20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

WHO VAX IMD Terms & Definitions

Master List

A

Absolute time: Coordinated Universal Time (UTC) time derived from an independent verified source (e.g. cellular tower, GPS, Internet time server), standardized according to ISO 860 Internet Date Time profile, using days, hours, minutes and seconds without separators, and including the time zone specifier "Z", short for "Zulu" and indicating zero offset from UTC.(YYYYMMDDThhmmssZ).

Absorption: appliances that use a heat source such as gas or kerosene to drive the cooling system.

Acceptable compartment humidity: the acceptable compartment humidity is 55% or lower at +2-8°C during relevant verification testing. However, transient excursions during testing above this value will be tolerated, with the following limits:

- no excursion may exceed 65% at +2-8°C when the appliance is supplied with power and after any initial starting period defined in verification protocols,
- the average compartment humidity during relevant verification testing remains 55% or lower at +2-8°C when the appliance is supplied with power and after any initial starting period defined in verification protocols.

Acceptable temperature range: the acceptable temperature range for storing vaccine is +2°C to +8°C. However, transient excursions outside this range will be tolerated, within the following limits:

- no excursion must exceed +20°C (± 0.5°C) for any amount of time,
- no excursion must drop below -0.5°C for any amount of time,
- no excursion must drop below 0°C for longer than 1 hour, and
- following an excursion below 0°C, the appliance must return to safe operating temperature (i.e. consistently between +2°C and +8°C) within two hours. This duration will be measured from the moment the temperature drops below 0°C and up until it returns to +2°C.

Acceptable temperature range (freezer rooms): the acceptable temperature range for all parts of the room designated for vaccine storage must remain between -25°C to -15°C when measured under any loading condition between empty and full and over the full ambient temperature range of the required temperature zone.

Acceptable temperature range (cold rooms): the acceptable temperature range for all parts of the room designated for vaccine storage must remain between +2°C to +8°C when measured under any loading condition between empty and full and over the full ambient temperature range of the required temperature zone. Rooms specified to have cold climate freeze prevention must maintain the room temperature between +2°C and +8°C at ambient temperatures down to -10°C.

Access: the ability of national EPI programmes to procure high-performing, quality and safe immunization devices and equipment, that respond to their own particular programmatic needs.

Active cooling: any cooling or other heat transfer that is powered or driven by anything besides the spontaneous, passive transfer of heat due to temperature differential and related passive effects such as natural convection.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Active surface (E006): a time-temperature sensitive indicator which changes shade and whose reaction rate closely matches the stability profile of the vaccine.
Adverse impact: any cause preventing an appliance from continually sustaining acceptable vaccine storage temperatures and/or water-pack freezing performance, as defined by applicable IMD-PQS appliance performance specification(s).
Alarm: an audio and/or visual indication of appliance or device performance that is outside safe or normal operating conditions and where the cause is driven primarily by appliance use or environmental conditions. Alarms are defined by WHO and/or immunization programmes.
Alternating current (AC): an electric current that reverses its direction at regularly recurring intervals whose value varies as a sine wave.
Ambient humidity: the relative humidity (%) of the chamber in which the appliance is being tested.
Annual Review: the 12-monthly review which all manufacturers of WHO-prequalified products are required to pass in order to remain on the register of prequalified products.
Appliance: a cold chain-related device or piece of equipment designed to perform a specific task.
Applicant: legal manufacturer or licensed reseller of a product, in the process of submitting that product for prequalification assessment by WHO IMD-PQS.
Approved Installer: a person or organization approved by the legal manufacturer or reseller as a competent installer of the system components and who has been appointed by the Employer to carry out the installation of the System.
AQL: Acceptance Quality Limit. The acceptable quality limit prescribes an industry standard for the allowed number of defective samples that are considered acceptable when testing random samples within a batch according to the required level of confidence in a product. (See ISO 2859-1.)
Asset tag: a label containing a unique barcode and other information attached to a cold chain device.
Audible alarm: monitoring device that emits sound under specified conditions or operations. Specify conditions for the alarm from the following possibilities: temperature, voltage, power, autonomy, holdover.
Auto-disable or Auto-disabling: a feature or characteristic of the syringe or device that passively and automatically activates upon administration of the intended dose to prevent subsequent re-use of the syringe. In order to avoid inadvertent or intentional re-use in the event such action is not taken, no secondary or additional action on the part of the user shall be required (adapted from ISO 7886-3).
Automatic transfer switch (ATS): self-acting equipment for transferring one or more load conductor connections from one electric power source to another.
Autonomy: time in days that a solar power system can maintain the vaccine load within the acceptable temperature range under low solar radiation conditions (e.g. rain).
Autonomy (freezer): time in days that the water-pack freezer can maintain the minimum capacity of fully frozen water-packs under low solar power conditions (rain) with battery power only.
Autonomy/holdover gauge: monitoring device displaying estimated time remaining in thermal storage system.
Autonomy (refrigerator): time in days that a solar refrigerator, or combined refrigerator and water-pack freezer, can maintain the vaccine load within the acceptable temperature range under low solar power conditions (rain) with battery power only. Installation site autonomy is determined as described in E003/PV01.
Backing card (E006-VVM): card to which the indicator is permanently attached containing information to activate (if necessary) and to interpret the appearance of the indicator. The card may be made from water resistant material
Back-up generator: a secondary prime power generator capable of independently powering 100% of all ULT freezer system electrical needs and battery recharging (if applicable).

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Back-up power: a secondary, auxiliary power source (e.g. generator) capable of independently powering 100% of all CR-FR electrical needs and battery recharging.

B

Basic EHC: an energy harvest control strategy where electrical energy is delivered via one USB-A port integrated in a solar direct drive appliance and limited to 5 watt (5 V dc, and 1-amp total) for up to a total of 60 Wh/day.
Basket: bin used to organize or support items including vaccines and diluents.
Battery: chemical energy storage device for DC electricity. Batteries are found in RTMD, 30-DTR, some thermostats, some types of solar power systems and some energy harvest load devices.
Battery charger: equipment that converts AC power to DC power and is used to recharge and maintain a station battery in a fully charged condition and to supply power to DC loads during normal operation and design basis events.
Battery charge/discharge control: electronic device to regulate the power in and power out of a battery bank that is recharged with solar electricity (aka “solar control”, “battery charge regulator”).
Battery set housing: enclosure to protect a battery from accidents and unauthorized contact.
Battery terminal: points where positive and/or negative electrical connections are fastened to a battery.
Battery voltmeter: monitoring device, displaying voltage of battery, typically in real time.
Break: material or component separation into pieces as a result of a blow, shock, or strain.
Build quality: issues related to appliance durability.
Burner/boiler: absorption refrigerator component where heat is applied to boil refrigerant.
Bypass diode: diode connected across one or more solar cells in a photovoltaic module such that the diode will conduct if the cell(s) become reverse biased. It protects these solar cells from thermal destruction in case of total or partial shading of individual solar cells while other cells are exposed to full light.

C

Cabinet: general term for the appliance enclosure.
Capacitor: device for accumulating and discharging an electric charge. Capacitors are found in refrigeration equipment where a short burst of electricity is needed to start the compressor motor.
Capillary tube: gas filled, thin tubing used either in thermostat control or in refrigerant piping to control the flow of refrigerant in the cooling system.
Certification body: a government department or agency or third-party organization that provides services for conformity assessment following completion of an independent assessment verification and qualification process.
Certified copy: wherever a certified copy or certified photocopy is requested, the copy must be certified as a true copy of the original document by a person registered to practice law in the legal manufacturer’s or licensed reseller’s country of origin and must be endorsed with the legal practitioner’s official stamp and signature. Self-certification of documents is not acceptable.
Circuit breaker: mechanical switching device, capable of making, carrying and breaking electric currents under normal circuit conditions. Circuit breakers are found as overcurrent protection devices in some appliances, energy harvest accessories and power systems.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Climatic classes: Hot Zone: 0°C to 50°C; Moderate Zone: 0°C to 32°C; Temperate Zone: 0°C to 27°C and Cold Zone -20°C to 32°C.
Cold chain equipment (CCE): equipment used to maintain the temperature of vaccines or other medical products and samples in an acceptable range. This definition includes, but is not limited to refrigerators, refrigerated rooms, carriers and cold boxes.
Cold climate extreme temperature prevention: any mechanism which prevents the temperature inside a refrigerated vehicle from falling below +2°C under low ambient temperature conditions, down to the temperature specified by the employer at the time of procurement, subject to a lowest temperature of -20°C ambient.
Cold climate freeze prevention: any mechanism which prevents the temperature inside a refrigerated vehicle from dropping below +2°C, under low ambient temperature conditions, down to the temperature specified by the employer, at the time of procurement, subject to a minimum of -10°C.
Cold climate freeze protection life: the empty container is stabilized at +15°C and loaded with warm packs which have been stabilized at the same temperature for a minimum of 24 hours. The cold climate freeze protection life is measured from the moment when the container is closed until the temperature of the coldest point inside the vaccine storage compartment first reaches 0°C at a constant ambient temperature of -20°C.
Cold life (E004): the empty container is stabilized at +43°C and loaded with ice-packs. Cold life is measured from the moment when the container lid is closed until the temperature of the warmest point in the vaccine storage compartment first reaches +10°C, at a constant ambient temperature of +43°C
Cold zone (refrigerated vehicles): cold zone units must maintain the acceptable temperature range while operating at any ambient temperature from +32°C to -20°C.
Combiner: electrical connection enclosure or fitting where solar module interconnects are joined to the solar array output cable. Combiners may be enclosure boxes or weather tight branch circuit connectors.
Communication latency: the maximum allowable period between data transfers between logger and EMD.
Compartment humidity: the relative humidity (%) of the vaccine compartment of the appliance.
Compressor: basic item of equipment for mechanically increasing the pressure of a gas.
Compressor electronic unit: electronic control unit matched to a specific appliance compressor. Also known as “electronic unit”, “electronic box”, “electronic control unit” or “ECU” or “controller for compressor”.
Condensation: water which collects on a cold surface when humid air is in contact with it.
Condenser: refrigeration heat exchanger in which a vapor is liquefied by removal of heat.
Connectivity: the ability of a computer, program, device, or system to connect with one or more others.
Container: a closed volume with walls designed to hold a phase change material (PCM).
Continuous electricity: the sustained supply of electricity adequate for an ultra-low temperature (ULT) freezing system.
Control panel: assembly incorporating all the regulation means necessary for the operation of an installation, with or without corresponding indicator(s). An appliance control panel could include appliance on/off switch, thermostat and LED indicator lights.
Coolant-pack:

- a generic PQS prequalified water-pack complying with specification PQS/E005/IP01.
- a purpose designed phase change material (PCM) pack complying with this specification.
- a purpose designed leak-proof container, filled with water, complying with this specification.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Cool-down: the time required to initially cool a walk-in cold or freezer room to achieve stable operating conditions within the acceptable temperature range for vaccine storage and achieve its full autonomy time.
Cool-down time: the time to reach stability from first switch-on.
Cool life: the empty container is stabilized at +43°C and loaded with cool-packs which have been stabilized at + 5°C for a minimum of 24 hours. Cool life is measured from the moment when the container is closed, until the temperature of the warmest point inside the vaccine storage compartment first reaches +20°C, at a constant ambient temperature of +43°C.
Cooling medium: the material used to cool a passive device to the target temperature. In the case of materials like water or phase change material (PCM) that may be used repeatedly, this includes the container.
Cool-pack: a water-pack pre-cooled to a temperature between + 2°C to +8°C before use. See "water-pack".
Correspondence: includes mail, fax, email and the WHO ePQS platform.
Corrosion: the irreversible damage or destruction of material due to a chemical or electrochemical reaction. Examples include aluminum oxidation, iron rust and plastic melt.
Coupler system: locking female and male coupler system with minimum IP rating of 65 ("plug and play"). Couplers are used where solar modules interconnect and where the solar array cable connects to the appliance.
Crack: a material that has split without breaking apart.
Custom EHC: an energy harvest strategy where electrical energy is delivered via one or more outputs that may be adjusted or modified to provide differing voltages without specific limitations to watt-hour per day capacity.
Cutting assembly: that part of the device which contains the cutting or shearing mechanism, which, when connected to a needle container constitutes the complete needle cutter device. The cutting mechanism and container can be either integral or separable.

D

Daily temperature report: written record of appliance internal temperatures. Traditionally entered twice per day by health worker.
Damage: injury or harm to a component or system that reduces function, value or usefulness. Input "Damage" and refine input by inputting a secondary cause from this selection: abuse, factory concealed, factory observable, impact, insect, installation, misuse, rodent, shipping handling, shipping sea freight, shipping trucking, shipping storage, sunlight, water.
Data object: a standardized identifier of a unique administration, performance, use or environmental metric that is used to record and analyse data.
Data retention period: the period following the de-activation of the device using the 'stop' function during which it must be possible to recover the data recorded during the recording period.
Dedicated voltage stabilizer: a stabilizer model integrated into the appliance for use with a specific product. The stabilizer cannot be removed from the appliance and therefore must be tested with the complete appliance. See Integrated and Standalone voltage stabilizers.
Defined load: specific load(s) matched to the energy harvest control (EHC) and supplied by the legal manufacturer / reseller. The defined load(s) would be permanently connected to the EHC or would connect to the EHC with a unique, non-standard electrical connector to restrict the addition of undefined loads with standard electrical connectors.
Degradation: deterioration of a material or process.
Design day: for purposes of sizing the solar power system, the design day requires the largest of the following three options for sizing the solar array to meet all cold room – freezer room (CR-

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

FR) electrical load requirements: 1) based on the lowest monthly solar radiation reference period; 2) based on the highest average daily electrical load requirement for a given month; or 3) both simultaneously.
Device: a cold chain-related product, unless specifically described as an 'injection device'.
Direct current (DC): an electric current flowing in one direction.
Direct observation: a method of collecting evaluative information in which the evaluator watches the subject in its usual operating environment without altering that environment.
Disintegration: the process of losing strength or cohesion.
Display: panel assembly indicating operation and control status of an installation. An appliance display may include temperatures, power-on light and error reports.
Disposable syringe: a syringe and needle assembly, of any capacity, complying with ISO standard 7886 - part 1.
Distributor sensor: thermocouple that is placed in the interior of the cold room or freezer room in order to measure air temperature
Door: operable entry into an upright appliance.
Door openings: each time an appliance interior is exposed to ambient air.
Drier: device for removing moisture from the refrigerant.
Dynamometer: a measuring device used to determine the torque, force, speed, and power required to operate the drive on a machine or motor, which can be measured by evaluating the torque and rotational speed of a motor simultaneously.

E

EEPROM: electrically erasable, programmable, read-only memory.
Electric cabling: see "wiring" and "power cable".
Electrical withstand: the root mean square (RMS) value of the maximum input voltage that the device can continuously tolerate without any form of electrical or mechanical damage.
Employer: the organization that contracts with the Prequalification Holder (legal manufacturer or reseller of a product with WHO prequalified status) who will supply the system components and the installation and maintenance advisory services described in this specification. The employer will typically contract with an installer who will install and commission the installation under the supervision of a quality assurance (QA) assessor and also with a maintenance contractor who will maintain the installation.
End point (E006): the point at which time-temperature exposure has altered the shade of the active surface so that it exactly matches the reference surface. At this point, and thereafter, the vaccine should no longer be used.
Energy harvest: the collection, distribution and use of surplus solar electricity for loads in addition to an immunization appliance.
Energy harvest control (EHC): accessory control device and/or system to enable the use of surplus solar photovoltaic electricity for powering other electricity consuming devices (loads) in addition to an immunization appliance or cold room – freezer room (CR-FR). An EHC may harvest surplus electricity when the active cooling circuit is off and/or when the active cooling circuit is on and sufficient surplus electricity is available.
EPROM: electrically erasable, programmable, read-only memory.
Equipment Monitoring Device (EMD): a device that functions to 1) retrieve data from the appliance logger and other onboard sensors and 2) store, analyse and communicate data, errors, and alarms, and is the subject of specification WHO/PQS/E006/EM01. An EMD may be integrated within or external to the appliance as further defined below:

- External Equipment Monitoring Device (E-EMD): An EMD that is not integrated in the appliance and utilizes the M2M connection for data transmission and optional

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

power supply.

- Integrated Equipment Monitoring Device (I-EMD): An EMD that has some or all its components built into the appliance at the point of manufacture. The I-EMD does not utilize the M2M for data transmission or power supply. The M2M affords access to the integrated logger for E-EMDs.

Equipment Monitoring System (EMS): component assemblies for advanced monitoring and communication of cold chain equipment (CCE) performance, events and alarms across administrative levels of the cold chain.
Error code: an alphanumeric code that is used to determine the nature of an appliance or device technical problem, and why it occurred. Errors are defined as related to equipment functionality that is not primarily user or environmentally related, but rather indicates hardware or software malfunction, defect, damage, or other issues.
Evaluator: an individual or organization (including a WHO-accredited testing laboratory) responsible for evaluating or assessing any aspect of a product as described in the relevant IMD-PQS Product Specification or Verification Protocol.
Evaporator: part of a refrigeration system in which the refrigerant evaporates by absorbing heat from the contacting fluid.
Excursion: deviation from a specified temperature range.

F

Failure: condition of not meeting the intended performance or safety requirements, and/or a breach of physical integrity. A failure is corrected by repair and/or calibration.
Failure cause: process that leads to a failure. Assessors are to input failure causes from the following selection: break, build quality, corrosion, cracking, damage (see additional damage definitions), degradation, disintegration, hot spot, incomplete, insufficient capacity, lack of maintenance, leak, missing, misplacement, open circuit, orientation, outage, power quality, power tampering, shading, short circuit, soiling, tampering, unauthorized use, ultraviolet degradation, voltage (low).
Failure consequence: way (or ways) in which a failure mode impacts intended performance.
Failure effect: description of what happens when a failure mode occurs.
Failure mode: the manner in which a failure occurs. A failure mode may be defined by the function lost or other change(s) that occurred.
Failure symptom: identifiable or measurable physical condition by which a potential failure can be recognized.
Fan: rotary machine which maintains a continuous flow of air (based on infinite impulse response - IIR). Appliance fans are used to circulate air over condensers and may also be used internally to control cabinet temperatures.
Field evaluation; an assessment of performance, acceptability and fit with systems in functioning immunization settings of a proposed product. If done for the purpose of WHO IMD-PQS prequalification, the protocol requires the advance written approval of the IMD-PQS Secretariat. It is a required prequalification validation step for the prequalification of new technology.
Firmware: computer programs contained permanently in a hardware device (such as a read-only memory).
Fixed container: a phase change material (PCM) container that is an integral part of the CCE and is not expected to be regularly removed from the CCE by the end user.
Fixed DC load: a laboratory test device to simulate the connection of a continuous direct current load (e.g. 5 V dc, 5-watt load or less if specified by legal manufacturer).

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Flue: metal duct for carrying away combustion gases and particulates. Found on absorption appliances.
Flue baffle: metal insert in flue to enhance heat transfer to absorption refrigerant.
Flue brush: metal bristle cleaning tool for absorption appliance maintenance.
Free shelving volume: the total volume of the shelving units, minus the volume occupied by the shelves. Vaccine should not be stored within 200mm of the floor or within 100mm of the ceiling.
Freeze alarm: any time vaccine storage compartment is below -0.5°C.
Freeze excursion time: excursion event during which a vaccine is exposed to temperatures outside the range(s) prescribed for storage and/or transport.
Freeze-protection classification:

- 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 freezing 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 in order to avoid vaccine freezing temperatures (e.g. the requirement to use baskets or other items).
- 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 temperatures (e.g. the requirement to use baskets and insolation barriers or covers).

Freezer compartment: distinct segment of an appliance used for freezing and storing vaccine or freezing and storing water-packs.
Freezing temperature (on walls/lining of vaccine compartment): 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 -0.5°C and 0°C for longer than one hour,
- excursion equal to or below -0.5°C for any amount of time, and/or
- inability to return to safe operating temperature (i.e. consistently between +2°C and +8°C) within two hours following an excursion equal to or below 0°C.

Frequency of freeze alarms per month: total number of freeze alarm events recorded in a month. Specified by manufacturer and appliance model.
Frequency of heat alarms per month: total number of heat alarm events recorded in a month. Specified by manufacturer and appliance model.
'Frozen' PCM-pack: a phase change material (PCM) pack cooled to the point specified by the PCM-pack manufacturer for the purpose of achieving the intended cold life. Whilst many PCM materials work as effective coolants when in a solid state, others may reach the desired cooling temperature in a sponge-like state, or may remain as a mixture of water and PCM without changing phase.
Fuel disruption: anytime fuel is unavailable for an absorption appliance. Specify circumstance (e.g. fuel shortage, budget shortage, diversion to other uses).
Functional status: device operational categorization. Per inventory or data analysis (metadata).
Fuse: electrical safety device containing a material which melts at a predetermined temperature, thereby relieving the (overcurrent) pressure. Fuses are found in appliances, accessories and systems.

G

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Gasket: component that ensures the air tight sealing of an appliance opening (door or lid).
Generator: an independent source of electrical power that consists of a fueled internal combustion engine (or engines) coupled directly to an electrical generator (or generators); the associated mechanical and electrical auxiliary systems; and the control, protection and surveillance systems.
Grid-connected: solar power system that imports electricity from a power grid (mains).
Grid-tied: grid-connected solar power system that also is synchronized to export electricity into a power grid (mains).
Gross volume: the measured volume of the airspace inside the internal compartment of the appliance with the door or lid shut. For combined appliances the gross freezer volume and the gross refrigerator volume are reported separately.
Grounding system: all the electric connections and devices involved in the earthing of an appliance, accessory or power system installation and equipment.

H

Handle: part that is designed to be held or operated with the hand.
Harvestable solar electricity: direct current electricity generated by the solar direct drive appliance solar power system.
Heat alarm: ten consecutive hours of continuous temperature excursions above +8°C in a vaccine storage compartment.
Heat excursions time: an excursion event during which a vaccine is exposed to temperatures outside the range(s) prescribed for storage and/or transport.
Heater: any device to introduce warming temperatures on or into the appliance. Heaters are used for absorption refrigeration to heat refrigerant and used for internal temperature control in compression refrigerators.
Heavy-weight appliance: a transportable, powered appliance movable by multiple people for short periods, intended primarily for temporary vaccine storage and transport by powered vehicle. All appliances shall be designated by the legal manufacturer as one of the three appliance types further defined in WHO/PQS/E003/TS01.1.
Hinge: jointed or flexible device that supports the turning or pivoting of a part, such as an appliance door.
Hinge cover: protection for a hinge.
Holdover gauge: monitoring device displaying estimated time remaining in thermal storage system.
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.
Host: the party responsible for managing the Remote Data System.
Hot spot: unintentional solar cell overheating caused by shading, soiling or mechanical faults. Detection is sometimes possible through visual inspection for evidence of heat damage but may require thermal imaging equipment and advanced techniques.
Hot zone: hot zone units must operate at a steady +43°C ambient temperature and earn a minimum rated ambient temperature of +10°C or lower.
Humidity control: A functional capability of a vaccine storage compartment, by which relative humidity levels are controlled while power is available such that limited or no condensation accumulates on compartment, vial or secondary carton surfaces and mould growth is inhibited.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Hybrid power system: two or more sources of power combined in a single system. A health facility powered by a diesel generator coupled with solar electricity is an example of a hybrid power system.
Hybrid solar power system: solar power system with one or more auxiliary sources of power (e.g. a diesel or petrol-fueled stand-by generator).

I

Ice-lined refrigerator (ILR): a mains-powered compression-cycle appliance meant for vaccine storage or combined vaccine storage and water-pack freezing. These appliances are designed for operation in areas with intermittent electricity supply.
Ice-pack: a water-containing coolant-pack frozen to a temperature between -5°C and -25°C before use, to the point where there is no remaining liquid water.
Ice-pack storage capacity: the maximum number of fully frozen water-packs that can remain fully frozen at the end of water-pack storage compartment testing over a multi-day period.
Impartial group or organization: an entity having no financial interest in the technology or outcome of the evaluation, also referred to as an independent or third party.
Impedance: the effective resistance of an electric circuit or component to alternating current, arising from the combined effects of ohmic resistance and reactance.
Implementing partner: an impartial group or organization with experience in planning, conducting, and evaluating immunization devices in low-resource settings who will lead the field evaluation.
Impulsive transient: a sudden, non-power frequency change in the steady-state condition of voltage, current, or both that is unidirectional in polarity – either primarily positive or negative. Often characterized by extremely high voltages that can drive high levels of current into an electrical circuit for periods ranging from a few milliseconds to a few microseconds.
Independence: the time in hours during which all points in the vaccine storage compartment remain between +2°C and +8°C, at a constant ambient test temperature of +43°C after all external power inputs have been disconnected or switched off. (This may include both passive cooling as well as active cooling if powered by internal sources integrated into the appliance, e.g. an integrated battery or evaporative cooling system. Independence is distinct from holdover time in that it may include both active cooling and passive cooling while holdover time only includes passive cooling capacity.)
Independent evaluator: person or organizations who has been appointed by WHO to conduct a type examination per this verification protocol.
Indicator light: lamp showing operating condition of some equipment or status of some metric. Appliances are required to use indicator light(s) to alert users of cooling system operation.
Injector or Injection system: the mechanism or system into which the disposable syringe attaches. The injector or injection system is held by the user and provides the energy to affect the injection, along with other ergonomic, triggering, and safety components. Although normally re-usable for multiple injections, it may itself be disposable after single use.
Insert (E006-VVM): general information card or sheet providing all the information necessary for correct use and interpretation of the indicator.
Installation: the complete physical installation of the equipment as described in the relevant IMD-PQS Product Specification and its companion Verification Protocol, and as per all the procurers' requirements, together with the commissioning (carrying out of all necessary tests and procedures) as specified in the WHO standards, to ensure that the product or device is able to function as intended.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Installation kit: assembly of components required to complete an appliance, accessory or system installation system and make ready for use. Example: IMD-PQS requires each solar direct drive (SDD) to be supplied with a solar power system installation kit that includes mechanical support structure, electrical wiring and hardware.
Installer: a person or organization who has been appointed by the employer to carry out the installation of a device, appliance or system. A qualified installer may be either a legal manufacturer or a reseller or an approved representative and must:

- supply a coherent, correctly sized installation where the settings of all the components have been adjusted for optimum performance at the installation site,
- have installed and supported (e.g. by providing on-going technical assistance, spare parts and system documents) at least five hybrid photovoltaic systems in a developing country or countries for at least two years (detailed references, including donors, locations and contacts, must be provided for independent verification),
- have the capacity and financial resources to provide long-term support to the systems in the country of destination.

Instructions: manuals and other written or digital information indicating how a product is to be installed, operated, maintained, repaired and/or disposed of.
Insufficient capacity: failure to fully provide intended service. Examples of insufficient capacity include an appliance where its vaccine storage volume is exceeded or a solar power system that functions adequately until the rainy season when its solar array can no longer operate the compressor for enough hours per day to sustain acceptable temperature range.
Integrated voltage stabilizer: a stabilizer model integrated into the appliance for general use or for use with specific products. The stabilizer can be removed from the appliance and be operated separately from the appliance for testing. See Dedicated and Standalone voltage stabilizers.
Intermediate vaccine store: stores that receive vaccine from a primary vaccine store where it is stored and distributed to health facilities. Such stores are typically located in a regional or district centre.
Interconnect (electrical): electrical wiring used to connect individual solar modules or batteries into larger groupings. Specify circumstance (e.g. solar array, battery bank). Also called "connector".
Inverter: electronic component to convert DC to AC electricity.
Inverter/charger: a combination of an inverter, battery charger and automatic transfer switch into one complete system. When AC power is available, the inverter/charger recharges the batteries. It also allows any surplus AC power to pass through and power downstream AC loads. When AC power is disconnected, the unit inverts DC battery power into AC electricity.
In writing: communication by letter, fax or email.

K

Key Performance Indicator (KPI) (E006): A metric computed using raw data object recordings, which provides a more summarized or aggregated assessment of the environment, performance, safety and/or use of cold chain equipment. KPIs are defined in the EMS Data Specification WHO/PQS/E006/DS01.
Kigali Amendment: the Kigali Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer entered into force on 1 January 2019, following ratification by 65 countries. The UN Environment Programme (UNEP, or UN Environment) announced the entry into force to help reduce the production of hydrofluorocarbons (HFCs) and potential greenhouse gases (GHGs).

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Kit: assembly of components necessary to support the completed installation of an appliance, accessory or system. Example: WHO PQS E003 PV01 solar power system kits are required to be sufficient for the service provider to complete an installation.
Kit EHC: an energy harvest strategy where electrical energy is delivered via one or more outputs that are within a pre-packaged kit. Kit EHC may provide multiple voltage outputs through integrated circuits without specific limitations to watt-hour per day capacity. Kit EHC may also provide defined loads (e.g. lights).
Kyoto Protocol: the Kyoto Protocol is an international treaty which extends the 1992 United Nations Framework Convention on Climate Change that commits state parties to reduce greenhouse gas emissions. It was adopted in Kyoto, Japan, on 11 December 1997 and entered into force on 16 February 2005.

L

Lack of maintenance: whenever preventive or corrective maintenance is not completed on schedule.
Lamp (absorption): clear glass shield around burner flame in kerosene absorption appliance.
LCD: Liquid Crystal Display.
Leak: escape of a liquid or gas from a hole or crack in a pipe or container.
LED: Light-Emitting Diode.
Legal manufacturer: the natural or legal person with responsibility for the design, manufacture or integration of components, packaging and labeling of a product or device before it is placed on the market under their own name, regardless of whether these operations are carried out by that person themselves or on their behalf by a third party.
Lid: operable entry into a chest type appliance.
Lightning protection: complete system used to protect against the effects of lightning.
Lightweight appliance: a transportable, powered appliance movable by a single person for extended periods, intended primarily for short-term transport with or without a vehicle for transportation. All appliances shall be designated by the legal manufacturer as one of the three appliance types further defined in WHO/PQS/E003/TS01.1.
Limited electricity: an existing electric power system with inadequate capacity to sustain the continuous supply of alternating current electricity adequate for an ultra-low temperature (ULT) freezing system.
Load: any end-use device in an electrical circuit that can consume power when the electrical circuit is energized. Load energy consumption is expressed as watt hours per day (wh/day).
Load (energy): any end-use device in an electrical circuit (other than the primary appliance and energy harvesting control (EHC)) that can consume power when the electrical circuit is energized.
Load (refrigeration): any vaccine and related commodities that require cooling.
Load storage system: the way in which vaccines are stored in a large cold room. Typically this will be on shelves, on fixed floor pallets, on movable floor pallets or on movable pallets stored in a pallet racking system.
Logger (E006): a data recording device that is integrated within an appliance or transport device and is the subject of specification WHO/PQS/E006/DL01. It stores data for use andcanalysis and provides access to its data.

M

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Machine-to-Machine (M2M) interface (E006): the standardized data and power transfer interface between logger and external electronic monitoring device (E-EMD), enabling interoperable function of EMDs and appliances. The M2M also enables portable devices like laptop computers and mobile phones to access logger data. The M2M is physically part of the appliance.
Mains electricity: power delivered by the utility, grid, or other domestic source.
Maintenance contractor: a person or organization contracted by the employer to maintain the installation.
Manual transfer switch (MTS): an electrical device that allows a user to switch a load between two different electric power sources.
Manufacturer: the legal manufacturer.
Maximum capacity: the number of 0.5ml AD syringes that a sharps box can contain without syringes projecting above the fill line printed on the outside of the container.
Maximum loaded mass: the mass of an appliance when fully loaded with vaccines at a density of 0.8 kg per litre of vaccine net storage capacity and with any components necessary to operate within the acceptable temperature range fully prepared and in place.
Maximum loaded weight: the weight of a container when fully loaded with coolant-packs and vaccines with a density of 0.8 kg per litre of vaccine storage capacity.
Maximum power point tracking (MPPT) control: a type of photovoltaic-to-battery charge control that optimizes solar array output by operating as a DC to DC converter. It uses the DC input from the photo-voltaic (PV) array and converts it back to a different DC voltage and current output so that the PV module is correctly matched to the battery. This allows a solar array to be wired at optimal voltage to overcome long cable distances that otherwise would result in excessive voltage drop or unacceptably large cable diameter.
Mean Kinetic Temperature (MKT) (E006): a single derived temperature that, if maintained over a defined period of time, affords the same thermal challenge to a drug substance or drug product as would be experienced over a range of both higher and lower temperatures for an equivalent defined period. The mean kinetic temperature is higher than the arithmetic mean temperature and takes into account the Arrhenius equation.
Medium-weight appliance: a transportable, powered appliance movable by a single person or multiple people for short periods, intended primarily for longer- range transportation by a vehicle (e.g. truck, motorbike, camel). All appliances shall be designated by the legal manufacturer as one of the three appliance types further defined in WHO/PQS/E003/TS01.1.
Member (E005): a geometrical part of a container such as a face, edge, corner, side or chime.
Minimum ambient cold life: cold life with a full coolant load at the minimum rated ambient temperature.
Minimum rated ambient temperature (E003): the lowest continuous ambient temperature at which the acceptable temperature range can be maintained. The warmest acceptable minimum rated ambient is +10ºC.
Minimum rated ambient temperature (E004): all containers will be tested to determine the lowest constant ambient temperature at which the vaccine storage compartment remains above 0°C. The test is carried out at +15°C unless the manufacturer specifies a lower figure.
Moderate zone: moderate zone units must operate at a steady +27°C ambient temperature and earn a minimum rated ambient temperature of +10°C or lower.
Moderate zone (refrigerated vehicles): moderate zone units must maintain the acceptable temperature range while operating at any ambient temperature from +32°C to 0°C.
Monitoring device: the device or system (e.g. EMS) that is receiving raw data collected from a monitored device.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
Mounting hardware: fasteners to attach support structure to solar module and attach support structure to foundation.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

N

Needle: in this context, includes the needle hub.
Needle container: that part of the device which stores cut, sheared or otherwise disabled needle remains prior to final disposal. The needle container can be an integral, non-detachable part of the device or can be removable. Separable needle containers can be designed to be either disposed of when full, or emptied, cleaned, and reused.
Needle cutter: a device which renders a plastic syringe of any type safe by cutting or destroying the needle, needle hub, or syringe nozzle and which encloses the remains of the needle in a needle container.
New technology: a device, equipment or product that fulfills one or more of the following:

- requiring a substantial PQS modification such as requiring specific tests not covered in the current verification protocols; or
- requiring creation of a new PQS equipment category; or
- functions using a new principle not previously encountered in any previous IMD-PQS device.

NIST: United States National Institute of Standards and Technology.
No electricity: the existing site condition when there is no alternating current electric supply System.
Nominal phase-change temperature: the nominal temperature at which the IMD-PCM changes phase as defined by the manufacturer.
Nominal ultra-low temperature (ULT): a single temperature below which the equipment is able to maintain the vaccine storage compartment, designated as a multiple of 5, between -25°C and -80°C (inclusive).

O

OD (E006): Optical Density – reflected OD in the case of this specification. The logarithmic measure of light reflected from the surfaces of the vaccine vial monitor (VVM) are measured by an appropriate instrument such as a spectrodensitometer or a densitometer. OD = - log 10 R, R reported in decimal format.
On/off switch: manual interrupter between an energy consuming load and its power or fuel supply. Specify circumstance (e.g. appliance on/off, power system on/off).
Open circuit: for a given terminal pair, electric circuit without a continuous path between the two terminals of the pair.
Operate(s) correctly: the component or components being referred to function as normally expected. More explicitly with respect to the appliance, the cooling circuit functions as required by the thermostat.
Operating life: in relation to replaceable batteries is the period following initial activation of the device. In the case of devices with non-replaceable batteries the period is measured from the date of delivery to the purchaser, regardless of whether the device is activated on that date.
Orientation: magnetic bearing of a solar array. Generally, the front (glazed) surface of solar arrays in the southern hemisphere will face north while arrays in the northern hemisphere will face south.
Outage: interruption in supply of electric power.
Overload: a situation where an electrical device is subjected to a greater electrical load than what it was designed for. Results in larger than design electric current passing through conductors, leading to excessive generation of heat and the risk of fire or damage to equipment.
Over-voltage: root mean square voltage greater than or equal to 110% of the nominal value for a period longer than a half cycle of the nominal input waveform.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

P

PCM-pack: a leak-proof container filled with phase change material (PCM) material designed to be coupled with the vaccine storage compartment. The PCM fill material must be certified to be non-flammable, non-corrosive and non-toxic. The PCM fill material must ensure fully effective cooling when PCM-packs are exposed to storage temperatures in the range +1°C and +6°C for the minimum period specified by the PCM-pack manufacturer.
Performance Specification: WHO IMD-PQS issued Standard that lays out the characteristics, features and functionality of a product that may be considered for WHO IMD-PQS prequalification. Performance Specifications are minimum requirements. However, going beyond these requirements with additional features, functionalities or other attributes that improve the product's performance, quality and safety as per user-needs is acceptable and encouraged.
Period of grace: period allowed to provide information or to complete a transaction, after formal notice in writing has been given.
Phase change material (PCM): a material, other than water, which changes state between solid and liquid or changes between two different solid crystallization states over a defined temperature range, absorbing or releasing heat during the phase change. This process is reversible and can be useful for thermal control in cold chain devices and products.
Phase failure: a loss of power on one or two phases of a three-phase system. Typically caused by a failed fuse, thermal overload, severed conductors, worn contacts or other types of mechanical failure.
Phase imbalance: a voltage variation in a three-phase system in which the voltage magnitudes and/or the phase angle differences between the different phases are not equal. Expressed as the percentage calculated by dividing the maximum voltage deviation from the phase voltage average, by the three-phase voltage average.
Piping: tubes for interconnecting the various parts of a refrigerant circulating system. Also called "tubing".
Power adapter: electronic device to match power supply characteristics with load power requirements.
Power cable: electrical wiring that connects an appliance or accessory to an electricity source (aka "power lead"). Specify circumstance (e.g. appliance power cable).
Power cable connector: the fitting of a power cable that connects to power source cable or receptacle.
Power quality: characteristics of the electric current, voltage and frequency at a given point in an electric power system, evaluated against a set of reference technical parameters.
Power tampering: unauthorized diversion of power to any load other than an IMD-PQS prequalified immunization appliance or energy harvesting system.
Prequalification Holder: a manufacturer or licenced reseller that is legally responsible for a product that has been granted (at the current time) WHO IMD-PQS prequalified status. All Prequalification Holder must fulfill all the IMD-PQS post-prequalification obligations. In addition, the IMD-PQS Secretariat only maintains communication with, and may only convene meetings with Prequalification Holders or prospective Prequalification Holders.
Preventive maintenance: activities associated with the upkeep of an appliance or solar power system to protect against normal wear and tear. This type of maintenance requires minimal skills and training, and is usually scheduled for regular intervals (daily, weekly, or monthly). On-site workers who have received appropriate training are responsible for preventive maintenance.
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.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Primary vaccine store: stores that receive vaccine directly from the vaccine manufacturer where it is stored and distributed to intermediate vaccine stores. Such stores are typically located in a national or regional centre.
Prime power generator: a generator that is able to run for an unlimited amount of time at variable loads up to the maximum rated power.
Procurement Agency: the organization which purchases the equipment covered by this specification and which provides the qualified supplier with details of the installation site(s).
Product: a cold chain-related product.
Production-run product: "samples" of the product submitted for IMD-PQS prequalification that are commercial-run / production-run products, NOT prototypes or models of products.
Programmable electronic load: laboratory test equipment capable of simulating AC and/or DC loads. Inductive, resistive, and capacitive loads can be simulated by adjusting a power factor setting, and loading modes can typically be constant power, constant current, or resistive.

Q

QA: quality assurance.
QA assessor: the person or organization appointed by the employer to assess the suitability of candidate installers, to evaluate their proposals and to monitor the assembly and commissioning of the installation on site.
Qualified Supplier: a qualified supplier may be either a legal manufacturer or a reseller and must:

- supply a coherent, correctly sized installation where the settings of all the components have been adjusted for optimum performance at the installation site,
- have installed and supported at least ten photovoltaic systems in a developing country or countries for at least two years (detailed references, including donors, locations and contacts, must be provided),
- have the capacity and financial resources to provide long term support to the systems in the country of destination,
- offer one or more refrigerators or combined refrigerator-water-pack freezers complying with PQS standards E003/RF04 and/or E003/RF05 and/or E003/RF06 and which are currently pre-qualified by WHO.

Quality System: a quality system that has been certified by the appropriate regulatory or notified body as specified in the relevant IMD-PQS Performance Specification. This quality system must be in current and continuous compliance.

R

R – I (E006): the reference surface value optical density (OD) minus the active surface value OD.
Rated current: maximum continuous current at which the device is intended to safely operate.
Rated frequency: the nominal design frequency for safe operation of the device.
Rated voltage: the nominal design voltage for safe operation of the device.
Rated water content: the volume of water, in cubic centimetres measured at 21.0°C, which the water-pack is designed to hold. The volume is defined by a fill line that is permanently marked on the face of the water-pack.
Reaction rate (E006): the rate at which the active surface responds to time-temperature exposure.
Receiver: the person or organization responsible for receiving the vaccine shipment.
Recording period: the period between the activation of the device using the 'start' button or switch and the de-activation of the device using the 'stop' button or switch.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Reference surface (E006): a patch surrounding the active surface against which the shade of the active surface can be directly compared.
Refrigerant: working gas or fluid that cools appliance and contents.
Region: a contiguous geographical area within which the legal manufacturer or reseller is able to provide the full range of services described in this specification.
Relative time (E006): a timestamp with an arbitrary but constant reference point (e.g. device commissioning is t=0), standardized according to ISO 8601 Durations profile, represented by the format PnDTnHnMnS, where the [n] is replaced by the value for each of the day and time elements that follow the [n].
Reliable electricity: the existing site condition where a sustained supply of alternating current electricity adequate for an ultra-low temperature (ULT) freezing system is continuous where power outages are rare with a maximum of one outage per month of less than one-hour duration.
Remote Data System: a networked, server-based storage system for the collection, management, and communication of electronic monitoring device (EMD) data. The Remote Data System is managed by the host.
Remote temperature monitoring device (RTMD): a system including programmable temperature and event monitor and peripheral devices in compliance with WHO PQS E006/TR03.
Removable container: a phase change material (PCM) container that is expected to be regularly removed from the CCE by the end user.
Removable insulation: thermal isolation material that can be manually moved in and out of position.
Reseller: a commercial entity, licensed to act on behalf of a legal manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.
Reserve time: the time that a fully charged battery can satisfy the load with no contribution from the charging source.
Reuse prevention feature syringe: a syringe and needle assembly, of any capacity, complying with ISO 7886-4.
Rolling load: the weight applied to a cold room or freezer room floor arising from the routine use of metal wheeled manual pallet trucks and/or powered or manually operated rubber wheeled pallet lifting equipment.
Root cause (analysis): systematic process to identify the cause of a fault, failure or undesired event, so that it can be removed by design, process or procedure changes.

S

Safety valve: device which automatically shuts off the supply of gas to an absorption appliance when the pilot flame is extinguished.
SD card: Secure Digital card (SD card) is a non-volatile form of flash memory for portable devices including cell phones. SD card may be found in some remote temperature monitoring devices (RTMDs).
Seal (sealant): filling material typically used in and around penetrations into appliances and buildings found at wiring, tubing or mechanical device entries.
Secondary carton: a carton, which contains a number of individual vaccine vials or vial pairs. Most countries have traditionally stored and distributed vaccines in these cartons.
Sender: the manufacturer responsible for packing and shipping the vaccine.
Sensor: device that senses either the absolute value or a change in a physical quantity and converts that change into a useful input signal. Temperature sensor(s) are an integral part of thermostat control.
Shading: shadows on solar array position that reduce incoming solar radiation. Solar siting tools can provide a shading analysis that instantly measure shading losses for each month of the year.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Shading analysis: means of quantifying the shading that may reduce the amount and duration of solar irradiance a site receives. This is important when checking that a site receives adequate solar power for solar refrigerators to operate effectively. See “shading”.
Sharps: in this context: syringes and needles; phlebotomy devices; IV insertion needles, including butterflies; lancets; scalpels and suture needles, which, through direct contact with health workers, waste handling/processing personnel, or the public at large, may penetrate the skin if brought into direct contact with it.
Sharps safety box: a container intended to safely hold used sharps.
Shelf: flat, horizontal support member. Typically, appliance shelves are removable.
Shipping container: the insulated packaging in which vaccine is transported to countries by international airfreight. Shipping containers accommodate a number of secondary cartons or tertiary cartons.
Short circuit: an accidental electrical circuit in a device with no or low resistance when compared to that of the normal circuit, especially one resulting from the unintended contact of components and consequent accidental diversion of current.
SIM card: Subscriber Identity Module card is a portable memory chip used in cell phones. SIM card may be found in some remote temperature monitoring devices (RTMDs).
Simulated solar power (SSP): a supply of power intended to simulate solar array output at specific instantaneous solar radiation values.
Site assessment: process of establishing the electrical power system needs of a specific health facility where an ultra-low temperature (ULT) freezing system is proposed.
Site assessor: a professional engineer with experience in the design of electrical generators and uninterruptible power systems.
SMPS: switched mode power supply.
SMS: Short Message Service.
Software: the programs and other operating information used by a computer.
Soiling: any dust, sand, bird droppings or other materials on the surface of a solar module that reduces solar power generation.
Solar array: solar module(s) mounted to a support structure, electrically connected with all other components as required, to form a direct current power producing unit. Also called “solar panel”.
Solar array cable: electrical wiring connecting a solar array to load.
Solar cell: basic solar subcomponent that generates direct current electricity when exposed to light. A solar module typically will require a quantity of interconnected solar cells that are encapsulated and not individually replaceable.
Solar direct drive (SDD): solar photovoltaic power system connected to electrical load(s), without the need for a battery to sustain the acceptable vaccine storage temperature range.
Solar direct drive (SDD) refrigerator: a vaccine refrigerator or combined vaccine refrigerator and water-pack freezer powered by a solar electric system with no battery used to power the compressor or cooling circuit.
Solar irradiance: amount of solar energy that arrives at a specific area at a specific time.
Solar module: a single complete assembly of solar cells with protective glazing (usually glass) and output terminals or cables. Also called (photovoltaic module, PV module, solar panel).
Solar power control: see battery charge/discharge control.
Solar power simulator (SPS): a supply of power intended to simulate solar array output at specific instantaneous solar radiation values.
Solar power system: an assembly of solar module(s), electrical cabling and support structure complying with WHO PQS E003/PV 01.
Solar radiation reference period: the minimum average daily solar radiation on the plane of the solar array that is required to properly power the solar refrigerator, or combined refrigerator and water-pack freezer, expressed in kWh/m²/day.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Solar radiation reference period (E001): the minimum average daily solar radiation on the plane of the solar array that is required to properly power the cold room – freezer room (CR-FR), expressed in kWh/m²/day.
Solar support structure: mechanical assembly where solar modules are secured. WHO IMD-PQS specifies that support structures are metal and intended to attach to a foundation such as roof, concrete base or pole.
Spare parts consumption: quantity of replacement components used per month.
Spectrodensitometer (E006): instrument to measure reflected optical density. Note that not all Spectrodensitometers have the ability to measure spectral data or display colorimetric information. Owing to the small size of the vaccine vial monitor's (VVM's) reference ring and indicator area, it is necessary to ensure the target and aperture centering of the spectrodensitometer is suitable for measuring the active surface and the reference surface. Conversion of spectral data to optical density is defined within ISO 5-3 Photography-Density measurements- Part 3: Spectral Conditions. All such instruments must be calibrated before use according to the instrument manufacturer's instructions.
Stable conditions: the temperature is stable when there is no marked trend or drift away from the mean temperature of a 24-hour measurement. If the temperature is cycling, it should repeat within 0.5°C during the periodicity. After stability, the appliance should exhibit manufacturer's stated holdover time. Note that temperature stability and compressor stability may not occur at the same time.
Standalone (E001): solar power system capable of independently powering 100% of all cold room – freezer room (CR-FR) electrical needs. It is the primary source of power for the CR-FR and can be coupled to a back-up power source (generator) to also operate as a hybrid solar power system.
Standalone (E006): solar power system capable of independently powering 100% of all equipment monitoring system (EMS) electrical needs.
Standalone voltage stabilizer: a stabilizer model external from the appliance for general use or for use with specific products. See Dedicated and Integrated voltage stabilizers.
Standard electrical connector: common electrical connectors including all USB receptacles, 12 VDC receptacles as used in vehicles and 120/230 VAC receptacles as used in buildings and electrical generators.
Start point (E006): the optical density of the active surface of the vaccine vial monitor (VVM) at the time when the VVM is received by the vaccine manufacturer. It is the vaccine manufacturer's responsibility to store the VVMs correctly to prevent any change in the start optical density (OD) during the period elapsing between the time of receipt of the VVM to the time of its application to the filled vaccine vial.
Starter relay: electrically operated switch used to transfer or disconnect power to an electric compressor motor.
Status indicator: device to display or demonstrate equipment operational condition. Note: add one or more levels of definition from this selection: audible alarm/autonomy gauge /battery/door opening/holdover gauge /led/voltage.
Storage life: in relation to non-replaceable batteries is the period measured from the date of delivery of the device to the sender to the time at which the 'start' function is activated.
Surplus solar electricity: any electricity the colar direct drive (SDD) appliance cannot use because:

- the appliance does not require electricity at that instant; or
- electricity being generated is insufficient to power the appliance at that instant; or
- electricity is powering the appliance and there is surplus electricity that the appliance cannot use at that instant.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

T

Tampering: unauthorized change to a component, appliance or system. Examples include thermostat tampering and power diversion.
Temperate zone: temperate zone units must operate at a steady +32°C ambient temperature and earn a minimum rated ambient temperature of +10°C or lower.
Temperate zone (refrigerated vehicles): temperate zone units must maintain the acceptable temperature range while operating at any ambient temperature from +27°C to 0°C.
Tertiary carton: a carton, which contains a number of individual secondary cartons. Cartons of this type are increasingly being used to store and to distribute vaccine.
Theft deterrent fastener: mechanical attachment device that requires unique or uncommon tools for assembly and disassembly. Uncommon tools are only found for sale through specialty stores or supply outlets.
Thermal storage: quantity of "cold" stored in sensible form (reducing the temperature of a mass of substance) or in latent form (e.g. the freezing of a liquid or a solution).
Thermocouple: heat sensing component of a gas safety valve used to confirm a pilot light is lit.
Thermometer: temperature measurement instrument. Appliance thermometers are both passive and actively powered by either mains, battery, solar power or ambient light.
Thermostat: device which automatically regulates the operation of a refrigerating system according to the temperature of the cabinet or of an evaporator.
Thermostat control card: electronic control logic assembly.
Thermostat sensor lead: electrical connection for transmitting information to a thermostat.
Thermostat tampering: unauthorized change to a temperature setpoint control or temperature sensor location.
Thermostat wiring: electrical connection for powering a thermostat.
Thirty Day Temperature Recorder (30-DTR): electronic refrigerator logger, with factory-programmed alarms and visual display for monitoring storage conditions in vaccine refrigerators over a 30-day period. The term 30-day temperature recorder (30-DTR) is used interchangeably.
Tilt: angle (degrees) of PV array as referenced to the horizontal.
Transformer: an electric energy converter without moving parts that changes voltages and currents associated with electric energy without change of frequency.
TTSPP: time and temperature-sensitive pharmaceutical products.

U

ULT cold life: ultra-low temperature cold life. The empty equipment is stabilized at +43°C and loaded with the specified amount and type of cooling medium. ULT cold life is measured from the moment when the equipment lid is closed until the temperature of the warmest point in the vaccine storage compartment warms to the designated nominal ULT after initially cooling to below the nominal ULT, at a constant ambient temperature of +43°C.
Ultra-low temperature (ULT): a temperature range attributed to materials that will be used at or lower than -25°C.
Ultra-low temperature (ULT) freezer: a vaccine freezer that complies with equipment performance specification E003/ULT01.1.
Ultra-low temperature (ULT) freezing system: a system of required electrical devices supporting a ULT freezing facility. The devices may vary from site to site and could include ULT vaccine freezers, standard water-pack freezers, vaccine refrigerators, equipment monitoring systems (EMS), lighting, communications, office devices, ventilation and space cooling.
ULT vaccine storage capacity: the total volume available for storing vaccine in the equipment when prepared for use at the nominal ULT.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Unauthorized item: placement of anything prohibited in an appliance (e.g. personal food, drinks).
Undefined load: user selected load devices that are not supplied by the legal manufacturer / reseller as a defined load with the appliance and energy harvesting control (EHC) system.
Under-voltage: an abnormal decrease in the root mean square voltage of less than or equal to 90% of the nominal value for a period longer than a half cycle of the nominal input waveform.
Uninterrupted: with respect to an electronic component or device, to operate continually, without pause.
Uninterruptible power supply (UPS): a backup stored energy system that protects a load from power outages using a stored energy system.
Unreliable power: the existing site condition where a sustained supply of alternating current electricity adequate for an ultra-low temperature (ULT) freezing system is less than 23 hours/day and may also experience power outages of more than once per month with one-hour duration or longer.
Uptime (refrigerator): percentage time per month that a refrigerator is functional and operating safely within +2 to +8°C range. Specified by manufacturer and appliance model.
USB-A port: a 5 V dc connection complying with USB.org power specifications specific to USB-A.
User: the person responsible for the day-to-day operation and monitoring of a device or appliance.
User-Dependent Freeze Protection (UDFP): refrigeration technology that requires appliance 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 appliance users (e.g. healthcare workers) to perform no specific actions (User-Interventions) in order to ensure vaccine protection against freezing temperatures.
User-intervention: any activity that is required to be executed by appliance users (e.g. healthcare workers) in order to ensure vaccine protection against freezing temperatures or other undesirable conditions. Activities could include, but are not limited to, basket storage, the requirement to use storage compartment covers, thermostat/fuel adjustment, placement of removable liners or barriers, charging a battery, or thermally conditioning the appliance or components thereof.
UV: ultra-violet light.

V

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.
Vaccine storage capacity: the volume of the vaccine storage compartment measured with the full number of coolant-packs in place. Capacity will be published as length, width and height in centimetres and volume in litres. If the volume is not rectangular in horizontal cross-section, the capacity may be published as area in square centimetres, height in centimetres and volume in litres
Vaccine storage compartment: the zone within the appliance which is designated by the legal manufacturer as suitable for storing vaccines.
Vaccine storage compartment (E004): the zone within an insulated container which is designated by the manufacturer as suitable for storing vaccine when the container is loaded with the full number of coolant-packs required to achieve the cold life specified in this document.
Variable DC load: a laboratory test device to simulate the range of secondary loads.

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 WWW.WHO.INT

Ventilation grill: opening in an appliance cabinet, electronic control or battery set housing to allow free flow of ambient air.
Verification protocol: a verification protocol describes in detail how the performance of a product or device will be tested or otherwise evaluated as part of the WHO IMD-PQS product prequalification procedure.
Vial: in the case of this specification, a "vial" also refers to other primary containers containing vaccine (onto which a vaccine vial monitor (VVM) may be applied), for example, droppers, ampules or pre-filled syringes.
Voltage: electrical potential measured between two points. Low voltage conditions are known to prevent or hinder operation of some electrical components. Abnormally high or low voltage can damage some electrical components.
Voltage stabilizer: electrical device designed to reduce fluctuations in input voltage and frequency and ensure a stable electricity supply for refrigerators and freezers in situations where the supply voltage is subject to wide fluctuation.
VVM: Vaccine Vial Monitor comprising, as a minimum, an active surface, a reference surface and the substrate to which these surfaces are applied by the VVM manufacturer.

W

Warm life: the empty container is stabilized at +18°C and loaded with warm-packs which have been stabilized at the same temperature for a minimum of 24 hours. Warm life is measured from the moment when the container is closed, until the temperature of the coldest point inside the vaccine storage compartment first reaches 0°C at a constant ambient temperature of -20°C.
Warm-pack: a water-pack typically stabilized at room temperature, up to a recommended maximum of +24°C. Warm-packs are used for the transport of freeze sensitive vaccines in countries where sub-zero temperatures are common.
Warm water-pack: a coolant-pack typically stabilized at room temperature, up to a recommended maximum of +24°C. Warm water-packs are used for the transport of freeze-sensitive vaccines during exposure to sub-zero ambient temperatures.
Water-pack: a flat, leak proof, plastic container, filled with tap water, complying generally with specification E005/IP01.
Water-pack freezing capacity: the daily maximum weight of fully frozen water-packs which remain at the end of the night phase of the water-pack freezing capacity test.
WHO ePQS: World Health Organization e-Prequalification system: a platform for all WHO prequalification applications and post-prequalification processes.
Wicks: fiberglass or cotton material that draws kerosene by capillary action to support a flame.
Wiring: general term for assembly made up of one or more insulated conductors, cables or busbars and the parts which secure their fixing and, if necessary, their mechanical protection.
Wiring connections: intentional electric contact between conductors. Both factory-made and field wiring connections are found in appliances, accessories and power systems.
Wiring terminals: mechanical connection points for electrical wiring
Worst-case temperature: the worst-case temperature in refrigerators is to be the lowest temperature measured during testing and the worst-case temperature in freezers is to be the highest temperature measured during testing. The reading must refer to a point lying within the zone allocated for the storage of vaccines.