

**TITLE: Guidance for the prequalification of single-phase voltage stabilizers***Specification reference:* E007/VS01.4*Product verification protocol:* E007/VS01-VP.4*Publication date:* 18 July 2017**1. Introduction:**

This document describes the steps required of suppliers to achieve WHO PQS prequalification for voltage stabilizers as part of category E007: Cold Chain Accessories. It provides information on verification processes, including those aspects of the performance specification that may be self-certified by suppliers, and those aspects that must be evaluated by an independent, WHO PQS approved verification laboratory. Information is also provided on the process by which a supplier may choose a non-WHO PQS approved verification laboratory

2. Background:

The PQS prequalification system is a range of standards and verification protocols created and managed by the WHO that specifies and verifies the critical criteria and minimum performance of immunization equipment, including refrigerators, temperature monitors and now voltage stabilizers.

WHO PQS has identified inconsistent and unstable electrical quality power to be a major contributing factor to the breakdown of mains-powered refrigerators and freezers used for immunization in resource-constrained settings. Poor quality power (i.e., long duration over- and under-voltages, short duration impulsive transients and frequency fluctuation) often damage unprotected refrigerators and freezers, as well as substandard voltage stabilizers. Thus, WHO PQS now requires all mains-powered vaccine refrigerators and freezers to be supplied with a WHO PQS prequalified voltage stabilizer.

3. Relevant documents:

The below documents are relevant for single-phase voltage stabilizers and can be found on the WHO PQS website, under E007: Cold Chain Accessories >> Category Documentation:

- Performance specification: E007/VS01.4
- Verification protocol: E007/VS01-VP.4
- Website:

http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/catdocumentation.aspx?id_cat=36

4. Self- and Laboratory certification requirements:

In order to simplify the procedures required to demonstrate and verify compliance with specific clauses of the performance specification, WHO PQS will allow suppliers to self-certify through submission of a dossier and relevant supporting documentation. Other clauses most relevant for safe and quality performance must still be verified by an independent, WHO PQS approved, ISO/IEC 17025:1999 certified laboratory and in accordance with performance specification E007/VS01-VP.4.

[Performance specification verification requirements via self- or laboratory certification:](#)

Clause	Description	Self-certification	Laboratory certification
4.2.1	Mode of operation	X	
4.2.2	Nominal input and output voltage and frequency	X	
4.2.3	Voltage regulation fluctuations		X
4.2.4	Voltage protection		X
4.2.5	Capacity rating		X
4.2.6	Input frequency fluctuations		X
4.2.7	Output voltage accuracy		X
4.2.8	Corrosion resistance of enclosure	X	
4.2.9	Electrical safety	X	
4.2.10	Electromagnetic compatibility	X	
4.2.11	Robustness		X
4.2.12	Protection against dust and water ingress	X	
4.2.13	Markings	X	
4.3.1	Ambient temperature range during transport, storage and use	X	
4.3.2	Ambient humidity range during transport, storage and use	X	
4.5.1	Compatibility with electronic circuits	X	
4.5.2	Power lead	X	
4.6.1	General (Human factors)	X	
4.6.2	Control panel	X	
4.7.1	Restricted materials	X	
4.8	Warranty	X	
4.9	Servicing provision	X	
4.10	Disposal and recycling	X	
4.11	Instructions	X	
5	Packaging	X	
	Total =	19	6

5. Supplier selection of verifying laboratory:

Suppliers may contract any reputable verification laboratory given written approval is received by WHO PQS prior to conducting the aforementioned tests. The verification laboratory will be approved provided that the following information is submitted and deemed sufficient by the WHO PQS secretariat:

- Full details of accreditation under ISO/IEC 17025:1999 certificate, including next reassessment date
- Full details of the accreditation body, positively confirming ILAC signatory status
- Names, contact details and information on type of testing conducted for at least 3 well-established organizations that have used the laboratory for testing relevant to voltage stabilizers or similar products during the past three years
- Details on the laboratory facilities and equipment that are relevant to performance specification E007/VS01.4 and verification protocol E007/VS01-VP.4
- CVs for the personnel who would carry out tests in accordance with performance specification E007/VS01.4 and verification protocol E007/VS01-VP.4
- Confirmation in writing by the laboratory of ability to conduct all type-examination and type-testing services in accordance performance specification E007/VS01.4 and verification protocol E007/VS01-VP.4, excluding aspects that are allowed to be self-certified by the supplier as stated above.

6. Steps to achieve WHO PQS prequalification:

WHO PQS prequalification may be achieved by following the below steps:

1. Submit to the WHO PQS secretariat a written request to conduct testing at laboratory of choice. This request should contain information confirming that the laboratory meets WHO PQS's minimum selection criteria, as specified above.
2. WHO PQS grants written approval to conduct testing at the laboratory of choice.
3. Contract laboratory and conduct testing for aspects requiring laboratory certification, as specified above;
4. Submit product dossier to WHO PQS, including self- and laboratory certified testing report;
5. WHO PQS evaluates the product dossier and provides any feedback or requests for additional information or testing prior to product prequalification;
6. WHO PQS provides written notification of prequalification outcome and product is listed on WHO PQS prequalification catalogue.