1. OBJECTIVE

1.1. To describe the processes on field-tests of products carried out under the IMD-PQS initiative.

2. SCOPE

2.1. This SOP outlines field-testing methods, for products being evaluated for WHO prequalification of immunization devices, indicates which of these is suitable for testing the various categories of immunization-related equipment and provides guidance on the development of field-test protocols.

2.2. It also establishes the administrative framework within which an IMD-PQS field-test should take place. This requires the active cooperation of national EPI programme managers, as well as the assistance of technical staff in WHO/UNICEF country and regional offices.

2.3. The purpose of IMD-PQS field studies is to ensure that devices and/or technologies perform according to the performances specifications when used in field settings, are acceptable to end-users and have no significant negative impacts on the health system.

2.4. Field testing is generally mandatory for products with the following characteristics:

2.4.1. Based on technology(ies) not previously employed in immunization or general health programmes in the developing world;

2.4.2. Require creation of a new IMD-PQS equipment category;

2.4.3. Consist of a new technology not previously IMD-PQS prequalified;

2.4.4. Require a substantial IMD-PQS modification, such as a need for specific tests not covered in the current verification protocols;

2.4.5. Require specific user training to be operated effectively;

2.4.6. Risk being rejected by health workers or patients; and/or

2.4.7. Product has an R&D history of technical failures.

2.5. In addition, field testing may also be justified for products which are safety-critical or which are used in very large quantities.

2.6. Field-testing provides manufacturers with information to improve product design and it can also help end-users to choose products that are best suited to their needs.

2.7. However, if test results are to be useful, there must be a completely clear understanding of the purpose to which they will be put.

2.8. This requires well-developed evaluation techniques and protocols based on standardised criteria.

2.9. The aim must be to obtain the maximum amount of useful information on product performance at minimum cost and with minimum disruption to the working lives of health care staff.

2.10. The IMD-PQS Secretariat (Secretariat), the IMD-PQS Working Group (WG), by all product manufacturers, implementing partners and Ministries of Health (MoH) involved in field testing an IMD-PQS product follow these procedures set out in this SOP for re-evaluating prequalified IMD-PQS products.

2.11.

3. CROSS-REFERENCES

Relevant KPI(s):	Nil
Background:	• *https://extranet.who.int/pqweb/immunization-devices/guides-and-resources* • WHO/IMD-PQS/GENERIC/GUIDE.1.1: *Generic Guide for the field evaluation of new technologies for IMD-PQS prequalification*: https://extranet.who.int/prequal/sites/default/files/document_files/Generic%20Guide%20For%20Field%20evaluation_4.pdf • Product performance specification relating to the product(s) under test. • Product verification protocol relating to the product(s) under test.
Under this SOP:	• Nil
Other QMS documents:	• IMD/SOP/01: Developing and publishing an IMD-PQS product performance specification. • IMD/SOP/03: Withdrawing an IMD-PQS product performance specification. • IMD/SOP/13: Obtaining feedback on the performance of an IMD-PQS product

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

Implementing partner(s)	• Remains independent and impartial

Ministries of Health (MoH)	• Approves the field test protocol; and • Provides required access for the implementing partner
Manufacturer	• Commissions a field test protocol; • Identifies implementing partner; • Funds the field test; and • Obtains country approvals for the field study.
IMD-PQS Secretariat	• Maintains a prioritised list of product types which justify field-testing and recommends appropriate field-tests for each of these types; • Determines, if a product requires field testing as part of the prequalification process including, if required consultation with the Working Group (WG); • Approves a protocol and/or implementing partner; • Reviews field studies proposals and field test reports; • Examines the proposals in liaison with the Working Group (WG) if deemed appropriate and, if satisfied of the need, directs that a model field-testing protocol be commissioned; and • Stores field test reports in the product dossier.

6. HIGH LEVEL FLOW CHART SUMMARY

Figure 1 – Field-testing techniques

Method	Strengths	Weaknesses
Field-survey	• Can produce statistically reliable, quantitative results. • Able to capture multi-dimensional factors, including user behaviour.	• Can be time consuming and expensive to administer. • Dependent on skills and motivation of the survey team.
MSF/WHO tool for the assessment of single use	• Well-researched product-specific tool. • Satisfactory internal consistency.	• Does not yet ensure with certainty 'reproducibility over time'.

injection devices (*Ibid* p.14)	• Can produce quantitative results.	
Real-time instrumentation	• Relatively cheap to administer. • Provides accurate and complete quantitative records. • Enables continuous monitoring to take place over extended time periods.	• Narrowly focused on a specific indicator. • Cannot directly capture user behaviour.

Figure 2 indicates which of the three techniques may be appropriate for the various categories of equipment on the IMD-PQS database. This model may not fit all future IMD-PQS categories

Figure 2 – Field-testing techniques for different categories of equipment

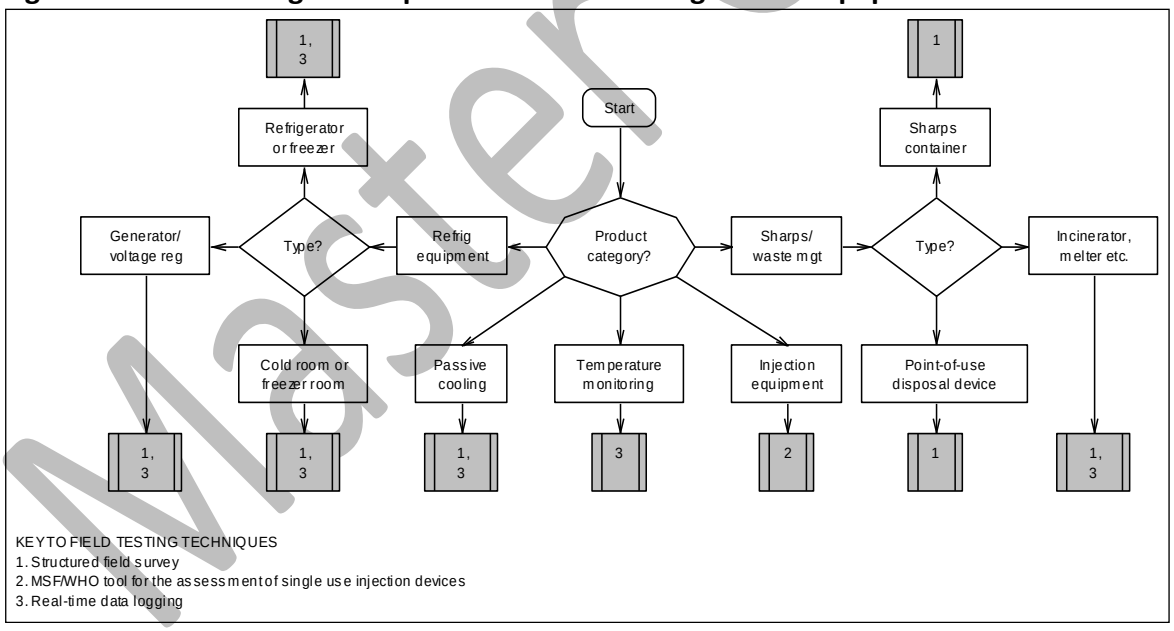
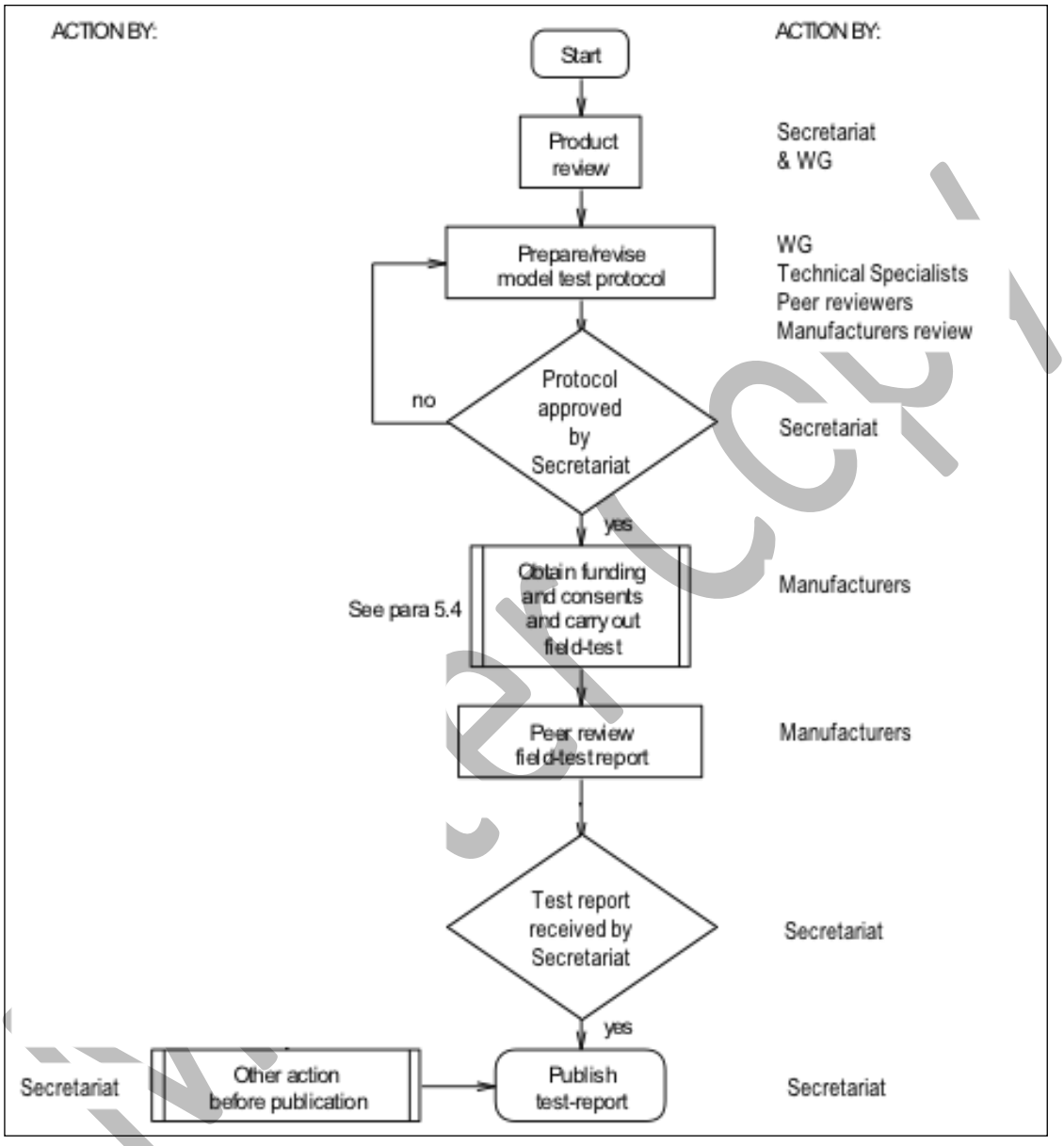


Figure 3 outlines the overall field-testing procedure which is described in more detail in Section 7 onwards.

Figure 3 – Developing a field-test protocol and implementing a field-test



7. PROCESS INSTRUCTIONS

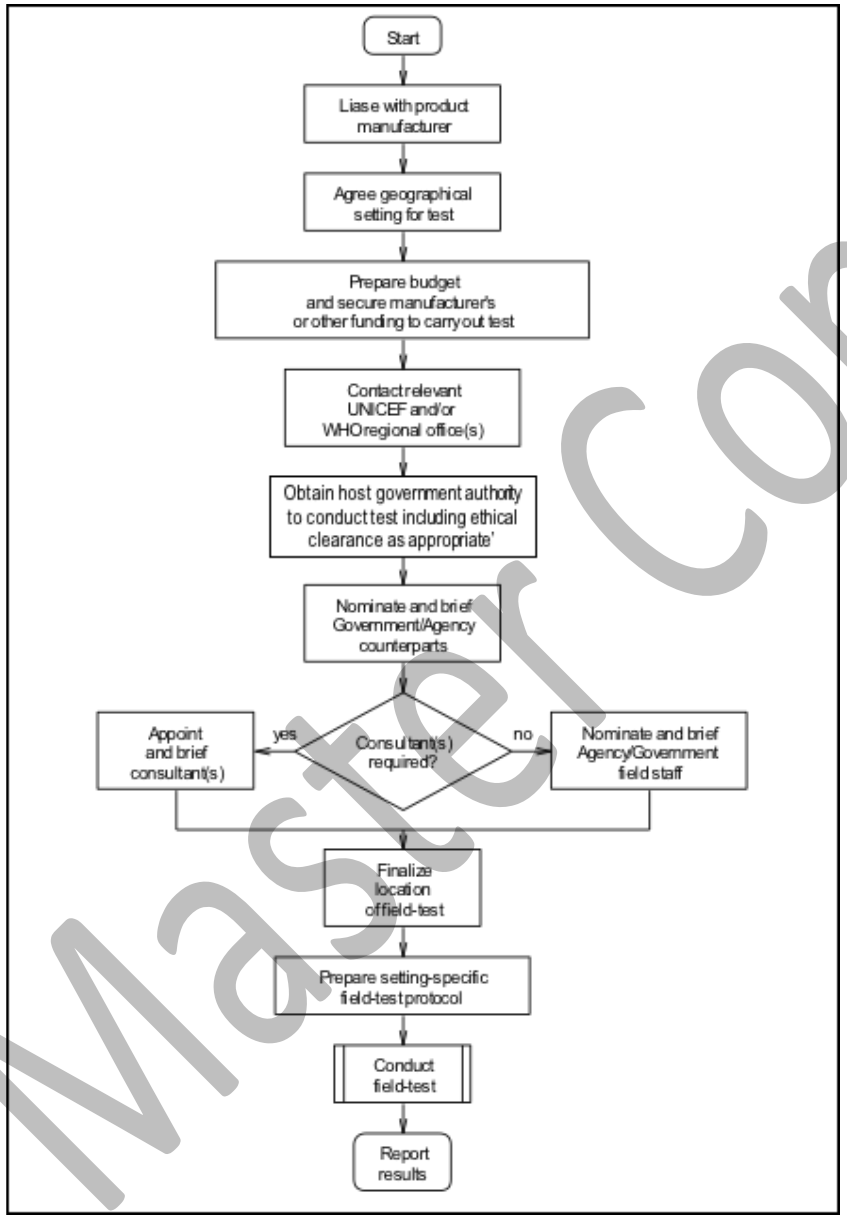
7.1. General

7.1.1. Obtaining good quality information on product performance in the field is a challenge. There are two generic methods that can be used to field-test IMD-PQS products: field surveys and real-time instrumentation.

7.1.2. In addition, there is a tailor-made field-survey based tool which has been specifically designed to evaluate the ease of use of AD syringes (*See Gergonne, B., Grandesso, F., Pinoges, L., Construction and validation of a tool for the assessment of single use injection devices under field conditions MSF Epicentre 2004*).

Figure 4 outlines the process.

Figure 4 – Finalise test protocol and carry out field-test



7.2. Identify products for field-testing (Secretariat)

7.2.1. In the course of its liaison with the Working Group (WG) and *Technical Specialists* (TS) on new and revised IMD-PQS performance specifications and product verification protocols, the Secretariat decides whether field-testing of a specified product is relevant or desirable. See IMD/SOP/1: *Developing and publishing a IMD-PQS product performance specification*. IMD/TP/1b, Clause 4.11.

7.2.2. Based on these discussions, the Secretariat draws up and maintains a *field-testing list.* This list prioritises product types for which field-testing is either mandatory or desirable and specifies the appropriate generic testing method for each product type (see Figure 1).

7.2.3. The Secretariat also maintains a watching brief on the product feedback reports that are posted on the IMD-PQS website. (See IMD/TP/13: *Obtaining feedback on the performance of an IMD-PQS product)*, and may subsequently amend the list to take account of evidence received from the field.

7.2.4. Field testing is generally mandatory for products with the following characteristics:

7.2.4.1. Based on technology(ies) not previously employed in immunization or general health programmes in the developing world;

7.2.4.2. Require creation of a new IMD-PQS equipment category;

7.2.4.3. Consist of a new technology not previously IMD-PQS prequalified;

7.2.4.4. Require a substantial IMD-PQS modification, such as a need for specific tests not covered in the current verification protocols;

7.2.4.5. Require specific user training to be operated effectively;

7.2.4.6. Risk being rejected by health workers or patients; and/or

7.2.4.7. Product has an R&D history of technical failures.

7.2.5. In addition, field testing may also be justified for products which are safety-critical or which are used in very large quantities.

7.3. Prepare model field-test protocol (Implementing partner, manufacturer)

7.3.1. Under normal circumstances the product manufacturer funds the cost of the field-test.

7.3.2. A generic format for a protocol document is provided in the 'Generic Guide for Field Evaluation' (Section IV), which can be accessed at

https://extranet.who.int/prequal/immunization-devices/prequalification-guidance-prospective-prequalification-holders

7.4. Peer review model field-test protocol (Secretariat, WG)

7.4.1. The Secretariat arranges for the field-test protocol to be reviewed.

7.4.2. Once a consensus has been reached between the TS and the reviewers, the WG submits the protocol to the Secretariat for formal approval.

7.4.3. The Secretariat decides which products most urgently need to be tested and prioritises their review by the WG.

7.5. Organize and carry out field-test (Government, manufacturer, implementing partner)

7.5.1. The Secretariat liaises with product manufacturer(s), member government(s), UNICEF and/or WHO regional offices, consultant(s) and to agree funding and set up the field test.

7.5.2. In the normal situation where the test is funded in whole by industry, the product manufacturer submits a copy of the test protocol, the work programme and budget to the Secretariat.

7.5.3. Nominate and brief counterparts (Manufacturer, implementing partner)

7.5.3.1. Once the relevant country's authorisation (including ethical clearance as appropriate) has been obtained, the Secretariat asks the regional/country office(s) to nominate and brief the counterpart(s) who liaise(s) with field staff during the testing programme.

7.5.4. *Finalize test locations* (Manufacturer, implementing partner)

7.5.4.1. The appointed field staff liaises with government and agency counterparts and, where relevant, with manufacturer(s) to finalise the test locations. The appointed field staff includes details in the test report.

7.5.5. *Prepare setting-specific field-test protocol* (Field staff, WG, manufacturer)

7.5.5.1. Using the model field-test protocol as a basis, field staff prepare a *setting-specific field-test protocol.*

7.5.5.2. Changes to the model document are confined to those aspects that have been left 'open' to suit test-setting conditions.

7.5.5.3. No changes are made to the basic test design or to the method of data analysis without the agreement of the WG. A copy of this document is annexed to the test report.

7.5.6. *Conduct the field-test* (Field staff)

7.5.6.1. Field staff conduct the field-test in accordance with the setting-specific field-test protocol.

7.5.7. *Report results* (Field staff)

7.5.7.1. Field staff prepare a test report and submit it to the Secretariat for peer-review within two weeks of leaving the field.

7.5.7.2. The layout of the report is as specified in the model field-test protocol.

7.6. Peer review (WG, Manufacturer, Secretariat)

7.6.1. Field staff send the test report to the WG and the product manufacturer(s) for peer review, before it is submitted to the Secretariat for the final approval process.

7.6.2. A minimum of two reviewers are members of the WG.

7.6.3. All review comments are documented.

7.7. Approval (Secretariat, WG)

7.7.1. IMD-PQS is responsible for the review of a device or product that has been submitted for prequalification and the Secretariat (alone) is responsible for its approval. (Note: there may be cases where a field-test report raises important policy-related issues. In such circumstances, the Secretariat may require further corroborative testing or may instruct other action before the test report can be published. On the other hand, if only minor changes are required, the Secretariat arranges for these to be made.)

7.8. Publication (Secretariat)

7.8.1. Test reports are published electronically in .pdf format on the IMD-PQS website.

7.8.2. A copy of the final report is also sent to the product manufacturer(s).

7.9. 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 websites

8. RECORDS

8.1. The Secretariat saves list of product types justifying field testing in WHO ePQS-Box / Sharepoint: Folders “Current Dossiers” & “Applications Archive”.

8.2. The Secretariat saves field study proposals in WHO ePQS-Box / Sharepoint: Folder “Current Dossiers” & “Applications Archive”.

8.3. The Secretariat saves field test reports in WHO ePQS-Box / Sharepoint: Folder “Current Dossiers” & “Applications Archive”.

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	4. Footnotes defining the IMD-PQS Working Group and the IMD-PQS Secretariat added in Clause 5. 5. IMD-PQS system structure simplified, removing FMWG, Steering Group. IVB/QSS is also renamed EMP/PQT. Revisions to this	Drafted by P. Mallins Approved by I. Gobina	27/01/2017

	SOP reflect these changes (text and figures). 6. 'Responsibilities' clause revised to separate out specific responsibilities of key actors and to remove process elements. 7. Clause 7.10 'Distribution' edited to include complete group of stakeholders. 8. 'Terms & definitions' moved to annex, revised, definitions updated in line with WG reviews of IMD-PQS glossary Feb 2018. 9. Sub-clause 7.4 'Organize and carry out a field-test' simplified: notably the field-test preparation phases. Field-test is responsibility of manufacturer. Replaced with references to 'Generic Guide to Field-testing' where relevant. 10. All 'Standard Letter' annexes removed. References to 'Generic Guide to Field-testing' added in text where relevant.		
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	11/2024