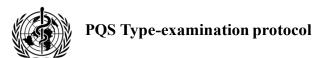
Distribution: General



TITLE: Power systems for ultra-low temperature freezing systems

Product verification protocol: E003/POW VP- 01.0
Product specification: E001/PVAC 01
Issue date: 22 December 2020

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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 Power systems for ultra-low temperature freezing systems is an equipment 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 pregualification 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.
- WHO PQS E001/PVAC 01, to which it refers.

#### 2. Terms and definitions

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

<u>Automatic transfer switch (ATS):</u> self-acting equipment for transferring one or more load conductor connections from one electric power source to another.

<u>Back-up generator:</u> a secondary prime power generator capable of independently powering 100% of all ULT freezer system electrical needs and battery recharging (if applicable). <u>Back-up power:</u> a secondary, auxiliary power source (e.g. generator, UPS) capable of independently powering 100% of all ULT freezer system electrical needs.

<u>Battery charger:</u> 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.

<u>Continuous electricity:</u> 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.

<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 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.

<u>Hybrid solar power system</u>: solar power system with one or more auxiliary sources of power (e.g. generator).

<u>Independent evaluator</u>: 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.

<u>Installation</u>: 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), uninterruptable power supply (UPS) systems, hybrid solar power systems, and voltage stabilizers where these are listed in the employer's requirements.

<u>Installer:</u> 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.

<u>Inverter/charger</u>: 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.

<u>Legal manufacturer</u>: 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. <u>Limited electricity</u>: an existing electric power system with inadequate capacity to sustain the continuous supply of alternating current electricity adequate for a ULT freezing system. <u>Load</u>: 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.

<u>Maintenance contractor</u>: a person or organization contracted by the employer to maintain the installation.

<u>Manual transfer switch (MTS)</u>: 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.

<u>No electricity:</u> the existing site condition when there is no alternating current electric supply system.

<u>Prime power generator</u>: a generator that is able to run for an unlimited amount of time at variable loads up to the maximum rated power.

<u>QA assessor:</u> 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.

<u>Region:</u> a contiguous geographical area within which the legal manufacturer or reseller is able to provide the full range of services described in this specification.

<u>Reliable electricity:</u> 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.

<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.

Reserve time: the time that a fully charged battery can satisfy the load with no contribution from the charging source.

<u>Site assessor:</u> a professional engineer with experience in the design of electrical generators and uninterruptible power systems.

<u>Site assessment:</u> process of establishing the electrical power system needs of a specific health facility where an ULT freezing system is proposed.

<u>User:</u> the person responsible for the day to day operation and temperature monitoring of the ULT freezer and/or continuous power system.

<u>Ultra-low temperature (ULT) freezer:</u> a vaccine freezer that complies with equipment performance specification PQS E003/ULTF.

<u>Ultra-low temperature (ULT) freezing system:</u> 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.

<u>Uninterruptible power supply (UPS)</u>: a backup stored energy system that protects a load from power outages using a stored energy system.

<u>Unreliable electricity:</u> 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 62040-1:2017/COR1:2019 Corrigendum 1 - Uninterruptible power systems (UPS) - Part 1: Safety requirements

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 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. Applicability

Type-examination will be carried out by an independent evaluator, appointed by WHO. The extent of the geographical limits of any grant of prequalification status will be reviewed and

decided upon by WHO.

## 5. Sample-examination checklist

#### 5.1 Evidence of conformity assessment

Key components must carry the CE mark and/or equivalent internationally accepted evidence of conformity assessment.

## 5.2 Samples and supporting material

The legal manufacturer or reseller must supply the independent evaluator with a full duplicate set of the Product Dossier already supplied to WHO in accordance with the requirements of specification Clause 7, together with the following:

#### 5.2.1 Generator sizing

The independent evaluator will provide the legal manufacturer or reseller all site assessment details necessary for legal manufacturer or reseller to complete a fully worked example of a continuous electricity power system including generator sizing and major power system component sizing.

Example to include a calculation to estimate the design day requirements for all load(s) included and at a specified location. The example to include confirmation of the model(s) of PQS prequalified ULT freezer(s) and other load(s) included as part of a complete ULT freezer system installation.

The generator sizing example to clearly indicate:

- ULT freezer Identification and POS code number;
- ULT freezer electrical input specification;
- Site elevation;
- Site ambient temperature data;
- ULT freezer operating environment temperature range;
- ULT freezer electricity consumption at legal manufacturer-specified ambient temperature;
- UPS battery charger input power;
- Other loads (lighting, air conditioner, etc.);
- Generator prime power rating;
- Generator output voltage and frequency;
- Generator controller type;
- Generator fuel type;
- Generator fuel consumption;
- Stored fuel capacity;
- ATS time startup and connect generator; and
- Generator sizing calculations.

Attach specification sheets for ULT freezer and generator.

## 5.2.2 UPS sizing

The legal manufacturer or reseller to complete a fully worked example of a UPS sizing based on a WHO PQS prequalified ULT freezer per WHO PQS E003/ULT01.0 Vaccine ultra-low temperature freezer: compression-cycle. The energy consumption of the ULT freezer is to be based on the legal manufacturer specifications and at a minimum must include the Watt hours/day and the operating ambient temperature at which the Watt hours/day are based on.

The UPS sizing example to clearly indicate:

- ULT freezer identification and PQS code number;
- ULT freezer electrical input specification;
- Site ambient temperature data;
- ULT freezer operating environment temperature range;
- ULT freezer electricity consumption at legal manufacturer-specified ambient temperature;
- Type of UPS (single conversion or double conversion);
- Battery charger specifications (input voltage and frequency, output voltage, input current, output current);
- Inverter specifications (input voltage and frequency, output voltage and frequency, input current, continuous watt output at ULT freezer ambient temperature);
- OR inverter/charger (input AC voltage and frequency, output AC voltage and frequency, nominal DC voltage, input AC current, input DC current, output DC current, continuous watt output at ULT freezer ambient temperature, current rating of ATS, ATS transfer time for mains to inverter and inverter to mains);
- Battery specifications (quantity, series/parallel configuration, battery voltage and amp hours, battery bank voltage and amp hours discharge at specified capacity hours and temperature and final voltage per cell);
- Battery depth of discharge (not to exceed battery manufacturer recommendations);
- UPS electrical input and output specifications;
- UPS continuous output in watt at specified temperature; and
- Battery capacity calculation for a continuous eight-hour output including derating factors (e.g. operating temperature, aging).

Attach specification sheets for ULT freezer and UPS (including inverter/charger and battery).

## 5.2.3 Equipment and Accessories

For a typical continuous power system supplied, the legal manufacturer or reseller must confirm the type(s) and quantities of typical equipment, spare parts, supplies, consumables and accessories included and specify if employer is to supply additional accessories. Use Annex 1 Compliance checklist to document compliance to WHO PQS E003/POW: 0.1.

## 5.2.4 Photographs

Detailed high-resolution digital images of the UPS, generator(s), battery, inverter, hybrid solar power system (if included) and related system components in jpeg format.

#### 5.2.5 Instructions

Legal manufacturer or reseller to supply a sample of the instructions in the English language and as specified in WHO PQS E003/POW: 0.1 Clause 4.11.

## 5.3 <u>Test 1 - type-examination</u>

- **Step 1:** Complete the compliance checklist in **Annex 1**. Record general comments and recommendations for each section.
- **Step 2:** Complete the generator sizing in Clause 5.2.1, the UPS sizing in Clause 5.2.2 and supply information per Clauses 5.2.3, 5.2.4 and 5.2.5.
- Step 3: Obtain any additional supporting information required in writing from the legal manufacturer or reseller and attach this information to the report.

**Acceptance criteria:** Inspection of Compliance checklist indicates full conformity with all major specification requirements and acceptable generator and UPS sizing submissions.

## 5.4 Criteria for qualification

A final report must be issued after the type-examination is complete. The report must contain the following data and analyses:

- Summary: Conclusions and recommendations.
- Compliance checklist: Completed Annex 1 checklist.
- Generator and UPS sizing: Acceptable submissions per Clauses 5.2.1 and 5.2.2.
- Information provided is complete per Clauses 5.2.3, 5.2.4 and 5.2.5.
- **Photographs:** Submitted photographs as listed in Clause 5.2.4.
- Annexes: Additional supporting documentation requested and received from the legal manufacturer or reseller during the course of the type examination.

# Annex 1 – Compliance checklist

Specification	Item	
clause	TCIII	
A. General inf	formation:	
7.	Dossier fee received:	Yes No Part payment
7.	Type-examination fee	Yes No Part payment
'	received:	Tes Tie Ture payment
	System identification:	
7.	Code:	
	Model:	
4.2.4	ULT Freezer(s) offered (include PQS	
	code)	
	Legal manufacturer details:	
	Name: Address 1:	
	Address 2:	
	Address 3:	
	Address 4:	
7.	Tel: Fax: Email: Web:	
	Reseller details:	Applicable Not applicable
	Name: Address 1:	
	Address 2:	
	Address 3:	
7.	Address 4:	
	Tel: Fax: Email:	
	Web:	
	Status:	Legal manufacturer Reseller
4.1.1		
	Countries/regions where support services can be offered:	
4.1.2	services can be offered.	
C 1		
General inform	nation comments:	
D.T. 1	1 ( ) 1 ( ) 1 ( ) 1	
B. Technical d 4.1.9):	letails (assumes example site assessment	t complete per Clauses 4.1.8 and
4.1.3	Continuous power sizing per site	Not
7.1.3	assessment.	applicable
4.1.3	Determination of AC electricity	Not
4.1.3		
	supply.	applicable

<sup>1</sup> This is a Word 'Form' document. It needs to be copied and 'protected' before it can be used for data entry. Then activate View/Toolbars/Forms and click the 'lock' icon on the Forms toolbar. See also Word Help. Margins can be adjusted so form fits on a single page.

4.1.4, 4.1.5, 4.1.6 or 4.1.7 Note: if "no electricity" solution includes a hybrid solar power system also complete E001 PVAC VP0.1. Comments on VP0.1.	General system design (note supply availability type).  availability and continuous electricity sy	Not applicable	ot applicable t	0
			T	
4.2.1	Uninterruptible power supply (UPS).	Conforms to specification?	Yes	No
4.2.1	UPS type (note if single or double	Conforms to	Yes	No
	conversion).	specification?	Type:	
4.2.1.1	UPS sizing.	Conforms to specification?	Yes	No
calculation in	cluding maximum battery depth of discha	arge and battery i	recharge time.	
4.2.1.2	UPS battery.	Conforms to specification?	Yes	No
4.2.1.2.1	Battery type.	Conforms to specification?	Yes	No
4.2.1.2.2	Battery set sizing.	Conforms to specification?	Yes	No
4.2.1.2.3	Battery set housing.	Conforms to specification?	Yes	No
4.2.1.2.4	Battery safety kit.	Conforms to specification?	Yes	No
4.2.1.3	UPS charger.	Conforms to specification?	Yes	No
4.2.1.4	UPS inverter.	Conforms to specification?	Yes	No
4.2.1.5	Transfer switch (note type(s)).	Conforms to specification?	Yes Type(s)	No
4.2.1.6	Disconnects.	Conforms to specification?	Yes	No

4.2.1.7	Monitoring and alarms.	Conforms to specification?	Yes	No
Comments o	n UPS system:	1 -1	<u> </u>	
			T	
4.2.2	Generator.	Conforms to	Yes	No
		specification?		
4222	Commenter to the Control Control Control	Conforms to		NT.
4.2.2.2	Generator type (note: fuel and type).	specification?	Yes Fuel:	No
		specification?	Type:	
			Турс	
4.2.2.3	Start-up time.	Conforms to	Yes	No
	The state of the s	specification?		
	Transfer switches (note type(s)).	Conforms to	Yes	No
4.2.2.4		specification?	Type(s)	
		-		
4.2.2.5	Generator sizing.	Conforms to	Yes	No
		specification?		
	n generator sizing: per Clause 5.21 of this			
	n of ULT freezers, PQS code number, othe			
	of operating environment, elevation, fuel	capacity estimation	on and electricit	y
consumption	at ambient operating temperature.			
4.2.2.6	Paralleled generators.	Conforms to	Yes	No
1.2.2.0	Turumenea generators.	specification?	Not applicable	110
		Specification.	Trot applicable	
4.2.2.7	Generator requirements.	Conforms to	Yes	No
		specification?		
4.2.2.8	Earthing.	Component	Yes	
		weights		No
		Weights		No
4.2.2.9		comply?		No
	Starting system.	comply? Conforms to	Yes	No No
4.2.2.10		comply? Conforms to specification?		No
4 2 2 11	Starting system.  Stored fuel capacity and fuel tank.	comply? Conforms to specification? Conforms to	Yes Yes	
4.2.2.11	Stored fuel capacity and fuel tank.	comply? Conforms to specification? Conforms to specification?	Yes	No No
1		comply? Conforms to specification? Conforms to specification? Conforms to	Yes	No
4 2 2 12	Stored fuel capacity and fuel tank.  Monitoring and alarms.	comply? Conforms to specification? Conforms to specification? Conforms to specification?	Yes Yes	No No
4.2.2.12	Stored fuel capacity and fuel tank.	comply? Conforms to specification? Conforms to specification? Conforms to specification? Conforms to	Yes	No No
	Stored fuel capacity and fuel tank.  Monitoring and alarms.  Accessories.	comply? Conforms to specification? Conforms to specification? Conforms to specification? Conforms to specification?	Yes Yes Yes	No No No
4.2.2.12       4.2.2.13	Stored fuel capacity and fuel tank.  Monitoring and alarms.	comply? Conforms to specification? Conforms to	Yes Yes	No No
4.2.2.13	Stored fuel capacity and fuel tank.  Monitoring and alarms.  Accessories.  Generator installation.	comply? Conforms to specification?	Yes Yes Yes Yes	No No No No No
	Stored fuel capacity and fuel tank.  Monitoring and alarms.  Accessories.	comply? Conforms to specification?	Yes Yes Yes Yes	No No No
4.2.2.13	Stored fuel capacity and fuel tank.  Monitoring and alarms.  Accessories.  Generator installation.  Operations manual.	comply? Conforms to specification?	Yes Yes Yes Yes Yes	No No No No No No
4.2.2.13	Stored fuel capacity and fuel tank.  Monitoring and alarms.  Accessories.  Generator installation.	comply? Conforms to specification?	Yes Yes Yes Yes	No No No No No

Comments	s on generator system:			
4.60				
4.6.2	Safe access.	If observed,	Yes	No
		conforms to		
		specification?		
4.7.1	Restricted materials.	Conforms to	Yes	No
		specification?		
4.8	Warranty.	Conforms to	Yes	No
		specification?		
4.9.1	Servicing provision.	Conforms to	Yes	No
		specification?		
4.9.2	Spare parts, supplies.	Conforms to	Yes	No
		specification?		
4.10	Disposal and recycling.	Conforms to	Yes	No
		specification?		
4.11	Instructions.	User	Yes	No
		instructions		
		conforms to		
		specification?		
		op controller.	Yes	No
		Installer	105	1,0
		instructions		
		Conform to		
		specification?		
4.11	Sample manual(s).	Is it	Yes	No
7.11	Sample manual(s).	satisfactory?	103	110
4.12	User training.	Conforms to	Yes	No
4.12	Osei training.	specification?	168	110
5.	Doolrosino	Conforms to	Yes	No
3.	Packaging.		res	NO
1 dditi on a	I tackwing I commonter	specification?		
Aaaiiiona	l technical comments:			
C. Norms	and standards:			
6.	On-site installation.	Offered?	Yes	No
7.	List of installations:	Details	Yes	No
		supplied:		
		Satisfactory?		
7.	Environmental audit	Type:		
	scheme.	Current?	Yes	No
		(Note: not		
		mandatory)		
7.	Laboratory test reports or declarations.	Details:	Yes	No
		Satisfactory?		
7.	Type approval details.	Details	Yes	No
		supplied:		
		Satisfactory?		

7.	Current ISO 9001 certification.	Conforms to	Yes No.
		specification?	Or Pending
8.	On-site maintenance service	Offered?	Yes No
	(optional).		
Norms and sta	ndards comments:		
D. Conclusion	S:		
Overall summa			
	•		
	<b>DECISION:</b>	Prequalify?	
		Reject?	
	QA Assessor		
	Contact info		

#### Annex 2 – Generator sizing example

(see Clause 5.2.1)

Each manufacturer or reseller seeking prequalification as a supplier of continuous electricity for a ULT freezer will be required to submit one completed sizing example for the generator coupled to a specified prequalified WHO PQS prequalified ULT freezer and additional ULT freezer system loads. The details of this fictitious example are to be provided by the quality assessor. The example may be submitted on the form as shown in this **Annex 2** or by other means with equal clarity of information.

The minimum detail required will be a fully worked example of the generator sizing including a fuel storage capacity calculation for the specific WHO PQS prequalified ULT freezer per WHO PQS E003/ULT0.1Vaccine ultra low temperature freezer: compression-cycle and the continuous electricity system per WHO PQS E003/POW0.1 Power systems for ultra-low temperature freezing systems.

The generator sizing example to clearly indicate:

- ULT freezer Identification and PQS code number;
- ULT freezer electrical input specification;
- ULT freezer operating environment temperature range;
- ULT freezer electricity consumption at legal manufacturer-specified ambient temperature;
- Elevation (used for sizing example)
- UPS battery charger input power;
- Other loads (lighting, air conditioner, etc.);
- Generator prime power rating;
- Generator output voltage and frequency;
- Generator controller type;
- Generator fuel type;
- Generator fuel consumption;
- Stored fuel capacity;
- ATS time startup and connect generator; and
- Generator sizing calculations.

Attach specification sheets for ULT freezer and generator.

## **Generator sizing example:**

ULT freezer	Mfc = ABC Ltd 230	Model = ULT-86C	PQS code = E003/tbd
Quantity = 2	Vac, 50 Hz	1000 watt/freezer	Ambient operating
(1 for vaccine, 1 for		10,000 Wh/day	temperature range
ULT coolant		@ +25°C	Max = +25°C
freezing)			$Min = -10^{\circ}C$
Additional loads:	Air Conditioner	Lighting, office loads	UPS battery charger
Quantity x watt	1 x 1500W	500W	1 x 4000W
UPS:	Model = I-230v/1200	Output 1200 watt	Battery charger max
Quantity = 1		continuous	input power = 4000W
(for vaccine freezer)			
Generator:	Mfc = ABC Co.	Model =	Capacity: 12,000W
Quantity = 1		GXX230V/12K	
Fuel:	Diesel	Fuel capacity (min) =	Fuel tank capacity =
Rate @ 100% load	100% = 3  L/h	72  hr x  3  l/hr =	250 gallons
Rate @ 25% load	25% = 1  L/h	216 liters	
<b>Location (example):</b>	Average air	Elevation = 1000 M	
	temperature = $+30$ °C		

## **Generator system calculations:**

- **Design day assumptions**: Location ambient can exceed +30°C therefore the freezers are to be located in air-conditioned space. ULT freezers and freezer system loads all to operate continuously at total connected watt in an air-conditioned room at +25°C.
- **Load** (total connected watt) = (2 x 1000 W ULT freezers + 1 x 4000 W battery charger + 1500 W AC + 150 W lights + 350 office equipment) = 8000 W total connected load.
- **Generator capacity** = 8000 W total load / 0.9 temperature derate / 0.95 altitude derate / 0.8 spare capacity = 11,696 W at total load or 12 kVA.
- **Fuel capacity** (minimum of three-day fuel storage capacity) = 3 Litre/h x 72 hours = 216 Litre of diesel fuel

## Annex 3 – UPS sizing example

(see Clause 5.2.2)

Each legal manufacturer or reseller seeking prequalification as a supplier of continuous electricity for a ULT freezer will be required to submit one completed sizing example for the uninterruptible power supply (UPS) coupled to a specified prequalified WHO PQS prequalified ULT freezer. The example may be submitted on the form as shown in this **Annex 3** or by other means with equal clarity of information.

The minimum detail required will be a fully worked example of the UPS sizing including a battery capacity calculation for the specific WHO PQS prequalified ULT freezer per WHO PQS E003/ULT0.1 Vaccine ultra-low temperature freezer: compression-cycle.

The UPS sizing example to clearly indicate:

- ULT freezer identification and PQS code number;
- ULT freezer electrical input specification;
- ULT freezer operating environment temperature range;
- ULT freezer electricity consumption at a manufacturer-specified ambient temperature;
- Type of UPS (single conversion or double conversion);
- Battery charger specifications (input voltage and frequency, output voltage, input current, output current);
- Inverter specifications (input voltage and frequency, output voltage and frequency, input current, continuous watt output at ULT freezer operating ambient temperature);
- Or inverter/charger (input AC voltage and frequency, output AC voltage and frequency, nominal DC voltage, input AC current, input DC current, output DC current, continuous watt output at ULT freezer operating ambient temperature, current rating of ATS, ATS transfer time for mains to inverter and inverter to mains;
- Battery specifications (quantity, series/parallel configuration, battery voltage and amp hours, battery bank voltage and amp hours discharge at specified capacity hours and temperature and final voltage per cell);
- Battery depth of discharge (not to exceed battery manufacturer recommendations);
- Battery recharge time;
- UPS electrical input and output specifications;
- UPS continuous output in watt at specified temperature; and
- Battery capacity calculation for a continuous eight-hour output.

Attach specification sheet for ULT freezer and UPS (including inverter/charger, battery).

## **UPS Sizing Example:**

ULT vaccine	Mfc =	Model =	PQS code =
freezer:	TTT Ltd.	-70C	E003/tbd
Quantity = 1	230 Vac, 50 Hz	1000 watt	
UPS:	Mfc =	Model =	Type: Single
	UPS Ltda.	W1500	conversion
Quantity = 1	Output (cont.) =	Battery capacity	Features:
	1500 W @ +25°C	= 8 hours	ATS, TC
Specifications	230 Vac, 50Hz	Battery charger:	ATS: 15A,
	input	48 Vdc, 30 amps	transfer time
	230 Vac, 50Hz	Output = $3000$	<5ms mains to
	output	Watt for 5	inverter, <7ms
		seconds @ 25°C	inverter to mains
<b>Battery:</b>	Mfc =	Model =	
	BATS Inc.	12-430	
Quantity = 4	4 series x 1	12 Vdc, 430 Ah	Maximum depth
	parallel	= 48  Vdc, 430	of discharge =
		Ah @ C/8 hours	80%
		@ +25°C to 1.75	
		Volts per cell	
Location:	Min. operating	Freezer ambient	Battery storage
	temp. = $+10^{\circ}$ C	air temperature	area ambient air
		= +25°C	=+32C

- **Location assumptions:** ULT freezer to operate in a +25°C room. Battery to be placed in an area that will be +32°C.
- **Battery calculation**: (1000-Watt ULT load x 8 hours) / 48 Vdc / 0.6 DOD / 0.9 inverter efficiency / 0.9 temperature derate / 0.8 ageing factor = 429 AH battery at 48 Vdc
- Battery recharge time calculations: (429 Ah battery x 0.6 DOD) / 0.9 battery inefficiencies / 30 A = 9.5 hours

Revision history				
Date	Change summary	Reason for change	Approved	