



**TITLE: Power systems for ultra-low temperature freezing systems**

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## 1. Scope

Ultra-low temperature (ULT) freezing systems including at least one ultra-low temperature (ULT) freezer operating to -86°C plus at least one ULT coolant freezer are required for specific vaccines including Ebola vaccine and possible future vaccines. WHO PQS has identified the requirements for ULT freezers and ULT freezing systems per the equipment performance specification **WHO PQS E003/ULT01.0 Vaccine ultra-low temperature freezer: compression-cycle**.

In addition, WHO PQS has identified the need for robust and reliable power systems to support ULT freezers and ULT freezing systems. **WHO PQS E003/POW01.0** is a power system specification and is intended to provide requirements for continuous electricity systems to sustain operations of at least one ultra-low temperature (ULT) freezer or an integrated ULT freezing system that may include any or all of the following electricity consuming load devices including ULT freezers for vaccines, ULT freezers for ULT coolants, standard water-pack freezers, vaccine refrigerators, voltage stabilizers, equipment monitoring systems (EMS), lighting, communications, office devices, ventilation and space cooling.

The **WHO PQS E003/POW01.0** equipment specification describes the requirements for a generic [prime power generator](#) system (single or three-phase [alternating current \(AC\)](#) electricity) and an [uninterruptible power supply \(UPS\)](#). It also describes the [installation](#) and maintenance advisory services that all [legal manufacturers](#) must offer in order to become a prequalified supplier of electric power systems for [ULT freezers](#) or an integrated [ULT freezing system](#).

Historically, [ULT freezers](#) and [ULT freezing systems](#) operate with electric vapor compression refrigeration, which is powered with single or three-phase [alternating current \(AC\)](#) electricity supplied by a [reliable electricity](#) supply and distribution system (e.g. “grid”, “mains”). This specification will include requirements for sites with [reliable electricity](#), [unreliable electricity](#), [limited electricity](#) or [no electricity](#).

Given the critical nature of Ebola vaccine and possible future vaccines requiring [ULT freezers](#) an electric power supply system must be [continuous](#) and therefore all power systems will be required to be backed-up by a second power supply capable of providing 100% of the [ULT freezing system](#) electrical requirements continuously. In addition, both [ULT vaccine freezers](#) will require a battery based [uninterruptible power supply \(UPS\)](#).

**WHO PQS E003/POW01.0** provides the specifications for [continuous electricity](#) systems capable of sustaining [ULT freezers](#) and [ULT freezing systems](#). This specification includes [generators](#) and [UPS systems](#).

Suppliers of electric systems per **WHO PQS E003/POW01.0** can prequalify through the requirements of **WHO PQS E003/POW-VP1** type examination protocol.

**WHO PQS E003/POW01.0** and a completed **WHO PQS E003/POW-VP2** quality assurance protocol, 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 and [installation](#) of the components required for a specific power system for [ULT freezers](#) and/or [ULT freezing systems](#). This also forms the basis for a contractual agreement between the [employer](#) and the approved [installer](#).

The following documents are associated with this equipment specification:

For [continuous electricity](#) systems see also:

- **WHO PQS E003/POW01.0-VP 0.1 Power systems for ultra-low temperature freezing systems** – type examination for prequalifying suppliers of power systems.
- **WHO PQS E003/POW01.0-VP 0.2 Power systems for ultra-low temperature freezing systems-** quality assurance protocol for specific [installation](#) requirements.

For [ultra-low temperature \(ULT\) freezer](#) appliances see:

- **WHO PQS E003/ULT01.0 Vaccine ultra-low temperature freezer: compression-cycle** - an equipment performance specification.
- **WHO PQS E003/ULT01.0 VP.1 Vaccine ultra-low temperature freezer: compression-cycle** - verification protocol for prequalification evaluations.

For [water-pack freezer](#) appliances see:

- **WHO PQS E003/FZ01 Vaccine freezer of combined vaccine and water-pack freezers** - an equipment performance specification.

For [hybrid solar power systems](#) see:

- **WHO PQS E001/PVAC01.0 Solar power system for cold and freezer rooms** - an equipment performance specification.
- **WHO PQS E001/PVAC-VP1** - a type-examination protocol.
- **WHO PQS E001/PVAC-VP2** – a quality assurance protocol.

## 2. Terms and definitions

[Alternating current \(AC\)](#): an electric current that reverses its direction at regularly recurring intervals whose value varies as a sine wave.

[Automatic transfer switch \(ATS\)](#): Self-acting equipment for transferring one or more load conductor connections from one electric power source to another.

[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).

[Back-up power](#): a secondary, auxiliary power source (e.g. generator, UPS) capable of independently powering 100% of all ULT freezer system electrical needs.

[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.

[Continuous electricity](#): the sustained supply of electricity adequate for a ULT freezing system.

[Design day](#): the maximum amount of energy expected to be consumed in a day by the ULT freezing system and associated loads like lighting and air conditioning. For purposes of sizing the continuous electricity system, the design day must be calculated using the largest of these three options: 1) the energy required by the entire system based on the peak ambient temperature the ULT freezers are exposed to; 2) the energy required by the entire system based on the highest average daily load requirement for a given month (e.g. months with a high air conditioning load); or 3) both simultaneously (e.g. months with a high air conditioning load and the peak ambient temperature around the ULT freezers).

[Direct current \(DC\)](#): an electric current flowing in one direction.

**Employer:** 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 and commission the installation under the supervision of a QA assessor and also with a maintenance contractor who will maintain the installation.

**Equipment monitoring systems (EMS):** remote temperature and event monitoring system.

**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.

**Hybrid solar power system:** solar power system with one or more auxiliary sources of power (e.g. generator).

**Independent evaluator:** person or organizations who has been appointed by WHO to conduct a type examination per this verification protocol.

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

**Installation:** the complete electrical generator power system installation described in this specification together with any other employer's requirements documentation issued for a specific installation or installations including equipment monitoring systems (EMS), uninterruptible power supply (UPS) systems, hybrid solar power systems and voltage stabilizers where these are listed in the employer's requirements.

**Installer:** a person or organization who has been appointed by the employer to carry out the installation of the generator 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 prime generator 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.

**Inverter/charger:** is 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.

**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.

**Limited electricity:** an existing electric power system with inadequate capacity to sustain the continuous supply of alternating current electricity adequate for a ULT freezing system.

**Load:** any end-use device in an electrical circuit that can consume power when the electrical circuit is energized.

**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.

[Montreal Protocol](#): Montreal Protocol on Substances that Deplete the Ozone Layer.

[No electricity](#): the existing site condition when there is no alternating current electric supply system.

[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.

[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.

[QA](#): quality assurance.

[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.

[Reliable electricity](#): The existing site condition where a sustained supply of alternating current electricity adequate for a ULT freezing system is continuous where power outages are rare with a maximum of 1 outage per month of less than one hour duration.

[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.

[Site assessor](#): a professional engineer with experience in the design of electrical generators and uninterruptible power systems.

[Site assessment](#): process of establishing the electrical power system needs of a specific health facility where an ULT freezing system is proposed.

[User](#): the person responsible for the day to day operation and temperature monitoring of the ULT freezer and/or continuous power system.

[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.

[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 a 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.

### 3. Normative references

Use most recent version.

BS EN 60529:1992+A2:2013: Degrees of Protection by Enclosures (IP Code)

EMAS: European Union Eco-Management and Audit Scheme.

EPA emissions, stationary emergency, Part 60 Subpart IIII: New Source Performance Standards (NSPS) for Stationary Compression Ignition Internal Combustion Engines. Directive 2006/42/EC: Machinery.

Directive 2014/35/EU Harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits

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

IEC 60335-2-24: Household and similar electrical appliances – Safety – Part 2-24: Particular requirements for refrigerating appliances, ice-cream appliances and ice makers.

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

IEC 60529:1989+AMD1:1999+AMD2:2013 CSV Consolidated version Degrees of protection provided by enclosures (IP Code)

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 62257-7-3: Recommendations for renewable energy and hybrid systems for rural electrification – Part 7-3: Generator set – Selection of generator sets for rural electrification systems.

IEC 62040-1:2017/COR1:2019 Corrigendum 1 - Uninterruptible power systems (UPS) - Part 1: Safety requirements

IEC 62477-1: Safety requirements for power electronic converter systems and equipment - Part 1: General.

IEC 62909-1: Bi-directional grid connected power converters - Part 1: General requirements.

IEEE Standard 446: Recommended Practice for Emergency and Standby Power Systems for Industrial and Commercial Applications.

IEEE Standard 485: Recommended Practice for Sizing Lead-Acid Batteries for Stationary Applications.

IEEE Standard 1184: Guide for Batteries for Uninterruptible Power Supply Systems.

INCO terms 2020.

ISO 3026-1: Reciprocating internal combustion engines — Performance.

ISO 8528: Reciprocating internal combustion engine driven alternating current generating sets.

ISO 9001: Quality Management Systems – Requirements.

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

WHO PQS E001/PVAC 01: Solar power system for cold and freezer rooms.

WHO PQS E001/PVAC 01-VP.1: PQS Independent type examination (TBD).

WHO PQS E001/PVAC 01-VP.2: PQS Quality Assurance Protocol (TBD).

WHO PQS E003/FZ01: Vaccine freezer or combined vaccine and water-pack freezers.

WHO PQS E003/ULT01.0: Vaccine ultra-low temperature freezer: compression-cycle.  
WHO PQS E003/ULT01 VP.1: Vaccine ultra-low temperature freezer: compression-cycle.

## 4. Design criteria

### 4.1 General

#### 4.1.1 *Initial prequalification*

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 enable a competent [maintenance contractor](#) to maintain the system. [Legal manufacturers](#) may offer products suitable for one or more [ULT freezer](#) and/or [ULT freezing system](#), multiple temperature zones and may restrict their offer to one or more named [regions](#). [Legal manufacturer](#) must supply a complete global list of all [resellers](#) approved by the [legal manufacturer](#).

#### 4.1.2 *Extended region prequalification*

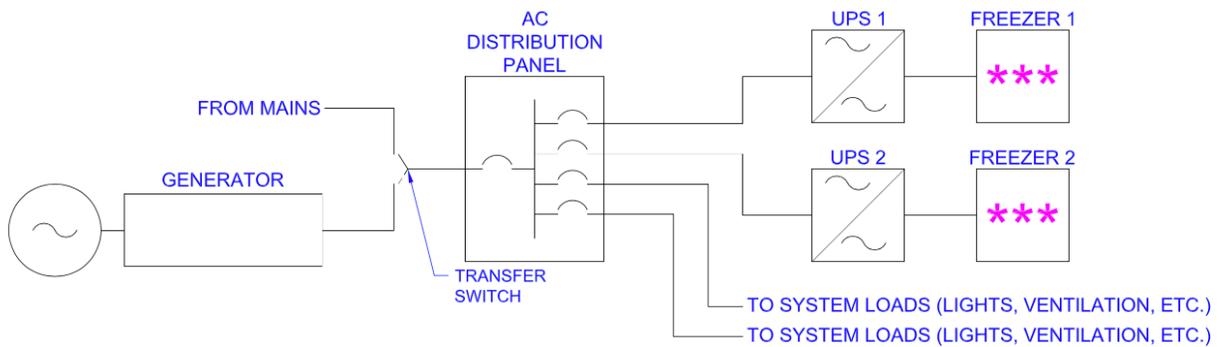
A prequalified [legal manufacturer](#) who wishes to extend the [region\(s\)](#) for which they are already prequalified may do so at the time of the annual review by providing WHO with supplementary evidence in writing that they are able to offer the complete service described in this specification to the additional [region\(s\)](#).

#### 4.1.3 *System characteristics*

The [continuous electricity generator](#) system will be dimensioned per the requirements documented within the required [site assessment](#) that will include a determination of [AC](#) power supply availability as either [reliable electricity](#), [unreliable electricity](#), [limited electricity](#) or [no electricity](#) including an assessment of UPS battery [reserve capacity](#). The [site assessment](#) will consider local conditions including climate, elevation, facility condition, on-site technical capabilities, repair response time and logistical challenges.

#### 4.1.4 *Reliable electricity*

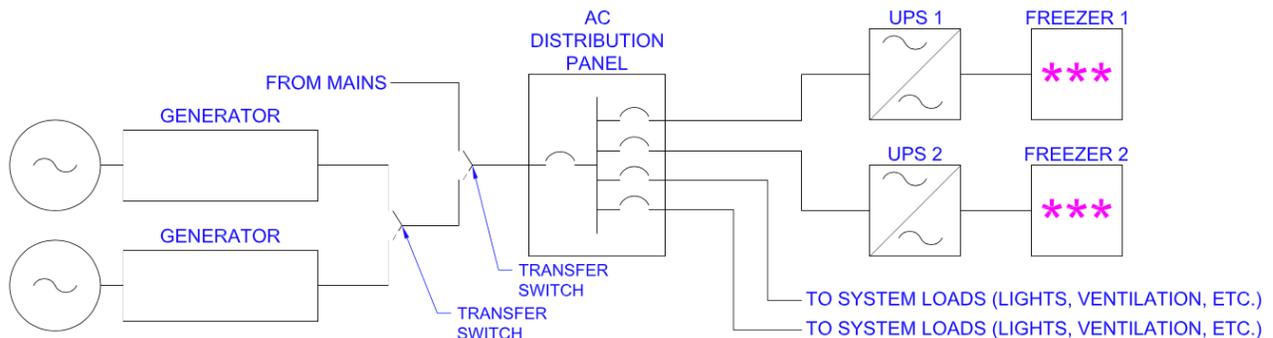
Sites with [reliable electricity](#) must include a [back-up generator](#) capable of providing [continuous electricity](#). The supplied [back-up generator](#) must be specified per requirements of this document and presented per the standard template found in **WHO PQS E003 POW VP0.2**. Each [ULT freezer](#) dedicated to vaccine storage must have a dedicated [UPS](#). The [back-up generator](#) must include an [automatic transfer switch \(ATS\)](#) which will automatically start the [generator](#) when [mains electricity](#) is outside of normal operating parameters. The [ATS](#) must return the continuous power system to the [mains](#) and stop the [generator](#) when parameters return to normal.



**Fig. 1: Reliable Electricity –**  
Example of Mains Electricity and Backup Generator System

#### 4.1.5 Unreliable electricity

Sites with **unreliable electricity** must require an electric power system capable of providing **continuous electricity**. The supplied **prime power generator** must be specified per requirements of this document and presented per the standard template found in **WHO PQS E003 POW VP0.2**. Each **ULT freezer** dedicated to vaccine storage must have a dedicated **UPS**. The **prime power generator** must include an **automatic transfer switch (ATS)** that will automatically start the **generator** when **mains electricity** is outside of normal operating parameters. The **ATS** must return the continuous power system to the mains and stop the **generator** when parameters return to normal. Further, a **back-up generator** must be provided in the event of a failure of the **prime power generator**. The **back-up generator** must automatically start and connect to the **continuous electricity** system in the event of a failure of the **mains** and **prime power generator**.



**Fig. 2: Unreliable Electricity –**  
Example of Prime and Backup Generator System

#### 4.1.6 Limited electricity

Sites with **limited electricity** must require an electric power system capable of providing **continuous electricity**. The supplied **generator(s)** must be specified per requirements of this document and presented per the standard template found in **WHO PQS E003 POW VP0.2**. Each **ULT freezer** dedicated to vaccine storage must have a dedicated **UPS**.

Sites with existing power systems where **mains** power distribution or electric generation components are undersized and cannot sustain the continuous operation of a **ULT freezing system** may consider increasing the size/capacity of necessary components in order to become a site with either **reliable electricity** or **unreliable electricity**. In such cases the site must then comply with either **reliable electricity** or **unreliable electricity** requirements as determined by **site assessment**.

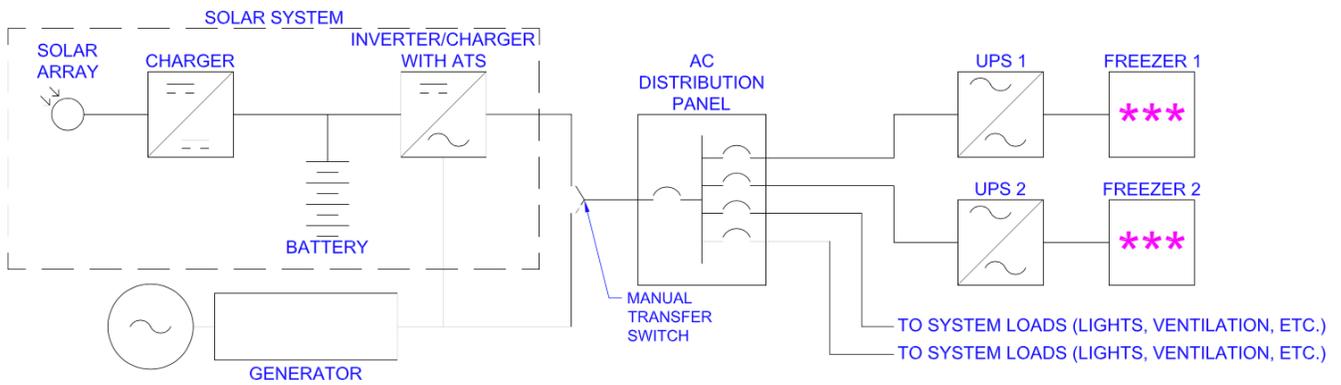
Sites with an existing solar electric power system that is undersized and cannot sustain the continuous operation of a **ULT freezing system** may consider increasing the size/capacity of necessary components in order to become a **hybrid solar power system** per **WHO PQS E001 PVAC**. Alternately a **prime power generator** with **back-up generator** may be considered where the **back-up generator** must be provided in the event of a failure of the **prime power generator**. The **back-up generator** must automatically start and connect to the continuous electricity system in the event of a failure of the **prime power generator**. In such cases the site must then comply with the **no electricity** requirements as determined by site assessment.

#### 4.1.7 No electricity

Sites with **no electricity** must require an electric power system capable of providing **continuous electricity**. For sites with **no electricity** there are two options:

1. **prime power generator** with **back-up generator**, where the supplied **prime power generator** must be specified per requirements of this document and presented per the standard template found in **WHO PQS E003 POW VP0.2**. A **back-up generator** must be provided in the event of a failure of the **prime power generator**. The **back-up generator** must automatically start and connect to the **continuous electricity** system in the event of a failure of the **prime power generator**; or
2. **hybrid solar power system** coupled to a **back-up generator** per **WHO PQS E001 PVAC** and per requirements of this document, and presented per the standard template found in **WHO PQS E003 POW VP0.2**.

Each **ULT freezer** dedicated to vaccine storage must have a dedicated **UPS**.



**Fig 3: No Electricity –**  
Example of Solar Power System with Backup Generator

#### 4.1.8 Site assessment responsibility

The **employer** will provide a pre-installation **site assessment** conducted by a qualified professional engineer. The specifics of the **site assessment** may vary from site to site. Key requirements of a **site assessment** are specified in this document and **WHO PQS E003/POW 01.0 VP 0.2 Power systems for ultra-low temperature freezing systems Annex 1**, Site assessment checklist and related examples.

#### 4.1.9 Design responsibility

The **employer** will specify the location, site conditions, **ULT freezer** capacity, **ULT** coolant pack freezer and characteristics of the **ULT freezing system** that is to be connected to the **generator(s)**.

The **employer** must specify location and site conditions including:

- site name and address,
- latitude and longitude,
- elevation,
- monthly ambient temperature range, and
- results of required pre-installation site assessment.

The **employer** must specify the freezer appliance **load(s)** and must define all **ULT freezing system loads**:

- characteristics - description, quantity,
- electrical - single or three phase, nominal voltage, operating voltage range, running amperes, peak amperes, frequency and
- time of operation (**design day**) - device on-time hours (consumption), starting times (peak demand), month or date(s) of **design day**.

The **legal manufacturer** or **reseller** must then size the **installation** to ensure that the specified **ULT freezing system** will receive **continuous electricity** within specified site conditions. **Equipment monitoring systems** must be compatible with **continuous electricity** system control and the **ULT freezer** or the **ULT freezing system** control(s).

The **continuous electricity** system designer must provide the **employer** with the data used to determine the **installation** design, including assumptions made regarding site conditions. The data must include the **design day** and assumed peak power requirements. Reference period climate conditions are to be in closest accordance with available meteorological data.

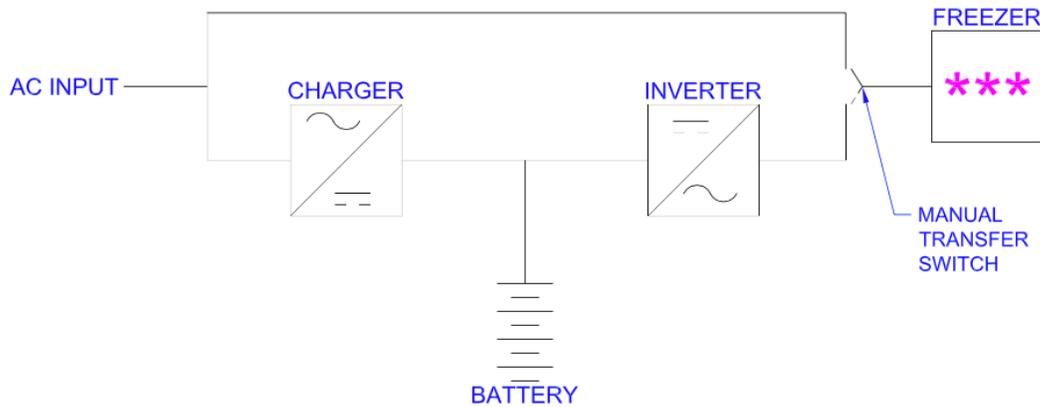
## 4.2 Performance

### 4.2.1 *Uninterruptible power supply (UPS)*

The **site assessor** must determine the required battery **reserve capacity**. A minimum of 8 hours is required; however, greater battery **reserve capacity** may be required for sites that do not have immediate access to a technician or due to other site-specific factors that may increase **load(s)** such as elevated ambient temperature at **ULT freezer** placement location.

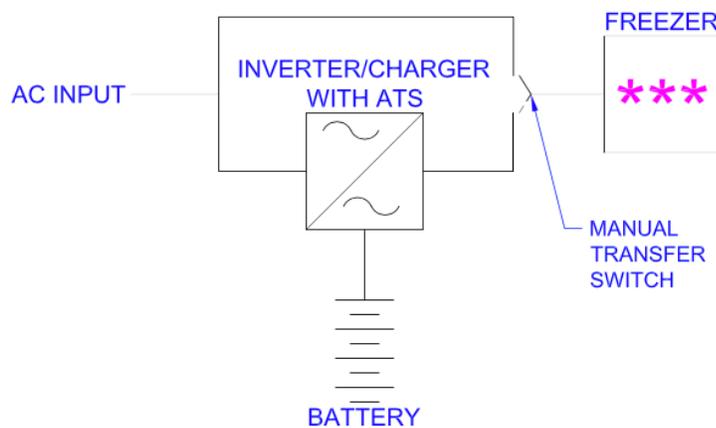
Each **ULT freezer** dedicated to vaccine storage and prequalified per **WHO PQS E003/ULT01.0 Vaccine ultra-low temperature freezer: compression-cycle** will be coupled to a dedicated **UPS** sized to provide the required battery **reserve capacity** based on power requirements and **load** when operated at installation site temperature conditions. Supplier prequalification will require a fully completed UPS sizing example per **WHO PQS E003/POW 01.0 VP 0.1 Power systems for ultra-low temperature freezing systems** type examination Clause 5.2.2.

Two different **UPS** designs are acceptable. The first uses a separate **charger** and **inverter** and the second uses an **inverter/charger**. In the first design, all electricity to the **load** must flow through the **charger** and the **inverter**. This is referred to as a double-conversion system as the electricity is converted from **AC** to **DC** and then from **DC** back to **AC**. This is less efficient; however, this does buffer the **load** from any voltage or frequency fluctuations. Refer to Clause 5.5.3.1 of **IEEE 446-1995**.



**Fig. 4: Uninterruptible Power Supply – Double Conversion System**

The second design uses an *inverter/charger*, this is referred to as a single-conversion system. The *inverter/charger* contains an *automatic transfer switch (ATS)* that allows the *load* to be directly connected to the input source of electricity. This is more efficient; however, does subject the *load* to possible fluctuations as well as a temporary loss of electricity as the unit switches from the input source to *inverter* (powered by the batteries). Refer to Clause 5.5.3.2 of **IEEE 446-1995**.



**Fig. 5: Uninterruptible Power Supply – Single Conversion System**

#### 4.2.1.1 UPS sizing

The battery must be sized as per **IEEE 1184-2006** Clause 7.

The [inverter](#) must be sized to support the full dedicated vaccine [ULT freezer](#) appliance [load](#) including any startup surges.

The [charger](#) must be sized to recharge the battery within 24 hours while still supporting the full [ULT freezer](#) appliance [load](#), including any losses (e.g. wire or line losses).

#### 4.2.1.2 UPS battery

##### A. Battery type

Both sealed and flooded lead acid batteries are acceptable, although sealed batteries are preferred for [installations](#) in remote areas where maintenance will be difficult.

The maintenance cycle for flooded batteries must be six 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.

Lithium, Ni Cad and NiMH batteries are not permitted.

##### B. Battery set sizing

The battery must be sized as per **IEEE 1184-2006** Clause 7.

Batteries must be sized to meet the [reserve time](#) determined as described in **IEEE 1184-2006** Clause 4.2.1, based on the energy required for the freezer [load](#) which the [UPS](#) system components are connected. Required battery capacity is estimated over the discharge rate and temperature most closely matching the [reserve time](#) and the temperature at the site (e.g. at C/8 hours at +25°C for an 8-hour [reserve time](#) 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 [reserve time](#) is maintained throughout the minimum required battery set life of 1800 cycles to 80% discharge.

The battery voltage must be as required to support the [inverter](#).

The number of parallel battery strings should be limited to four.

##### C. Battery set housing

The battery set must be housed within a lockable room or a ventilated cabinet with an IP rating of 11 (interior) or IP33 (exterior) and 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 near the battery and the fuse-holder must be of non-corroding material.

#### **D. Battery safety kit**

Provide comprehensive safety instructions, hazardous materials data sheets and a lead acid battery safety equipment kit.

The safety equipment for valve regulated lead acid (VRLA, sealed) batteries must include the following:

- eye, hand and clothing protection
- sodium bicarbonate for cleaning corrosion.

The safety equipment for flooded lead acid batteries must 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 must be provided if the electrolyte is supplied in containers of more than five liters.

#### **4.2.1.3 UPS Charger**

The [charger](#) must comply with **IEC 60335-1: Household and similar electrical appliances – Safety – Part 1: General requirements** or comply with **IEC 62040-1:2017/COR1:2019 Corrigendum 1 - Uninterruptible power systems (UPS) - Part 1: Safety requirements**

The [charger](#) must be sized to recharge the battery within 24 hours while still supporting the freezer appliance [load\(s\)](#), including any losses.

The [charger](#) must use a charge algorithm and settings as recommended by the battery manufacturer.

The [charger](#) must provide protection from transient electrical events. The [charger](#) 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.

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

#### 4.2.1.4 UPS Inverter

The [inverter](#) must comply with one of the following normative references:

- **Safety; IEC 60335-1: Household and similar electrical appliances – Safety – Part 1: General requirements OR IEC 62040-1:2017/COR1:2019**
- **Corrigendum 1 - Uninterruptible power systems (UPS) - Part 1: Safety requirements or**
- **IEC 62477-1: Safety requirements for power electronic converter systems and equipment – General; or**
- **IEC 62909-1: Bi-directional grid connected power converters - Part 1: General requirements; or**
- **IEC 62109-1: Safety of power converters for use in photovoltaic power systems – General requirements and**
- **IEC 62109-2: Safety of power converters for use in photovoltaic power systems – Part 2: Particular requirements for inverters.**

The [inverter](#) must be sized to support the full [load](#) including any startup surges and losses (e.g. wire or line losses).

[Inverter](#)(s) must be pure sine wave quality and match battery voltage, [ULT](#) freezer voltage, frequency and phase requirements.

Due to the high human value of the vaccine, if a low voltage driven [load](#) disconnect feature is included it should be disabled, and the [inverter](#) should operate to the lowest battery voltage possible.

LEDs or an acoustic alarm may be included to indicate a low battery warning.

#### 4.2.1.5 UPS Transfer switch

An [automatic transfer switch \(ATS\)](#) must be included with the [inverter/charger](#) and must have a maximum transfer time of 10ms for both [mains](#) to [inverter](#) and [inverter](#) to [mains](#).

A manual transfer switch must be provided for maintenance and in the event of an [inverter](#) failure.

Both transfer switches must be sized for the full [load](#) including any startup surges.

#### 4.2.1.6 Disconnects

Disconnects and over-current protection must be provided as required between the battery and [inverter/charger](#) or if separate components between the battery and [charger](#) and the battery and [inverter](#).

#### 4.2.1.7 Monitoring and alarms

Meter(s) must be provided to display the following information:

- battery voltage
- battery charge current
- battery discharge current
- battery temperature
- inverter output voltage
- inverter output frequency
- inverter output power

The alarms may be integrated into a single ULT freezer equipment monitoring system (EMS) device. A technician or supervisor must be notified via text or email for the following events:

- low battery
- charger failure
- inverter failure

ULT freezer appliance alarms may also be included per **WHO PQS E003/ULT01.0 Vaccine ultra-low temperature freezer: compression-cycle specifications**.

Internet access will be provided by the user.

#### 4.2.2 Generator

All power systems will require a complete generator set that must include engine, alternator, control panel, starting equipment, fuel tank and all other accessories, spares and consumables (excluding fuel) for autonomous operation.

##### 4.2.2.1 Construction and specification standards

The generator set must be produced and performance specified according to this specification including all applicable Normative References.

The legal manufacturer must provide internationally-recognized certifications/factory test for any ordered units and all generators must be in accordance with international standards specified as a Normative Reference.

##### 4.2.2.2 Generator type

Diesel, propane, natural gas or gasoline fired generators are acceptable. Water-cooled or air-cooled generators are acceptable.

#### 4.2.2.3 Startup time

The [generator](#) must startup and be connected to the load within two to five minutes of a [mains](#) failure.

The generator must have a minimum runtime of 15 minutes, and a minimum off time of 15-30 minutes to prevent excessive cycling of the generator.

#### 4.2.2.4 Transfer switches

An [automatic transfer switch \(ATS\)](#) must be included. The [ATS](#) must automatically detect when the mains are outside or normal operating parameters and must automatically start the [generator](#) and transfer the [AC loads](#) from the [mains](#) to the [generator](#). This must be a “break-before-make” connection. The entire process must take less than the time specified in Clause 4.2.2.3. Upon [mains](#) return to normal parameters, the [ATS](#) must transfer the [AC loads](#) from the [generator](#) back to the [mains](#) (again using a “break-before-make” connection) and shut down the [generator](#) after any necessary “cool-down” period.

A [manual transfer switch \(MTS\)](#) must be provided to allow the user to directly connect the [AC loads](#) to the [generator](#).

Both transfer switches must be sized for the full [load](#) including any startup surges.

#### 4.2.2.5 Generator sizing

[Generator\(s\)](#) will be sized to provide sustained power for 100% of [loads](#) identified during the [site assessment](#). Further the sizing must include any system losses and have the ability to recharge the [UPS](#) batteries as per Clause 4.2.1.1.

[Generator](#) selection and sizing must be as per **IEC TS 62257-7-3** Clause 5.2, with particular attention to the derating factors in Clause 5.2.4. Supplier prequalification will require a fully completed generator sizing example per **WHO PQS E003/POW 01.0 VP 0.1 Power systems for ultra-low temperature freezing systems** type examination Clause 5.2.1.

#### 4.2.2.6 Paralleled generators

If paralleled [generators](#) are required, they must be paralleled as per **IEC TS 62257-7-3** and **IEEE 446-1995** Clause 4.2.6.

#### 4.2.2.7 Generator requirements

A [generator](#) in compliance with **E003/POW 01.10** is required to provide 100% of the [ULT freezing system](#) electrical [loads](#). The [generator](#) must have an automatic and manual start, as well as an emergency stop button. The automatic start must work in conjunction with the [ATS](#).

The engine must have the following characteristics:

- synchronous speed (for diesel fired up to 1500 rpm for 50Hz systems or 1800 rpm for 60Hz systems, all other fuels up to 3000 rpm for 50Hz or 3600 rpm for 60Hz)
- speed governor
- heavy duty air cartridge filter
- cartridge oil filter
- external fuel filter
- residential silencer
- exhaust with suitable flexible piping
- emissions per **EPA emissions, stationary emergency, Part 60 Subpart III:** New Source Performance Standards (NSPS) for Stationary Compression Ignition Internal Combustion Engines.
- noise must comply with **IEC 62257-7-3** Clause 5.2.7 (less than 100 dBA untreated with noise mitigation and no more than 70 dBA measured at 7 meters from generator).

The alternator must be:

- synchronous, air cooled, brushless
- protection Class IP 23
- automatic fast voltage regulator, maintaining the output within 2 % under normal conditions
- screen protected
- mounting of the engine and the alternator must be connected with a heavy-duty elastic coupling and should be mounted on a common rigid base frame with anti-vibration dampers and lifting eyes flexible for transportation. Engine, alternator, and panel should be one integrated unit mounted on skid.

#### **4.2.2.8 Earthing**

The generator must follow the earthing requirements of **IEC TS 62257-7-3** Clause 6.2.5.

#### **4.2.2.9 Starting system**

The [generator](#) starting system must be as per **IEC TS 62257-7-3** Clause 5.2.5 and include batteries, leads and automatic battery charging equipment.

#### **4.2.2.10 Stored fuel capacity and fuel tank**

The [site assessor](#) must determine the required onsite storage capacity of fuel. A minimum of 3 days is required for all configurations. Several months may be required for sites with seasonal or access limitations.

The onsite fuel requirements are calculated based on the [generator](#) continuous full load consumption rate for the required number of days determined through the required [site assessment](#).

The fuel tank must include all necessary piping for operation and filling and conveniently positioned fuel level indicator.

#### **4.2.2.11 Monitoring and alarms**

Meter(s) must be provided to display the following information:

- volts (with selector switch to show phases to zero and phase to phase voltages)
- amperes (three meters: one per phase or one meter with selector switch for successive reading of phase amps)
- frequency
- running hours counter.

The [generator](#) must be equipped with automatic shutdown equipment, as well as acoustic and visual alarms for when fatal parameters are exceeded including low oil pressure, high engine temperature and over-speed. Further a technician or supervisor must be notified via text or email of the failure. If a [back-up generator](#) is available, it must be automatically started and connected to the [loads](#).

[ULT freezer](#) appliance alarms may also be included per specification in **WHO PQS E003/ULT01.0 Vaccine ultra-low temperature freezer: compression-cycle**.

Internet access will be provided by the [user](#).

#### **4.2.2.12 Accessories**

Spare parts catalogs, drawings and information concerning the foundation, erection requirements, electrical connections to load and earth, and tool kit including pipe spanners for injectors and other specific tools required for either installation or maintenance.

#### **4.2.2.13 Generator installation**

The [generator](#) may be installed indoors, outdoors protected from the weather, or open air. For [generators](#) installed in open air a protective enclosure or canopy must be provided. The [generator](#) must be installed as per **IEC TS 62257-7-3** Clause 5.3.

#### **4.2.2.14 Operations manual**

The [generator](#) set must be delivered with a full and detailed operating and service manual in English including full workshop documentation for both motor and alternator. The manual should also be available in the official country language.

#### 4.2.2.15 Spare parts

Spare parts must be provided as per Clause 4.9.2.

#### 4.2.3 *Electrical safety*

All on-site electrical [installation](#) work must comply with **IEC 60364-1**.

#### 4.2.4 *Electrical protection*

The system design must prevent damage to all components in the event of short circuits, electrical storms and reversed polarity connections. The generator must be equipped with automatic shutdown equipment if fatal parameters are exceeded including low oil pressure, high engine temperature and over-speed.

#### 4.2.5 *Lightning surge protection and grounding*

Lightning surge protection must be provided per component manufacturers requirements. [Inverters](#), [chargers](#), electrical controls, [generators](#), electrical distribution systems and any other system component requiring lightning surge protection must also be protected per [legal manufacturer\(s\)](#) requirements and local and national electrical codes.

#### 4.2.6 *User maintenance and installer tool kits*

All [continuous electricity](#) systems are to be supplied with one complete [user](#) maintenance kit(s) for [generator\(s\)](#), [UPS](#), [inverters](#) and batteries consisting of all necessary operations and maintenance tools as proposed by [legal manufacturer](#). All [continuous electricity](#) system sites are to be supplied with one complete [installer's](#) kit consisting of all unique [installations](#) tools as proposed by [legal manufacturer](#).

#### 4.2.7 *Electromagnetic compatibility*

The [legal manufacturer](#) must certify component compliance with the requirements of the latest edition of **IEC 61000-6-1** and **IEC 61000-6-3**.

#### 4.2.8 *Fire safety equipment*

For [UPS](#) fire safety equipment is recommended per **IEEE 1184-2006** clause 9.2.1. [Generator](#) fire safety equipment must be provided per **IEC TS 62257-7-3** Clause 6.5.

### 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*

Equipment 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*

[Site assessment](#) to determine if there any dimensional limitations for [generator](#) and [ULT freezers](#).

#### 4.4.2 *Weight*

System components must be capable of being safely moved into their final positions. 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. Mechanical lifting equipment at the [installation](#) sites is necessary when component weight exceed practical weight limits of the workforce.

### 4.5 Interface requirements

#### 4.5.1 *Ultra-low temperature freezing systems*

In order to complete the [installation](#) and comply with this specification the [legal manufacturer](#) must supply all the [continuous electricity](#) system components needed to connect and commission the specified [ULT freezer](#) or [ULT freezing system](#).

### 4.6 Human factor

#### 4.6.1 *Generally*

The completed [installation](#) must be usable by the widest practicable range of [users](#) and 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 *Safety and safe access*

General safe practices and safety consideration should comply **Directive 2006/42/EC: Machinery** unless more stringent instructions are provided by [legal manufacturer](#) or per equipment instructions. Power system components must be

mounted in positions that allow safe access for [installation](#), maintenance and cleaning, using appropriate fixed access equipment as necessary.

## 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 on-site replacement warranty in the event of any component failure arising from defective design, materials or workmanship.

An optional service warranty or system performance warranty must be offered by the [legal manufacturer](#), [reseller](#) or [installer](#).

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:

- three years (or 2000 hours of operation) for the generator,
- five years for the UPS,
- 10 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 Servicing provision

### 4.9.1 *Maintainability*

[Installations](#) are to be substantially maintenance-free. [Legal manufacturers](#) must publish and provide a recommended plan for maintenance including task intervals and parts replacement intervals.

#### 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 user tools/supplies, **user** and technician maintenance manuals (see Clause 4.11 *Instructions*), must be determined and agreed upon in advance of order placement.

**Legal manufacturer** must publish a list of spare parts recommended for five years of operation. **Legal manufacturer** must also 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 (except fuel) sufficient for two years of normal operation at the specified location(s).

**Generators** must include spares for 2000 hours of operation in the first two years as recommended by the engine manufacturer as a minimum and including: oil filter, air filter cartridges, full sets of v-belts and 1 full set of cylinder head gaskets), full set of replacement switches/ sensors for detection of fatal parameters (low oil pressure, high engine temperature, belt failure etc.)

#### 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 Directive 2002/96/EC** is mandatory.

#### 4.11 Instructions

Each **continuous electricity** 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 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
- basic troubleshooting
- 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
- [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.

[Installation](#), repair and servicing instructions must be supplied in printed format, and optionally on DVD, USB and/or on-line to instruct the [installer](#) in [installation](#) standards and practices specific to the [continuous electricity](#) system. In addition, supporting video material supplied on DVD, USB and/or on-line can be provided to assist the instructor when delivering on-site [user](#) training.

#### 4.12 Training

If specifically required, 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 [ULT](#) freezing system [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 **WHO PQS E003/POW-VP2** [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 others 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](#) must 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),
- a list of at least five [continuous electricity generators](#) 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, [employer](#) 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,
- a complete global list of all [resellers](#) approved by the [legal manufacturer](#),
- 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 etc.,
- 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, and
- indicative cost of a comparable [continuous electricity generator](#) power system for a given ULT freezing system, EXW (Incoterms 2010).

## 8. On-site maintenance

Not required but may be offered.

## 9. Change notification

The [legal manufacturer](#) or [reseller](#) must 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.

<b>Revision history</b>			
Date	Change summary	Reason for change	Approved