PQS performance verification protocol

TITLE: Programmable remote temperature and event monitoring systems

Product verification protocol:	E006/TR03-VP.2
Applies to specification ref(s):	E006/TR03.2
Date of origin:	30 November 2006
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1. **Scope:**
This document describes the procedure for verifying the performance of *programmable electronic temperature and event logging systems with remote alarming and remote, periodic, and automatic reporting* for monitoring storage conditions in the administrative levels of the cold chain. The relevant specifications can be found in the document E006/TR03.2.

2. **Normative references:**
CE: *Conformité Européenne.*
EMAS: *European Union Eco-Management and Audit Scheme.*
EN 12830:1999: *Temperature recorders for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice cream. Tests, performance and suitability.*
European Union Directive 2002/96/EC: *Waste Electrical and Electronic Equipment.*
ETSI EN 300-220: *Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Technical characteristics and test methods for radio equipment to be used in the 25 MHz to 1 000 MHz frequency range with power levels ranging up to 500 mW.*
FCC: *Federal Communications Commission.*
IEC 60529: Consolidated Edition 2.1 (incl. am1): *Degrees of protection provided by enclosures (IP Code).*

ISO 9001: 2000: *Quality Management Systems – Requirements.*
ISO 14001: 2004: *Environmental management systems - Requirements with guidance for use.*
ISO/IEC 17025: 2000: *General requirements for the competence of testing and calibration laboratories.*
US 21 CFR Part 11: Food and Drug Administration, Department of Health and Human Services, Electronic records and electronic signatures.
WHO/PQS/E006/TR03.2: *WHO performance specification for programmable electronic temperature and event monitoring systems*
WHO/PQS/E006/TR03-VP.2: *WHO independent type-testing protocol for programmable electronic temperature and event monitoring systems*
GAMP5: *Good Automated Manufacturing Practice, International Society for Pharmaceutical Engineering.*

3. Terms and definitions:

Approved Installer: A person or organization approved by the Legal Manufacturer or Reseller as a competent installer of the system components and who has been appointed by the Employer to carry out the installation of the System.
Employer: The organization that contracts with the Approved Installer to carry out the system installation and commissioning.
In writing: means communication by letter, fax or email.
Intermediate vaccine store: stores that receive vaccine from a primary vaccine store where it is stored and distributed to health facilities. Such stores are typically located in a regional or district centre.
Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labeling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
NIST: United States National Institute of Standards and Technology.
Primary vaccine store: stores that receive vaccine directly from the vaccine manufacturer where it is stored and distributed to intermediate vaccine stores. Such stores are typically located in a national or regional centre.
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.
System: The programmable remote temperature and event logging system specified in this document.

4. Applicability:

The verification protocol consists of two steps, the first mandatory for all applications for PQS certification, the second being requested by the WHO PQS Secretariat depending on fulfilment of criteria mentioned in Section 4.2. At all stages, WHO PQS reserves the right to require an independent, in-person audit of the Reseller or Legal Manufacturer by an official authorized by WHO PQS.

4.1. *Step 1: Operational verification.* Submission of a comprehensive dossier by the Reseller or Legal Manufacturer. The dossier is to include the following:

- Dossier examination fee in US dollars.

- Type examination document that includes a detailed list of internationally recognized standards, certificates (not limited to the list in Section 2), and other evidence of conformity (e.g., screenshots of web portal to illustrate the required capabilities, data from tests of robustness and accuracy), to the specifications in the document E006/TR03.2. This document must be verified and signed off by WHO PQS or an independent party authorized by WHO PQS. Section 5 details the content of the type examination document.
- Copies of all certificates and other evidence of conformity listed in the document mentioned above.
- Proof of adherence to an internationally recognized quality management system (e.g., relevant parts of the ISO 9001-2008 series).
- A minimum of three recent customer references for the Reseller or Legal Manufacturer involving order quantities greater than 100 units of the product. The references are to also address customer service of the Reseller or Legal Manufacturer.
- List of countries where the Legal Manufacturer has a service network capable of installing and maintaining the offered system.
- Certified photocopy of Certificate of Traceability and Calibration traceable to an ISO/IEC 17025 accredited testing laboratory, to NIST, or to another internationally recognized standards agency for all system components intended for temperature measurement.
- Where relevant, certified photocopies of the legal manufacturer'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 manufacturers who are able to demonstrate compliance with good environmental practice.
- Indicative cost of each system component EXW (Incoterms 2000).

In addition to the dossier, the Reseller or Legal Manufacturer is required to provide PQS with a sample unit of the system, along with detailed instructions on its setup and operation. The sample unit must comprise a minimum of:

- Two temperature sensors
- One "door open" sensor (where offered)
- One voltage sensor (where offered)
- Two logging units (where part of system)
- One base station
- Web portal access information
- Installation, commissioning, and user instructions for the system in English language.

Where appropriate, the Reseller or Legal Manufacturer may demonstrate the setup and operation of the sample unit in person to WHO PQS or to an independent party authorized by WHO PQS.

4.2. *Step 2: Field testing.* WHO PQS may require the system to be field tested for the following two reasons: 1) the Reseller or Legal Manufacturer has no prior experience in other markets that have similar performance requirements to the vaccine cold chain (e.g., pharmaceutical) or 2) the proposed product involves a technology of system architecture that is different from the ones known to WHO PQS and currently included in its catalogue. In this case, the Reseller or Legal Manufacturer will be required to provide one additional document:

- Report of any field test conducted in collaboration with a local independent partner agency (UN Organization, NGO), with the report including (but not limited to) country of testing, number of units involved, focus level in the cold chain, successes and limitations experienced. The report is to be jointly authored by the Reseller or Legal Manufacturer as well as the independent agency.

5. Type examination checklist:

Tabulate the following information for all sample system components submitted for examination. The information must be tabulated after the installation, setup, and operation of the sample system is demonstrated and verified. Obtain any additional supporting information required in writing from the Legal Manufacturer or Reseller and attach this information to the dossier described in Section 4.1.

System characteristics:

- Generic description of system including minimum system setup and details of expansion options;
- List of submitted system components, including software.

Identification of system components:

- Code (a unique identifier to be assigned by the testing laboratory);
- Brand/model;
- Legal Manufacturer or Reseller;
- List of OEMs of all sourced components in the product;
- Mode of operation;
- Country of origin;
- Conformity assessment markings (e.g. CE mark).

Performance characteristics of hardware components:

Sensors (specification clause 4.1.1):

- Temperature sensor operating range conforms/does not conform;
- Temperature sensor accuracy conforms/does not conform;
- Temperature sensor resolution conforms/does not conform;
- Temperature sensor response time conforms/does not conform;
- Temperature sensor type conforms/does not conform;
- "Door-open" event sensor conforms/does not conform;
- Voltage sensor conforms/does not conform;
- Sensor lead length restrictions (if any) are acceptable;
- Sensor fixings conform/do not conform;
- Sensor IP rating conforms/does not conform.

Logging units (specification clause 4.1.2 – where applicable):

- Logging unit operating parameters conform/do not conform;
- Logging unit power source conforms/does not conform;
- Logging unit memory conforms/does not conform;
- Logging interval conforms/does not conform;
- Logging unit casing conforms/does not conform;
- Logging unit fixings conform/do not conform;
- Logging unit IP rating conforms/does not conform;

- Connection to base station conforms/does not conform.

Base station (specification clause 4.1.3):

- Base station channels conforms/does not conform;
- Base station memory conforms/does not conform;
- Base station power source conforms/does not conform;
- Base station data connection capability conforms/does not conform;
- Base station IP rating conforms/does not conform.

Audio-visual alarm and response/mute button (specification clause 4.1.4):

- Alarm and mute button location conforms/does not conform;
- Sound intensity for audio alarms conforms/does not conform;
- Light intensity for visual alarms conforms/does not conform;
- Alarm mode of operation conforms/does not conform.

Modem (specification clause 4.1.5):

- Modem power source conforms/does not conform;
- Modem functionality conforms/does not conform;
- Modem connectivity conforms/does not conform.

Display (specifications clause 4.1.6):

- Display information conforms/does not conform.

Calibration (specification clause 4.1.7):

- System component calibration certificate(s) conforms/does not conform.

Power leads (specification clause 4.1.8):

- Power leads conform/do not conform.

Electromagnetic compatibility (specification clause 4.1.9):

- Electromagnetic compatibility conforms/does not conform.

Performance characteristics of software:

Front-end software and back-end software (specification clause 4.1.10):

- "Plug-and-play" functionality conforms/does not conform;
- Remote configuration capability conforms/does not conform;
- Alarm threshold conform/do not conform;
- Alarm escalation features conform/do not conform;
- Action-oriented alarms conform/do not conform;
- "Grouping" of sensors conforms/does not conform;
- Unit of measurement conforms/does not conform.

Web portal (specification clause 4.1.11)

- Multiple layers of access privileges conform/do not conform;
- Web page and map view for cold chain status conform/do not conform;
- Web page for cold chain report conforms/does not conform;
- Periodic emailed report conforms/does not conform;
- Raw data and graphs conform/does not conform;
- Exporting files conforms/does not conform;
- Security features conform/do not conform.

Shareable application programming interface (specification clause 4.1.12)

- Shareable application programming interface capability conforms/does not conform.

Robustness to environmental conditions:

Robustness to ambient temperature range (specification clause 4.2.1)

- Design conforms/does not conform.

Robustness to ambient humidity range (specification clause 4.2.2)

- Design conforms/does not conform.

Robustness to voltage fluctuations (specification clause 4.2.3):

- Design and Reseller or Legal Manufacturer capabilities conform/do not conform.

Physical characteristics: Not critical

Interface requirements:

Software compatibility (specification clause 4.4.1):

- Software compatibility conforms/does not conform.

Materials:

Ozone depleting chemicals (specification clause 4.5.1):

- Materials in the product conform/do not conform.

Other restricted materials (specification clause 4.5.2):

- Materials in the product conform/do not conform.

Packaging (specification clause 4.5.3):

- Packaging materials conform/do not conform.

Warranty:

Warranty (specification clause 4.6):

- Warranty conforms/does not conform.

Servicing provision:

Servicing provision (specification clause 4.7):

- Servicing provision conforms/does not conform.

Disposal and recycling:

Disposal and recycling (specification clause 4.8):

- Disposal and recycling conforms/does not conform.

Instructions:

Instructions (specification clause 4.9):

- Manuals for users and technician installation conform/do not conform.
- The type examination report must assess the ease of various and usage tasks specified in the manuals (e.g., replacement of batteries, sensors).

Training:

Training (specification clause 4.10):

- Training capabilities conform/do not conform.

6. Quality control checklist:

6.1. *Quality control standards:* All testing and reporting must be carried out in accordance with the requirements of ISO 17025:2005 or later edition.

6.2. *Quality control inspection:* An on-site inspection of the manufacturing plant and quality management systems is not required, unless WHO PQS deems this

necessary, as explained in Section 4. However, the prequalification process must consider demonstration of installation, settings procedures and working status

7. **Pre-qualification evaluation:**
   A system will qualify for inclusion on the register of PQS pre-qualified programmable remote temperature and event-monitoring systems in accordance with WHO procedures provided the final dossier as defined in Section 4.1 is deemed complete, satisfactory, and indicates full conformity with the requirements in specification **E006/TR03.2.**

8. **Modified systems:**
   The Legal Manufacturer or Reseller must notify WHO in writing of any changes which affect the performance of the offered system. WHO will carry out a desk evaluation of the reported change(s). If any change is deemed adversely to affect the performance of the system, WHO may request full or partial re-verification based on the procedures described in this document.

Annex: Verification protocol check-list for evaluator, see excel tool E006/TR03-VPT.2

Revision history:			
Date	Change summary	Reason for change	Approved
21 Sep, 2006	5.3: Reference to specification clause 4.2.11, 4.3.1 and 4.3.2 added. 5.4 step 6: '2' changed to '0'.	Consistency with other VPs during final review.	UK (30 November 2006 - PQS secretariat)
3 Sep 2015	Comprehensive revision and updating of verification protocol based on revised specifications to reflect the introduction of new technologies	Updating specifications and verification protocol based on recent advancements in technology, ensuring certain minimum level of quality without restricting innovation	DM