Generic Guide for

THE FIELD EVALUATION OF NEW TECHNOLOGIES

for

WHO PQS Prequalification

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GLOSSARY

Immunization devices	All devices used for the transport, storage, administration and disposal of vaccines.
Cold chain equipment	For purposes of this document, cold chain equipment includes all vaccine refrigerators, combined refrigerator water-pack freezers, vaccine freezers and water-pack freezers, their power systems and their accessories well as passive containers such as vaccine carriers and cold boxes.
EPI	Expanded Program on Immunization, the department within many countries responsible for managing the public immunization program. It is often housed within the Ministry of Health.
Field evaluation or field evaluation	An assessment of performance, acceptability, and fit with systems in functioning immunization settings of a proposed product. If done for the purpose of WHO PQS prequalification, the protocol requires the advance written approval of the PQS Secretariat. It is a required prequalification validation step for the prequalification of 'new technology' as defined below.
Impartial group or organization	An entity having no financial interest in the technology or outcome of the evaluation, also referred to as an independent or third party.
implementing partner	An **impartial group or organization** with experience in planning, conducting, and evaluating immunization devices in low-resource settings who will lead the field evaluation.
In writing	Communication by letter, fax or email.
legal manufacturer or 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 his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. For purposes of this document the term **manufacturer** and **legal manufacturer** shall have the same meaning.
MOH	Ministry of Health
New Technology	A device, equipment or product that fulfills one or more of the following: 1.) Requiring a substantial PQS modification such as requiring specific tests not covered in the current verification protocols; or 2.) Requiring creation of a new PQS equipment category; or 3.) Functions using a new principle not previously encountered in any previous PQS device
PQS	WHO's Performance, Quality and Safety program that prequalifies a comprehensive range of cold chain equipment, injection devices and other products needed for safe and effective immunization delivery. It is a part of the WHO Department of Essential Medicines and Health Products.
UNICEF (SD)	United Nations Children's Fund (Supply Division)
WHO	World Health Organization

PART I: BACKGROUND

1. Introduction and Scope

The Performance, Quality, and Safety team (PQS) under the WHO Department of Essential Medicines and Health Products, Prequalification Team is responsible for prequalifying a comprehensive range of immunization related equipment needed for safe and effective vaccine delivery. The PQS approach to equipment and device prequalification has been revised in 2015 to require a successful field evaluation of most new equipment, in addition to the laboratory validation that has been required for some time. This is important because new products lack performance history or end-user experience in actual scenarios of use.

This document is divided into an introductory part and three technical parts. It provides guidance for manufacturers and immunization stakeholders on how to engage with WHO PQS to carry out the field evaluation as well as guidance on the planning and the implementation & reporting of the evaluation as part of an application for WHO PQS prequalification. It goes through all the steps required, including protocol development, approvals, evaluation implementation and results reporting.

2. The aim of the field evaluation

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

These three parameters are further described in the next paragraphs. Costing data and potential to impact coverage rates, while important, are outside the scope of this evaluation.

2.1. Performance

The evaluation intends to ensure that performance validated by laboratory tests are reasonably matched when the technology is placed in field conditions. However, criteria will not only depend on the PQS specifications and verification protocol for that category of product, but also on relevancy and feasibility in the field. Therefore these criteria will have to be selected on a case by case basis depending on the type of technology assessed. Further guidance on selecting criteria can be found in Part III of this document, in the section on setting evaluation objectives and research questions.

The second objective of measuring performance in the field is to discover any performance limitations that would not be measured during laboratory tests but only emerge when the technology is evaluated under non laboratory conditions. For example, conditions experienced during shipping can sometimes be more demanding than laboratory conditions, or requirements for operation of the device can sometimes turn

out to be impractical in real-life use. Field experience with the device is critical to uncovering these issues so that manufacturers can address them.

The design of the evaluation will provide exposure to various field conditions that can be encountered and that might affect the performance of the device. For example, seasons, ambient temperatures, exposure to dust and moisture, etc.

Some performance data may be collected through use of tracking forms, observation checklists and/or digital photographs. Manual recording of any equipment breakdown or malfunction, as well as any actions taken, should be planned for.

The field evaluation also provides information on the performance of the equipment over time and may detect changes in performance with continuous use, something that cannot be achieved with the laboratory tests.

2.2. Acceptability

The evaluation also aims to assess the end-user's reaction to the requirements for product use and maintenance. The evaluation can identify whether any interventions are required by the user to ensure correct use, and what these interventions are. Input should be sought from users of the device as well as supervisors and other decision-makers whose perceptions will be important to overall acceptability. (Users should be broadly defined to include all who handle a device, including installation and maintenance technicians, drivers of mobile equipment, etc.). Acceptability data is generally collected using qualitative methods such as in-depth interviews or focus group discussions. Researcher observation of device interactions is another possible tool.

2.3. System impact

It is possible that properly using the new device will require changes in the existing system or procedures compared to the status quo. Some examples of this might be the requirement for additional staff time for maintenance activities, a change in vaccine delivery frequency due to storage capacity increase or decrease, a new supply item or spare part that needs to be included in deliveries from the district, logistical challenges due to the size of the equipment or the need for accompanying equipment such as a new icepack freezer. It is important to document those changes and collect information from key stakeholders about the positive and negative aspects of those changes. In the case where the new technology would create a new reliance on a regular system operation, provisions may be necessary to create for back-up process in the case of break-down. To assess systems impact, both quantitative data (e.g., transport distances and frequency, cold storage capacity) and qualitative data (user and supervisor descriptions of system interactions and their impact) may be collected.

PART II: INSTRUCTIONS FOR MANUFACTURERS

1. Introduction

This part of the document describes only the steps for interacting with the WHO PQS team in the course of preparing and submitting field evaluation results as part of the PQS dossier for a specific piece of equipment. The rest of the process related to submission is described for each category of equipment in the existing guidelines for manufacturers, found on the PQS website at the following links:

- Guidelines for manufacturers of cold rooms and freezer rooms
- Guidelines for manufacturers of vaccine refrigerators, vaccine freezers, and icepack freezers
- Guidelines for manufacturers of insulated containers and coolant packs
- Guidelines for manufacturers of temperature monitoring devices
- Guidelines for manufacturers of injection devices for immunization
- Guidelines for manufacturers of waste management equipment

The steps for designing and preparing a field evaluation protocol are explained in **PART III** of this document (Planning a Field Evaluation). A proposed structure for the evaluation protocol is contained in **PART IV** of this document (Protocol Outline).

2. Determination of the need for a field evaluation

As described in the Guidelines for manufacturers referenced above, the first step in formal interaction with WHO-PQS is a brief written application from the manufacturer expressing their desire to apply for WHO-PQS prequalification for a specific product or product range. PQS then reviews the information submitted and determines if there is a need for the product and to which category it most closely fits. Within one month of the application date, WHO-PQS will issue a letter stating whether or not the product at hand is one of interest. Included in this communication will be information as to whether or not a field evaluation will be required for pre-qualification. In general, products requiring field testing will include at least one of the following: 1.) requiring a substantial PQS modification such as requiring specific tests not covered in the current verification protocols; or 2.) requiring creation of a new PQS equipment category; or 3.) Consisting of a new technology not previously PQS prequalified.

3. Key field evaluation steps

The purpose of the field evaluation is to demonstrate performance, acceptability, and compatibility with systems in a real immunization program. The field evaluation may be done either in parallel or sequentially with the independent laboratory testing described in

the existing Guidelines referenced above. Please note that if either the independent laboratory testing or field testing indicates the need for major changes to the product, then either or both of the laboratory or field tests may need to be repeated after those changes have been implemented. The product can be conditionally prequalified on the basis of the positive laboratory results, with final prequalification determined on the results of the field evaluation.

This field evaluation requires the following steps:

3.1. Approval of a country setting and an independent evaluation implementation partner

If WHO-PQS determines that a field evaluation will be required for a product (as communicated in the expression of interest from WHO-PQS, described above) then the manufacturer should identify a country in which to work, and an implementing partner to work with in order to design the protocol, and who will have responsibility for implementing the evaluation. The implementing partner could be a technical organization with supply chain expertise, an academic organization, an NGO or a research institute for example. The country and implementing partner may be proposed by the manufacturer, or alternatively the manufacturer may ask WHO-PQS to identify some possible candidates. In either case the implementing partner must be approved by WHO-PQS before the manufacturer proceeds much further in the process. This can be accomplished either through email or in-person communication between the manufacturer and WHO-PQS. The manufacturer bears the responsibility for funding the implementing partner, either through their own funds or possibly through available public funding. WHO-PQS can provide input and suggestions for potential sources of funding.

3.2. Approval of the field evaluation protocol

Once the implementing partner is identified, the product manufacturer works together with that partner to develop a protocol for the evaluation. (See Part III of this document for guidance on designing the evaluation.) The manufacturer submits the protocol along with the field evaluation application form (available in Annex 1 of this document) to WHO-PQS. WHO-PQS will respond with comments to the protocol within one month of submission. The final protocol must be approved by WHO-PQS prior to the start of the evaluation. (Note that other approvals may be required as well; please see the planning guideline referenced above.)

3.3. Review of the field evaluation results

Once the field evaluation has been completed, the results are written up and a final report is submitted to PQS by the implementing partner. PQS will review the results along with the rest of the product dossier and make a prequalification determination. Assuming the product meets all other requirements, if the field evaluation shows performance in line with PQS specifications, user acceptability, and compatibility with the system, the product will be fully prequalified. If the product requires non-critical changes following the field evaluation,

the prequalification will be suspended until those changes are achieved and approved by PQS. If the product requires major changes, a new prequalification submission will be necessary. A critical change is required if the field evaluation shows that the product is unusable in its current form.

PART III: PLANNING A FIELD EVALUATION

1. Prepare for the evaluation

1.1. Establish a team

As noted in Part II (Instructions for Manufacturers), manufacturers are required to select a country or countries for the evaluation, and identify an implementing partner who will lead the field evaluation in country. WHO-PQS can advise on suitable individuals or institutions with experience in planning, conducting, and evaluating cold chain equipment in low-resource settings. The Ministry of Health (MOH) Expanded Program on Immunization (EPI) can advise on suitable candidates in country and provide contact information. The main responsibilities of the implementing partner will be to develop the evaluation protocol according to these WHO PQS guidance notes and, in collaboration with in-country partners, identify and obtain required approvals, coordinate evaluation logistics to meet timelines, train evaluation participants, oversee evaluation monitoring, and analyze and report evaluation data. In the course of designing the evaluation, roles and responsibilities of all participants will be defined. The manufacturer might require the declaration of conflict of interest by the implementing agency. Some useful contributors include:

MOH/EPI national staff responsibilities

- Approve the initiation of the new product field evaluation in their country.
- Advise on details of evaluation protocol including evaluation sites selection, timing and condition for transition from mock to real vaccines (if at all).
- Approve the field performance evaluation protocol and confirm whether evaluation requires additional approvals.

MOH/EPI district coordinator responsibilities

- Advise on details of evaluation protocol.
- Participate in training on new equipment and evaluation procedures.
- Assist or take a lead role in evaluation monitoring.
- Participate in interviews to provide feedback on the acceptability and fit of the device.

Immunization program staff responsibilities

- Conduct daily activities during the evaluation implementation according to the evaluation protocol.
- Alert appropriate contacts if questions or problems arise related to the evaluation or the equipment.
- Provide feedback on training, performance, acceptability, and fit of the device.

1.2. Set evaluation objectives and research questions

Before designing the evaluation, it is important to define the main objectives and key research questions that the evaluation will seek to answer. Keep in mind that WHO PQS is expecting this evaluation to yield information about the performance, acceptability, and fit of the product within immunization systems.

In order to establish research questions, consider what is known about the device as well as the environment in which it will be tested. Consider the performance specifications outlined

by PQS for the device category. The list of questions should be realistic—a single evaluation cannot answer the full range of questions that could be asked about this device in the field. Prioritize a list of three to five additional key questions, which may include some from the list below:

- Are there any noticeable defects in the device upon arrival in country?
- Were all tools needed for installation either supplied or readily available?
- How long did installation take?
- Are the instructions and labeling easy to understand?
- Are there any unexpected user-interface issues?
- What is the energy consumption of the product?
- Does the product operate as expected in the level of humidity <or other environmental condition> experienced?
- Does the product require a change in behavior of users compared to the status quo? What are the implications?
- What do users like about this device?
- What do users complain about when using this product?

From the evaluation objectives and research questions it should be possible to develop a data analysis plan. This plan details ahead of time how the various data collected during the evaluation will be analyzed and reported. The research team may want to develop success and failure criteria for some of the performance parameters, where appropriate. However, if the evaluation demonstrates a major failure in the field—for example: it is realized that a component of a device fails systematically due to environmental conditions—then the product will have to be suspended from the PQS list until the issue is resolved. This will be done in agreement with the manufacturer. Consequently, specifications might be revised as well to cover the identified issue.

2. Design the evaluation

Once the objectives of the evaluation and key research questions are defined, the field evaluation can be designed to collect quantitative and qualitative evidence on parameters of performance, acceptability, and system impact in order to answer those questions. The evaluation should be conducted in functioning immunization settings within resource-constrained environments in order to represent typical scenarios of use.

2.1. Site identification

Working closely with the MOH, identify two or more evaluation sites where the use scenarios are appropriate for the equipment type to be tested. Sites should be representative of the environments of use in the low-resource setting and should include both peri-urban and rural settings, if applicable. Sites should not be the most challenging, poor performing, and remote; nor should they be the closest, highest-functioning urban facilities. Depending on the specific goals and research questions of a specific evaluation,

one or more control sites may also be included in the evaluation. Some additional questions to consider when choosing the evaluation site include:

- What is the maximum distance from the evaluation team to the sites in order to enable active monitoring and support at reasonable cost?
- Which different climate conditions exist in the country and could these have an impact on product performance? If so, try to select sites in multiple climate zones.
- Does the product provide sufficient capacity for vaccine storage or transport needs in all sites?
- For solar technologies, are the sites appropriate for sufficient solar energy collection? (A qualified solar technician should be consulted to make this determination).
- Are sufficient grid electricity and mobile telephone and/or data networks available for the product and evaluation requirements?

The final set of selection criteria should be documented in the protocol and explained in the final report.

2.2. Technology comparisons

In some cases, it may be useful to compare a new technology to an existing one. This may be especially applicable for technology categories for which only one or very few PQS-prequalified products exist, so that the existing technology is perceived as the standard. If this approach is taken, the protocol should clearly state how each technology will be treated and what indicators will be compared.

2.3. Length of evaluation

The evaluation should last long enough to gather sufficient information for PQS to determine the suitability of the device for low-resource settings. This guidance covers a large range of device types and the appropriate length of the evaluation will vary depending on device category. For example, the minimal time for a field evaluation of a new temperature monitor might be four to five weeks, while that for a complex refrigerator/freezer incorporating novel technology could be six to twelve months. When determining the evaluation length, the evaluation designers should take into account possible dependency of the device on seasonality of the evaluation settings, the novelty of the device, and the complexity of the monitoring set-up. Upfront time to work out the kinks in the beginning should be included.

2.4. Selection of monitoring devices

Some field studies might require specific equipment to monitor and assess performance of the new product. All necessary monitoring equipment should be identified and quantified, and ordering, receipt, and installation of this equipment should be included in the project plan and timeline as well as in the budget.

For example, during field evaluation of cold chain equipment, temperatures inside the equipment as well as ambient temperatures will need to be monitored with continuous temperature recorders. Other parameters may also require electronic monitoring devices.

Monitoring equipment should be selected based on available electricity, required memory for data storage, data access method available, and available budget. There may also be a need for some analog monitoring equipment, for example stop watches or timers to assist in evaluation procedures.

2.5. Mock vs actual vaccines

If the equipment to be field tested has been conditionally pre-qualified by PQS based on laboratory test results it may ease the way for approval to use the device with actual vaccines. However, the recommendations of the MOH will need to be followed in this regard. If use of the technology in conjunction with actual vaccines for administration is not approved by the MOH, then an alternative plan will need to be devised. Based on the objectives of the evaluation, this could include either an equivalent thermal load (in the form of water bottles, for example) or a load of vaccine vials similar to the actual load, but which will not be administered. If mock vaccine is used, these vials should be clearly marked as unsafe for use, to avoid accidental administration. In any case, the evaluation design should strive to mimic real use scenarios as closely as possible: it will need to build in simulated use activities, for example opening of appliance test refrigerator for a set period of time at appropriate intervals or the introduction of a small number of warm vials at the end of each day, simulating return from outreach activities.

It is possible that the MOH will require simulated use of the device for an introductory period of time, and then would consider use with actual vaccines if results during the simulation period are positive. The period of time for simulated use should be agreed upon in discussions with the MOH. A plan should be made for data review at the end of the established interval, and criteria for a successful simulation should be determined ahead of time.

2.6. Data sharing provisions

Depending on the funding source for the field trial, there may be requirements for sharing the resulting data. Private- and public-sector donors often have data sharing provisions as a condition of funding. In that case it is helpful if all parties involved in the evaluation understand this aim and agree in advance what results of the report will be shared in which format, and with whom. This could include, for example WHO and UNICEF program staff, UNICEF procurement personnel, potential buyers in other countries, and international communities interested in technologies for immunization and other health supply chains. Expectations about data sharing should be clear to all parties from the beginning, for example through the signing of a non-disclosure agreement, or a formal agreement naming parties with whom data can be shared.

2.7. Risks/benefits

The evaluation should be designed to minimize the risks posed to users or the community. Potential risks of a new product evaluation include failure of the equipment due either to device malfunction or human error, physical injury from an unstable device, stress to participants caused either by added work load associated with the evaluation, or unfamiliarity of the evaluation device. These risks can be mitigated by careful development

of evaluation protocol and training materials, pre-testing of data collection forms to be used by health workers, and regular supportive supervision visits. The benefits of the evaluation will accrue from collecting lessons from new equipment used in real immunization settings in order to identify any major performance or acceptability issues prior to final PQS pre-qualification.

3. Document the evaluation

The Protocol Outline proposes a structure to be used to document the field evaluation design. (See Part IV of this document.) It will need to be adapted for the type of new product being tested. Examples of data collection tools are included in the Annexes of this document.

4. Gather required approvals

The protocol will need to be reviewed by PQS and one or more country organizations, as well as possibly the institution of the evaluation implementing partner. Approvals are required from these parties before research can begin. The protocol may require translation for one or more reviewing parties, depending on the situation. The MOH is a critical reviewer. They may request orientation meetings for EPI staff at the national and/or regional levels, and funding may be necessary to support these meetings.

5. Order equipment

For project planning, it is important to consider the lead time required for product and equipment order, delivery, and customs clearance. Large cold chain equipment is often most cost-effectively shipped by sea and can take multiple months to arrive. The manufacturer and implementing partner should coordinate on the shipment of the evaluation device. Consider any spare parts and additional equipment that may be required to support the field evaluation as well. The implementing partner may be best placed to order monitoring equipment. This should be done as soon as possible in the project timeline, but perhaps not before it is reasonably sure of receiving approvals needed for the evaluation to move forward. The implementing partner should coordinate with MOH and possibly the Ministry of Finance or other bodies to begin preparing for customs clearance. Sometimes import tax can be waived for studies done in collaboration with the country government.

6. Develop materials

6.1. Data collection tools

Review the evaluation design and determine what tools may be needed to collect data for the evaluation. These could include:

- Product installation instructions

- Electronic monitoring equipment (for temperature, solar insolation, energy consumption, etc.)
- Daily use monitoring forms
- Maintenance tracking forms
- Breakdown or malfunction reporting forms
- Supervision or evaluation monitoring visit forms and checklists
- In-depth interview guides
- Focus group discussion guides

The implementing partner should be familiar with qualitative research tools and will likely be responsible for developing these for the evaluation. Sample templates of some of these forms are available in Part IV of this document (Protocol Outline).

6.2. Training materials for district and health center staff

User and installation manuals with clear standard operating procedures will be required from the product manufacturer in order to train the implementing partner and MOH team to install and use the new product. Clear graphics including labeled equipment are an especially useful part of these materials. These will also be used for a hands-on training session for technicians and for responsible health facility staff. The manuals may need to be translated by the manufacturer or implementing partner into another language for the field evaluation. The training should not be any more detailed or comprehensive than users will typically get when the device is delivered after prequalification. The field evaluation can also serve as an evaluation of the user and installation manuals—feedback can be provided to manufacturers to help them improve the information that is provided with their equipment. In addition to the materials from the manufacturer, the implementing partner may need to develop training materials describing the evaluation procedures for participants.

7. Receive and install equipment

7.1. Receipt and customs clearance

The implementing partner should work with the MOH and other government stakeholders to arrange for customs clearance and transport of the device and equipment. A clear procedure should be outlined in the protocol explaining how the various shipments will be verified, and what to do if components are missing or insufficient. If practical, the working condition of equipment should be validated while it is still at the point of receipt. Appropriate and safe storage of the equipment should be planned for the period after receipt and before transport to the evaluation sites

7.2. Transport to evaluation sites

Once all equipment is received in country and verified, it will need to be allocated and transported to each evaluation site. This will likely be done by the implementing partner in collaboration with the MOH and EPI. Once the equipment has arrived at the evaluation site, a checklist should be available to verify that the shipment is complete and undamaged.

8. Train participants and launch evaluation

Training can be organized either at a central location for multiple evaluation sites, or at each individual evaluation site. Training should include information about the use of the device as well as procedures required for the evaluation. Training on the new product should be specific to the role of the trainee, for example technicians for cold chain equipment should receive the training intended for installers/technicians while health workers would receive the training intended for equipment users. Evaluation participants should know who to contact if they have any questions after the training, and training should be reinforced by job aids and during early supervision visits to the evaluation sites. There should also be clear instructions in case the device malfunctions or in the event of temperature excursions.

9. Monitor the evaluation

Personnel from the implementing partner, likely joined by EPI staff from district and/or regional centers, should plan to visit the evaluation sites on a regular basis during the evaluation. The purposes of these visits are:

- To reinforce evaluation procedures and answer questions of staff who are working with the device.
- To deal with any unexpected issues that arise with the device.
- To check on compliance with evaluation procedures.
- To check functionality of data monitoring equipment and collect interim data as applicable.

10. Collect and monitor data

Interim data checks can help researchers identify any unexpected performance issues while everyone is engaged and there is still time to work with the manufacturer and MOH to rectify problems. Any interventions need to be thoroughly reported as part of the evaluation findings. At the end of the evaluation period, planned in-depth interviews and focus group discussions should be conducted, and all electronic and paper-based data needs to be gathered and sent to the team who will conduct the data analysis and reporting.

11. Close out the evaluation

11.1. Analyze data

Quantitative and qualitative data will be analyzed by the implementing partner. An outline of the principal research themes developed during the evaluation design should be consulted and the findings impartially reported according to plan. Raw data tables and forms should be preserved in case they are needed for reference later. Data analysis steps should be documented so they can be explained or repeated by others.

11.2. Prepare final report

The implementing partner will be responsible for all data analysis and reporting to PQS and to the manufacturer. The manufacturer and the MOH will have the opportunity to review the report prior to completion by the implementing partner. The final report should be submitted to PQS within six weeks of evaluation completion. A typical evaluation report outline would include:

- Introduction (introduce key partners involved in the evaluation)
- Objectives of the evaluation and key research questions
- Evaluation methods (site selection, key aspects of evaluation design, timeframe, data collection methods, analysis methods)
- Results
- Discussion
- Evaluation limitations
- Conclusion and recommendations

11.3. Remove or hand over evaluation devices

Prior to beginning the evaluation, the final disposition of the evaluation equipment and devices should be agreed to by all partners, as well as responsibility for any associated costs. This can be conditional based on the performance of the device during the evaluation. At the end of the evaluation, this plan should be implemented as agreed. In the case where no agreement exists, the manufacturer should assume responsibility to move or remove the evaluation devices and equipment as appropriate.

PART IV: PROTOCOL OUTLINE

Provided below is the recommended structure of a field evaluation protocol to evaluate cold chain equipment, with suggestions for completing each section.

1. Background

Describe the background and context for the evaluation. Briefly highlight the innovations of the new product to be evaluated.

2. Evaluation objectives and research questions

State the specific objective(s) of the evaluation and highlight key research questions, keeping in mind that the intended purpose of this evaluation from a PQS perspective is to ensure that products:

1) Perform according to the specifications when used in field settings,

2) are acceptable to end-users, and

3) Have no significant negative impacts on the health system.

See Part III of this document (Planning a Field Evaluation) for further guidance on this section.

3. Equipment description

Provide a detailed description of the new product including:

- Key features and dimensions; include photos/graphics.
- Unique features that make the equipment best suited to certain environmental conditions of expected use.
- Separate components provided and needed for routine use (e.g. number and description of coolant packs, solar array, and spare parts).
- Required systems for equipment to function including freezer for coolant packs, transportation

- Installation and user manuals.

4. Evaluation sites

Describe the specific countries and sites where the product will be evaluated, and how these sites were chosen. Where it is relevant to the evaluation, describe the climate of the chosen sites. Describe the involvement of the Ministry of Health and/or other in-country partners. A brief background on the country's health system and immunization program may be appropriate. Note any country approvals that are required.

5. Use case

Describe in detail how the device will be used in the evaluation setting. Include information to answer the following questions:

- Will the product be evaluated under real use or simulated use conditions?
- What changes to current user behavior will be required as part of the evaluation?
- Will there be control sites or comparisons to existing technologies?

6. Evaluation methods

This section describes the evaluation procedures in detail, and makes clear what will be measured and monitored and how this will be accomplished. All aspects of the evaluation design should be captured in this section. Reference may be made to data collection tools, which can be placed in an annex. (Note: there are sample data collection forms contained in this document, Annexes 2-3.)

- Describe any monitoring equipment that will be used to measure performance, and how and when the data will be collected.
- What will constitute acceptable and unacceptable ranges of measurements? Describe how unacceptable ranges or device malfunctions will be managed.
- Describe how data on health system impacts will be collected.
- Describe any procedures that users will need to conduct and on what frequency, and how any related information is to be recorded.
- Describe any planned in-depth interviews and/or focus group discussions, who they will target, who will perform them, and when they will be scheduled. Carefully consider the interview targets: for some equipment, useful information can come not only from the user, but from installers and repair technicians as well.
- Describe what will happen to the equipment at the end of the evaluation.
- Describe the language to be used for training and data collection tools.

7. Data analysis

State the plans for data analysis. What software will be used to analyze the data? How will qualitative data be analyzed? In this section it is also important to include an outline of the intended final report so that reviewers of the protocol can see what to expect. This will allow WHO PQS to confirm that the information they will need to prequalify the device will be included in the report.

8. Roles and responsibilities

Provide a table that describes the different people involved in the evaluation and their responsibilities. The specific roles of the manufacturer and of the partner implementing the evaluation can be clarified in this section. Table 1 below can be used as an example.

Table 1: Example evaluation roles and responsibilities

Location	Personnel	Activities	Frequency
Implementing partner country office	Field evaluation coordinator	• Finalize protocol • Ensure approvals received • Train staff to evaluation procedures	Throughout evaluation
		• Supervise some monitoring visits • Analyze data • Write and submit report	Monthly
Evaluation sites	Manufacturer's chief engineer	• Install product at evaluation sites • Train product users • Train product maintenance staff	Beginning of evaluation
Health Facility	Head Nurse	• Open door of test device for 5 minutes	Daily
		• Manually record temperature	AM and PM daily
	Facility technician	• Clean solar panels	Monthly
District Health Center	District Expanded Programme on Immunizations officer	• Perform supervisory visits to monitor evaluation procedures	Twice monthly
		• Collect data from electronic data loggers and send to evaluation investigator	Twice monthly
ETC…			

9. Timeline

The field evaluation activities should be displayed in a project timeline as shown in Table 2 below.

Table 2: Example field evaluation timeline

Month	1				2				3				4				5				6			
Week	1	2	3	1	1	1	1	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
1. Develop protocol																								
2. Obtain approvals																								
3. Order equipment																								
4. Develop evaluation materials																								
5. Transport equipment to site(s)																								
6. Install equipment																								
7. Train evaluation participants																								
8. Evaluation begins																								
9. Monitoring visits																								
10. Focus groups																								
11. Evaluation ends																								
12. Data analysis and reporting																								

10. Budget

Expected expenses for the field evaluation can be detailed and displayed in a budget table. A sample budget table is provided in Annex 4. This may be omitted from the protocol document for some audiences.

ANNEXES

ANNEX 1: Field Evaluation Application Form

Device name:

Date: Identifying number:

Manufacturer: PQS number/date (If applicable):

Type of PQS equipment being evaluated (Check box)	
E001 Cold rooms, freezer rooms ☐ E001 Cold rooms, freezer rooms and related equipment E003 Refrigerators and freezers ☐ Vaccine freezer or combined vaccine/icepack freezer: compression cycle ☐ Water pack freezer ☐ Refrigerator or combined refrigerator-icepack freezer: compression cycle ☐ Refrigerator or combined refrigerator-icepack freezer: absorption cycle ☐ Ice-lined refrigerator or combined refrigerator-icepack freezer: compression cycle ☐ Refrigerator or combined refrigerator-icepack freezer: compression, solar, battery storage ☐ Refrigerator or combined refrigerator-icepack freezer: compression, solar direct drive ☐ Refrigerator or combined refrigerator-icepack freezer: compression, solar direct drive, with ancillary rechargeable battery ☐ Solar power system for compression-cycle vaccine refrigerator with or without freezer	E004 Cold boxes and vaccine carriers ☐ Vaccine cold box with freeze prevention ☐ Vaccine carrier with freeze prevention ☐ Vaccine carrier ☐ Vaccine cold box ☐ Large capacity vaccine cold box ☐ Vaccine cold box—long term storage, 35 days ☐ Vaccine cold box—long term storage, 10 days E005 Coolant packs ☐ Coolant packs E008 Injection devices for immunization ☐ Single-use auto-disable needle-free syringe injectors E010 Waste management equipment ☐ Needle cutter ☐ Safety box for disposal of used sharps
If new product is not applicable to any of the above categories, please describe the technology here:	

Enter the name and address of the organization funding the field trial:

Name: Street address:

City: State/province Postal code:

Country:

Enter the organization, names, titles, and contact information of the implementing partner(s) who are responsible for conducting the evaluation.

Organization	Individual name	Title	Email

Reason for conducting research (i.e., new product category, PQS recommendation, has not been evaluated in a field setting, etc.)

_____
_____

- Commercial availability of equipment (or phase of development such as commercially available or pre-production). Note the date when the product passed PQS testing in an independent lab and/or manufacturer's lab; describe results and recommendations.

  _____
  _____

- Approvals by any regulatory agencies and countries of registration, if applicable.

  _____
  _____

Results of studies already conducted and organization who conducted evaluation. Please attach the evaluation protocol along with this form

- _____
  _____

ANNEX 2: Example Record of Daily Temperatures and Refrigerator Opening & Closing

Location: _____

Device ID: _____ **User ID: _____**

Date	Time	Morning			Afternoon			Action
		Ambient Temperature	Internal Temp	Device left open for 5 minutes	Ambient Temperature	Internal Temp	Device left open for 5 minutes	

ANNEX 3: Example In-Depth Interview Guide

[Generally used for regular monitoring sessions throughout the evaluation, so it may be repeated with the same evaluation participants more than once. Should be brief and focus on key issues for evaluation researchers to track.]

Date: _____ **Location: _____**

Device ID: _____ **User ID: _____**

Monitor's Name:
_____

Questions	Health Worker Response		Monitor Observations
	Yes	No	
Temperature performance:			
1. Was there evidence of freezing in the vaccine compartment since previous monitoring visit? Describe *Note the means of verification: electronic monitoring data, manual temperature data, shake test.*			
2. Are any vaccine vials frozen? Note means of verification: electronic monitoring data, manual temperature data, shake test.			
3. Was the shake test performed on suspected frozen vials? Describe results			
4. Did temperatures remain in +2° to +8° C range for refrigerators? 0 to +10C for passive devices? Note means of verification – electronic monitoring data, manual temperature data, shake test.			
5. Were there water droplets or wetness on walls of the vaccine compartment or on vaccine vials or boxes? Describe			
Robustness:			
1. Did any component of the cold chain equipment break or malfunction in the past month? How many times? Describe			
2. What, if any, repairs were performed?			
3. Were spare parts used?			
4. Did this malfunction result in the inability to use the equipment?			
Usability:			

Questions	Health Worker Response		Monitor Observations
1. How easy or difficult is it to load and remove vaccines from the vaccine compartment ensuring a "first expired, first out" method? Very easy, not easy but not difficult, difficult. Describe			
2. Other observations or comments:			

ANNEX 4: Example Budget

PERSONNEL

Title	Name	Days	Daily rate	Subtotal
Implementing partner staff				

CONSULTANTS

Role	Name	Days	Daily rate	Subtotal
Translators (for training materials)				
Interpreters				
Photographers				

TRAVEL

Trip To/From	Airfare, etc.	No. of travelers	Per diem	Subtotal
International travel				
Domestic travel (monitoring trips)				
Vehicle rental for in-country travel				
Travel per diems for MOH staff				

EQUIPMENT & SUPPLIES

Equipment	Cost per unit	No. of units	Subtotal
Equipment for field test			
Monitoring equipment (temp monitors, voltage, etc.)			
Additional equipment (ice packs, power adapters, etc.)			

TRANSPORT & DELIVERY

	Cost per unit	No. of units	Subtotal
Sea freight or air cargo (freight forwarding)			
Loading/Unloading at port			
Secure storage per month			

Delivery (port city to major inland city)			
Delivery (major inland city to health facilities)			
Customs clearance fees, VAT, etc.			

WORKSHOPS & TRAININGS

Initial stakeholder workshop		**Subtotal**
Training (Location 1)		
Training (Location 2, etc.)		

OTHER COSTS

Overhead rate		**Subtotal**
Printing training documents		
Copying, duplicating		
Telephone, fax		
Legal fees		
TOTAL COSTS		