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PQS Target Product Profile

TITLE: Enhanced mains-powered refrigerators or combined mains-powered refrigerator and vaccine freezer

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Contents

1. Need

Recent public sector consultations and reports from the field have identified the need for some amendments and additions to the current PQS specifications for mains-powered refrigerators. Recent field experiences with mains-powered refrigerators have revealed certain shortcomings in performance, and have also highlighted robustness issues due to sub-optimal power conditions in the field. These matters need to be addressed so that the next generation of mains-powered refrigerators better meets country needs.

The purpose of this preliminary Target Product Profile is to propose enhancements designed to resolve these issues and to initiate a consultation process with industry which will lead to revised PQS performance specifications and verification protocols and to products with improved overall performance.

2. Normative references

Refer to relevant PQS specifications and verification protocols.

3. Terms and definitions

Acceptable temperature range in designated vaccine storage space:
The acceptable temperature range for storing vaccine is +2.0°C to +8.0°C. However, transient excursions outside this range will be tolerated, within the following limits:

- No excursion must exceed +10°C.
- No excursion must be below +1.5°C.

The cumulative effect of any excursions within the above range will be assessed over the five-day period of the day/night test. For this test, the calculated mean kinetic temperature (MKT)[1] must remain within the range +2.0°C to +8.0°C when the default activation energy is set at 83,144 kJ per mol. Using the recorded temperature data, an MKT figure will be calculated for each sensor. The worst-case result will determine the outcome of the test. Excursions in other tests will be noted. None of these excursions must exceed the upper and lower limits defined above.

Clarifying note: The acceptable temperature range in designated vaccine storage space is different from the freezing temperature on the wall / lining of the vaccine compartment. The latter refers to temperatures when sensors are *in direct contact with the wall / lining of the vaccine storage compartment*. The former refers to temperatures when sensors are in the designated safe storage area, i.e., when the centres of the sensors are placed *50 ±10 mm away from the lining of the vaccine storage compartment*, as specified in E003/RF03-VP.2.

Reason for change: Excursion criteria should be tightened in order to exclude the possibility of freezing vaccines and also to reduce the upper excursion limit to achieve greater compliance with the designated +2.0°C to +8.0°C operating range.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

Freezing temperature on walls / lining of vaccine compartment:

[1] Refer to Seevers, R. et al. *The Use of Mean Kinetic Temperature (MKT) in the Handling, Storage and Distribution of Temperature Sensitive Pharmaceuticals*. Pharmaceutical Outsourcing, May/June 2009.

For sensors placed in direct contact with the walls /lining of the vaccine compartment, freezing temperature is defined as any of the following conditions:

- Excursion between -1°C and 0°C for longer than 1 hour.
- Excursion equal to or below -1°C for any amount of time.
- Inability to return to safe operating temperature (i.e., consistently between +2°C and +8°C) within 2 hours following an excursion equal to or below 0°C.

Reason for change: Excursion criteria should be tightened in order to exclude the possibility of freezing vaccines.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

Freeze-protection classification: As described in **E003/TPP01.2**

- Grade A, user-independent freeze protection (UIFP): when the appliance is used within its nominated temperature range (temperature zone +43°C, +32°C or +27°C and minimum rated ambient temperature) there is no intervention required by the user to ensure that the vaccines will not be exposed to temperatures below 0°C whatever the position of the vaccine in the vaccine compartment.
- Grade B, user-dependent freeze protection (UDFP): Even if the appliance is used within its nominated temperature range, the user must comply with a procedure provided by the manufacturer and requiring one level of intervention (e.g., the requirement to use baskets or other items) in order to avoid vaccine freezing.
- Grade C, user-dependent freeze protection (UDFP): Even if the appliance is used within its nominated temperature range, the user must comply with a procedure provided by the manufacturer requiring more than one level of intervention in order to avoid vaccine freezing. (e.g., the requirement to use baskets and insolation barriers or covers).

Reason for change: In view of the increasing number of freeze-sensitive vaccines in immunization schedules and the problem of procedure compliance in the field, freeze protection during storage has become a priority. This grading will provide an indication on the level of user intervention required for vaccine freeze protection.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016.

Gross storage capacity:
This is the volume of the air space inside the internal compartment with the door or lid shut.

Holdover time:

- The time in hours during which all points in the vaccine compartment remain between +2°C and +8°C, at the maximum ambient temperature of the temperature zone for which the appliance is rated, after the power supply has been disconnected.
- Any thermal barriers that are easily moved by users (e.g., covers in certain products) will not be permitted in future testing of holdover times.

Reason for change: The upper threshold temperature for holdover time has been reduced from +10°C to +8°C. This is to align holdover time measurement with programmatic guidance for vaccine storage, which sets the threshold at +8°C.

The prohibition of easily removable thermal barriers in holdover testing is intended to mimic field usage of the appliance: easily removable thermal barriers are likely to be removed, lost, damaged, etc., causing an adverse impact on holdover times.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

Hot zone:
Hot zone appliances must operate at a steady +43°C ambient temperature and over a +43°C/+25°C day/night cycling temperature range. All appliances are required to comply as hot zone appliances. They can additionally be tested and certified for other temperature zones.

Rated minimum ambient temperature:
In addition to the day/night test, the appliance will be challenged by testing at three low ambient temperature conditions:

1. At 5°C above the minimum ambient temperature rating specified by the manufacturer
2. At the minimum ambient temperature rating specified by the manufacturer
3. At 5°C below the minimum ambient temperature rating specified by the manufacturer.

This test is designed to verify the lowest constant ambient temperature at which the acceptable temperature range can be maintained with a full vaccine load.

Moderate zone:
Moderate zone appliances must operate at a steady +27°C ambient temperature and over a+27°C/+10°C day/night cycling temperature range.

Vaccine net storage capacity:
The net storage capacity is the space where it is suitable (both thermally and ergonomically) to store vaccines. Where manufacturers are declaring more than one vaccine storage capacity for the same gross volume and external dimensions, manufacturers must prequalify with different branding, one model for each different storage volume.

Reason for change: To provide manufacturers with storage capacity definitions that are consistent with existing WHO PQS cold box performance specifications.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

Primary container:
Vial, ampoule, prefilled device, plastic dispenser or tube containing vaccine or diluent. Some products are supplied in a light card carton containing a single vial, ampoule, vial pair, vial-ampoule pair, or prefilled device.

Reason for change: To recognize and address the practise of storing individual vaccine vials and ampoules.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

Temperate zone:
Temperate zone appliances must operate at a steady +32°C ambient temperature and over a+32°C/+15°C day/night cycling temperature range.

User-dependent freeze protection (UDFP):
Refrigeration technology that requires equipment users (e.g., healthcare workers) to perform specific actions (user-interventions) in order to ensure vaccine protection against freezing temperatures (e.g., store vaccines in baskets, away from compartment wall surfaces).

User-independent freeze protection (UIFP):
Refrigeration technology that requires equipment users (e.g., healthcare workers) to perform NO specific actions (user-interventions) in order to ensure vaccine protection against freezing temperatures.

User-intervention for freeze protection:
Any activity that is required to be executed by equipment users in order to ensure vaccine protection against freezing. Activities could include, but are not limited to, basket storage, storage compartment covers, thermostat/fuel adjustment, combustion component replacement, etc.

4. Design criteria

4.1 Vaccine storage capacity

- Net vaccine storage capacity bands of the refrigerator are based on the capacity bands prescribed and utilized by UNICEF SD. These are: <30L, 30 L to less than 60 L, 60 L to less than 90 L, 90 L to less than 120 L, 120 L to less than 150 L, 150 L and above.

Mains-powered equipment is typically deployed at sites ranging from the national and regional stores down to district stores, and maybe even some primary health centers.

Reason: To provide certainty for manufacturers and to simplify procurement decisions for countries.

Timing for PQS Inclusion: 2015, subject to change upon further discussions.

4.2 Vaccine / water-pack freezing compartment (optional)

- Freezers are to be used as either vaccine freezers or water-pack freezers.
- Both stand-alone freezers and combined refrigerators/freezers are permitted in this product category.
- Additionally, a new methodology for measurement of ice production is presented in the Annex. This will be reflected in the verification protocol for freezers.

Reason: Freezing capacity is essential for ice pack generation. This is a crucial function, since ice packs are widely utilized for transporting vaccines between different levels of a cold chain. Freezing capacity at the district level could also help to service one or more long-holdover cold boxes at peripheral health facilities.

Alternatively, freezers may be dedicated at certain sites for use in storing certain vaccines (e.g., OPV).

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

4.3 Temperature in designated vaccine storage space

- The zone within the vaccine compartment that is designated for vaccine storage must remain within the acceptable temperature range at all times.
- Bulb and capillary tube thermostats will no longer be accepted.

Reason: To eliminate the risk of vaccine coming into contact with freezing surfaces.

Timing for PQS Inclusion: 2015.

Reason: Field exposure of elevated temperatures has caused failure in some bulb and capillary tube thermostats.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

4.4 Humidity control

- The environmental conditions within the zone designated for vaccine storage must be designed so that vaccine primary containers and vaccine cartons are not exposed to levels of humidity which may cause damage to cartons or primary container labels or create a risk of mould growth. These conditions must be maintained in operating environments where ambient humidity is 100%.
- The following scenarios must not occur in the vaccine storage compartment at any time and without requiring any user interventions:
  - Direct condensation of moisture on vaccine primary containers and vaccine cartons
  - Dripping of condensed water from the roof of the vaccine compartment on to vaccine primary containers or vaccine cartons
  - Uncontrolled drainage of condensed moisture leading to (among other things) collection of excessive quantities of water at the bottom of the refrigerator, or seepage of water on to the floor of the facility.
- The appliance must include a user-friendly drain to remove water from the cabinet. In addition, manufacturers are to propose containers for vaccine storage and/or other refrigerator features to help alleviate humidity.

Reason: Instances have occurred where cartons and vials in mains-powered refrigerators have been damaged by exposure to excessive moisture. This has resulted in the labels peeling off vials and mould growing on cartons. According the immunization policies in many countries, such vials and cartons must immediately be discarded. Therefore, such appliances with excessive condensation would result in significant increase in vaccine wastage.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

4.5 Design of vaccine storage compartment

- The vaccine storage compartment must be designed so that no part, which is outside the acceptable temperature range, can be used to store vaccines either by inadvertent or deliberate misuse.
- As per the classification of freeze prevention features (section 3, Terms and definitions) appliances complying with this requirement without demanding any intervention from the user will be published as Grade A. Others will be published as Grade B or Grade C depending on the level of interventions required.

Further, the vaccine storage compartment must provide some means, such as baskets, to enforce physical separation between the vaccines and any surfaces that potentially have condensate on them, such as the floor, ceiling and/or walls of the compartment. Those are not optional but have to be provided.

Reason: Users in the field, for a variety of reasons, are likely to be unable to perform interventions necessary to protect vaccines from freezing in the refrigerator. For example, baskets may not always be used in a refrigerator in the field due to the desire to use all the available space in the vaccine compartment. Hence, the need for designs that are user-independent, and will ensure proper vaccine protection regardless of user practices. Manufacturers are encouraged to move towards Grade A user-independent freeze protection (UIFP) designs.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

Some current products have removable baskets, which if not used, allow vaccines to be stored in areas which may drop below 0°C. This risk needs to be removed in second-generation products.

Timing for PQS Inclusion: 2017, subject to change upon further discussions.

4.6 Ambient temperature operation

- All mains-powered refrigerators must be able to operate in the hot zone classification of ambient temperature (i.e., +43°C) whilst maintaining the acceptable temperature range in the vaccine storage compartment.
- All mains-powered refrigerators must be able to operate at a continuous rated minimum ambient temperature of +10°C or lower whilst maintaining the acceptable temperature range in the vaccine storage compartment.

Reason: Some current products have a very narrow operating temperature range. Suitability for a wide range of ambient temperature conditions makes product selection, procurement, and relocation simpler for countries, especially in countries with different climate zones or with pronounced summer and winter temperature ranges.

Furthermore, standardizing the hot zone ratings for all equipment will simplify product selection by countries as well as product development by manufacturers.

Timing for PQS Inclusion:

- Standardized hot zone ratings: 2015.
- Minimum ambient temperature requirement: 2015, i.e., effective starting in 2016

4.7 Refrigerant

- As specified in WHO/PQS/E003/RF03.2, WHO is proposing that future specifications require the use of HC refrigerants such as R600a or other gases with GWP ≤11 and zero ODP. R134a will be phased out over a transition period of two years in accordance with the next publication of WHO/PQS/E003/RF03. The suitability of alternative refrigerant gases will continue to be assessed.

Reason: To provide visibility to manufacturers into the WHO's future refrigerant specifications, which is in line with international regulations.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

4.8 Holdover times

- Holdover times of refrigerators will henceforth be categorized as follows:
  - Short: Holdover starting at 20 hours and up to 48 hours.
  - Medium: Holdover starting at 48 hours and up to 120 hours.
  - Long: Holdover starting at 120 hours and above.

Reason: The reliability of mains electricity supply varies widely within and across countries. Having equipment with different holdover times will provide countries with the ability to select appropriate appliances for their context.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

4.9 Power source

- Direct supply of mains electricity.

Reason: Specifying the power source

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

4.10 Input voltage and frequency

- 220-240 Volt 50-60 Hz and 100-127 Volt 50-60 Hz options are to be offered. Performance is to be identical for both options, irrespective of the nominal voltage and frequency rating of the appliance.

Reason: While 220-240 Volt 50-60 Hz is by far the most common rating in the developing world, 110-127 Volt 50-60 Hz rating is found in some developing world countries. Both options are therefore required.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

4.11 Temperature monitoring

- The refrigerator compartment must be equipped with a temperature recording device that supports the transfer of data to another system for analysis purposes. Acceptable options include the following:
  1. **Type 1:** A currently prequalified disposable 30 day temperature logger, certified by WHO PQS as complying with WHO/PQS/E006/TR06.3, with or without an external sensor lead, located in an integrated holder within the vaccine storage compartment. The holder must be positioned so that the device can easily be read by the health worker, and must be located so that temperature readings are taken in the coldest temperature spot within the compartment.
  2. **Type 2:** A currently prequalified programmable remote temperature and event monitoring system, certified by WHO as complying with WHO/PQS/E006/TR03.2.
- Integration of temperature monitoring devices with the refrigerator must satisfy the following requirements:
  - The display must be visible to the healthcare worker from outside the refrigerator, i.e., even with the refrigerator door closed
  - In accordance with WHO policy, a backup system of temperature display must be provided in the form of digital or a stem or vapour thermometer

- If the manufacturer ships temperature monitoring devices with refrigerators, the temperature monitoring device and its battery are not adversely impacted by the shipping and storage conditions as specified in Clause 4.17.
- If the manufacturer ships temperature monitoring devices separately, they should arrive at the same destination as the refrigerator shipment, on the same date, and addressed to the same consignee. This is necessary to allow for smooth in-country receipt and assembly of the refrigerators and temperature monitoring devices.
- The refrigerator manufacturer must also provide the consignee with replacement temperature monitoring devices throughout the 10-year expected lifetime of the refrigerator, so that the temperature monitoring device is always active on-site. This cost is expected to be included in the upfront price of the refrigerator that is quoted to WHO PQS.

Reason: 30-day temperature recorders are now the WHO-recommended standard for temperature monitoring at lower levels in the supply chain. It is important that the logging device's temperature sensor is consistently located in the refrigerator so that temperature readings accurately reflect the worst case temperature to which vaccines are exposed. Existing PV-powered thermometers have shown mixed results in the field, with a significant incidence of failure.

Timing for PQS Inclusion:

Type 1: 2015, i.e., effective starting in 2016

Type 2: 2019, subject to change upon further discussions.

- Future product development by manufacturers must aim for the following capabilities of integrated temperature monitoring:
  - Minimum battery lifetime of 10 years, to achieve equivalent usage lifetime with the underlying refrigerator
  - Robustness of all components (especially the battery and sensors) to the shipping and storage conditions of humidity and temperature, as specified in Clause 4.17

Reason: Increased usage lifetime and robustness of temperature monitoring devices will enable more reliable usage in the field.

Timing for PQS Inclusion: 2017, i.e., effective starting in 2018

4.12 Performance Degradation

- Product design must account for performance degradation over the target life of the product in order to sustain acceptable vaccine storage temperatures, water pack freezing or cooling (if included) and other product features (if included).

Reason: Certain insulation materials and other components may degrade over time potentially impacting temperature control and energy consumption.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

4.13 User-centred design features

- Advantages of chest appliances are known; however, it is to be recognized that front opening refrigerators are preferred at the health facility level. Therefore this option should be made available to this segment of the market.

- Products must be designed for simplified maintenance and troubleshooting, such that there is a minimum requirement for work by trained technicians, and should include a minimum number of components requiring service actions.

Reason: There are advantages with front opening refrigerators that need to be taken into consideration. Particularly at health facility level, vaccines are easier to handle and earliest-expiry-first-out (EEFO) principles can be practiced with greater simplicity. Front-opening refrigerators also offer more convenient access to the vaccine stock at health facility level where frequent access to individual primary containers is required.

Some current products are overly complex. This makes repair and maintenance difficult and error-prone.

Timing for PQS Inclusion: 2019, subject to change upon further discussions.

- In order to make efficient use of available storage space and to protect primary container labels against physical damage and moisture damage, the refrigerator compartment should be equipped with an adjustable system of racks, stackable boxes or drawers designed to hold primary containers in a secure manner. These storage devices must be designed to accommodate the full range of vial and ampoule sizes used for WHO-prequalified vaccines. In addition there must be provision for safe storage of vaccines in secondary cartons where these are supplied and also for storage of vaccines in other presentations such as compact pre-filled devices (e.g. Uniject™) and oral cholera vaccine.
- A standard for optional storage containers for vials and ampoules could be envisioned. This would lead to better-organized contents and higher volume utilization in health facility refrigerators.

Reason: Vaccines are often removed from secondary cartons at district level and are supplied to smaller health facilities in primary containers. Frequently, a mix of primary containers and cartons is observed. Current mains-powered refrigerators have no specific provision for storing loose vials and ampoules which leads to poor stock management, label damage and poor utilization of available storage volume. Although some countries resolve these problems by using plastic boxes and trays, these ad-hoc arrangements are unsatisfactory.

Timing for PQS Inclusion: 2017, subject to change upon further discussions.

- Control panels and integrated thermometers must be able to present legible information to a reader at a standing position. For example, the product could make use of a larger and/or higher contrast LCD screen to enable better legibility.

Reason: In response to end users demand. Control panels close to floor level are inconvenient, even if the panel is tilted.

Timing for PQS Inclusion: 2017, subject to change upon further discussions.

- In addition to the PQS temperature zone sticker the device should carry the following additional information:
    - Near-Term: Manufacturer and model number (unless already located on the front of the unit), serial number, date of manufacture, PQS identification number, applicable service phone number, and website URL fixed to the front of the cabinet.

- Near -Term: An operations and maintenance pictogram fixed to the lid or near the top front of chest refrigerators and near the top of the door on upright refrigerators.
- Long-Term: The above information, plus a bar code to identify the fridge (actual definition of bar code is still to be decided) fixed to the front of the cabinet.

- Given the large amount of information, it is expected that separate stickers could convey the totality of information.
- PQS stickers should remain readable for the expected age of the equipment.

Reason: To simplify data gathering for in-country equipment inventories.

Timing for PQS Inclusion:

Near-Term: 2015, i.e., effective starting in 2016

Long-Term: 2019, subject to change upon further discussions.

4.14 Build quality

- Legal Manufacturer to certify compliance that internal and external cabinet, lid and frame are protected against corrosion as appropriate to EN ISO 6270-1 / ASTM D2247 / EN 13523-26 Determination of resistance to humidity – Part 1: Continuous condensation, EN ISO 6270-2 / EN 13523-25 Determination of resistance to humidity - Part 2: Procedure for exposing test specimens in condensation-water atmospheres, ISO 6272 / EN 13523-5 Impact resistance – external cabinet, and ISO 2409: 2013: Paints and varnishes – cross cut test (external cabinet).
- To ensure product meets EMC emissions requirements, Legal Manufacturer must certify compliance to the latest version of IEC 61000-6-3. Note at the time of publishing, the latest draft is Edition 2.1 February 2011.
- To ensure product meets EMC immunity requirements, Legal Manufacturer must certify compliance with the requirements of the latest version of IEC 61000-6-1. Note at the time of publishing, the latest draft is Edition 2.0 February 2005.
- To ensure product meets EMC harmonic distortion requirements where appropriate, Legal Manufacturer must certify compliance with the requirements of the latest version of IEC 61000-3-2. Note at the time of publishing, the latest draft is Edition 4.0 May 2014.
- The build quality of the product and all ancillary components must be to a standard consistent with the conditions under which these appliances are used, including, but not limited to, the following:
  1. Transport over rough road surfaces.
  2. High temperatures in transport and operation.
  3. Low temperatures in transport and operation.
  4. High humidity.

Reason: Specific issues noted with current prequalified refrigerators include: insufficient robustness to withstand transport; deformation of thermal storage components affecting use of the vaccine storage baskets; failure of bulb and capillary tube thermostats; poorly routed and retained wiring; component corrosion; and accessibility for service.

Timing for PQS Inclusion: 2015 for both sets of requirements

4.15 Service provision

- The product must be designed, and components selected, with the aim of achieving a zero-repair life of not less than 10 years.
- Maintenance activities should be confined to tasks that can be carried out by the health worker or storekeeper; these tasks should be confined to routine de-frosting and cabinet cleaning. The installation kit provided for each site must include the specialized maintenance supplies and/or tools needed to carry out these routine tasks. Wherever possible, the means for routine maintenance should be built into the product: for example, a drainage tray or spout for defrosting.

Reason: Equipment breakdowns expose vaccines to risk and skilled maintenance staff are frequently not available in resource-poor settings.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

4.16 Instructions

- Printed user, installation, and routine maintenance instructions specifically directed at the health centre or store staff must be pictorial. All key information should be summarized on a single sheet fixed onto the appliance cabinet; the sheet should be sufficiently durable to last the life of the product and must be available in Arabic, Mandarin Chinese, English, French, Russian, and Spanish. In addition supporting video material supplied on DVD and/or on-line can be supplied to assist the instructor when delivering on-site user training.
- The user, installation, and maintenance documents must address five aspects:
  - Introductory information. This should consist of the following:
    - Title page with image of unit, supplier name, supplier model #, PQS code, and version number
    - Table of contents
    - General information on unit, its functionality, and intended use
    - Relevant warnings related to transportation, any corrosive or toxic substances in the construction of the appliance, power source, or disposal
  - Model specifications and details. This should include the following:
    - Parts and equipment list
    - Detailed technical specifications, including wiring diagram
    - Safety procedures, including warranty information and supplier contact information
    - Directions for safe transportation
  - Installation and operation. This aspect must cover the following:
    - Detailed installation procedure, including installation checklist
    - Detailed operational procedures covering both vaccine storage, as well as ice-pack / cold-pack preparation

        - Disposal guidelines
    - Maintenance. This component should consist of the following:
        - Detailed guidance on preventative maintenance, including checklists and standard operating procedures (SOPs)
        - Trouble-shooting guide for corrective maintenance, including table detailing common issues and step-by-step remedial actions
        - Typical replacement cycle for spare parts
    - Format and usability. The document developer should keep in mind the following aspects:
        - Include clear graphics to illustrate tasks, with multiple view-points (e.g., top, side) and clear labelling
        - Be published in English, with translations readily available in all UN languages (Arabic, English, French, Mandarin, Russian, and Spanish). Translations to other languages specific to certain countries are to be provided if requested by the buyer
        - Be specific to a given model and avoid covering multiple devices in same document
        - Have a clear and consistent structure that covers installation, operation, and maintenance and repair
        - Be accessible and downloadable from a central repository.
- Installation, repair and servicing instructions must be supplied in printed format, and optionally on DVD and/or on-line to instruct the installation teams in installation standards and practices specific to the product and its power system.

Reason: High quality instructions are a pre-requisite for high quality installations and good routine maintenance. Increasingly, countries are using video instructions for training purposes.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

4.17 Shipping and storage conditions

- Manufacturers must be aware that products may be exposed to very high temperatures during shipping and dockside storage and must take appropriate actions to mitigate this risk.
- Materials used for packaging the finished appliance are to be free of ozone-depleting compounds as defined in the Montreal Protocol.
- The packaging is to be a sturdy export quality and of a commercial standard that will provide adequate protection of the goods for carriage by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions and high humidity. The packaging is to be not less than 17kN edge crush resistance with minimum 60% remaining with 90% humidity at a temperature of +70°C (tropical conditions).
- To avoid destructive unpacking prior to installation Legal Manufacturers are encouraged to add a re-sealable observation opening in their packaging to aid inspectors in finding labelling and/or placing additional markings prior to installation. Instructions on the packaging alerting inspectors to use of the opening and what information will be revealed are also advised.

- The general specification of shipping containers will be subject to agreement with the individual procurement agencies.

Reason: Instances have occurred where some appliances, especially solar direct drive (SDD) refrigerators, have been damaged during transit and storage due to exposure to high ambient temperatures in shipping containers. This risk is also true for mains-powered refrigerators.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

4.18 Accessories

- Every appliance must be provided with either an integrated or a standalone voltage stabilizer, with integrated voltage stabilizers likely to become the requirement in future. The voltage stabilizer must be certified by WHO PQS as complying with WHO/PQS/E007/VS01.2.
- Specialized tools and materials required for installation and/or required for technical maintenance are to be clearly identified to prospective buyers and offered as an option by the manufacturer.
- Accessories not required for regular operations and/or not required for routine user maintenance are to be offered as an option by the manufacturer.
- Items that are required for regular operation and routine maintenance are not considered accessories and must be included as standard with each appliance supplied.

Reason: Appliances have been provided without items required for regular operations and maintenance such as ice scrapers for defrosting and condensate catchment pans. These items and specialized installation tools and materials are not always readily available in the area of installation and additional funds may not be available for installer or user purchases.

Timing for PQS Inclusion:

Standalone voltage stabilizers: 2015, i.e., effective starting in 2016

Integrated voltage stabilizers: 2017, pending further review and re-evaluation

4.19 Spare parts

- Manufacturers are to publish a list of spare parts recommended for purchases of 10 and 50 units.

The minimum spare parts for 10 refrigerators or combined refrigerator water pack freezer is:

1 no. compressor or complete cooling unit, to suit supplied refrigerators.

1 no. electronic unit (compressor control or cooling system control).

1 no. thermostat (or temperature control components).

1 no. canister R600a x 100 grams, if used.

1 no. fan, if used.

Reason: Spare parts can be assessed at time of purchase based on manufacturer specific requirements, country conditions, existing spare parts stocks and geographic distribution of installations.

Timing for PQS Inclusion: 2015, i.e., effective starting in 2016

Annex

Fully Frozen Water-pack determination:

The following tests are used to determine whether a water-pack is fully frozen, partially frozen, or unfrozen. While the assessment is not 100% accurate, misclassifications are usually conservative in nature: water-packs that are fully frozen are sometimes classified as partially frozen rather than partially frozen water-packs being classified as fully frozen. A fully frozen water-pack contains only ice. A partially frozen water-pack contains both ice and water. An unfrozen water-pack contains only water

Perform the all of the following tests on the water-pack:

- Shake test - Shake the water-pack while holding the water-pack near the assessor's ear. If the sound of water sloshing in the water-pack is heard, then the water-pack fails the shake test.
- Tilt test – Tilt the water-pack back and forth while looking for the movement of air or water in the water-pack. If the movement of air or water is observed, then the water-pack fails the tilt test.
- Bulge test – Water expands when it freezes. Examine the water-pack for localized bulging near the centreline of the water-pack when viewing the water-pack from the side. If localized bulging is not present, then the water-pack fails the bulge test.
- Classify the water-pack as follows:
    - If the water-pack passes all three tests, then the water-pack is fully frozen.
    - If the water-pack fails one or more tests, then the water-pack is partially frozen or unfrozen and fails the test.

5. Revision history			
Date	Change summary	Reason for change	Approved