An assessment methodology for WHO PQS-prequalified cold chain equipment





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Contents

ACK	(NOWLEDGMENTS	1
ABB	BREVIATIONS	2
EXE	CUTIVE SUMMARY	3
ASS	ESSMENT METHODOLOGY FOR COLD CHAIN EQUIPMENT	4
Bacl	kground	4
1.	Introduction	4
1.1.	WHO PQS-prequalified cold chain equipment performance	4
1.2.	Objectives of assessment methodology	5
1.3.	Purpose of documentation	5
2.	Planning for implementation	5
2.1.	Equipment scope	6
2.2.	Data collection tool	6
2.3.	Inspection structure	6
3.	Inspection procedures	7
3.1.	Data fields	7
3.2.	Health facility inspection	8
	3.2.1. Equipment	8
	3.2.2. Procedure	9
3.3.	Cold chain equipment inspection	10
	3.3.1. Equipment	10
	3.3.2. Procedure	11
1	Discussion	22

REFERENCES	26
ANNEXES	27
Annex A. Data collection fields	27
Annex B. Diagrams and photos to identify CCE parts and components	27
List of Annex B figures	29

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Abbreviations

30-DTR thirty-day temperature recorder

AC alternating current

ADC amperes, direct current

app application (as in mobile application)

ARC anti-reflective coating

CCE cold chain equipment

CCEI cold chain equipment inventory

DC direct current

EPI Expanded Programme on Immunization

EVA ethylene-vinyl acetate

ID identification

Ino normally operating current

IR infrared

Isc current, short circuit
LED light emitting diode

PMM post-market monitoring

PQS Performance, Quality and Safety (WHO)

PV photovoltaic

RH% relative humidity percentage

SDD solar direct drive

UNICEF United Nations Children's Fund

USB universal serial bus

VAC alternating current voltage

VDC direct current voltage

Vno normally operating voltage

Voc open circuit voltage
VVM vaccine vial monitor

WHO World Health Organization

Executive summary

This document details an assessment methodology for vaccine cold chain equipment (CCE), specifically vaccine refrigerators and freezers. It is primarily a thorough inspection procedure for this CCE to gather a comprehensive set of inventory, physical, and functional data on the equipment. This procedure was used by PATH in collaboration with the World Health Organization (WHO), ministries of health, Expanded Programme on Immunization (EPI), and United Nations Children's Fund (UNICEF) country offices to conduct a multicountry assessment of WHO Performance, Quality and Safety (PQS)-pregualified vaccine refrigerators. The large, consistent dataset collected through these inspections was used to analyze refrigerator failure modes by brand, model, and age. However, the detailed inspection procedure (or portions of it) could serve other purposes in addition to collecting data for the statistical analysis of failure modes and investigation of root causes. Target use of the data fields might be useful in assessing immediate causes of failure, assisting in repair and maintenance, evaluating equipment design and longevity, or other purposes. This document describes the data fields recorded, the procedure used to collect these data, and the equipment required to do so. The intent of this document is to provide access to the procedure, structure, and data fields in an "as-used" format that was used by PATH and consultants in order for others to apply it in part or in whole for other purposes. This document is not intended to directly provide guidance on diagnosing and repairing problems with CCE, although much of the data collected may be useful to a technician when fixing equipment. This methodology is most suitable for the systematic collection of data from multiple refrigerators when statistical analysis of CCE is of interest.

Assessment methodology for cold chain equipment

Background

From 2018–2019, the World Health Organization (WHO) Immunization Devices Assessment Team (formerly known as the Performance, Quality and Safety (PQS) team) and PATH collaborated with the ministries of health, Expanded Programme on Immunization (EPI), and United Nations Children's Fund (UNICEF) country offices to conduct a limited, post-installation assessment of PQS-prequalified cold chain equipment (CCE) at health service delivery points in Malawi, the Philippines, and Ghana.¹

In each country, after the PATH team contacted stakeholders and the EPI team communicated willingness to collaborate on an equipment assessment, the team reviewed the most recent national CCE inventory (CCEI). The equipment sample was selected by the assessment team upon arrival, in close collaboration with national and regional EPI staff as well as UNICEF EPI focal points.

This assessment methodology was conducted on a sample of 57 PQS-prequalified vapor compression, grid-powered, and solar-powered vaccine refrigerator systems across the three countries. The structured inspection process collected technical and system data using visual observations and instrumented measurements.

1. Introduction

1.1. WHO PQS-prequalified cold chain equipment performance

National EPI teams rely on specialized vaccine refrigerators that maintain a temperature-controlled environment (+2°C to +8°C), even in the most challenging conditions, to ensure vaccines are effectively delivered to the people who need them.² There are many types of vaccine refrigeration systems. Some have separate refrigerator and freezer compartments; some can function as either a refrigerator or freezer; some are powered by electrical mains and others are powered by solar energy. To help achieve the necessary temperature performance across various types of vaccine refrigeration systems, the WHO PQS prequalification system sets and validates CCE performance specifications and makes this technical data publicly available, in part to support EPI to make informed procurement choices. WHO PQS prequalification is a requirement for procurement by United Nations agencies or by countries using Gavi, the Vaccine Alliance, funding or Gavi's Cold Chain Equipment Optimisation Platform.

While manufacturers are responsible for meeting PQS equipment prequalification performance requirements in an independent laboratory setting, prior to 2019 there was no mechanism for WHO to monitor and validate long-term quality and safety standards of this prequalified equipment over its functional lifetime. An analysis of functional status from national CCE inventories suggests that as much as 20% of installed CCE is broken and more than 50% of CCE is nonfunctional or poorly performing, putting temperature-sensitive vaccines at risk of potency damage.³

1.2. Objectives of assessment methodology

The equipment assessment activities were conducted to better understand how and why prequalified vaccine refrigerators fail to meet WHO PQS temperature performance requirements outside of laboratory testing conditions. While these assessments were initially designed with an expectation that data would support a complex root cause of failure analysis, these activities ultimately achieved two more limited but practical objectives:

- To develop and pilot a standard equipment assessment methodology on the quality of PQS-prequalified CCE at service delivery points or lowest distribution points, incorporating data collection on key systemic factors with the potential to impact equipment performance. This report explains the equipment assessment methodology that was developed.
- To inform evidence-based recommended actions for WHO PQS, manufacturers, and immunization
 programs and their partners that will strengthen CCE quality and performance. These
 recommendations were communicated to the appropriate partners and are not discussed within this
 report.

By supporting efforts to assess equipment after installation, WHO PQS is leading a collaborative effort to improve global immunization supply chain and logistics policies, CCE design and manufacturing, and national immunization supply chains. The assessment methodology documented here was intended to be a comprehensive approach to performance monitoring of prequalified CCE systems in actual use.

1.3. Purpose of documentation

This report documents in detail the mobile application (app), data collection questions, and inspection process used to evaluate CCE in Malawi, the Philippines, and Ghana. The intent of sharing this methodology publicly is for others to understand the process used and potentially take and improve upon the process and format in part or in whole to assess CCE. This methodology provides a set of questions and standardized data collection procedure for cases where thorough, consistent inspections of CCE are desired. The inspection procedure is intended to guide technicians trained in refrigeration and solar equipment through the data collection process. Some of the data fields could be completed by other users of CCE with less technical training. However, the procedure is not necessarily detailed enough to guide an untrained user through the evaluation. Many of the data fields do not have a corresponding procedure based on the assumption that users have a certain level of technical knowledge.

2. Planning for implementation

The inspection procedure documented here is intended to complement a protocol for WHO PQS-prequalified CCE and system failures assessment that was first drafted by PATH in 2017 with input from the PQS working group and CCE manufacturers. The original protocol is a document that outlines the objectives, study design, and methodology to collect, analyze, and use data to support the WHO PQS Secretariat, UNICEF Supply Division, CCE manufacturers, and EPI teams in detecting root causes of failures and coordinating responses to address technical and systemic gaps contributing to premature CCE failures. The study protocol did not include a comprehensive list of the specific data fields collected or details on the procedure for recording measurements during inspections, which are retroactively documented here.

2.1. Equipment scope

This inspection procedure was used only for PQS-prequalified vapor compression, solar-powered, or alternating current (AC)-mains powered refrigerators and freezers and may not be applicable to other types of CCE.

2.2. Data collection tool

To support a rapid and standardized data collection methodology, a mobile data collection tool was developed using the Fulcrum mobile platform and Apple iPad Pro® tablets and implemented in the Philippines and Ghana. This documentation is intended to be application-agnostic, although much of the utility as well as effort and complexity comes from implementation on a useful and deliberately thought-out platform that allows easy, logical data entry, extraction, and processing as well as storage of data and images.

The Fulcrum application on the iPad tablet captured both photos and data, including GPS coordinates and weather data downloaded from local weather beacons. Specialized iOS applications captured data on irradiance, sun pathway, array inclination, and other important factors that were attached to equipment data records.^c

2.3. Inspection structure

The data collection tool included two types of entries: health facility inspections and CCE inspections.

Facility inspections were completed for each facility where equipment was installed. Health facility inspections were typically completed prior to CCE inspections and were brief relative to the equipment inspections. Collected data included information on the ambient temperatures and humidity, environmental risks, and dimensions of doors and windows of the rooms where equipment was installed. Health facility records were referenced within CCE records to link equipment to the correct facility.

CCE inspections captured information on technical and systemic factors that could potentially contribute to existing or future equipment performance failures. The structured inspection process collected technical and system data using visual observations and instrumented measurements. Technical data included information on physical faults, such as corrosion of hinges, and system data included potential indicators of preventive maintenance gaps, such as lack of routine lubrication. The number of data elements collected in the full inspection dataset was large, in an effort to support analysis of currently unknown factors that could potentially contribute to equipment failures.

The data elements were organized into four modules:

- Metadata: Identification data for equipment and facilities. In PATH's multicountry assessment, some
 of this data was generated from country CCE inventories.
- Screening: Temperature measurements and review of temperature-monitoring data.
- Assessment: Collection of data describing maintenance, installation, and temperature-monitoring practices. Data on equipment management and monitoring practices were collected during this

^a More data on the Fulcrum data collection platform can be found at https://www.fulcrumapp.com/.

^b iPad Pro is a registered trademark of Apple Inc.

 $^{^{\}rm c}\,\text{iOS}$ is a registered trademark of Cisco Systems, Inc.

evaluation to help identify how systemic criteria and end-user practices contributed to long-term equipment performance.

• **Visual Inspection & Measurements:** Faults and test data for each refrigeration system; both the refrigerator and photovoltaic (PV) systems for solar-powered equipment.

When assessing solar direct drive (SDD) CCE systems and solar systems with batteries, additional technical data were collected on the solar array, including the modules, wiring, support structure, and location, to support analysis of SDD system failures or weaknesses.

Full inspection of an AC-powered refrigerator required approximately 3.5 hours per refrigerator, and inspection of an SDD refrigerator and integrated PV solar array performance took at least 5 hours.

3. Inspection procedures

3.1. Data fields

The spreadsheet in Annex A contains all the data fields that PATH collected during inspections. The following information is captured in the spreadsheet for all data fields:

- Inspection type: health facility or CCE inspection.
- Inspection module: for CCE inspections, one of the four modules (Metadata, Screening, Assessment, or Visual Inspection & Measurements).
- Topic: some questions are grouped by topic.
- Element: subgrouping of questions within a topic.
- · Component: subgrouping of questions within an element.
- Question number.
- Skip logic: inclusion or exclusion of certain questions was dependent upon the answers provided for
 previous questions. The skip logic documented in the spreadsheet includes the question numbers of
 the relevant previous questions and the conditions that had to be met by the answers to those
 questions in order for the question at hand to be visible to the user in the data collection tool. If skip
 logic columns are blank for a question, the question was always asked regardless of answers given for
 previous questions.
- Question: the data collection prompt as it was written in the data collection tool.
- Required: certain data fields, denoted with an asterisk, required an answer to save an inspection entry.
- Answer field type (the following types of data fields were included in this evaluation):
 - o Boolean
 - Date/time
 - Numeric
 - String
 - List: inspector selects answer from a predetermined list of options
 - Image
 - Video

- Barcode: scan barcode with camera or enter barcode manually
- Upload: upload a document, image, web link, or data from iPad
- Selection type: for list fields, inspector can either choose one option or select all that apply.
- List options: for list fields, the options included in the list.
- In-app information: certain questions, denoted with an informational symbol, provided additional information about the question when the symbol was tapped.
- Equipment needed: the type of equipment necessary to collect a measurement or other data for the field.

When planning for data collection, it is important to consider the interpretation of questions left blank. Data fields left blank within an inspection entry may indicate that the question was not applicable, that the question was unable to be answered given the available time and equipment, or that the inspector did not find anything out of the ordinary and therefore did not feel it was necessary to record an answer. However, differentiating between these possibilities during data analysis can be challenging and therefore it is beneficial to be explicit about when a data field should and should not be left blank prior to starting data collection.

3.2. Health facility inspection

3.2.1. Equipment

The specific device models and mobile applications listed (Table 1) were used by PATH during inspections and could perform all the functions required by the inspection procedure.

Certain substitutions may be acceptable for those wishing to utilize this inspection procedure; however, not all brands and models will have the same capabilities. For example, an iPad was used to complete evaluations but other internet-enabled smart devices (tablets or phones) may be suitable replacements for those wishing to utilize this inspection procedure. Using a different device for data collection would require identification of compatible mobile applications that are required for inspections. Similarly, the Fulcrum mobile application was used for data collection, but this inspection procedure was written with the intention that another data collection tool with similar capabilities may be used. This is not a specific endorsement or recommendation for any of the devices or brands.

Table 1. Devices and tools used by PATH during health facility inspections.

Devices	Other tools
Environmental meter [Extech EN100]	Tape measure
Laser distance meter [Fluke 414D]	Ladder
Inclinometer [iHandy Carpenter mobile app]	
 iPad loaded with the following mobile applications: Fulcrum Sun Surveyor Camera Compass Hukseflux Thermal Sensors Pyranometer iHandy Carpenter 	

The following general instructions for equipment use apply to all questions in the inspection:

- If roof access is required to answer a question, use a ladder to safely access the roof. For any roof unsuitable to support a person, modify inspection so that getting on the roof is not required or ignore parts of the inspection.
- For any questions requiring photos, use the iPad camera to link photos directly to the correct equipment and facility. Photos not linked correctly should be attached to the correct equipment and facility after the inspection.

3.2.2. Health facility inspection procedure

PATH's inspections of health facilities required several steps to answer the questions in the Fulcrum data collection tool. Instructions, definitions, and/or clarification are provided for select questions to assist inspectors who wish to use this methodology. Any definitions provided in the procedure are intended to define a term only as it was used during PATH's evaluations and should not be interpreted as universal definitions. As previously described, skip logic was used, so some questions would not appear during an inspection, depending on the answers provided to previous questions.

Question numbers correspond to the questions listed in Annex A. Instructions are not provided for all questions; if instructions are not provided for a question, an inspector should be able to answer through visual observation or by interviewing health workers and/or other equipment users.

- 3. Administrative location. This field provides country-specific options for regions, subregions, districts, villages, and/or neighborhoods to correctly identify the health facility. These data and the organization of health facilities and levels in a given country need to be accurate and comprehensively documented before starting data collection on equipment that needs to be linked to facility locations.
- 20. <u>Power source(s)</u>. Record all the relevant power sources at the facility. Ask a health facility worker if the facility pays the government for power (likely a national grid) or pays a local/community-based organization for power (likely a microgrid). The presence of a solar system or generator can be visually assessed on site. More than one option can be selected if applicable; for instance, a facility with a solar system may be connected to a microgrid. Definitions of each power source are provided below.
 - a. National grid: a system of wires that transports electricity from power sources to multiple parts of a country.
 - b. Microgrid: defined by US Dept of Energy Microgrid Exchange Group as "a group of interconnected loads and distributed energy resources within clearly defined electrical boundaries that acts as a single controllable entity with respect to the grid. A microgrid can connect and disconnect from the grid to enable it to operate in both grid-connected or island-mode."d
 - c. Generator: a machine typically powered by fuel that converts mechanical energy into electrical energy. An example can be found in Annex B, Figure 2.
 - d. Solar system: assembly of solar array, electrical cabling, support structure, control, and energy storage.
- 23. <u>Mobile network coverage</u>. Use Opensignal mobile application to determine the type(s) of mobile network coverage available at the health facility.

9

^d More information on microgrids can be found at https://www.energy.gov/articles/how-microgrids-work.

- 33. <u>Room airflow/ventilation.</u> Use environmental meter to measure air flow. This yes/no Boolean field can be answered subjectively based on expert opinion if not measured or if direction on what is adequate is unclear.
- 34. Ambient temperature (°C). Use environmental meter to measure ambient temperature.
- 35. Relative humidity percentage (RH%). Use environmental meter to measure relative humidity.
- 42. Orientation. Use compass to determine orientation of outdoor-facing door or window.
- 48. Roof type/style. See Annex B, Figure 1.e
- 51. Roof slope (°). Use inclinometer to measure roof slope.
- 52. Roof azimuth (°). Use compass to determine roof azimuth.
- 53. <u>Substructure material.</u> The substructure is the collection of beams supporting the roof. Substructure material can be determined by observation if the roof supports are visible from inside or outside of the health facility.
- 54. <u>Substructure support spacing.</u> Use laser distance meter to measure linear distance between substructure support beams.

3.3. Cold chain equipment inspection

3.3.1. Equipment

The device models and mobile applications listed (Table 2) were used by PATH during inspections. These specific device models and mobile apps could perform all the functions required by the inspection procedure.

Certain substitutions may be acceptable for those wishing to utilize this inspection procedure; however, not all brands and models will have the same capabilities. For example, an iPad was used to complete evaluations but other internet-enabled smart devices (tablets or phones) may be suitable replacements for those wishing to utilize this inspection procedure. Using a different device for data collection would require identification of compatible accessories (e.g., thermal camera) and mobile applications that are required for inspections. Similarly, the Fulcrum mobile application was used for data collection, but this inspection procedure was written with the intention that another data collection tool with similar capabilities may be used. This is not a specific endorsement or recommendation for any of the devices or brands.

Table 2. Devices and tools used by PATH during cold chain equipment inspections.

Devices	Other tools
Solar power meter [TES-132]	Tape measure
Digital multimeter [FLIR DM93]	Ruler
Inclinometer [iHandy Carpenter mobile app]	Ladder
Thermal imaging camera accessory for iPad [FLIR ONE] and compatible software	Thermocouple and datalogger
Moisture meter [FLIR MR77]	Test leads (at least two, black and red, crocodile clamps)
Infrared (IR) video thermometer [Extech VIR50]	Level within mobile app [iHandy Carpenter mobile app]
Earth ground resistance tester kit [Extech 382252]	Hexagon wrenches, US and metric
Digital multimeter and insulation tester [FLIR IM75]	Allen wrenches

^e For this assessment, PATH utilized the JTC Roofing Contractors Ltd website to identify roof type/style. More information is available at https://www.jtcroofing.co.uk/roof-types/.

Devices	Other tools
Laser distance meter [Fluke 414D]	Wire stripper and cutter
Environmental meter [Extech EN100]	Flat and Philips screwdrivers
Clamp meter [FLIR CM174]	Insulated handle pliers
iPad loaded with the following mobile applications:	Flashlight
 Fulcrum 	
Sun Surveyor	
 Camera 	
 Compass 	
 Hukseflux Thermal Sensors Pyranometer 	
iHandy Carpenter	

The following general instructions for equipment use apply to all questions in the inspection:

- If roof access is required to answer a question, use a ladder to safely access the roof. For any roof
 unsuitable to support a person, modify inspection so that getting on the roof is not required or ignore
 parts of the inspection.
- For any questions requiring photos, use the iPad camera to link photos directly to the correct
 equipment and facility. Photos not linked correctly should be attached to the correct equipment and
 facility after the inspection.
- For any questions requiring thermal photos, use the thermal imaging camera accessory for the iPad.

3.3.2. CCE inspection procedure

PATH's inspections of CCE required several steps to answer the questions in the Fulcrum data collection tool. Instructions, definitions, and/or clarification are provided for select questions to assist inspectors who wish to use this methodology. Any definitions provided in the procedure are intended to define a term only as it was used during PATH's evaluations and should not be interpreted as universal definitions. As previously described, skip logic was used, so some questions would not appear during an inspection, depending on the answers provided to previous questions.

The following terms appear multiple times throughout the inspection procedure and are defined here for reference:

- AC systems: CCE powered by alternating current electricity supplied by an external source (national grid).
- Direct current (DC) systems: CCE powered by direct current solar electricity.
- Azimuth: geographic direction that a solar panel/module is facing, expressed as the angle between the
 vector pointing to geographic north and the component of the vector normal to the panel/module
 surface in the horizontal plane.
- Orientation: cardinal direction that a solar panel/module is facing.
- Inclination: angle between the back of a solar panel/module and the horizontal plane.
- Braze damage: damage at the joint(s) between pipes due to brazing itself or corrosion or other degradation at the brazed location.
- Hotspot: unintentional solar cell overheating caused by shading, soiling, or mechanical faults.⁵

This inspection methodology collects data on several common components of CCE. These components are listed in Table 3. Annex B contains resources that are intended to assist an inspector in locating and identifying these components. These general resources are not specific to a particular brand or model. Every model will be different, and some models may not contain all components included in the inspection procedure.

Table 3. Components referenced in cold chain equipment inspection within Fulcrum mobile application. Figures noted appear in Annex B. Components listed without a resource for identification either do not have an applicable resource in this document, or have more details provided in the inspection instructions.

Refrigerator		
Element	Component	Resource(s) to identify
	Casing	Figure 19
	Base	Figure 19
Cabinet	Access cover	Figure 19
Cabinet	Vents	Figure 19
	Manufacturing labels	Figure 20
	Condensation drainage	Figure 24
	Handle	Figure 9
	Gasket	Figure 9
	Hinges	Figure 9
Door or lid	Hardware	N/A
	Latch/clasp	Figure 21
	Lock	Figure 9
	Key	N/A
	Keypad	Figure 9 "control panel"
	Temperature display	Figure 9 "display/thermometer"
External controls	Power light emitting diode (LED)	Figure 9 "indicator light"
	Power switch	Figure 9 "on/off switch"
	AC power cable	Figure 11
	Voltage stabilizer	Figure 10, Figure 25
Power supply	PV cable	Figure 22
	DC input receptacle	Figure 22
	Shelving/baskets	Figure 9
	Wall	Figure 26
	Bottom	Figure 26
Vaccine	Grate	N/A
compartment	Condensation baffle	N/A
	Support bridge	N/A
	Drain	Figure 26
	Mount	Figure 23
	Cable seal	Figure 23
Temperature sensors	Thermostat sensor	Figure 4, Figure 10, Figure 23
	External display sensor	Figure 23
	Internal circulation fan	N/A
	Water packs	Figure 26
Ice bank	Ice bank panels	N/A
Electronics	Base plate	Figure 26
compartment	Thermostat plug	N/A

	Fan	Figure 4, Figure 10
	Compressor	Figure 4, Figure 10, Figure 27, Figure 29
	Compressor controller	Figure 31
	Compressor starting device	Figure 9, Figure 10, Figure 32
	Piping	Figure 4, Figure 10, Figure 27
	Thermostat controller	Figure 27, Figure 28
	Internal condenser	Figure 4, Figure 10, Figure 29
	Starting capacitor	Figure 32
	External condenser	Figure 30
	Filter dryer	Figure 27, Figure 28
	Capillary	Figure 28
Solar array		
Element	Component	Resource(s) to identify
	Glass	Figure 13
	Encapsulant	Figure 13
Modules	Frame	Figure 13
Wodules	Junction box	Figure 13
	Cell	Figure 6, Figure 13
	Backsheet	Figure 13
	Interconnects	Figure 3, Figure 5
Wiring	Combiner boxes	N/A
	PV output cable	Figure 3, Figure 4 "solar array cable"
Support structure	Mounting	Figure 17, Figure 3
Grounding		
Element	Component	Resource(s) to identify
	Lightning rod	N/A
System	Ground rod	Figure 18
Oystem	Ground pit	Figure 18
	Ground rod lug	Figure 18
PV array	Ground conductor	Figure 18 "ground rod"
	Support structure	Figure 3
Equipment	Earth conductor	Figure 18 "ground rod"
Other		
Element	Component	Resource(s) to identify
Spare parts	Fuses	Figure 4, Figure 5

Question numbers correspond to the questions listed in Annex A. Instructions are not provided for all questions; if instructions are not provided for a question, an inspector should be able to answer through visual observation or by interviewing health workers and/or other equipment users. Furthermore, definitions are provided below for some (but not all) terms that appear in questions and as answer choices in the Annex A spreadsheet.

Stage 1: Metadata (questions 1-67)

1. <u>Brand and model.</u> All brands and models of PQS-prequalified CCE and legacy equipment produced under Product Information Sheets, the precursor to PQS, as well as certain domestic models were provided as options for this field during PATH's evaluations. The options for this field should be defined before starting data collection based on the inspection sample.

- 9. PQS product identification (ID). Match within PQS product catalogue.
- 10. PQS valid until. Find date in PQS product catalogue.
- 11. <u>Solar direct drive or AC mains powered.</u> If CCE is connected to solar array without a battery, it is solar direct drive powered. If CCE is connected to power supply from a large/national grid, it is AC mains powered.
- 12. Technology type. Indications of each technology type are provided below:
 - a. AC mains powered: CCE is connected to power supply from large/national grid.
 - b. *DC solar with battery:* CCE is connected to a solar array, and energy is stored in a battery.
 - SDD: CCE is connected to a solar array, and energy is stored by freezing water or other phase change material.
- 19. <u>Power (W).</u> Use solar power meter to measure power (in watts) of the solar array.
- 20. <u>Voltage (direct current voltage [VDC]).</u> Use multimeter on VDC setting with test leads connected to the array output cable to measure voltage of the solar array. This cable is labeled in Figure 4 as "solar array cable."
- 21. <u># Modules.</u> A module is a collection of solar (photovoltaic) cells. One or more modules form a solar panel, as shown in Figure 6. Count the number of modules.
- 22. <u># Series.</u> Solar modules in series have the positive terminal of the first module connected to the negative terminal of the second module, the positive terminal of the second module connected to the negative terminal of the third module, and so on, as shown in Figure 7. The number of modules in series can be counted based on the wiring of the array.
- 23. <u># Parallel.</u> Solar modules in parallel have all positive terminals connected and all negative terminals connected, as shown in Figure 8. The number of modules in parallel can be counted based on the wiring of the array.
- 24. <u>Module rated power (W).</u> Module rated power is the power expected from a PV module when operating under standard test conditions and is measured in a laboratory. Rated power is also referred to as rated capacity, nameplate capacity, or installed capacity. This information should be available from the manufacturer and listed on a label or in the manual/other documentation.
- 25. <u>Module short circuit current (Isc).</u> This value is determined in a lab under standard test conditions. This information should be available from the manufacturer and listed on a label or in the manual/other documentation.
- 26. <u>Module open circuit voltage (Voc).</u> This value is determined in a lab under standard test conditions. This information should be available from the manufacturer and listed on a label or in the manual/other documentation.
- 27. Module width (mm). Use tape measure or laser distance meter to measure module width.
- 28. Module length (mm). Use tape measure or laser distance meter to measure module length.
- 29. <u>Module thickness (mm).</u> Use tape measure or laser distance meter to measure module thickness (smallest dimension of module).
- 30. Rated operating temperature (°C). This information should be available from the manufacturer and listed on a label or in the manual/other documentation.
- 31. <u>Orientation type.</u> Use a compass to determine if the support structure orients the solar panel to face north and south or east and west.
- 32. <u>Angle/slope configurations.</u> Use inclinometer to determine the tilt angle of the solar panels in reference to the horizontal. More than one option can be selected if multiple panels/modules are tilted at different angles.
- 33. <u>Number of supports.</u> Count the number of individual, independent structures supporting the solar modules.

- 34. <u>Total required surface area (length).</u> Use laser distance meter to measure length of the combined footprint of all support structures on roof.
- 35. <u>Total required surface area (width).</u> Use laser distance meter to measure width of the combined footprint of all support structures on roof.
- 36. <u>Total required surface area (area).</u> Calculate the area of the combined footprint of all support structures on roof by multiplying the length and width recorded in the previous questions.
- 37. PV array output cable (m). Use laser distance meter to measure length of PV output cable.
- 38. <u>PV array to ground conductor (m).</u> Use laser distance meter to measure length of cable connecting solar array to ground conductor.
- 39. Refrigerator to ground conductor (m). Use laser distance meter to measure length of cable connecting refrigerator to ground conductor.
- 41. <u>Functional status.</u> *Operational:* CCE is fully functional (turns on, runs, and cools to desired temperature range). *Damaged:* equipment is functional, but something is wrong (e.g., damaged hardware or cooling to wrong temperature part of the time). *Broken:* equipment is nonfunctional (e.g., temperature outside of desired range 100% of time, or not turning on).
- 53. <u>Temperature monitoring devices in use.</u> Reference Figure 33–Figure 39 to identify the type(s) of temperature monitoring device(s) in use.
- 65. Administrative location. This field provides country-specific options for regions, subregions, districts, villages, and/or neighborhoods to correctly identify the health facility. These data and the organization of health facilities and levels in a given country need to be accurate and comprehensively documented before starting data collection on equipment that needs to be linked to facility locations.

Stage 2: Screening (questions 68-94)

- 68. Equipment fully installed. The equipment is fully installed if it is usable in current condition.
- 69. <u>Refrigerator operational.</u> The equipment is operational if it is fully functional (turns on, runs, and cools to desired temperature range).
- 71. <u>Adequate locale.</u> Locale can be considered adequate if the refrigerator is in a secure space, accessible to appropriate users, and shielded from harsh outdoor conditions. The refrigerator should not be placed where water damage or direct sunlight exposure may occur.
- 73. <u>External display working.</u> External temperature display is working if a temperature can be read from the display. Accuracy of reading is evaluated separately.

Stage 3: Assessment (questions 95-137)

- 98. <u>Minimum voltage (alternating current voltage [VAC]).</u> Use multimeter on VAC setting with test leads connected to the AC power supply. Observe voltage fluctuations for approximately 60 seconds and record minimum voltage observed.
- 99. <u>Maximum voltage (VAC).</u> Use multimeter on VAC setting with test leads connected to the AC power supply. Observe voltage fluctuations for approximately 60 seconds and record maximum voltage observed.
- 100. <u>Minimum frequency (Hz).</u> Use multimeter on frequency setting with test leads connected to the AC power supply. Observe frequency fluctuations for approximately 60 seconds and record minimum frequency observed.
- 101. <u>Maximum frequency (Hz).</u> Use multimeter on frequency setting with test leads connected to the AC power supply. Observe frequency fluctuations for approximately 60 seconds and record maximum frequency observed.

Stage 4: Visual Inspection & Measurements (questions 138-542)

In this section, components of the cold chain equipment are inspected. Certain questions about CCE components list potential factors that may have problems; select any of these factors to bring up additional questions about the severity of a problem or the quality of a component attribute.

When problems with a component are identified, the severity of the problem is evaluated according to the following scale: *None, Minor, Significant, Major, Extreme*. Although the severity is ultimately determined by the opinion of the inspector, the following definitions used during PATH's evaluations may be helpful to distinguish between severity levels.

- None: no detectable problem.
- *Minor:* noticeable but does not impede function. Repairs not required at this point but may be required if problem worsens.
- Significant: problem is suspected to be/could be impeding function of component enough to prevent component from working as desired. Repair is desirable but not urgent.
- Major: component partially functions but problem has clear negative impact on performance or usefulness of component. Should be repaired as soon as possible.
- Extreme: component cannot function at all and/or presents a danger to users due to problem. Requires attention/correction/repair immediately for safety and/or return of function.

Similarly, the quality of component attributes (e.g., design or location) is evaluated according to the following scale: *Excellent, Good, Fair, Poor, Bad.* Although the quality is ultimately determined by the opinion of the inspector, the following definitions used during PATH's evaluations may be helpful to distinguish between quality levels.

- Excellent: best possible quality. Cannot be improved.
- Good: close to the best possible quality. Some improvement is possible but unnecessary.
- Fair: satisfactory quality with potential to improve. Minimum quality that does not require attention/correction.
- Poor: attention/correction is needed.
- Bad: worst possible quality. Attention/correction is needed urgently.
- 138-141. <u>Sun exposure.</u> Use Sun Surveyor mobile application to evaluate the potential for direct sunlight exposure.
 - 146. <u>Level reading screenshot.</u> Use the level tool within the mobile application iHandy Carpenter. Place the level on top of the CCE on a flat surface and take a screenshot of the level reading on the iPad.
 - 147. <u>Level reading x-axis (°).</u> Record the level reading x-axis from the level tool on the iHandy Carpenter application.
 - 148. <u>Level reading y-axis (°).</u> Record the level reading y-axis from the level tool on the iHandy Carpenter application.
 - 194. Gasket integrity thermal photos. Take gasket integrity thermal photos with the door closed.
 - 195. <u>Gasket integrity moisture readings.</u> Use imaging feature on moisture meter to capture an image of gasket moisture. Example image shown in Figure 40.
 - 208. Latch/clasp. Broken: latch/clasp does not keep door closed tightly when engaged.

- 223. <u>Gap offset (mm).</u> Use ruler to measure the distance between the refrigerator door edge and the refrigerator cabinet edge in two places (i.e., one measurement near the hinged side of door and one near the free side of door). The difference between these two measurements is the gap offset.
- 224. <u>Keypad.</u> *Unresponsive*: keypad buttons do not trigger the intended response. *Broken:* keypad is unusable due to physical damage or other issue.
- 228. <u>Temperature display</u>. *Broken:* temperature display does not turn on and/or display a temperature reading. Accuracy of reading is evaluated separately. *Digits:* some part of a temperature reading is displayed but there are digits or parts of digits that do not display correctly. *Fixation:* there is a problem with the attachment between the temperature display and the cold chain equipment.
- 235. <u>Power LED</u>. *Broken:* external power LED is broken if it does not turn on when the equipment is receiving power. For DC systems, check power LED when the solar power system is receiving sunlight.
- 241. AC power cable. Damaged: the AC power cable has visible destruction (e.g., rodent damage).
- 242. <u>Voltage stabilizer</u>. A voltage stabilizer is an electrical device designed to reduce fluctuations in input voltage and frequency to ensure a stable electrical supply.⁵ Functionality may be assessed by the readout or status indicator on the voltage stabilizer, or with a multimeter. *Malfunctioning:* voltage stabilizer somewhat regulates incoming power supply but is not functioning entirely as intended and could be improved/repaired. *Non-functional:* voltage stabilizer does not regulate incoming power supply. *Surge arrester:* see Figure 11 for examples.
- 243. <u>PV cable.</u> *Loom:* woven layer surrounding cable. *Insulation:* check the insulation around the cable for damage. *Connector:* the physical PV cable connection (usually an M4 connector).
- 249. <u>Vaccine vial monitor (VVM) stage.</u> VVM stage should be interpreted according to Figure 12. Report highest VVM stage observed among all vials.
- 255. Moisture reading (%). Use moisture meter to take moisture reading of matte/uncoated packaging.
- 260. <u>Moisture reading (%).</u> Use moisture meter to take moisture reading of glossy/polycoated packaging.
- 271. Walls. To evaluate temperature distribution, open the door and immediately use infrared (IR) thermometer to read temperature at 5–6 points distributed around the storage compartment walls. Record minimum and maximum values observed, which will be required for questions 277 and 278. Evaluate the consistency of readings. Alternatively, or in conjunction with the IR thermometer analysis, a thermal photo of the storage compartment walls can be taken immediately after opening the door using thermal imaging camera with software to identify minimum and maximum temperatures.
- 279. <u>Bottom.</u> To evaluate temperature distribution, open the door and immediately use IR thermometer to read temperature at 5–6 points distributed around the storage compartment bottom. Record minimum and maximum values observed, which will be required for questions 284 and 285. Evaluate the consistency of readings. Alternatively, or in conjunction with the IR thermometer analysis, a thermal photo of the storage compartment bottom can be taken immediately after opening the door using thermal imaging camera with software to identify minimum and maximum temperatures.
- 288. <u>Condensation baffle.</u> Certain CCE models have a condensation baffle in the vaccine compartment. Use a manual to identify this component if necessary. *Damaged:* condensation baffle has physical damage.
- 290. <u>Support bridge.</u> Certain CCE models have a support bridge in the vaccine compartment. Use a manual to identify this component if necessary.
- 296. Drain temperature (°C). Use the IR thermometer to measure drain temperature.
- 307. <u>Cable seal surface temperature (°C).</u> Use the IR thermometer to measure cable seal surface temperature.

- 308. Thermostat sensor. Accuracy: if possible, locate the thermostat sensor (the equipment manual may provide guidance) and temporarily remove any components blocking the sensor (e.g., vaccines, storage compartment shelves or walls). Thermostat sensors may not be accessible in some models. To evaluate accuracy of the sensor, take a thermocouple reading as close to the thermostat sensor as possible and compare thermocouple reading to thermostat reading. Record thermocouple reading to answer question 315. Airflow: evaluate airflow using environmental meter.
- 317. External display sensor. Accuracy: if possible, locate the external display sensor (the equipment manual may provide guidance) and temporarily remove any components blocking the sensor (e.g. vaccines, storage compartment shelves or walls). External display sensors may not be accessible in some models. To evaluate accuracy of the sensor, take a thermocouple reading as close to the external display sensor as possible and compare thermocouple reading to external display reading. Record thermocouple reading to answer question 325. Airflow: evaluate airflow using environmental meter.
- 326. Refrigerator center thermocouple reading (°C). Record thermocouple reading taken in the center of the refrigerator storage compartment.
- 327. <u>Internal circulation fan.</u> Certain Vestfrost models contain an internal circulation fan. *Nonfunctional:* fan does not turn on and rotate.
- 328. <u>Ice bank water level (cm).</u> Use a ruler to measure the distance from the top of the filling tube neck to the water surface.
- 330. <u>Ice bank photos.</u> An ice bank may be an internal lining surrounding the vaccine storage compartment that is filled with ice, cold water, or other coolant.⁵ In some refrigerators, the ice bank does not completely surround the vaccine storage compartment and instead sits inside a compartment adjacent to the vaccine storage compartment.
- 334. Minimum temperature (°C). Use a thermocouple to read temperatures at 5–6 points distributed around the ice bank module/panel. Record minimum value observed. Alternatively, take a thermal image of the panels and analyze the image to find the lowest value. This may require additional software.
- 335. <u>Maximum temperature (°C).</u> Use a thermocouple to read temperatures at 5–6 points distributed around the ice bank module/panel. Record maximum value observed. Alternatively, take a thermal image of the panels and analyze the image to find the lowest value. This may require additional software.

Questions 336–447 refer to the electronics/motor compartment. To access the electronics/motor compartment, the ventilation grill may need to be removed using screwdrivers, wrenches, or specialized instruments, depending on manufacturer.

- 336. Ambient temperature (°C). Use environmental meter to measure ambient temperature. Temperatures at certain locations may be elevated due to warm componentry, so try to take an indicative measurement of the general temperature inside the compartment.
- 337. Relative humidity (RH%). Use environmental meter to measure relative humidity.
- 344. Thermostat plug. Identify the cable connecting the thermostat controller to the thermostat sensor. Check the seal at the location where this cable enters the vaccine compartment (or leaves the motor compartment)
- 349. # of cooling circuits. If equipment can keep separate compartments (i.e., refrigerator and freezer compartments) at different temperatures, the equipment has 2 cooling circuits. Check for the presence of 2 compressors to confirm 2 cooling circuits.
- 350. <u>Fan #1.</u> *Damaged:* fan has physical damage or is not working entirely as intended. *Miswired:* visually check fan for loose wires or other signs of illicit repairs. If fan is suspected to be miswired based on visual inspection, compare wiring to circuit diagram to confirm.
- 351. <u>Fan #1 input voltage (VDC).</u> Use multimeter on VDC setting with test leads connected to the fan input wires.

- 352. Fan #1 input voltage (VAC). Use multimeter on VAC setting with test leads connected to the fan input wires.
- 363. Compressor #1 input pipe temperature (°C). Use thermocouple to measure temperature of compressor input pipe.
- 364. Compressor #1 surface temperature (°C). Use thermocouple to measure temperature of compressor surface.
- 365. Compressor #1 output pipe temperature (°C). Use thermocouple to measure temperature of compressor output pipe.
- 366. Compressor #1 controller or starting device. Miswired: visually check compressor controller/starting device for loose wires or other signs of illicit repairs. All spade terminals should be connected with appropriate wires. If compressor is suspected to be miswired based on visual inspection, compare wiring to circuit diagram to confirm. Damaged: controller/starting device has physical damage or compressor does not run after refrigerator has been open for >10 minutes.
- 368. Compressor #1 controller input voltage at +/- terminals (VDC). Use multimeter on VDC setting with test leads connected to compressor controller positive and negative input terminals to measure voltage.
- 369. Compressor #1 controller input current at +/- terminals (amperes, direct current [ADC]). Use DC clamp meter surrounding compressor controller positive or negative input terminals to measure current.
- 370. Compressor #1 starting device input voltage (VAC). Use multimeter on VAC setting with test leads connected to starting device input wires to measure voltage.
- 371. <u>Piping #1</u>. *Broken*: piping cannot function in its current state (i.e., fluid cannot pass through or is all released).
- 374. Thermostat controller #1. Setting: thermostat controller turns on and gives a reading but user cannot select or change the temperature setting. Damaged: thermostat controller does not turn on or does not give a temperature reading or has physical damage interfering with the use of the controller. Miswired: visually check controller for loose wires or other signs of illicit repairs. If controller is suspected to be miswired based on visual inspection, compare wiring to circuit diagram to confirm.
- 380. <u>Internal condenser #1 center surface temperature (°C).</u> Use thermocouple to measure temperature at the center of internal condenser surface.
- 381. <u>Internal condenser #1 input pipe temperature (°C).</u> Use thermocouple to measure temperature of internal condenser input pipe.
- 382. <u>Internal condenser #1 output pipe temperature (°C).</u> Use thermocouple to measure temperature of internal condenser output pipe.
- 383. <u>Starting capacitor #1.</u> Some models will have a starting capacitor. *Damaged:* starting capacitor has physical damage.
- 387. External condenser #1 center surface temperature (°C). Use thermocouple to measure temperature at the center of external condenser surface.
- 388. External condenser #1 input pipe temperature (°C). Use thermocouple to measure temperature of external condenser input pipe.
- 389. External condenser #1 output pipe temperature (°C). Use thermocouple to measure temperature of external condenser output pipe.
- 390. <u>Filter dryer #1.</u> *Broken:* inspect the filter dryer for physical damage that may impact function. Other signs that a filter dryer may be broken include freezing evaporator coils, a drop in temperature across the filter dryer, or low condenser coil temperatures. Use thermocouple to evaluate temperatures across the filter dryer if needed. Additionally, if it appears that previous

For more information on liquid line filter drier issues visit https://www.hunker.com/13409094/signs-and-symptoms-of-a-bad-liquid-line-filter-dryer.

- repairs have been done, poor brazing or other indications of possibly problematic technique may indicate that the filter dryer could be clogged or otherwise broken. Without troubleshooting the cooling circuit in depth, it may be difficult or impossible to know if the filter dryer is broken if it has already been established that there is a cooling circuit issue.
- 393. <u>Filter dryer #1 input temperature (°C).</u> Use thermocouple to measure temperature of filter dryer input pipe.
- 394. <u>Filter dryer #1 surface temperature (°C).</u> Use thermocouple to measure temperature of filter dryer surface.
- 395. <u>Capillary #1.</u> Broken: capillary cannot function in its current state (i.e., fluid cannot pass through or all fluid is lost at that point). Potential symptoms of a broken capillary may include a compressor running hot.
- 398. Capillary #1 temperature (°C). Use thermocouple to measure temperature of capillary.

For instructions and term clarification regarding cooling circuit #2 (questions 399–447), refer to corresponding questions about cooling circuit #1 (questions 350–398).

- 449. <u>Glass.</u> Fracture: glass sheet has a crack but is still held together. Breakage: piece(s) of glass are detached from glass sheet. Anti-reflective coating (ARC) delamination: ARC comes off the module glass surface.⁹
- 450. Encapsulant. Discoloration: See Figure 14 for an example of encapsulant discoloration.
- 451. Frame. Damaged: frame has physical damage.
- 453. <u>Cell.</u> Broken: cell has physical damage that makes it unusable. Snail trails: micro-cracks in solar cells (see Figure 15). Solder ribbon discoloration: see Figure 16 to identify solder ribbons connecting solar cells. Check for discoloration of solder ribbons. Poor solder wetting/contact: solder ribbon has poor contact with cell (e.g., loose or gaps). Finger interruption/metallization smudges: see Figure 16 to identify solar cell fingers. Check for interruptions or smudges in cell fingers. Cell mismatch: cells of varying current are connected in series. Poor edge isolation: grooves cut around the cell are not isolating the front of the cell from the back of the cell as they are intended to. Polarized cells: solar cells that are at a positive voltage relative to the ground due to an inadequate grounding system, resulting in reduced power output. This failure mode is unlikely to occur in the size of solar system typically used to support a refrigerator but may be diagnosed if reduced power output and/or an inadequate grounding system are observed. 6
- 454. <u>Backsheet.</u> *Delamination from ethylene-vinyl acetate (EVA):* backsheet has separated from EVA encapsulant.
- 456. <u>Interconnects.</u> Interconnects are electrical wiring used to connect individual solar modules or batteries into larger groupings.⁵
- 461. <u>Combiner boxes.</u> A combiner box is an electrical connection enclosure or fitting where solar module interconnects are joined to the solar array output cable.⁵ Check the combiner boxes for physical damage such as embritlement or poor connections with solar cables.
- 462. <u>PV output cable.</u> *Connector:* the fitting of a power cable that connects to power source cable or receptacle.⁵
- 474-478. Array sunpath/shading. Use Sun Surveyor mobile app to evaluate sun exposure at the array and take screenshots.

For questions 479–521, 'normally operating' refers to the solar array in its normal state, connected to an external load (the CCE while it is running). No changes need to be made to the wiring to answer questions about normally operating measurements. However, be sure that the refrigerator compressor is running while normally operating measurements are recorded. If the refrigerator is not running, open the door for a few minutes to trigger the compressor to start before taking measurements. 'Short circuit' refers

20

For more information on delamination and other solar PV module issues visit https://www.ee.co.za/article/solar-pv-module-faults-failings.html.

^h For more information on causes and effects of cell mismatch visit https://review.solar/solar-panel-hot-spot/.

to electrical circuits with no resistance. Modules/panels/arrays will need to be changed to short circuits by connecting positive and negative output wires to answer questions about short circuit measurements. 'Open circuit' refers to electrical circuits without a continuous path between terminals such that the net current is zero. Modules/panels/arrays will need to be changed to open circuits by disconnecting positive and negative output wires from any external loads to answer questions about open circuit measurements.

- 479. <u>Sufficient solar power.</u> Use solar power meter or pyranometer mobile app to measure solar radiation. 'Sufficient solar power' is defined as solar radiation > 400 W/m².
- 481. <u>Array horizontal solar radiation (W/m²).</u> Use solar power meter or pyranometer mobile app to measure the solar radiation received on a horizontal plane at the location of the array.
- 482. <u>Array voltage open circuit (Voc).</u> With the array disconnected from any load, use multimeter on VDC setting with test leads connected to the PV array output cable to measure open circuit voltage.
- 483. <u>Array current short circuit (Isc).</u> While the array is short circuited, use clamp meter on DC ampere setting to measure short circuit current.
- 485. <u>Array current normally operating (Ino).</u> While array is operating normally, use clamp meter on DC ampere setting to measure current.
- 486. <u>Array voltage normally operating (Vno).</u> While array is operating normally, use multimeter on VDC setting with test leads connected to the PV array output cable to measure voltage.
- 488. Panel orientation. Use compass to determine panel orientation.
- 490. <u>Panel normally operating thermal photos.</u> Take thermal photo(s) of panel while panel is normally operating (connected to external load).
- 491. Panel azimuth (°). Use compass to measure panel azimuth.
- 492. <u>Panel inclination (°).</u> Use inclinometer to measure panel inclination.
- 493. Panel level (°). Use level placed on top edge of panel to measure panel level.
- 494. Ambient temperature (°C). Use environmental meter to measure ambient temperature.
- 495. Relative humidity (RH%). Use environmental meter to measure relative humidity.
- 496. Panel normal solar radiation (W/m²). Use solar power meter to measure solar radiation received normal to the front of the panel.
- 497. Panel voltage open circuit (Voc). With the panel disconnected from any other panels or loads, use multimeter on VDC setting with test leads connected to the panel output terminals to measure open circuit voltage.
- 498. <u>Panel current short circuit (Isc).</u> While the panel is short circuited, use clamp meter on DC ampere setting to measure short circuit current.
- 499. Panel short circuit thermal photos. Take thermal photo(s) of panel while the panel is short circuited.
- 502. <u>Module orientation</u>. Use compass to determine module orientation.
- 503. Module azimuth (°). Use compass to determine module azimuth.
- 504. Module inclination (°). Use inclinometer to measure module inclination.
- 505. Module level (°). Use level placed on top edge of module to measure module level.
- 507. <u>Module normally operating thermal photos.</u> Take thermal photo(s) of module while module is normally operating.
- 508. # of hotspots in normally operating module. Detection of hotspots is sometimes possible through visual inspection for evidence of heat damage but may require thermal imaging equipment and advanced techniques (such as IR video thermometer or thermal imaging camera and software).⁵ See Figure 41 for an example of hotspot detection using thermal imaging equipment. While module is normally operating, inspect the module for hotspots visually or with thermal imaging equipment.

- 509. <u>High temperature behind junction box in normally operating module.</u> Use IR thermometer to read temperature behind junction box.
- 510-512. Module normally operating cell temperatures. While the module is normally operating, use IR thermometer to take temperature of 5–6 cells in the module. Record minimum and maximum temperatures observed, and record average of all observations. Alternatively, use thermal imaging equipment with software.
 - 513. <u>Module normal solar radiation (W/m²).</u> Use solar power meter to measure solar radiation received normal to the front of the module.
 - 514. Module voltage open circuit (Voc). With the module disconnected from any other modules or loads, use multimeter on VDC setting with test leads connected to the module terminals to measure open circuit voltage.
 - 515. Module current short circuit (Isc). While the module is short circuited, use clamp meter on DC ampere setting to measure short circuit current.
 - 516. Module short circuit thermal photos. Take thermal photo(s) of module while the module is short circuited.
 - 517. # of hotspots in short circuit. Detection of hotspots is sometimes possible through visual inspection for evidence of heat damage but may require thermal imaging equipment and advanced techniques (such as IR video thermometer or thermal imaging camera and software). Error! Bookmark not defined. See Figure 41 for an example of hotspot detection using thermal imaging equipment. While module is short circuited, inspect the module for hotspots visually or with thermal imaging equipment.
 - 518. <u>High temperature behind junction box in short circuit.</u> Use IR thermometer to read temperature behind junction box.
- 519-521. Module short circuit cell temperatures. While the module is short circuited, use IR thermometer to take temperature of 5–6 cells in the module. Record minimum and maximum temperatures observed, and record average of all observations. Alternatively, use thermal imaging equipment with software.
 - 523. <u>Ground rod.</u> *Protrusion:* ground rod sticks out of the ground too far, potentially creating an obstacle or trip hazard.
 - 525. <u>Ground rod earth bond resistance (ohms).</u> Use earth resistance tester, with probe attached to the ground rod, to measure earth bond resistance of ground rod. Follow the instructions provided for the model of earth resistance tester in use to take the measurement.
 - 526. <u>Ground rod lug earth bond resistance (ohms).</u> Use earth resistance tester, with probe attached to the ground rod lug, to measure earth bond resistance of ground rod lug. Follow the instructions provided for the model of earth resistance tester in use to take the measurement.
 - 530. Support structure earth bond resistance (ohms). Use earth resistance tester, with probe attached to the solar array support structure, to measure earth bond resistance of support structure. Follow the instructions provided for the model of earth resistance tester in use to take the measurement. If the support structure is aluminum, the probe of the earth resistance tester that contacts the aluminum may need to scratch through the thin oxide layer on the aluminum to obtain an accurate measurement; otherwise, the resistance may appear to be too high.
 - 531. Lowest module frame earth bond resistance (ohms). Use earth resistance tester, with probe attached to the frame of the lowest solar module, to measure earth bond resistance of the lowest module frame. Follow the instructions provided for the model of earth resistance tester in use to take the measurement. If the module frame is aluminum, the probe of the earth resistance tester that contacts the aluminum may need to scratch through the thin oxide layer on the aluminum to obtain an accurate measurement; otherwise, the resistance may appear to be too high. Some earth resistance tester probes may not be sharp enough to get through the oxide layer.
 - 532. <u>Highest module frame earth bond resistance (ohms).</u> Use earth resistance tester, with probe attached to the frame of the highest solar module, to measure earth bond resistance of the highest module frame. Follow the instructions provided for the model of earth resistance tester in

use to take the measurement. If the module frame is aluminum, the probe of the earth resistance tester that contacts the aluminum may need to scratch through the thin oxide layer on the aluminum to obtain an accurate measurement; otherwise, the resistance may appear to be too high. Some earth resistance tester probes may not be sharp enough to get through the oxide layer.

- 533. <u>Earth conductor.</u> *Length:* if earth bond resistance is higher than expected, according to the inspector's expertise and discretion, the earth conductor may not be long enough. Without removing the conductor from the ground, it may not be possible to determine if the conductor length is adequate for the system requirements.
- 534. <u>Device status.</u> *Nonfunctional:* thirty-day temperature recorder (30-DTR) is not able to record temperatures.
- 538. <u>Display.</u> *Nonfunctional:* display does not turn on or does not show anything. *Damaged:* display turns on and shows content but has physical damage or is malfunctioning in some way.
- 541. <u>Data.</u> Recorded data should be recovered through the universal serial bus (USB) port on the 30-DTR.
- 542. <u>Fuses.</u> A fuse is an electrical safety device containing a material that melts at a predetermined temperature, thereby relieving the (overcurrent) pressure.⁵ Check for spare fuses attached to the equipment or stored nearby. Ask health facility worker if spare parts are kept in stock.

Summary (questions 543–546)

- 543. <u>Context.</u> Provide a short narrative description of the context of the fridge, location, etc. that describes major immediate issues found and any context that may be helpful for someone returning to this assessment record.
- 544. <u>Findings.</u> Provide a short narrative of any key findings regarding the equipment. This may be large failings or conclusions that someone returning to this assessment record should be aware of.
- 545. <u>Proxy causes.</u> Provide a short narrative description of causes that may be relevant to failures and faults, even if they are not root causes or are based on assumptions.
- 546. Repairs by assessors. Select any repairs undertaken during the visit.

4. Discussion

The inspection procedures documented here were used on a set of refrigerators to obtain data that would allow for root cause of failure analysis across refrigerators of different brands, models, and ages. However, this root cause of failure analysis was ultimately not completed due to unexpected, diverse, and complex implementation challenges that were encountered in each cold chain system where the CCE assessment was implemented, requiring adaptation of the assessment methodology and resulting in variations in the equipment sample and assessment approach in each country. Despite these implementation and equipment sampling challenges and inability to control for numerous confounding factors to determine the root cause of failure, the inspection framework was successful in standardizing an approach to describing the degree and presence of problems with prequalified vaccine refrigerators.

Full inspection of an AC-powered refrigerator required approximately 3.5 hours per refrigerator, and inspection of an SDD refrigerator and integrated PV solar array performance took at least 5 hours. While inspection takes time, it delivers a standard dataset capturing faults for each component of the vaccine refrigerator or PV array. However, inspection is not able to ascertain the cause of an existing temperature performance failure; rather, it examines CCE for signs of potential future premature failures, which may be useful to indicate conditions leading to future equipment performance or quality problems. Collection of

the full inspection dataset was labor, time, and test equipment intensive, and ultimately it may not be successful for root causes of failure analysis, in particular without a much larger, randomized equipment sample and better access to historical 30-DTR data. For future assessments, or post-market monitoring (PMM) systems, it may be possible to simplify and reduce the inspection dataset while still providing valuable equipment performance and quality information. Assessment findings are intended to help identify actions for manufacturers, WHO PQS, and EPI that will help prevent premature failures of prequalified CCE. Both approaches (full inspection and simplified inspection) are supported with a new mobile data collection and management application developed during this project that could be adapted and used to guide a standard approach to equipment inspection as a tool for PMM.

Future implementations of this standardized assessment methodology (Table 4) should plan for flexibility and refinements to the tool, as each country will be different, and the age and type of equipment, logistics, and technical expertise of partners will vary. The inclusion of a user guide to accompany the mobile data collection tool, such as the inspection procedures set out here, can also help to facilitate adherence to the standardized investigation protocol.

Table 4. Summary of the inspection methodology and recommendations for future implementers of this methodology.

 Standardized inspection approach supports high-quality data collection by different assessors. Can target data collection on technical criteria on design or production issues. Less dependent on 30-DTR data to identify performance problems. Less dependent on accurate CCEI data to locate equipment. Potential approach for PMM of quality and performance.
Time intensive in current form.
 Faults cannot be linked to causes of equipment failures unless large datasets or random samples collected.
Specialized test equipment required for many data points.
 Analysis complicated by variable and sometimes large numbers of criteria scored for each component.
Analysis remains undeveloped to link any causation to identified faults.
 Reduce inspection data collection fields according to CCEI, technical expertise, time, and resources available.
 Require completion of all inspection data fields, including confirming no issue, N/A, or unknown.
Modify equipment/country selection to control for age and external factors.

Abbreviations: 30-DTR, thirty-day temperature recorder; CCEI, cold chain equipment inventory; PMM, post-market monitoring.

In the context of PMM surveillance efforts in which highly specialized technical experts will not be available and where temperature performance problems may not be detectable due to a lack of access to 30-DTR data, a simplified version of the inspection approach may be highly appropriate.

It will be important to refine the data entry fields to ensure they are objective and, in some cases, reduce the number of assessment questions to focus on indicators of faults, such as a lack of routine maintenance or corrosion. Inspection of SDD solar arrays' production and installation quality may help identify important gaps that might limit the expected lifetime of these systems.

Future work could include optimization of the assessment data collection tool and expanded implementation of the CCE assessment protocol in additional CCE systems and countries to build a larger dataset that could help enable predictive analytics and machine learning approaches to extract insights on root causes of PQS-prequalified vaccine refrigerator failures.

As it stands and for its designated purpose, the Fulcrum tool is a robust, tested, and useful mobile application for collecting and consolidating data on CCE component status and faults and can continue to be used and modified as needed. The level of detail collected provides a strong foundation for future work.

References

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Annexes

Annex A. Data collection fields

Please click on the pin icon below to open the spreadsheet.



Abbreviations for Annex A

3D three-dimensional

30-DTR thirty-day temperature recorder

3G third generation (mobile communication system)

4G fourth generation (mobile communication system)

ADC amperes, direct current

ARC anti-reflective coating

CCE cold chain equipment

DC direct current

DOH Department of Health

EPI Expanded Programme on Immunization

EU European Union

EVA ethylene-vinyl acetate

ext. external

GAVI Global Alliance for Vaccines and Immunizations

GSK GlaxoSmithKline

GSM global system for mobile communication

ID identification

Ino normally operating current

IR infrared

Isc current, short circuit

JICA Japan International Cooperation Agency

LED light emitting diode

LPG liquid petroleum gas

MSF Médecins Sans Frontières

PQS Performance, Quality and Safety (WHO)

PV photovoltaic

RH% relative humidity percentage

SDD solar direct drive

S/N serial number

SOP standard operating procedure

UNICEF United Nations Children's Fund

USAID United States Agency for International Development

USB universal serial bus

VAC alternating current voltage

VDC direct current voltage

Vno normally operating voltage

Voc open circuit voltage
VVM vaccine vial monitor

WHO World Health Organization

Annex B. Diagrams and photos to identify CCE parts and components

List of Annex B figures

Figure 1. Roof types	31
Figure 2. Example of a generator	31
Figure 3. Generic solar array	31
Figure 4. Generic vapor compression cooling circuit (solar powered)	32
Figure 5. Generic battery system with solar recharge	32
Figure 6. Solar cell, module, panel, and array	33
Figure 7. Example of solar panels wired in series	33
Figure 8. Example of solar panels wired in parallel	33
Figure 9. Generic CCE components	33
Figure 10. Generic vapor compression cooling circuit (AC mains powered)	34
Figure 11. Surge arrester and AC power cord	34
Figure 12. Vaccine vial monitor interpretation	34
Figure 13. Solar module components	35
Figure 14. Solar module encapsulant discoloration	35
Figure 15. Snail trails on a solar panel	35
Figure 16. Solar cell diagram	36
Figure 17. Roof mounting of solar modules	36
Figure 18. Grounding system	36
Figure 19. Refrigerator cabinet components	37
Figure 20. Example of manufacturing label	37
Figure 21. Refrigerator latch/clasp	37
Figure 22. DC power supply	38
Figure 23. Temperature sensor components	38
Figure 24. Condensation drainage with plug	38
Figure 25. Voltage stabilizer	38
Figure 26. Vaccine compartment components	39
Figure 27. Compressor compartment components	39
Figure 28. Filter dryer and capillary	40
Figure 29. Internal condenser and compressor	40
Figure 30. External condenser	40
Figure 31. Compressor controller (DC systems)	41

Figure 32. Compressor starting device (AC systems) and starting capacitor	41
Figure 33. Example of a 20-day electronic shipping indicator	41
Figure 34. Example of a 30-day electronic temperature logger	41
Figure 35. Example of a chemical temperature indicator	42
Figure 36. Example of a cold chain monitor card	42
Figure 37. Example of an electronic freeze indicator	42
Figure 38. Example of a remote temperature monitoring system	43
Figure 39. Example of a user programmable temperature data logger	43
Figure 40. Example image of a vaccine refrigerator taken with FLIR moisture mete	43
Figure 41. Infrared image from FLIR ONE camera indicating hotspots in solar panels	43

Figure 1. Roof types.

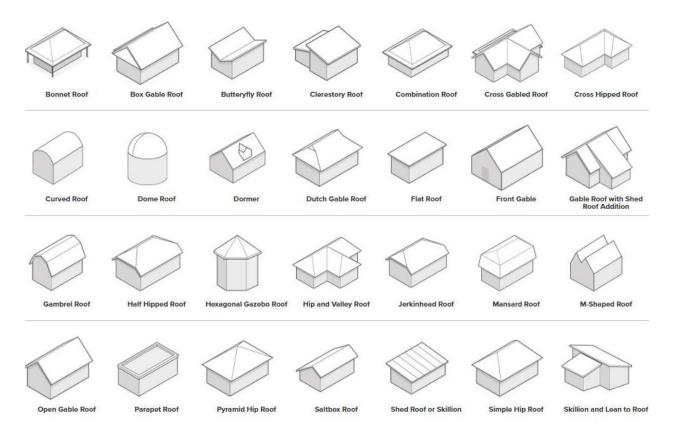


Image: JTC Roofing Contractors Ltd.

Figure 2. Example of a generator.



Figure 3. Generic solar array.⁵

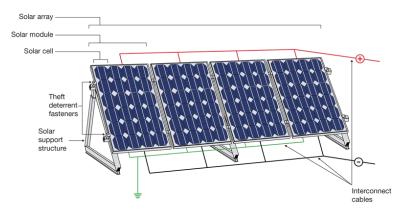


Figure 4. Generic vapor compression cooling circuit (solar powered).⁵

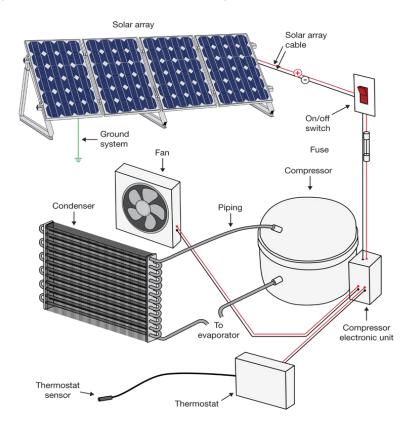


Figure 5. Generic battery system with solar recharge.⁵

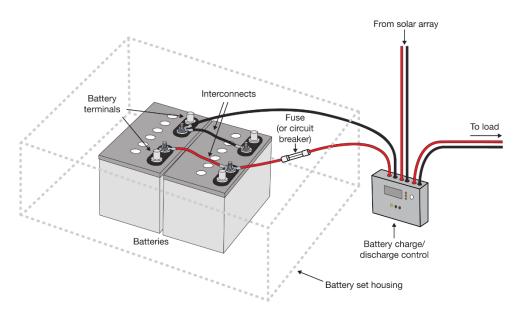


Figure 6. Solar cell, module, panel, and array. Multiple solar cells constitute a solar module; one or more modules constitute a panel; and one or more panels constitute an array.

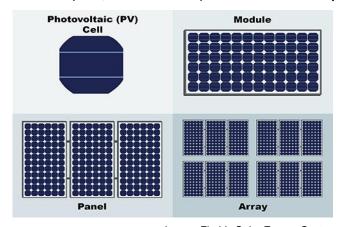
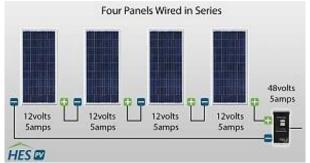


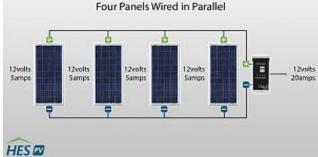
Image: Florida Solar Energy Center.

Figure 7. Example of solar panels wired in series.

Figure 8. Example of solar panels wired in parallel.

Four Panels Wired in Parallel





Images: HES PV.

Figure 9. Generic CCE components.5

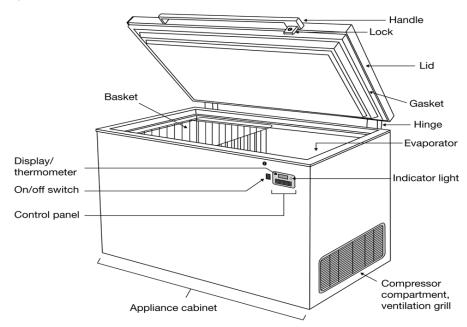


Figure 10. Generic vapor compression cooling circuit (AC mains powered).⁵

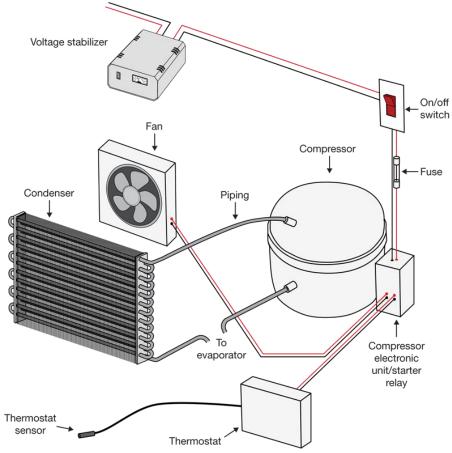


Figure 11. Surge arrester and AC power cord.



Photo: PATH.

Figure 12. Vaccine vial monitor interpretation.

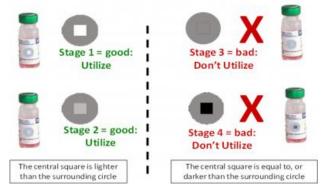


Image: Pandit Dindayal Upadhyay Medical College, Rajkot.

Figure 13. Solar module components.

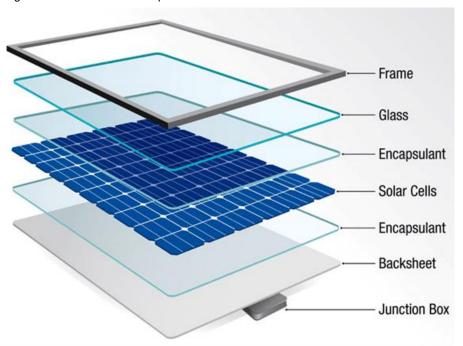


Image: Solar Magazine.

Figure 14. Solar module encapsulant discoloration.



Photo: Atlas Material Testing Solutions.

Figure 15. Snail trails on a solar panel.



Image: Institute for Solar Energy Research.

Figure 16. Solar cell diagram.

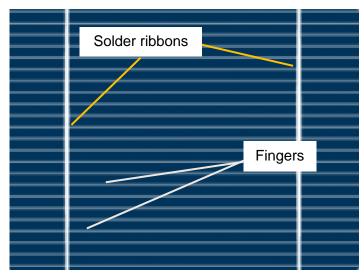


Image: US Department of Energy, Office of Efficient Energy & Renewable Energy.

Figure 17. Roof mounting of solar modules.

Figure 18. Grounding system.



Figure 19. Refrigerator cabinet components.



Figure 20. Example of manufacturing label.



Figure 21. Refrigerator latch/clasp.



Figure 22. DC power supply.

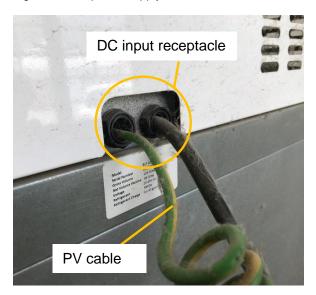


Figure 23. Temperature sensor components.

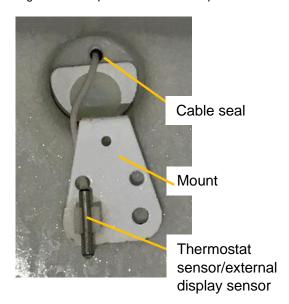


Figure 24. Condensation drainage with plug.



Figure 25. Voltage stabilizer.



Figure 26. Vaccine compartment components.

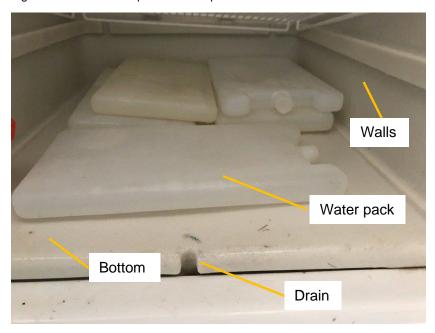


Figure 27. Compressor compartment components.

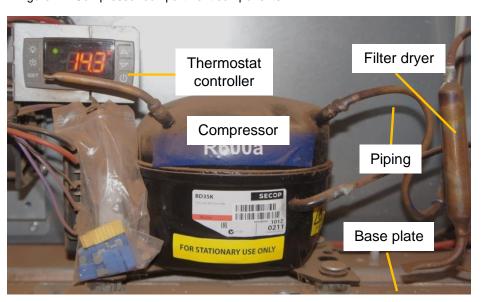


Figure 28. Filter dryer and capillary.

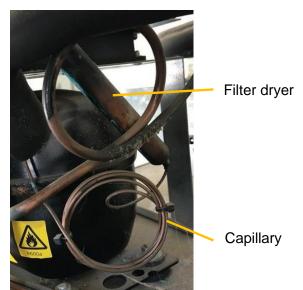


Figure 29. Internal condenser and compressor.

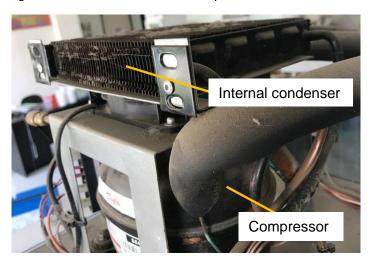


Figure 30. External condenser.



Figure 31. Compressor controller (DC systems).



Photos (Figures 30 and 31): PATH.

Figure 32. Compressor starting device (AC systems) and starting capacitor.

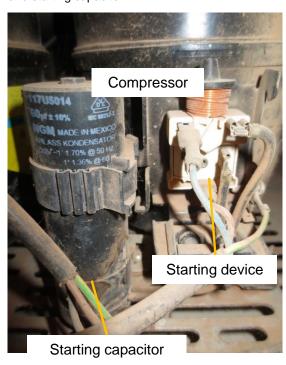


Figure 33. Example of a 20-day electronic shipping indicator.



Photo: Berlinger & Co AG.

Figure 34. Example of a 30-day electronic temperature logger.



Photo: LogTag Recorders Ltd.

Figure 35. Example of a chemical temperature indicator



Figure 36. Example of a cold chain monitor card.

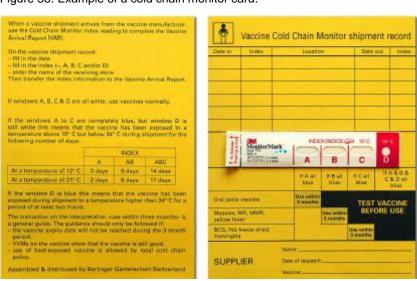


Photo: Berlinger & Co AG.

Figure 37. Example of an electronic freeze indicator.



Photo: Sensitech Inc.

Figure 38. Example of a remote temperature monitoring system.



Photo: Zero Appliances (Pty) Ltd.

Figure 39. Example of a user programmable temperature data logger.



Photo: Modum.io AG.

Figure 40. Example image of a vaccine refrigerator image taken with FLIR moisture meter.

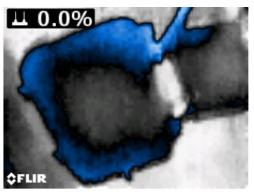


Photo: PATH.

Figure 41. Infrared image from FLIR ONE camera indicating hotspots in solar panels.

