quality.

7.2.4. In the absence of effective QC procedures, laboratory testing (which relies on a limited number of [production-run product](#) samples) cannot provide the assurance that a [product](#) will perform satisfactorily in the field.


7.2.5. Consequently, a key element of all three of the verification routes described below is an examination of the [manufacturer's](#) QC procedures.

7.2.6. The distinction between the first two routes and the *Full quality assurance* route is that examination of QC in the latter case extends to on-site operations.

7.2.7. **Type-examination** verification involves the systematic inspection of [production-run product](#) samples supplied by the [product manufacturer](#) who wishes to be prequalified. The technique is checklist-based.


7.2.7.1. It is a suitable verification method for technologically simple items that are supplied in relatively small quantities.

7.2.7.2. Where the risks (e.g. risks to life of patients, or major loss of vaccine potency) associated with [product](#) failure are low, type-examination may also be a suitable method of verification for simple high-volume items as well as for more complex items that are supplied in small quantities. (Product failures should be reported and corrective actions taken by manufacturer; such as the

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replacement of goods, or correction of the manufacturing process. See SOP IMD/SOP/13 – Obtaining feedback on the performance of an IMD-PQS product.)

- 7.2.7.3. Type examination verification may also be justified where quality control standards in the relevant industry are uniformly high.
- 7.2.7.4. Type examination can be carried out in-house by WHO and UNICEF or the work may be delegated to an independent inspecting organization.
- 7.2.7.5. Alternatively, a *type examination certificate*, issued by a reputable independent body, may be an acceptable substitute.
- 7.2.8. **Independent type-testing** verification involves the physical testing of a number of [production-run product](#) samples against a rigorously defined test [verification protocol](#).
 - 7.2.8.1. This route is required for complex high value [products](#) and also for simple high-volume [products](#) where the issues that may arise from [product](#) failure are high-risk.
 - 7.2.8.2. Independent type testing must be carried out by an ISO/IEC 17025 accredited testing laboratory.
- 7.2.9. **Full quality assurance** verification is required for complex high value, low volume [products](#) which require an element of site-specific design as well as on-site assembly and commissioning work; cold rooms and standby generator installations are examples that fall into this category.
 - 7.2.9.1. [Manufacturers](#) or [approved installers](#) offering such [products](#) cannot be prequalified solely on the basis of type-examination or type-testing because every instance of the [product](#) will in some way be unique.
 - 7.2.9.2. Instead, prequalification must be based on a thorough assessment of technical specifications and quality control procedures, supported by references from other customers.
 - 7.2.9.3. To achieve full quality assurance, the [manufacturer](#) or [approved installer](#) must generally be ISO 9001-accredited; in most cases the completed installation will also be inspected and approved by an independent inspecting organization. (See SOP No IMD/SOP/01: Developing and publishing a IMD-PQS product performance specification Annex 1).
 - 7.2.9.4. The fees for the independent inspection are paid either by the donor agency that has paid for the equipment, or by the client government.

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7.3. Establish a verification protocol grouping (IMD-PQS Secretariat, TS, WG)

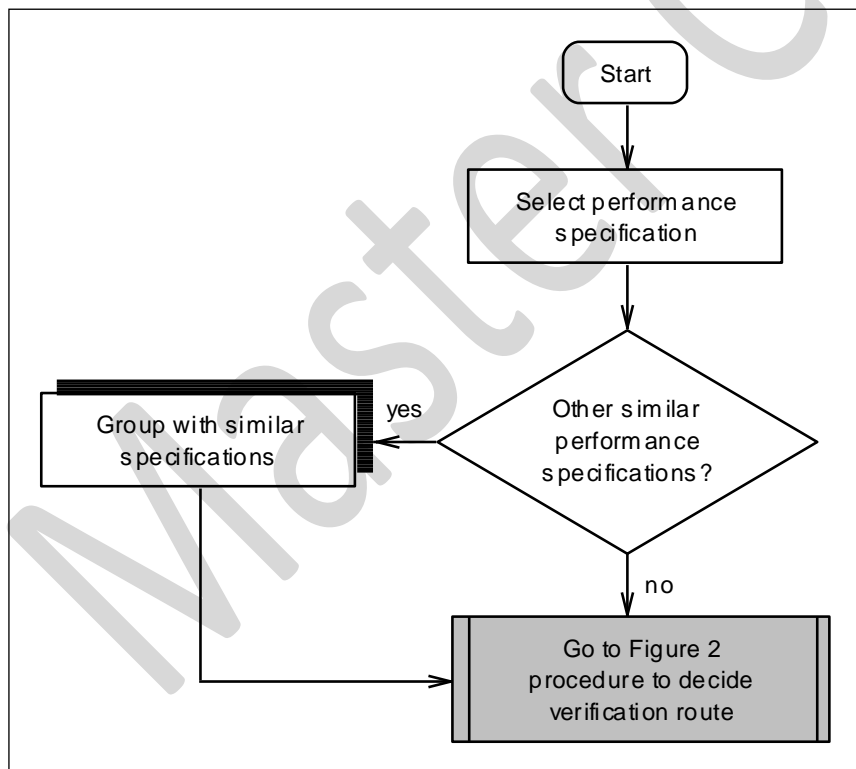
7.3.1. Every [product performance specification](#) is associated with a compatible [verification protocol](#).

7.3.2. In some cases, a [performance specification](#) has its own unique [verification protocol](#).


7.3.3. In other cases, a [verification protocol](#) is common to a group of specifications. For example, all absorption cycle refrigerators may use the same [verification protocol](#), even though there may be more than one [performance specification](#) for this category of equipment.

7.3.4. The TS, in consultation with the WG, agrees this basic *verification protocol group*. Figure 1 outlines this process.

Figure 1 – Define the verification protocol group

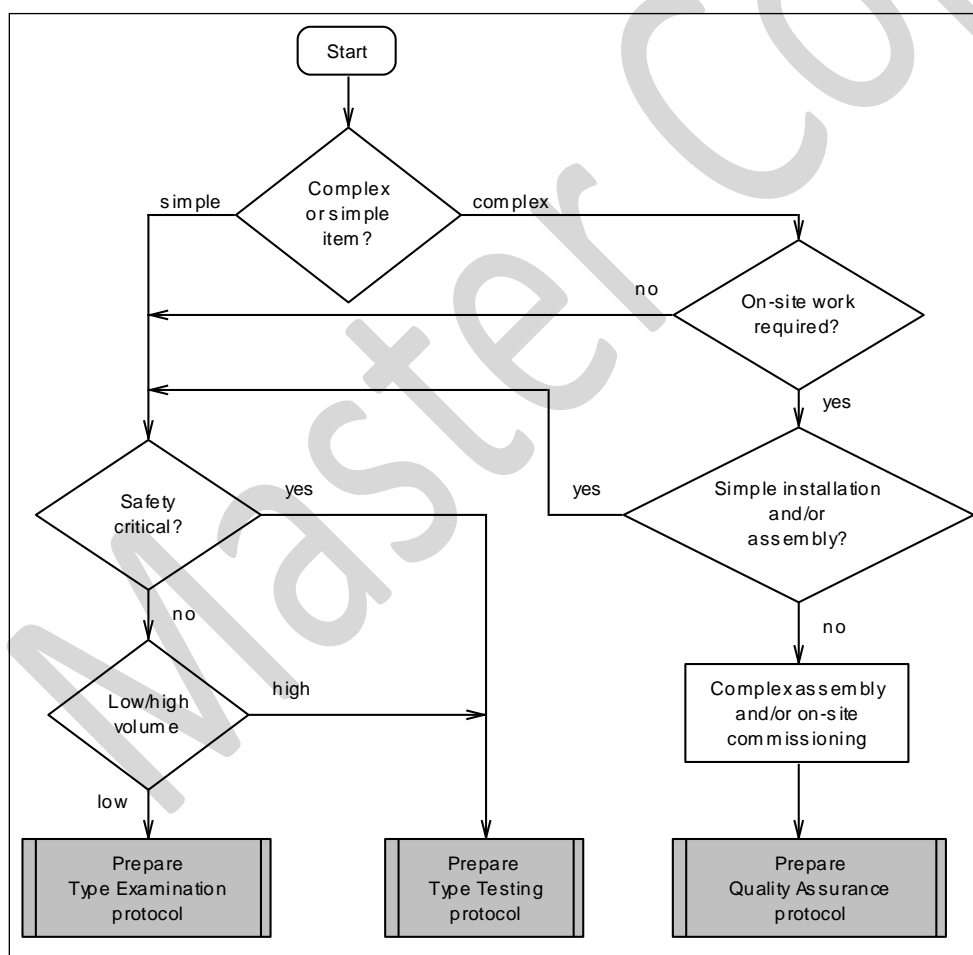



7.4. Agree a verification route for each grouping (TS, WG)

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- 7.4.1. Figure 2 shows the decision tree for selecting the suitable [product](#) verification route, using criteria set out in Clause 7.3.
- 7.4.2. The TS, in consultation with the [WVG](#), follows this procedure and decides which of the three verification routes are chosen for a particular grouping of equipment or devices.
- 7.4.3. For safety-critical items the default decision is generally to adopt type-testing, unless the quality control standards of *all* prequalifying [manufacturers](#) are likely to be high.

Figure 2 – Choose the product verification protocol type



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7.5. Prepare a verification protocol (TS, WG)

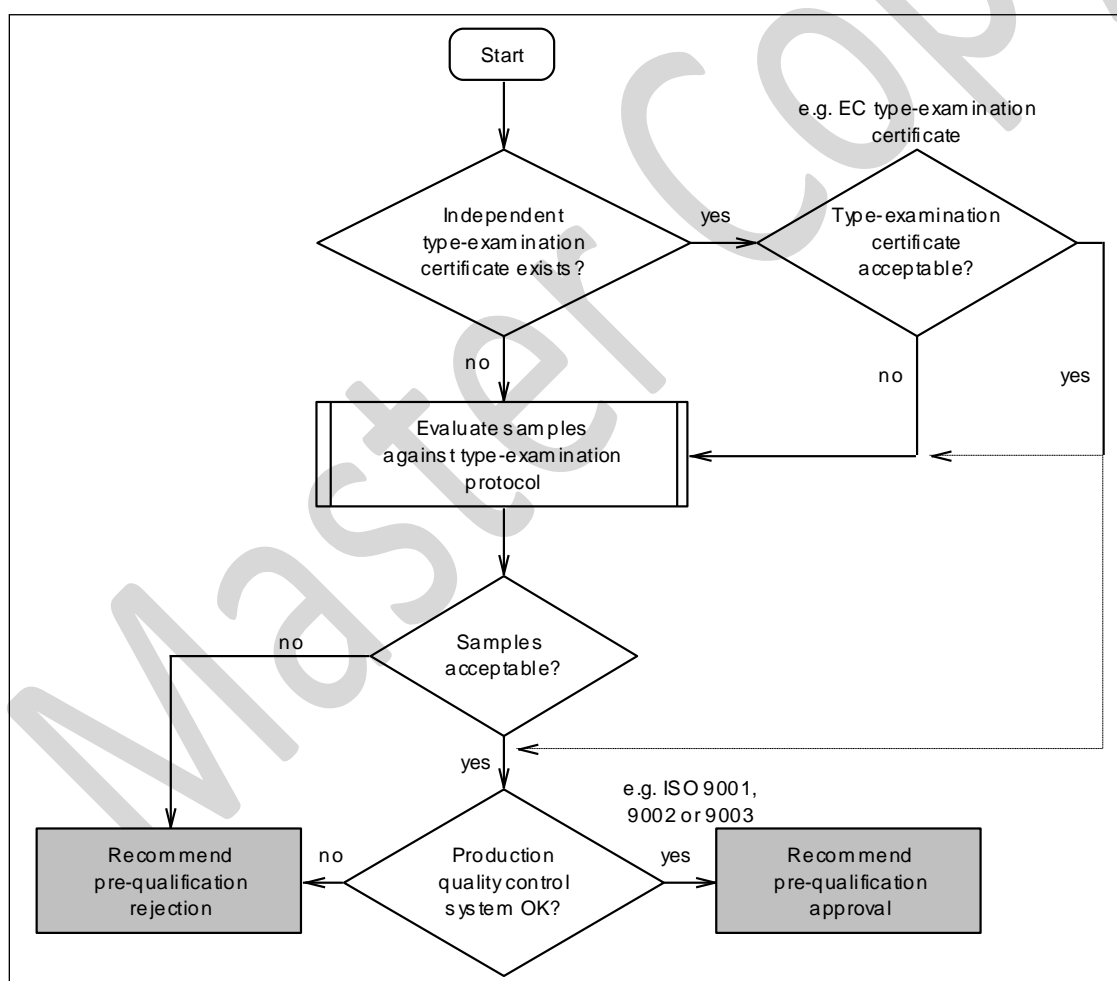
7.5.1. Once a verification route has been chosen the TS prepares the relevant protocol.


7.5.2. The TS consults with the WG and considers controlled recommending the inclusion of field trials in the [product](#) verification process.

7.5.3. The following sections describe how to prepare each type of [verification protocol](#).

7.5.4. Prepare a type-examination protocol

Figure 3 – Type-examination protocol



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Document IMD/TP/04c provides a model format for a type examination protocol.

- 7.5.4.1. A *Type Examination Certificate* is evidence that the [product](#) conforms to certain minimum standards; it is only accepted if it has been issued by a recognised independent body and if the standards certified are at least as stringent as those set out in the [product performance specification](#).
- 7.5.4.2. If this is the case, then it may not be necessary to evaluate samples against the assessment checklist. However, if there is any doubt about quality or suitability carry out these additional checks.
- 7.5.4.3. No [products](#) are prequalified unless the [manufacturer](#) can show that they have a satisfactory production *Quality Control* system in place.
- 7.5.4.4. Ideally the system is required to be certified or audited by a *Notified body* in accordance with the ISO 9000 series standard(s) appropriate to the industry. If there is any doubt about the standard of quality control, an on-site inspection of the production facilities is carried out. The UNICEF Quality Assurance Centre also inspects the premises and Quality Control systems of many of its manufacturers as part of its normal procurement procedures. If the [manufacturer](#) subsequently modifies a prequalified [product](#), they are required to notify WHO of the alteration(s) under the change notification procedure set out in the relevant IMD-PQS [performance specification](#). See SOP IMD/SOP/01: Developing and publishing a IMD-PQS product performance specification Annex 1.


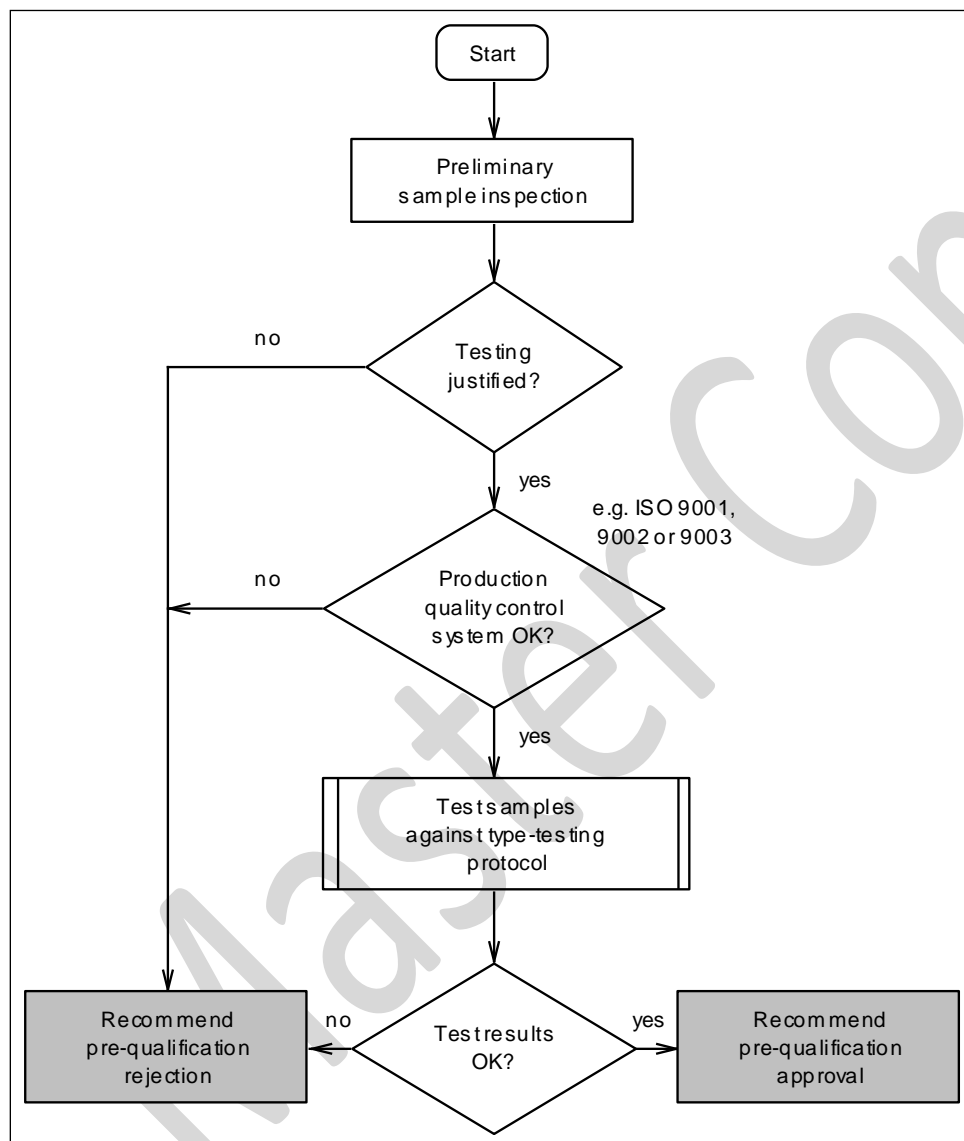

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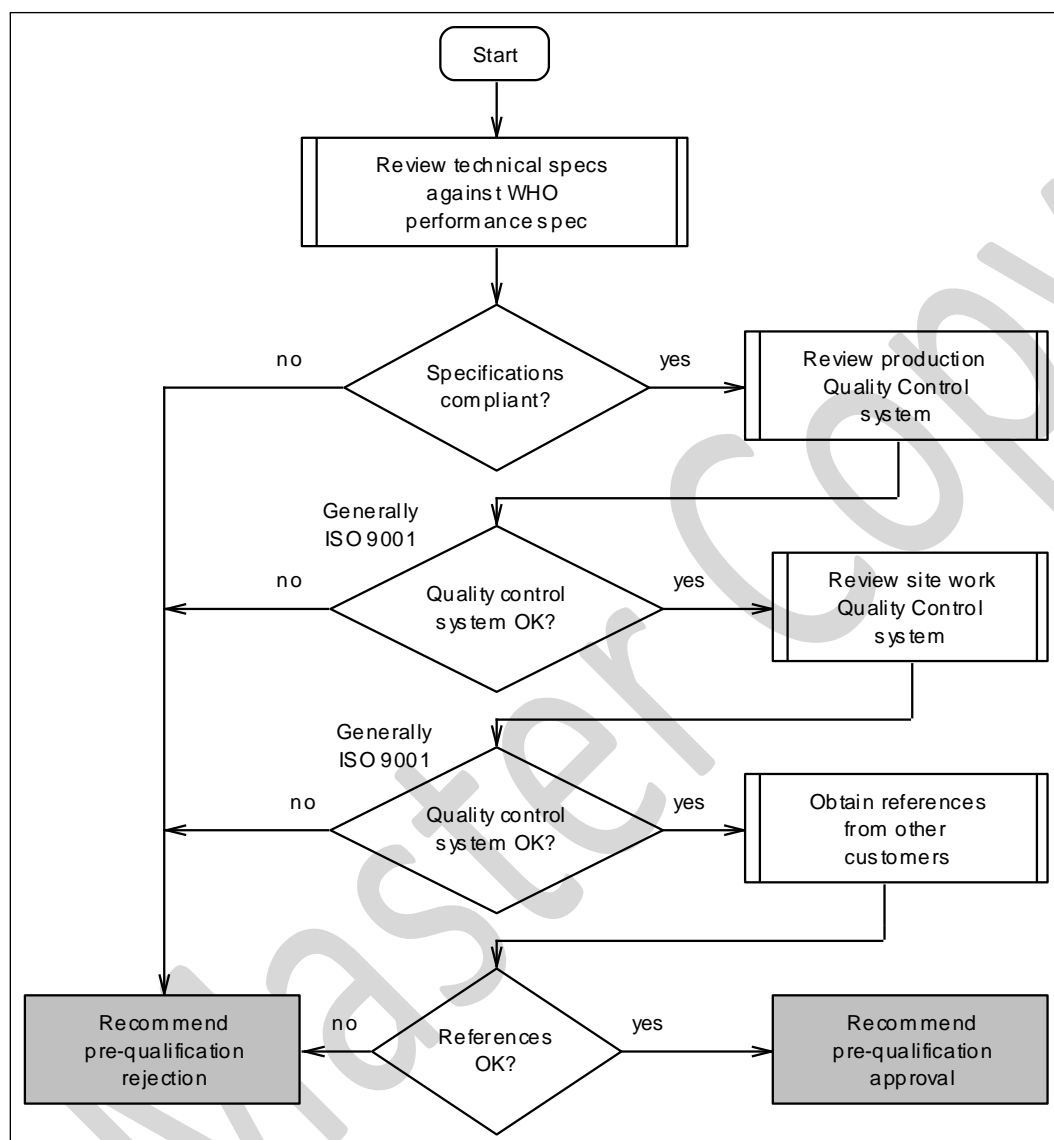
Figure 4 – Independent type-testing protocol



Document IMD/TP/04b provides a model format for an independent type-testing protocol.

Figure 5 – Quality assurance protocol

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Document IMD/TP/04c provides a model format for a quality assurance protocol.

7.6. Review process (Secretariat, WG, Manufacturers, TS)

7.6.1. The [Secretariat](#) requests the [WG](#) to review the draft [verification protocol](#).

7.6.2. The draft protocol goes through at least one round of [WG](#) review, with the initial reviewing lasting approximately four to six weeks.

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7.6.3. The number of reviews is determined by the complexity of the protocol and decided at the discretion of the [Secretariat](#).

7.6.4. Subsequent rounds of [WG](#) review align (at the latest) with the [WG](#) quarterly meetings.

7.6.5. The [Secretariat](#) determines when the draft protocol is ready for [manufacturer](#) review.

7.6.6. The [Secretariat](#) sends the draft protocol to [manufacturers](#) for review, via email and by posting to the IMD-PQS website. [Manufacturers](#) are given one month to respond with comments.

7.6.7. The WG Lead/s and/or TS collate all [manufacturers'](#) comments and prepare a revised draft with recommendations for the WG and [Secretariat](#) to review.

7.6.8. The [Secretariat](#) incorporates [WG](#) and [Secretariat](#) comments into a revised draft. The [Secretariat](#) determines if another round of [manufacturer](#) review is required.

7.6.9. Depending on the complexity and issues that may arise from the [manufacturer](#) review, there may need to be multiple [manufacturer](#) review cycles.

7.7. Documenting revisions (TS, WG and/or Secretariat)

7.7.1. All changes are clearly identified in the 'revisions' section of the protocol.

7.7.2. The [Secretariat](#) is responsible for approving all revisions.

7.7.3. The revision section of the [protocol](#) also:

7.7.3.1. Gives the date of the amendment;

7.7.3.2. Identifies the amendment; and

7.7.3.3. Briefly describes the reason for the amendment.

7.8. Approval (Secretariat)


7.8.1. The fully reviewed and corrected [protocol](#) is submitted to the [Secretariat](#) for formal approval. Final decision for approval rests solely with the [Secretariat](#).

7.9. Publication (Secretariat)

7.9.1. Immediately after approval of the amended document, the [Secretariat](#) publishes it on the IMD-PQS website, in electronic (.pdf) format.

7.9.2. In addition, notification of publication is posted on the TechNet-21 website.

7.9.3. The Secretariat informs all IMD-PQS [manufacturers](#) and related innovators of the publication by email.

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7.9.4. The previous edition is archived.

7.10. Distribution (Secretariat)

This SOP is 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 a [verification protocol](#),
- All relevant [manufacturers](#),
- IMD-PQS and TechNet-21 websites.

8. RECORDS

- 8.1. The Secretariat saves product specifications in WHO ePQS-Box / Sharepoint: Folder “Specs, VPs & PQS Guides”
- 8.2. The Secretariat saves verification Protocols in WHO ePQS-Box / Sharepoint: Folder “Specs, VPs & PQS Guides”
- 8.3. IMD Product Catalogue - WHO IMD Prequalification Website: “WHO Catalogue of Prequalified Immunization Devices”.

9. REVISION HISTORY

Version	Reason for revision	Author	Drafted
01	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 1. Hyperlink to each IMD-PQS category added in the ‘Purpose’ clause. 2. Footnotes defining the IMD-PQS Working Group and the IMD-PQS Secretariat added in Clause 5. 3. IMD-PQS system structure simplified, removing FMWG, Steering Group. IVB/QSS is 	Drafted by P. Mallins Approved by I. Gobina	27/01/2017

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	VACCINES ASSESSMENT TEAM	
STANDARD OPERATION PROCEDURE		
DEVELOPING AND PUBLISHING AN IMD-PQS PRODUCT VERIFICATION PROTOCOL		
Doc No: IMD/SOP/04	Version No: 2	Revise before: 15 Jun 2027
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Approved by:	TL-VAX, date: 10 Jun 2024	UH-PQT, date: 13 Jun 2024
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	<p>also renamed EMP/PQT. Revisions to this SOP reflect these changes (text and figures).</p> <ol style="list-style-type: none"> 'Responsibilities' clause revised to separate out specific responsibilities of key actors and to remove process elements. Footnotes added to sub-clause 7.2.7 to define product failure and describe its risks. Clause 7.10 'Distribution' edited to include complete group of stakeholders. 'Terms & definitions' moved to annex, revised, definitions updated in line with WG reviews of IMD-PQS glossary Feb 2018. In Clause 7 'Procedure' an introduction has been added (sub-clause 7.1). Sub-clause of 7 'Prepare a memorandum for the IMD-PQS-SG' removed as standalone sections reflecting the changes to the IMD-PQS system. Clause 7.7 'Documenting revisions' added. Clause 7.6 expanded to cover full 'Review process' and timelines. 		
02	<ol style="list-style-type: none"> Updating to new RPQ format New department, unit and team names Changed supervisors name from Group Lead to Team Lead Assignment of IMD as code for the product stream on PQ of immunization devices and equipment and used for numbering of QMS documents Inclusion of KPIs and their targets where applicable Transforming some annexes into templates related to the SOP PQS updated to IMD-PQS (Immunization Devices Performance, Quality and Safety) 	Approved by I. Gobina	01/2024