



TITLE: Solar power system for vaccine refrigerator or combined refrigerator and water-pack freezer.

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1. Scope

This specification describes the requirements for a photovoltaic (PV) solar power system that provides direct current electricity for a vaccine refrigeration appliance (vaccine refrigerator, water-pack freezer or combined vaccine refrigerator and water-pack freezer). [Qualified suppliers](#) are also free to offer the [installation](#) and maintenance services described in this document, although the provision of these services is not a condition for pre-qualification. On-going supply of spare parts is a mandatory requirement.

Two alternative systems are covered by this protocol. **Type 1** systems use a solar power system to charge an electrical storage battery pack, which then powers an appliance complying with specification **E003/RF04**. **Type 2** systems use a solar power system directly to power the appliance. A direct drive appliance complying with specification **E003/FZ03** and **E003/RF05** are entirely battery free. A direct drive appliance complying with specification **E003/RF06** uses an integrated battery to power ancillary equipment such as fans, instrumentation and control. This ancillary battery is charged from the solar power system.

2. Normative references (use most recent version of each reference)

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.*

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.*

3. Terms and definitions

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 radiation conditions (e.g. rain). Autonomy is determined as described in clause 4.1.2 and measured as described in **E003/RF05-VP** and **E003/RF06-VP**.

Autonomy (freezer): Time in days that a solar direct drive water-pack freezer can maintain the minimum capacity of fully frozen water-packs under low solar radiation conditions (e.g. rain). Autonomy is determined as described in **E03/FZ03-VP**.

In writing: means communication by letter, fax or email.

Installation: The solar power system components specified in this document connected to an appliance complying with specification **E003/FZ03**, **E003/RF04**, **E003/RF05** or **E003/RF06**.

Installation technician: The person who installs the solar power system and associated appliance on behalf of the procurement agency.

Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

Maximum power point 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.

Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.

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).

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 (e.g. by providing on-going technical assistance, spare parts and system documents) at least 50 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.

- Offer one or more refrigerators or combined refrigerator and 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.

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.

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.

4. Design criteria

4.1 General

4.1.1 *System characteristics*

The solar power system will be connected to appliances complying with PQS specifications **E003/FZ03**, **E003/RF04**, **E003/RF05** or **E003/RF06**. This equipment is used primarily in areas without any electricity or where there is less than 4 to 8 hours of reliable electricity over a typical day. Reliability, durability and effective maintenance are essential for a successful installation.

Each power system must be purpose-designed to match the power consumption of the connected appliance and the site-specific climate conditions, taking account of ambient temperatures, available solar radiation resource and autonomy requirements. Each power system must be complete to allow the entire installation to occur without the need for additional components.

No additional loads, such as lighting or pumping, are to be connected to the solar power system.

4.1.2 *Design responsibility*

The **procurement organization** will specify the capacity and characteristics of the appliance that is to be connected to the solar power system. The **installation** must then be sized to ensure that the specified appliance 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 5 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: Toma, H. and Markvart T. *Solar Autonomy Calculation Tool*, University of Southampton, UK, 2009.

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*.

Two design cases apply: when the **installation** site is known and when it is unknown.

- **Known sites:** The **procurement organization** will specify as accurately as possible the site location for each **installation**, including the country name, site name, latitude and longitude and, where possible, the elevation in meters above sea level.
- **Unknown sites:** The **procurement agency** will specify the country name and, where possible, the region within the country.

In both cases the **qualified supplier** must then design the **installation** to provide the required **autonomy** anywhere within the specified geographical area.

In both cases, the **qualified supplier** must provide the **procurement agency** with the data used to determine the **installation** design, including reference periods for temperatures, **solar radiation reference period**, **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.

4.2 Performance

4.2.1 *Photovoltaic array and array output cable*

Solar modules must comply with IEC 61215 (crystalline solar modules) or IEC 61646 (thin film solar modules). Individual solar module open circuit voltage of up to 45 Voc is acceptable. The power warranty is to be a minimum of 25 years to 80% of the initial power rating. The minimum solar array capacity is to be no smaller than an array capable of sustaining the maximum load, including all power system losses, x 1.25.

Except for equipment grounding conductors all solar module cables, module to module interconnect cables and solar array output cables to provide a locking female and male coupler system with minimum IP rating of 65 (“plug and play”) for cable to cable interconnection and 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 its suitability for exterior use in direct sunlight and direct burial if used underground. Exterior rated conduit with weatherproofing or equal protection must be provided at the point where cable enters the building. A minimum solar array output cable length of 20 meters is to be supplied. A separate equipment grounding conductor of 20 meters is also to be supplied. Manufacturers are to provide instruction for estimating cable diameter and for ordering non-standard lengths of cable.

4.2.2 *Solar array support structure*

The photovoltaic array support structure forms part of the installation and must be constructed of anodized aluminum, stainless steel or steel, hot dip galvanized to ISO

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

1461 after cutting and drilling. Generalized roof/ground mounts with adjustable tilt angle of up to 45 degrees and/or pole mounts are to be offered by all manufacturers. Generalized roof/ground with adjustable tilt angle of up to 45 degrees mounts are to be supplied unless one of the following location-specific mounts is specified at time of procurement:

- **Pitched roof mounting:** The support frame is provided with adjustable tilt angle of up to 45 degrees for connection to a pitched roof structure. Any type of pitched roof finish may be encountered, including corrugated sheeting, tiles and slates.
- **Flat roof mounting:** The support frame should hold the solar array at the optimum angle and orientation for the site. Depending upon the roof construction the frame may either be mechanically fixed to the roof, or held down with weights.
- **Wall mounting:** The support frame should hold the solar array at the optimum angle for the site. Orientation will follow the alignment of the wall. Any type of wall construction may be encountered, including brick, stone, concrete, steel or timber framing.
- **Ground mounting:** The support frame should hold the solar array at the optimum angle and orientation for the site. The frame will either be bolted to concrete pads or to a concrete slab.
- **Pole mounting:** The support frame should hold the solar array at the optimum angle and orientation for the site and may be top mounted or side mounted.

The combined array structure and photovoltaic panel assembly must be designed to withstand wind loads at site of installation. A solar array must be able to withstand the full force of the wind (wind load force) expected at the installation site 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 to calculating the wind load force can be found in internationally accepted building codes.

All solar array structure fasteners are to 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 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 generalized roof/ground mount is to include all fasteners needed to attach to a pitched roof, flat concrete roof, or ground 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 solar module manufacturer's instructions.

Where site-specific works are required to install the support structure, these will be designed by the [qualified supplier](#) and constructed by a local contractor.

4.2.3 *Battery set sizing*

Batteries must be sized to meet the autonomy period determined as described in clause 4.1.2, based on the energy required for the appliance(s) to which the solar

system components are connected. In no case should the battery have a capacity of less than 3 days. 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 5 day autonomy period to a final voltage that ensures the minimum required battery set life of 1800 cycles to 80% discharge at +20°C). Battery capacity must be sufficient to ensure that the designed autonomy period is maintained throughout the minimum required battery set life of 1800 cycles to 80% discharge.

4.2.4 Battery type

Both sealed and flooded lead acid batteries are acceptable for **Type 1** systems, although sealed batteries are preferred for installations in remote areas where maintenance will be difficult. Only sealed lead acid batteries are acceptable for **Type 2** ancillary batteries.

The maintenance cycle for flooded batteries must be 6 months or greater, they must have clear casings to allow the user to inspect electrolyte levels and they must be supplied dry/charged with the electrolyte packed in separate hermetically-sealed containers.

4.2.5 Battery set housing

Note: Applies to **Type 1** system only.

The battery set must be housed within a lockable ventilated cabinet with a clear viewing window for maintenance inspection by the user. The housing for flooded batteries must include protection against spilled electrolyte. Circuit breakers or fuses must be installed in the positive line, near the battery, and the fuse-holder must be of non-corroding material. If fuses are used there must be a set of 10 spare fuses for each fuse size and type used and supplied in a polyethylene bag fixed near to the fuse box.

4.2.6 Battery charge regulator

Note: Applies to **Type 1** system only.

Maximum power point controls are acceptable when used to connect a solar array of higher voltage to a battery of lower voltage battery. The battery charge regulator must be sized for a DC current rating of at least 150% of the solar array short circuit rating. The load disconnect current rating must be 200% of the maximum load current and must operate the appliance compressor under all starting load surge conditions. The regulator is to 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 and they must disconnect the load when the battery has reached a state of charge which can be repeated a minimum of 1800 cycles to 50% depth of discharge. If battery voltage drops below the load disconnect set point, the load must be disconnected and the solar array must remain connected. The load must be automatically reconnected when the system voltage recovers.

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.

The regulator unit must have a clearly marked color-coded voltmeter, LED's or other indicators to show:

- Array charging (green).

- Low battery (orange or yellow), with a clearly labelled warning: *Do not freeze water-packs* in the appropriate language.
- Load disconnected (red).

An acoustic alarm may be included as a supplementary high/low battery and/or load disconnect warning device.

4.2.7 *Lead acid battery safety kit*

Note: Applies to **Type 1** systems only.

Provide comprehensive safety instructions, hazardous materials data sheets and a lead acid battery safety equipment kit. The safety equipment for lead acid flooded batteries is to include the following:

- Temperature compensated hydrometer.
- 1.0 liter plastic decanting jug.
- Plastic filling funnel.
- Eye, hand and clothing protection.
- Sodium bicarbonate for cleaning electrolyte spills.
- A hand pump for electrolyte is to be provided if the electrolyte is supplied in containers of more than 5 liters.

4.2.8 *Power switch*

At least one method to isolate (disconnect) the appliance from the solar power system must be supplied. This switch can be built into the appliance or wall mounted. Disconnecting cables is not an acceptable means of disconnect, although this method can be used in case of emergency.

4.2.9 *Electrical safety rating*

Manufacturer to 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.

4.2.10 *Electrical protection*

The system design must prevent damage to all components in the event of short circuits, electrical storms and reversed polarity connections. Circuit breakers or fuses must be installed in the positive line, near the battery, and the fuse-holder must be of non-corroding material. The fuse type and rating must be marked close to the fuse holder. Ten spare fuses must be provided in a polyethylene bag fixed near to the fuse box.

4.2.11 *Lightning surge protection*

Lightning surge protection must be provided per manufacturers requirements. At minimum a complete wire and hardware kit must be supplied to provide an equipment grounding conductor to bond the photovoltaic modules and support structure to earth per the solar module manufacturer's requirements. Any other system component requiring lightning surge protection must also be included per manufacturer(s) requirements. The equipment grounding conductor must be a minimum of 20 meters with a minimum of 1.5 meter grounding rod with connectors.

4.2.12 *User maintenance and technician installation tool kits*

All sites are to be supplied with one complete user maintenance kit consisting of all necessary operations and maintenance tools as proposed by [Legal Manufacturer](#). All sites are to be supplied with one complete installation kit consisting of all necessary installations tools as proposed by [Legal Manufacturer](#).

Solar direct drive installation sites must be sufficiently shade free as determined by a solar site analysis that accounts for the daily average site shading on no less than a monthly basis. Specialized tools for shading analysis must be offered to prospective buyers.

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

4.2.13 *Electromagnetic compatibility*

[Legal Manufacturer](#) to 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*

Photovoltaic panels may be exposed to temperatures from -40°C to +90°C when mounted in their final positions. Battery sets 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*

System components must be able to fit through an 830mm wide door opening (with the door leaf removed if necessary).

4.4.2 *Weight*

System components must be capable of being safely manhandled into their final positions. Mechanical lifting equipment will typically not be available at the installation sites. It is recommended that individual component packages should be designed so that they can be lifted in such a way that no single worker is required to carry more than 25 kg whilst working on their own, or in a group.

4.5 Interface requirements

4.5.1 *Appliances*

In order to complete the [installation](#) the [qualified supplier](#) must supply all the solar system components needed to connect to the specified appliance. Appliances for **Type 1** systems must comply with PQS specification **E003/RF04**. Appliances for **Type 2** systems must comply with specification **E003/FZ03**, **E003/RF05** or **E003/RF06**.

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 installation technicians 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 color 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 where safe access is not possible 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*

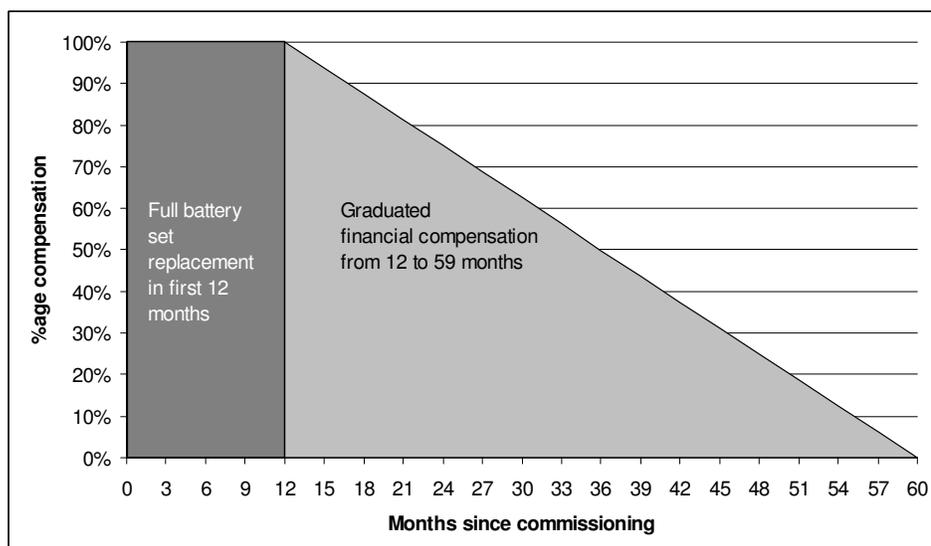
The product and its constituent components, must not contain lead (except in batteries), mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).

4.8 Warranty

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

- 25 years for the solar module power output.
- 5 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, in accordance with Figure 1.
- 2 years for all other components.

Figure 1 – Battery set failure compensation chart



4.9 Servicing provision

4.9.1 *Maintainability*

Installations are to be substantially maintenance-free other than PV array cleaning, routine battery servicing (flooded batteries) and periodic battery replacement. [Legal Manufacturers](#) are to publish a recommended battery replacement plan.

4.9.2 *Essential spare parts and user maintenance 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 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. The spares fuses are to be attached within the appliance or within accessible power system enclosures.

[Legal Manufacturers](#) are to publish a list of spare parts recommended for 5 years of operation for purchases of 10 and 50 power systems. [Legal Manufacturer](#) must ensure supply of spare parts for a minimum of 5 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 purchasing agency.

Supply sufficient spare parts for the first 5 years of operation. Spare parts are to be provided in kit form for storage in appropriate quantities at central or regional level in the purchasing country, as agreed with the purchasing agency.

4.10 Disposal and recycling

The [legal manufacturer](#) is to provide information to the buyer 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 Directive 2002/96/EC is mandatory.

4.11 Instructions

Each solar power system to include a separate user manual and [installation technician](#) 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 laboratory testing. Instructions to 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; and
- Routine maintenance tasks (e.g., daily, weekly, and monthly).

The [installation technician](#) 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;
- Compatible types of appliances;

- 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; and
- User training guidance.

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

Installation, repair and servicing instructions must be supplied in printed format, and optionally on DVD and/or on-line to instruct the **installation technician** in **installation** standards and practices specific to the appliance and its power system. In addition, supporting video material supplied on DVD and/or on-line can be supplied to assist the instructor when delivering on-site user training.

4.12 **Training**

Specific user training must be provided to the responsible, on-site appliance user. User training conducted by installers at time of installation is recommended.

Optional training courses are to be offered by the **qualified supplier** or a designated representative.

4.13 **Verification**

In accordance with PQS Verification Protocol **E003/PV01-VP2 Legal Manufacturer's** 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 individual **procurement agencies**.

6. **On-site installation**

Unless otherwise requested, **installation** will be carried out by the **procurement agency** or by others designated by the **procurement agency**. The **qualified supplier** is free to offer this service directly, or through a designated representative.

7. **Product dossier**

The **legal manufacturer** or **reseller** is to provide WHO with a pre-qualification 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).
- A list of at least 50 solar photovoltaic systems **installations** in one or more less-developed countries completed and supported over a period of at least two years prior to the date of dossier submission. Provide full details of each

[installation](#), including details of installed equipment, country and location, procurement agency and named contacts.

- A list of the countries or regions in which the [legal manufacturer](#) or [reseller](#) is able to offer the optional support services described in clauses 6 and 8, together with details of these services.
- Unique identification reference for the system type.
- System type offered (**Type 1**, **Type 2** or both).
- 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.
- Laboratory test report(s) proving conformity with the product specifications.
- Indicative cost of the product per unit, per 10 units and per 100 units, EXW (Incoterms 2010) including appliance and solar power system.

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](#) is to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

Revision history			
Date	Change summary	Reason for change	Approved
16/11/2015	Revised for consistency		DM