WHO/PQS/E003/TPP2.1
PQS Target Product Profile

Original: English
Distribution: General

TITLE: TARGET PRODUCT PROFILES FOR ILRs & SDDs

TPP reference:	E003.TPP2.1
Issue date:	23 March 2022 2021
Date of previous revision:	New TPPs

The purpose of this preliminary Target Product Profile (TPP) document is to propose enhancements to the E003 category of cold chain equipment and is intended to initiate a consultation with industry. After industry inputs are received PQS will review comments and consider revision of PQS performance specifications and verification protocols to ensure that technical or operational shortcomings identified through equipment performance data, stakeholder feedback and manufacturer inputs are adequately addressed. There are notes after each item in the TPP that indicate some of the considerations and questions that remain after extensive input from users, stakeholders, and industry representatives globally. This revision of the document is intended to initiate actions to take regarding each item remaining in this TPP.

Recent public sector consultations, reports from the field, and a global cold chain needs assessment survey have identified potential amendments and additions to the current PQS specifications for vaccine refrigerators. PQS authorized a survey of World Health Organization (WHO) Expanded Programme on Immunization (EPI) staff at the regional and country level to obtain feedback on their priority needs relating to cold chain equipment and the core users. The items below were synthesized from this effort along with ongoing inputs from equipment monitoring and assessment efforts. The included items were screened based on priority, feasibility, and applicability by a group of global health supply chain experts. The functionalities listed in this TPP document are being considered so that the next generation of vaccine refrigerators better meet country end user needs.

Contents

---

1. Improved user and technician resources (manuals)

Description:	More detailed specification of the main, minimum components for user manuals and technician manuals will be developed and included in the relevant equipment specification. Laboratories will be required to assess or score the manuals in the type examination, meaning that E003 manufacturers will be required to submit finalised manuals to the testing laboratory during the testing of their equipment.
Reasons for change:	The survey showed that users were frequently not satisfied with the current quality and content of both user manuals and technician manuals. Better training resources and more user-friendly manuals will support staff skills and knowledge as well as longer CCE service life.
Timing:	**2024**

---

2. Improved vaccine basket and vial storage racks

Description:	Current vaccine baskets are not consistently well designed for the storage of vaccine vials. The average size of the basket holes and wire spacing should keep the vials from falling through.
Reasons for change:	There is need for baskets which can handle single vials, outside of secondary packaging. Vials and other primary containers (e.g. tubes for some orally-administered vaccines) frequently fall out of or are removed from secondary packaging (e.g. paperboard boxes). These individual primary containers then end up in the bottom of the refrigerator, sometimes sitting in standing water, and are difficult to retrieve.
Timing:	**2024**

3. Sturdier and more robust drain plugs

Description:	Poor condensate draining puts vaccines/diluents and the CCE at risk. Having sturdier drain plugs or modified condensate management designed into the equipment could reduce maintenance and cleaning requirements.
Reasons for change:	Liquid condensate control has been an issue in current prequalified fridges. Some appliances have addressed it while others have not. Some of the current drain plugs provided are not robust enough, break easily, and/or are easily misplaced. The purpose of this change is to formalise this functionality and make it verifiable during PQS laboratory type testing.
Timing:	**2024**

---

4. Additional solar power for use in powering other devices

Description:	Allow for increased solar capacity and more energy-harvesting from the solar PV and SDD installations. Provide guidance on and add comprehensive optional changes across refrigerator, PV, EHC specs, and installation/inspection documentation to work toward higher output solar installations and increased power available for non-cold chain uses.
Reasons for change:	There is an increasing need and request for extra power by health facilities. This could strengthen capacity in remote health centres. Evidence indicates there is additional energy available for harvest.
Timing:	**2026**

---

5. Humidity and condensation control

There is already an advanced Humidity and Condensation TPP which has gone through several rounds of industry review and will not be repeated here. That separate TPP is listed as **E003/TPP05.1**, dated 27 July 2020, and available on the WHO-PQS website.

---

6. Wheels on fridges

Description:	Robust wheels with locks on at least two wheels. Improved requirements on spacers in the rear of the fridge to ensure the wheels do not increase the instances of fridges located too close to walls and damaging components or hindering air flow.
Reasons for change:	Refrigerators are difficult to move, which increases risk of damage to the equipment when moved in the facility, between facilities, or transported for repair as is practice in some countries. This is also intended to facilitate routine maintenance, cleaning, installation and inspection of connections and issues.
Timing:	**2026**

7. Additional compartment for storage of non-vaccine products

Description:	A dedicated storage compartment for the storage of non-vaccine products within the appliance or a removable lockable container which can be fixed in the vaccine storage compartment by the user in a specially designed location and that can be removed for differing capacity needs, cleaning, or loading with non-vaccine products.
Reasons for change:	An additional compartment to be used for non-vaccine products within the health system that require cold storage (e.g. other pharmaceuticals or drugs) will reduce the chances of vaccination errors (assuming that this mixed storage happens regardless) and make the fridge more versatile in supporting multiple health centre needs. There is a potential increase in the need for non-vaccine products as part of emergency response plans and pandemic preparedness efforts. General efforts are underway globally to support the health systems more holistically and put more of an emphasis on primary health care and less on traditional health area “silos”. This may allow use of equipment for more than one dedicated purpose.
Timing:	**2026**

8. Robust voltage protection

Description:	The problems and the needs are rather clear – that integrated and stand-alone voltage protection for grid powered equipment is currently inadequate, fails frequently and improvements are necessary. However, the most effective ways to address this are not as clear. The current, intended direction is to increase the thoroughness of robustness testing of voltage stabilizers (or other devices used for power protection), improve the requirements to include or bundle protection with the core cold chain equipment, and possibly to improve field testing requirements.

Reasons for change:	PQS prequalified voltage stabilizers need to be more robust in the settings they are used in and have a longer working life. More generally, mains powered cold chain equipment needs to be more effectively protected from the variability in mains power that it is exposed to in actual use.
Timing:	Voltage stabilizer specification VS01 has been in the revision process for some time, with version VS01.6 due to be published imminently. It increases robustness requirements, adds a category of DC-output stabilizers, and includes provisions for stand-alone stabilizers and those integrated into CCE.

---

9. Improved maintenance access for technicians

Description:	Better technician guidance is a simple way to improve on this and can be addressed by one of the other items in this document. This should include improved wiring diagrams and minimum checklist items for information in those diagrams. Designing for serviceability and maintenance would address the intent of this item more fully.
Reasons for change:	Repairing or replacing thermostats, fans, compressors etc. is a maintenance challenge evidenced by EVM data. Improved maintenance access for technicians is needed. This is particularly important as more integrated components are discussed such as voltage protection, telemetry and EHC.
Timing:	**2026**

---

10. Increased ice-pack freezer capacity

Description:	Increase the number or volume of ice-packs that can be frozen in combined fridge/freezers and decrease the amount of time it takes to freeze the ice-packs. Recommend and provide a testing route for a “fast-freeze” option in combined equipment.
Reasons for change:	Most combined fridge/freezers have limited ice-pack freezing capacity and the health care workers often need both more ice-packs and to be able to re-freeze and re-use the ice-packs more quickly.
Timing:	As soon as possible – in the next scheduled revision. Subject to change upon further discussion and feasibility assessment.

---

11. Solar panels that are easier to clean

Description:	Solar panels are not cleaned as frequently as they need to be. There are many options for improving this situation, but it is very difficult to completely address through innovation or technology alone.
Reasons for change:	Some areas are extremely dusty leading to poor PV performance and high routine cleaning burden. Generally, cleaning the solar panels is difficult, sometimes hazardous, and not consistently carried out. This would help improve refrigerator uptime and reduce burden on health care workers.
Timing:	Pending further discussion and feasibility.

---

12. Holdover requirement at temperature lower than +43°C

Description:	Anecdotal field reports and lab testing have shown that ILRs may not perform optimally in relation to holdover when ambient temperatures are consistently below +43°C for long periods of times. We have noted this effect particularly for temperatures around or below +30°C for a period of 5 days prior to a power outage. The working hypothesis is that at these ambient temperatures the ice-bank is not being completely frozen due to reduced compressor on-time. PQS intent is that ILR and SDD units should have equal or greater holdover at lower ambient temperatures compared to the rated holdover at +43°C.
Reasons for change:	Since ambient temperatures less than +43°C are very common, full holdover protection defined by the current PQS specifications may frequently be unmet. If a device has lower holdover at lower ambient temperatures, publishing the smaller holdover value will set user expectations properly.
Timing:	Near term: self-reporting by suppliers on current device holdover at +25°C Likely in the next scheduled revision: require +25°C holdover to meet or exceed +43°C holdover, with a reasonable implementation timeline permitted (likely 1-2 years' timeline).

---

13. . Holdover/autonomy time visual display gauge on fridge

Description:	A visual indicator for the end user to know how much longer the refrigerator can maintain safe temperatures for the vaccines in the event of the power being out or reduced. PQS initially investigated the feasibility of holdover/autonomy time prediction by algorithm with manufacturers through the TPP feedback process. There was general agreement that it would be feasible, if difficult, but would need to be model specific.
Reasons for change:	Knowing remaining holdover/autonomy time is highly desirable to health care workers to allow time to implement contingency plans before vaccines are exposed to damage when power or other issues arise. It would also allow them to have confidence that the equipment is continually in a state able to maintain its temperature if power issues do arise.
Timing:	**2028**

14. Equipment Monitoring Systems (EMS)

Description:	EMS broadly describes next generation appliance monitoring for performance, use and environmental condition visibility on-site and remotely. EMS specifications have just been published through partnership between WHO PQS and an Industry Working Group. EMS encompasses a data logging function that will be required for integration within refrigerator appliances, and optional display and telemetry components that may be integrated or external to the appliance.
Reasons for change:	Evolution in IoT and remote monitoring systems require more flexible specifications so that industry can bring novel solutions to the market. Current RTMDs are limited in the functionality and have certain drawbacks in their use and design, such as requiring field-fitting of sensors that are prone to breaking, improper positioning, breaking the door seal, etc.
Timing:	EMS specifications have been finalized and published by WHO PQS as of January 2022. Any new ILR or SDD prequalified after January 2024 must satisfy the requirements in PQS_E006_DS01.1 by including data logging and a M2M connection, with EMD functionality optional. All ILR and SDD appliances, including previously prequalified devices, will be required to incorporate this functionality by January 2026.