World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT
	VACCINES ASSESSMENT TEAM

STANDARD OPERATION PROCEDURE		
RE-EVALUATING A PREQUALIFIED IMD-PQS PRODUCT		
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Approved by:	TL-VAX, date: 31 Oct 2024	UH-PQT, date: 31 Oct 2024
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1. OBJECTIVE

1.1. This SOP describes the procedure for product re-evaluation.

1.2. The IMD-PQS Secretariat *(Secretariat)*, the IMD-PQS Working Group *(WG)* and by all *Technical Specialists (TS)* commissioned by the Secretariat follow these procedures set out in this SOP for re-evaluating prequalified IMD-PQS products.

2. SCOPE

2.1. This SOP is applicable to any product or device prequalified through the IMD-PQS initiative, with the exception of syringes.

2.2. A product can only be prequalified if it complies with the relevant IMD-PQS performance specification and with the related IMD-PQS product verification protocol.

2.3. Once a product has been prequalified it must be re-evaluated annually to ensure that it continues to be fit for purpose.

2.4. The SOP covers the re-evaluating process of all immunization-related products or devices in the following categories before they can be maintained to the IMD-PQS database (*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):	• KPI Website: https://extranet.who.int/prequal/about/who-prequalification-key-performance-indicators-kpis • % IMDs prequalified ≤ WHO target time for full assessment (120 days) • % IMDs prequalified ≤ Manufacturer target time for full assessment (30 days)

	• % of IMDs post-PQ reportable change 1st actions ≤ target time (30 days)
Background:	• https://extranet.who.int/pqweb/immunization-devices/product-evaluation-and-re-evaluation • WHO/BCT/03.09: Procedure for assessing the acceptability, in principle, of single-use injection devices for procurement by United Nations agencies. • Declaration of Interests (WHO Experts)
Under this SOP:	• IMD/TP/10a: Standard letter A - Notification of problems identified during product re-evaluation • IMD/TP/10b: Standard letter B - Notice of suspension of prequalification status • IMD/TP/10c: Model format for product re-evaluation report • Information brief to IMD PQ applicants v3: Revisions to the administration of payment of prequalification fees.
Other QMS documents:	• 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/04: Development 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/09: Evaluating a prequalified IMD-PQS product • IMD/SOP/11: Removing a prequalified product from the IMD-PQS database

4. DEFINITIONS

Device	A medical device such as a syringe or temperature monitor for example.

Evaluator	An individual or organization (including a testing laboratory) responsible for evaluating the suitability of the components and services described in this specification for inclusion in the register of IMD-PQS prequalified products.
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)	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
In writing	Communication by letter, fax or email. (A hard copy will be kept on file.)
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.
Performance Specification	An IMD-PQS product performance specification is a published standard which sets out the detailed performance requirements for an immunization-related product. A performance specification defines the functional requirements of a product and describes the environment within which it must operate. It also describes any interface and inter-changeability requirements. Although it should set out clear verification criteria, it must not attempt to describe how the functional requirements are to be met. Rather, stimulating the device manufacturer to determine how the functional requirements may be best met creates room for innovation.
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.
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*.

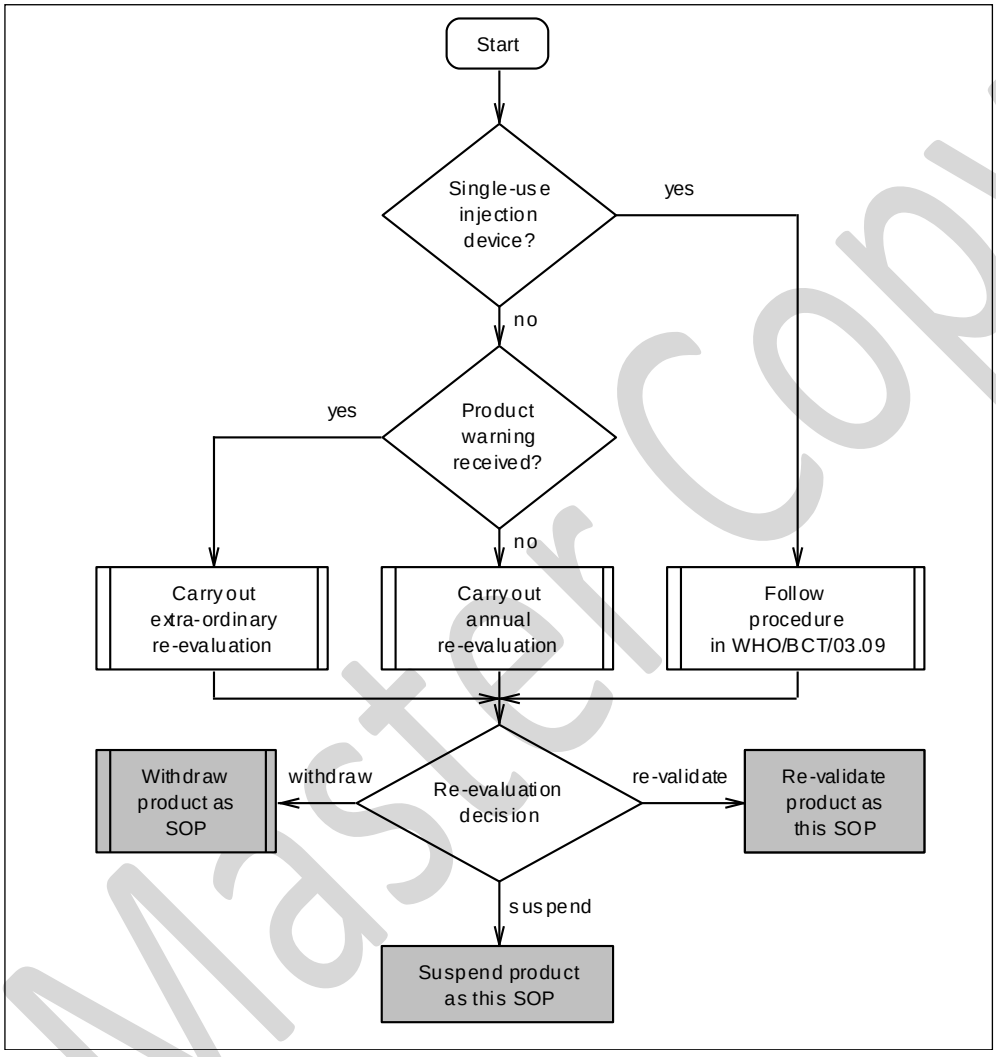
5. RESPONSIBILITIES

IMD-PQS Working Group (WG)	• Re-evaluates product dossiers; and • Makes recommendations to the Secretariat.
Technical Specialist (TS)	• Re-evaluates dossiers as directed by the Secretariat; and • Makes recommendations to Secretariat.

IMD-PQS Secretariat	• Ensures that every product on the database is re-evaluated annually; • Receives dossiers from applicants, establishes and maintains a register that records the details of all applications for product prequalification; • Convenes Working Group (WG) members and/or Technical Specialists to carry out annual review; • Reviews product dossiers; • Corresponds with applicants if any clarifications are required on product dossiers; • Takes the final decision to retain, suspend or remove a product's prequalified status; • Informs IMD-PQS product manufacturers of their decision; and • Publishes re-evaluation status on the IMD-PQS website and circulates it to the relevant members of staff of WHO, UNICEF and manufacturers.

6. HIGH LEVEL FLOW CHART SUMMARY

Figure 1 – Re-evaluation process



7. PROCESS INSTRUCTIONS

7.1. Identifying the need for withdrawal of a specification (WG)

7.1.1. The WG identifies performance specifications which may need to be withdrawn for any of the following reasons:

7.1.1.1. Feedback from country EPI programmes;

7.1.1.2. WHO and UNICEF immunization programme changes;

7.1.1.3. Comments received from testing laboratories, technical specialists and manufacturers identifying fundamental technical shortcomings in the performance specification;

7.1.1.4. Feedback reports from field monitoring activities highlighting fundamental specification-related problems; or

7.1.1.5. Technical or other developments which may render a performance specifications obsolete.

7.1.2. The WG sends its withdrawal proposals to the Secretariat for formal approval. This can happen at any time but usually occurs at the next IMD-PQS WG quarterly meeting.

7.2. Re-evaluation for single-use injection devices (Secretariat)

7.2.1. All re-evaluations relating to single-use injection devices are processed strictly in accordance with the procedure described in document WHO/BCT/03.09: *Procedure for assessing the acceptability, in principle, of single-use injection devices for procurement by United Nations agencies.*

7.2.2. As with other IMD-PQS products, the Secretariat files its decisions in the IMD-PQS product register.

7.3. Re-evaluation for all other products (Secretariat)

7.3.1. The Secretariat is responsible for the re-evaluation process.

7.3.2. Normally the Secretariat carries out a re-evaluation on an annual basis. However, there are circumstances when it may be necessary to carry out an extraordinary re-evaluation.

7.3.3. *A re-evaluation exercise considers the following:*

7.3.3.1. UNICEF Supply Division Quality Assurance Centre (QAC) reports;

7.3.3.2. Results of structured field performance monitoring;

7.3.3.3. Performance feedback from governments and donor agencies;

7.3.3.4. Manufacturers' Change Notifications (See *IMD/SOP/04: Development and publishing a IMD-PQS product verification protocol. IMD/TP/04a)*;

7.3.3.5. Manufacturers' Product Defect Reports (Ibid);

7.3.3.6. Questionnaires;

7.3.3.7. Anecdotal reports from the field; and

7.3.3.8. Relevant policy decisions.

7.3.4. *Annual re-evaluation*

7.3.4.1. The normal annual re-evaluation exercise takes place on an agreed date each year.

7.3.4.2. It covers all products on the IMD-PQS database irrespective of the original date of acceptance of the product onto the database.

7.3.4.3. Thus, in the first year following prequalification, a product may be re-evaluated less than 12 months.

7.3.5. *Extraordinary re-evaluation*

The Secretariat conducts an extraordinary re-evaluation under the following circumstances:

7.3.5.1. If and when major changes have been made to the product;

7.3.5.2. If there has been a failure on the part of the manufacturer to notify WHO of complaints received about the product;

7.3.5.3. If UN agencies or organizations have reported receiving non-compliant products; and/or

7.3.5.4. If complaint investigations have indicated significant quality or safety defects.

If such circumstances arise, the product must be re-evaluated *immediately*.

7.3.6. *Courses of action*

7.3.6.1. Where minor concerns regarding quality or performance have come to light, the Secretariat notifies the manufacturer and asks for comments, using *Standard letter A* (IMD/TP/10a) for this purpose.

7.3.6.2. Where major concerns arise, it may be necessary to suspend a product's prequalification status; for example, a product change has resulted in a material reduction in performance, or a change in manufacturing site has resulted in a noticeable loss of quality.

7.3.6.3. In these circumstances, the Secretariat uses *Standard letter B* (IMD/TP/10b) to notify the manufacturer, who is given the following options:

7.3.6.3.1. In the case of *quality concerns:* To satisfy the Secretariat that quality issues have been addressed;

7.3.6.3.2. In the case of *performance concerns:* To re-test against the current verification protocol; or

7.3.6.3.3. To withdraw the product voluntarily.

7.3.6.4. The Secretariat requests the manufacturer to act within six months of the date of notification.

7.3.6.5. In the event of any dispute or disagreement between the manufacturer and WHO arising from or relating to the prequalification reassessment process, an SOP (PQT/SOP/04) established by WHO for the handling of such disputed and disagreements is followed to discuss and resolve the issue.

7.4. Re-evaluation report (Secretariat)

7.4.1. In the case of an extraordinary re-evaluation, the Secretariat prepares a special re-evaluation report for circulation to the WG.

7.4.2. In the case of the annual re-evaluation, the Secretariat prepares a report covering all products on the database. Reports follows the format set out in IMD/TP/10c.

7.5. Approval process (Secretariat)

7.5.1. The Secretariat reviews the recommendations in the re-evaluation report and takes the final decision to either to re-validate, to suspend or to withdraw a product.

7.6. Subsequent action (Secretariat)

7.6.1. The Secretariat files its decisions in the IMD-PQS product register.

7.6.2. Products that are directed to be withdrawn are processed in accordance with *IMD/SOP/11: Removing a prequalified product from the IMD-PQS database.*

7.6.3. Products that are suspended are followed up to ensure that the manufacturer responds adequately.

7.6.4. The suspension is not lifted until the manufacturer has responded effectively.

7.6.5. In addition, the relevant IMD-PQS website entry is overwritten with the words:

PRODUCT SUSPENDED ON <DD.MM.YY>

7.6.6. UNICEF Supply Division is also notified of the notice of suspension.
7.6.7. No further action is required for products that are to be re-validated.

7.7. 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 the product prequalification process,
- All relevant manufacturers,
- IMD-PQS and TechNet-21 website.

8. RECORDS

8.1. The Secretariat saves Annual Review dossiers in WHO ePQS-Box / Sharepoint: Folder "Annual Review <YEAR>" & "Annual Reviews".
8.2. The Secretariat saves revalidation letters in WHO ePQS-Box / Sharepoint: Folder "Annual Reviews".
8.3. The Secretariat saves notices of suspension in WHO ePQS-Box / Sharepoint: Folder "Annual Reviews".

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
01.06	4. Hyperlink to each IMD-PQS category added in the 'Purpose' clause.	Drafted by P. Mallins	27/01/2017

	5. Footnotes defining the IMD-PQS Working Group and the IMD-PQS Secretariat added in Clause 5. 6. 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). 7. 'Responsibilities' clause revised to separate out specific responsibilities of key actors and to remove process elements. 8. Clause 7.7 'Distribution' edited to include complete group of stakeholders. 9. 'Terms & definitions' moved to annex, revised, definitions updated in line with WG reviews of IMD-PQS glossary Feb 2018. 10. Added sub-clause 7.1 'Identifying the need for withdrawal of a specification.'	Approved by I. Gobina	
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 PQS updated to IMD-PQS (Immunization Devices Performance, Quality and Safety)	Approved by I. Gobina	04/2024