WHO/PQS/E006/PVDC01



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1. Scope

Solar power is a reliable and efficient source of power for crucial cold chain devices with low power requirements, including Equipment Monitoring Systems (EMS) such as remote temperature monitoring devices (RTMD) and other necessary peripherals, such as secondary (i.e. rechargeable) batteries. This specification sets out the requirements for solar power systems that are appropriate for present day EMS and for other devices with similar power requirements of less than 400 Wh/day. This specification also details the requirements for a generic low voltage DC standalone solar power system with a photovoltaic solar module powering an EMS, such as an RTMD that complies with the current WHO PQS E006/TR03.2 specification. These requirements are also applicable to any other devices that require low power input.

Note: the current specification document does NOT apply when using solar direct drive energy harvesting to power an RTMD or similar device (see WHO PQS E007/EHC01.1 for relevant requirements).

2. Terms and definitions

<u>Alternating current (AC):</u> An electric current that reverses its direction at regularly recurring intervals the value of which varies as a sine wave.

<u>Autonomy:</u> Time in hours that a solar power system can maintain the EMS load under low solar radiation conditions (e.g. rain). Autonomy is determined as described in Clause 4.2.3: Battery set sizing.

<u>Design day</u>: The day that is selected to size the solar power system to meet all EMS electrical load requirements (the "design day") must be largest of the following three options 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) or both if occurring simultaneously.

<u>Direct current (DC):</u> An electric current flowing in one direction.

<u>Employer:</u> The organization that contracts with the legal manufacturer or reseller 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, commission and maintain the installation.

<u>Equipment Monitoring System (EMS)</u>: Measurement and recording device intended to monitor cold chain temperature, performance, events and alarms in walk-in cold rooms and freezer rooms (PQS E001) and refrigeration appliances (PQS E003).

<u>In writing:</u> Communication by letter, fax or email.

<u>Installation:</u> The complete solar power system installation described in this specification and in the companion **E006/PVDC-VP.2** document, together with any other employer's requirements documentation issued for a specific installation or installations.

<u>Installer:</u> A person or organization who has been appointed by the Employer to carry out the installation of the system.

<u>Legal manufacturer</u>: The natural or legal person with responsibility for the design, manufacture or integration of components, packaging and labelling of a product or device before it is placed on the market under the person's own name, regardless of whether these operations are carried out by that person or on that person's behalf by a third party.

Load: Any end-use device in an electrical circuit that can consume power when the electrical

<u>Load:</u> Any end-use device in an electrical circuit that can consume power when the electrical circuit is energized.

Maximum power point tracking (MPPT) control: A type of photovoltaic (PV) to battery charge control that optimizes solar array output by operating as a DC-to-DC converter. It uses the DC input from the PV array and converts it back to a different DC voltage and current 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.

<u>Montreal Protocol</u>: The Montreal Protocol, finalized in 1987, is a global agreement to protect the stratospheric ozone layer by phasing out the production and consumption of ozone-depleting substances (ODS).

<u>QA Assessor:</u> The person or entity appointed by the employer to assess the quality and suitability of manufacturing sites and/or candidate approved installers <u>QA:</u> Quality Assurance.

Remote temperature monitoring device (RTMD): A system including programmable temperature and event monitor and peripheral devices in compliance with WHO PQS E006/TR03.

<u>Reseller:</u> 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.

<u>Solar radiation reference period:</u> The minimum average daily solar radiation on the plane of the solar array that is required to properly power the EMS, expressed in kWh/m²/day. <u>Standalone:</u> Solar power system capable of independently powering 100% of all EMS electrical needs.

<u>User:</u> The person responsible for the day-to-day operation of the cold chain equipment and/or solar power system.

3. Normative references (use most current version)

EMAS: European Union Eco-Management and Audit Scheme.

IEC 60335-1: 2006 Household and similar electrical appliances - Safety - Part 1: General requirements.

IEC 60364-1: 2005 Low-voltage electrical installations - Part 1: Fundamental principles, assessment of general characteristics, definitions.

IEC 61000-6-1 edition 2.0: 2005 Electromagnetic compatibility (EMC) Generic standards - Immunity for residential, commercial and light-industrial environments.

IEC 61000-6-3 edition 2.1: 2011 Electromagnetic compatibility (EMC) Generic standards - Emission standard for residential, commercial and light-industrial environments.

IEC 61194: 1992 Characteristic parameters of stand-alone photovoltaic (PV) systems.

IEC 61215: 2005 Crystalline silicon terrestrial photovoltaic (PV) modules - Design qualification and type approval.

IEC 61646: 2008 Thin film terrestrial photovoltaic (PV) modules – Design qualification and type approval.

IEEE 1562: 2007 Guide for Array and Battery Sizing in Stand-Alone Photovoltaic (PV) Systems.

ISO 1461: 2009 Hot dip galvanized coatings on iron and steel articles - specifications and test methods.

ISO 9001: Quality Management Systems – Requirements.

ISO 14001: 2004 Environmental management systems - Requirements with guidance for use.

ISO 20282-1: 2006 Ease of operation of everyday products - Part 1: Context of use and user characteristics.

Solar Autonomy Calculation Tool, H.Toma and T. Markvart, University of Southampton, UK 2009.

UL2054: Second edition, 2009 Household and Commercial Batteries.

UL1642: First edition, 2012 Standard for Safety, Lithium Batteries.

WHO PQS E006/PVDC-VP.1: PQS Independent type examination.

WHO PQS E006/PVDC-VP.2: PQS Quality assurance protocol (TBD).

WHO PQS E006/TR03.2: Programmable remote temperature and event monitoring systems.

WHO PQS E007/EHC01.1: Solar direct drive surplus energy harvest control.

4. Design criteria

4.1 General

4.1.1 Capacity and requirements

The solar power system must be capable of providing 100% of the EMS electrical requirements as a standalone solar power system operating with no back-up power system. Typically, standalone solar power systems will require a solar module (or an array of 2 or more modules), mounting structure, overcurrent devices, battery recharge control system and wiring. The battery must be integrated in the EMS or solar power

system by the legal manufacturer, including all battery management controls such as charging, discharging and safety protections.

The following documents are associated with this requirement.

- **E006/PVDC-VP1** is a type-examination protocol which will be used for prequalification evaluations.
- **E006/PVDC-VP2** is completed by an employer or his QA assessor and sets out the requirements for a specific installation. The document also specifies the installation, commissioning and handover procedure. The completed protocol should be read in conjunction with **E006/PVDC** specification, to which it refers.

E006/PVDC-VP2, together with an employer's other documents, are intended to form the basis for a contractual agreement between the employer and the legal manufacturer or reseller for the supply of the components required for a specific installation. This also forms the basis for a contractual agreement between the employer and the approved installer. A legal manufacturer or reseller seeking prequalification under the terms of this specification must satisfy WHO that they are able to supply a complete package of components, including an installation and maintenance advisory service to enable a competent installer to assemble and commission the installation and to maintain the system.

4.1.2 Design responsibility

Standalone solar power systems must be purpose-designed to independently provide 100% of the power consumption of all connected EMS device electrical loads (e.g. RTMD system) based on the site-specific climate conditions taking account of ambient temperatures, minimum solar radiation reference period and autonomy requirements. Each power system must be complete to allow the entire installation to occur without the need for additional components. The EMS or other load devices are not included in this specification.

Reliability, durability and effective maintenance are essential for a successful installation. Installations are to be designed to achieve a service life of not less than 10 years, excluding battery replacement, routine cleaning and programmed maintenance.

The employer will specify:

- site name and address
- latitude and longitude
- elevation
- monthly temperature range
- *if available*, results of pre-installation site assessment (e.g. shading analysis, options for solar array mounting, location for battery, cable distances, cable placement, etc.).

The legal manufacturer is to specify the EMS electrical load including:

- characteristics description, quantity
- electrical nominal voltage, operating voltage range, running amperes, peak amperes
- time of operation (e.g. day, night modes) and on-time hours (consumption).

The legal manufacturer must then size the installation to ensure that the specified electrical loads will operate continuously within specified temperature limits, both when solar radiation is powering the system and throughout the autonomy period.

All solar systems must provide a minimum of five days of autonomy unless an alternative autonomy (of greater or lesser days) can be calculated using one of the two methods defined in the normative reference: Tome, H. and Markvart T. *Solar Autonomy Calculation Tool*, University of Southampton, UK, 2009. In no case should the battery have a capacity of less than three days.

The two methods are:

- 1. Selection of autonomy for the specific locations listed in the supporting document to the *Solar Autonomy Calculation Tool* ¹.
- 2. Calculation of autonomy using the formulas and the required long-term daily solar radiation data as described in the *Solar Autonomy Calculation Tool*.

The installation must then be sized to provide the required autonomy at the specified location.

The legal manufacturer must provide the employer with the data used to determine the installation design, including reference periods for temperatures, solar radiation, autonomy determination and assumptions made regarding site conditions. The data must include the assumed monthly minimum solar radiation reference period, assumed average minimum and maximum ambient temperatures and the month requiring the most power. Reference period climate conditions are to be in closest accordance with available meteorological data.

¹ Instructions for Autonomy Calculation (For Solar Vaccine Refrigeration Systems per the WHO PQS). Table 1 includes a subset of sites for which the data are considered to be sufficiently accurate for solar vaccine refrigerator applications. PQS E03 PV1.2.doc 5 of 13 06 July 2010

4.2 Performance

4.2.1 Solar module, solar array and array output cable

Solar modules must comply with **IEC 61215** (crystalline solar modules) or **IEC 61646** (thin film solar modules). The power warranty is to be a minimum of 25 years to 80% of the initial power rating.

The combined solar array structure and solar module assembly must be designed to withstand wind loads at site of installation whether it is fixed to a roof, ground, building or pole structure. This force should be calculated from knowledge of local conditions including wind speed and local features. Particular attention should be given to force caused by wind gusts and possible resonance conditions. Guidance on calculating the wind load force can be found in internationally accepted building codes.

At a minimum, the solar array support structure must be certified to meet or exceed the solar module mechanical load test results per **IEC 61215** and the solar modules must be fastened to the solar array support structure per solar module manufacturer's instructions to attain IEC test results or a greater mechanical load rating. Sites that experience Category One hurricane and/or F1 tornado must have a solar array support structure that is manufacturer certified or engineered to be capable of withstanding local wind conditions.

Individual solar module open circuit voltage of up to 45 Voc is acceptable. Solar array input voltage must be matched to battery charge control requirements including MPPT controls that allow higher solar array voltages.

The minimum solar array capacity is to be no smaller than an array capable of sustaining the maximum daily load, including all power system losses, x 1.25.

Cables must be equipped with strain relief fittings unless otherwise permanently fixed or in conduit. All cable and connectors not in conduit must display a rating confirming their suitability for exterior use in direct sunlight and direct burial if used underground. If cable is run in conduit then the conduit must have a cable strain relief system at each termination of the conduit and the conduit must be fixed at regular intervals of no less than every 350mm on the horizontal and 450mm on the vertical. Exterior rated conduit with weatherproofing or equal protection must be provided at the point where cable enters the building.

Manufacturers must provide instruction for estimating cable diameter and for ordering non-standard lengths of cable.

4.2.2 Solar module or array support structure

Typically, a dedicated solar array structure will be required. It may be possible to add the EMS solar array to a solar array structure serving other purposes however this is not permitted unless:

- 1. the EMS solar array does not shade the host solar array at any time throughout the year, *and also*
- 2. the entire solar array assembly of the host solar array and added EMS solar array complies with all specifications described herein (section 4.2.2.), *and* also
- 3. the addition of the EMS solar array to a host solar array is approved in writing by the employer.

The photovoltaic array support-structure forms part of the installation and typically will match site-specific requirements. All support structures must be constructed of anodized aluminum, stainless steel or hot dip galvanized steel complying with **ISO1461** after cutting and drilling.

All solar array structure fasteners must be theft deterrent, including fasteners required to fix the structure to building, foundation or pole. All solar array structures packages are to be supplied with a complete set of all unique tools typically unavailable in local markets and required for fixing the theft deterrent fasteners supplied. It must be possible for an authorized person to adjust or remove the array assembly if required. Breakaway nuts and similar devices are not acceptable.

The support structure must include all fasteners needed to attach to the site-specific foundation. The array structure package is also to be supplied with sealant for weather-proofing building penetrations and all other necessary subsidiary components, including the components needed to bond the solar array and the structure for lightning protection purposes in accordance with the component and solar module manufacturer's instructions.

Where site-specific works are required to install the support structure, these will be designed by the legal manufacturer and constructed by the installer.

For a roof installation, the roof must be structurally capable of supporting the load of the modules and racking. The modules and racking must be non-combustible. Roof or wall penetrations (such as to attach the racking to the roof) must be flashed and sealed to prevent water, rodents or insects from entry. Rooftop solar systems must meet the same fire classification as the roof assembly.

4.2.3 Battery set sizing

Battery autonomy must be sized to provide sufficient capacity to power the load. If the load is an RTMD as specified in **PQS E006/TR03.1** then autonomy is specified for each use segment (see table below).

Segment 1	Segment 2	Segment 3
5 days	5 days	7 days

Autonomy period is determined as described in Clause 4.1.4, based on the energy required for the EMS or other load to which the solar system components are connected. Required battery capacity is estimated over the discharge rate and temperature most closely matching the autonomy period and the temperature at the site (e.g. at C/120 hours at +25°C for a five-day autonomy period). Battery capacity must be sufficient to ensure that the designed autonomy period is maintained throughout the minimum required battery set life of five years.

4.2.4 Battery type and battery charge/discharge control

Lithium, nickel metal hydride and sealed lead acid batteries are permitted when in compliance with normative references **UL1642** (and **UL2054** for lithium batteries).

The type of regulator is not specified and can include series, pulse width modulated and maximum power point controls. Shunt type regulators are not permitted.

Maximum power point controls are acceptable when used to connect a solar array of higher voltage to a battery of lower voltage. The regulator must use either varistor, spark-gap or surge protection. The regulator must be pre-set to suit the installed battery type. Voltage regulation set points must not be user-adjustable. The set points must be set precisely to meet the charge and temperature requirements of the installed battery set.

If a load disconnect feature is used it must disconnect the load when the battery has reached a state of charge which can be repeated to assure a five-year life.

The regulator must automatically compensate for temperature changes. If temperature compensation becomes disabled, the regulator must regulate at voltage regulation set points at +25°C.

At least one method to isolate (disconnect) the battery from the solar power system must be supplied. This switch can be built into the control, the EMS or be a separate component.

The regulator unit must have a battery capacity indicator. An acoustic alarm may be included as a supplementary high/low battery and/or load disconnect warning device.

Series and pulse-width-modulated charge controllers must be sized for a DC current rating of at least 156% of the solar array short circuit rating. Maximum power point controls must be sized for 100% of the peak solar array power.

Battery control(s) and EMS must be compatible. The battery control shall not interfere with the correct functioning of the EMS. The EMS shall not interfere with the correct functioning of the battery control.

4.2.5 Battery set housing

The battery set must be integrated into the EMS system by the legal manufacturer. The battery may be housed within the EMS or in a separate, protective enclosure provided by the legal manufacturer. Circuit breakers, fuses and other protection must comply with UL1642 (and UL2054 for lithium batteries).

4.2.6 Battery safety

The legal manufacturer must provide comprehensive safety instructions, hazardous materials data sheets and battery chemistry type.

4.2.7 Electrical safety rating

The legal manufacturer must certify compliance with IEC 60335-1 with particular reference to Section 8: *Protection against access to live parts*, and Annex B: *Appliances powered by rechargeable batteries*. All on-site electrical installation work must comply with IEC 60364-1.

4.2.8 Electrical protection

The system design must prevent damage to all components and the facility in the event of short circuits, over charge, over discharge, impacts and temperature extremes per **UL1642** (and **UL2054** for lithium batteries).

4.2.9 Lightning surge protection

Lightning surge protection must be provided per component legal manufacturer requirements. At minimum, a complete wire and hardware kit must be supplied to provide an equipment grounding conductor to bond the photovoltaic module(s) and support structure to earth per the solar module manufacturer's requirements. Any other system component requiring lightning surge protection must also be protected per legal manufacturer requirements.

4.2.10 User maintenance and installer tool kits

All power systems are to be supplied with one complete user maintenance kit consisting of all necessary operations and maintenance tools as proposed by legal manufacturer. All power systems sites are to be supplied with one complete installers kit consisting of all unique installations tools as proposed by legal manufacturer.

Note: sites with multiple solar powered EMS can be supplied with a single installation maintenance kit suitable for the type of solar power system provided.

4.2.11 Electromagnetic compatibility

The legal manufacturer must certify compliance with the requirements of the latest edition of IEC61000-6-1 and IEC 61000-6-3.

4.3 Environmental requirements

4.3.1 Ambient temperature range during transport and storage

-30°C to +70°C when components are in transit.

4.3.2 Ambient temperature range during use

Solar modules may be exposed to temperatures from -40°C to +90°C when mounted in their final positions. Battery and battery charge regulators may be exposed to temperatures from -10°C to +43°C after installation and commissioning.

4.3.3 Ambient humidity range during transport and storage

5% to 95%, non-condensing.

4.4 Physical characteristics

4.4.1 Overall dimensions

Not specified.

4.4.2 Weight

Not specified.

4.5 Interface requirements

4.5.1 Equipment Monitoring System (EMS)

In order to complete the installation, the legal manufacturer must supply all the solar system components needed to connect to the specified EMS (e.g. an RTMD).

4.6 Human factors

4.6.1 Generally

The solar system components must be easy to assemble and commission, using normally-available hand tools, by installers who have received basic training. The completed installation must be useable by the widest practicable range of health workers, regardless of age, gender, size or minor disability, including colour blind users and long-sighted people without glasses, in accordance with the general principles laid out in **ISO 20282-1: 2006**.

4.6.2 Safe access

Photovoltaic arrays must be mounted in positions that allow safe access for installation, maintenance and cleaning, using appropriate fixed access equipment as necessary. Avoid array mounting locations which require access across fragile roof structures and finishes. In locations without safe access, provide specialized cleaning tools (e.g. extended handle glass cleaning tools) to allow cleaning from a safe and secure position.

4.7 Materials

4.7.1 Restricted materials

The product and its constituent components, must not contain lead (except in batteries), mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).

4.8 Warranty

Installations must be covered by a three-year warranty in the event of any component failure arising from defective design, materials or workmanship. All warranty rights begin when they are passed from the approved installer to the employer after the installation has been commissioned and has been formally accepted by the employer. Where the employer is a UN agency, the warranty rights are to pass to the host government.

Any component which fails due to defective design, materials or workmanship must be covered by a replacement warranty. The minimum periods for the component warranty must be as follows:

- 25 years for the solar module power output
- five years for the battery, with a full like-for-like replacement warranty for the first 12 months and pro-rated financial compensation, based on the purchase cost of the battery set, for the remaining period
- three years for all other components.

4.9 <u>Servicing provision</u>

4.9.1 Maintainability

Installations must be substantially maintenance-free other than solar array cleaning and periodic battery replacement. Legal manufacturers must publish and provide a recommended battery replacement plan.

4.9.2 Essential spare parts, consumables and user tools/supplies

Based on product design and requirements the type and quantity of spare parts, basic installation tools/supplies, user and technician maintenance manuals (see Clause 4.11 Instructions), must be determined and agreed upon in advance of order placement.

As a minimum, each solar power system to be supplied with 10 spare fuses of all fuse size and types used in the system and two spare circuit breakers of all breaker size and types used in the system. The spares fuses are to be attached within accessible power system enclosures.

Legal manufacturers are to publish a list of spare parts recommended for five years of operation. Legal manufacturer must ensure supply of spare parts for a minimum of five years from the time of cessation of the last production of equipment. Spare parts are to be provided in kit form for storage in appropriate quantities at National or Sub-national level in the purchasing country, as agreed with the employer.

Provide consumables sufficient for two years of normal operation at the specified location(s).

4.10 Disposal and recycling

The legal manufacturer must provide information to the employer on the toxic and hazardous materials contained within the components and suggestions for resource recovery/recycling and/or environmentally safe disposal. For the European Union, WEEE compliance in accordance with European Union Directive2002/96/EC is mandatory.

4.11 Instructions

Each solar power system to include a separate user manual and installers manual in Arabic, English, French, Mandarin Chinese, Russian and Spanish. An English version of all instructions and manuals are required to be supplied at time of prequalification.

Instructions must include easy to understand visuals whenever possible to avoid reliance on text.

The user manual must include the following information:

- health and safety guidance
- basic operations description
- routine maintenance tasks (e.g., daily, weekly, and monthly)

The installer manual must include the following information:

- health and safety guidance
- detailed operations description
- correct handling to avoid component damage and for the safety of handling persons
- solar array site shading assessment tools and procedures
- installation procedures
- technical maintenance tasks (e.g. daily, weekly and monthly)
- periodic preventative maintenance procedures
- diagnostic and repair procedures
- itemized list of spare parts including part numbers
- end-of-life resource recovery and recycling procedures
- user training guidance

Printed user and routine maintenance instructions specifically directed at the EMS user must be pictorial. All key information must be summarized on a single sheet that can be fixed onto an EMS, a wall or cabinet at time of installation; the sheet should be sufficiently durable to last the life of the EMS and must be in a locally-understood language.

Installation, repair and servicing instructions must be supplied in printed format and optionally on DVD, USB and/or online to instruct the installer in installation standards and practices specific to the EMS. In addition, supporting video material supplied on DVD, USB and/or online can be provided to assist the instructor when delivering on-site user training.

4.12 Training

If specifically required, the legal manufacturer should provide a practical hands-on training course for installers and/or maintenance contractors. The course may be conducted in country or at the legal manufacturer's own workshop.

Specific user training must be provided to the responsible, on-site EMS user. User training conducted by legal manufacturer or reseller or installer at time of installation is recommended

4.13 Verification

In accordance with PQS Verification Protocol **E006/PVDC-VP1** legal manufacturers will be required to present evidence of conformity.

5. Packaging

Materials used for packaging components are to be free of ozone-depleting compounds as defined in the Montreal Protocol. The general specification of shipping containers will be subject to agreement with the employer.

6. On-site installation

Unless otherwise requested, installation will be carried out by the employer or by other installers designated by the employer. The legal manufacturer or reseller is free to offer this service directly, or through a designated representative installer.

7. Product dossier

The legal manufacturer or reseller is to provide WHO with a prequalification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer including name and address.
- General information about the reseller including name and address (where applicable).
- Unique identification reference for the system type.
- Full specifications of the components being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- Certified photocopies of all type-approvals obtained for the product, including CE marking and the like.
- Certified photocopies of the legal manufacturer or reseller's **ISO 9001** quality system certification.
- Where relevant, certified photocopies of the legal manufacturer or reseller's **ISO 14001** certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however, preference will be given to legal manufacturers who are able to demonstrate compliance with good environmental practice.
- Laboratory test report(s) proving conformity with the product specifications.
- Indicative cost of a comparable standalone solar power system for a given EMS, EXW (Incoterms 2010).

8. On-site maintenance

Not required, but may be offered.

9. Change notification

The legal manufacturer or reseller is to advise WHO in writing of any changes which adversely affect the performance of the product after PQS prequalification has taken place.

10. Defect reporting

The legal manufacturer or reseller must advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events. Report to be issued immediately upon knowledge of such event.

Revision history						
Date	Change summary	Reason for change	Approved			