TITLE: Programmable remote temperature and event monitoring systems

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Contents

1. Scope

This specification describes the performance requirements for *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.

This specification is focused on remote temperature monitoring and local temperature monitoring systems, but not other means to monitor temperature in the vaccine cold chain. The differences between remote and local systems are summarized as follows:

- **Remote temperature monitoring** uses some means of communication (mobile network, GPRS, UHS, satellite, etc.) to periodically transmit data to the cloud. **Local temperature monitoring** does not transmit to the cloud, and instead uses LAN or some other means to transmit to a local PC. Local temperature monitoring devices therefore binds the data to the same location, unless physically transported using print-outs, USB sticks, or by voluntarily exporting data using various software for data export.
- With **remote temperature monitoring**, relevant officials can access the data globally by logging into the server through a web portal. This is not possible with **local temperature monitoring**.
- With **remote temperature monitoring**, relevant officials can also remotely control settings of the devices globally (e.g., frequency of transmission, SMS alarm destinations, reporting format) through the web portal while this is not feasible with **local temperature monitoring**.
- Security of the cloud-based data needs to be ensured with **remote temperature monitoring**, with two formats being possible: 1) Solution as a Service (SAAS), where the manufacturer hosts the data and offers services such as the web portal, technical support and maintenance of the server, and 2) Hosted, where the country itself owns and maintains a server where the data are stored. Data security is different for **local temperature monitoring**, since data will not be cloud-based; in this case, the PC in which data is stored will need to be secure.

Given the cloud-based capabilities and benefits of remote temperature monitoring, this is the preferred option unless infeasible due to constraints relating to infrastructure (e.g., cellular connectivity) or cost.

For local temperature monitoring systems, only those clauses that are relevant to these systems are to be considered.

The **E006/TR03-VP.2** verification protocol is associated with this specification. It is a checklist protocol, which will be used to verify that the solution meets all performance requirements. It is also a quality assurance protocol to be used for system commissioning in the field.

Guidance note: The equipment described in this specification will be purchased to suit the individual requirements of a specific vaccine store. Consequently this document characterizes the required performance of typical components of a temperature monitoring system; it does not specify particular configurations of these components.

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.
EEPROM: Electrically erasable, programmable, read-only memory.
In writing: means communication by letter, fax or email.
LCD: Liquid Crystal Display.
LED: Light-Emitting Diode.
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.
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.
SMS: Short Message Service.
System: The local or remote programmable electronic temperature and event logging system specified in this document.

3.1 Segmentation approach

As discussed in the introduction to Category E006, operating conditions and product requirements vary depending on the level in the cold chain. Factors that are likely to vary include: reliability of power, type of power (AC vs. DC), reliability of cellular connectivity, type of equipment to be monitored (walk-in cold room vs. refrigerator).

For this reason, the requirements specified in the following section adopt a segmentation approach. There are four commonly encountered administrative levels in the cold chain. However, in order to reduce the number of product segments, the variation of product requirements is aggregated into three segments:

- Segment 1: Higher levels of the cold chain (Primary and Sub-National). These levels have comparatively reliable access to either mains power or backup generators, and are likely to have better cellular connectivity. The equipment to be monitored at each site could be walk-in cold rooms or freezer rooms or multiple refrigerators.
- Segment 2: Middle levels of the cold chain (Lowest Delivery). These levels are likely to have more challenges with access to reliable mains power or backup generators. Cellular connectivity could be an issue at some sites. The equipment to be monitored at each site could be multiple refrigerators and/or freezers.
- Segment 3: Lower levels of the cold chain (Service Point). These levels are likely to have the greatest challenges with access to reliable mains power or backup generators. Cellular connectivity could also be an issue at many facilities. The equipment to be monitored at each site will usually consist of one or two refrigerators.

3.2 Generalized system design

Programmable temperature and event logging systems with integrated alarm, automatic transmission to a server, and data access through a web portal are used for monitoring storage conditions at different levels of the vaccine cold chain. Systems must be configurable to suit specific applications and scalable to allow for the later installation of additional temperature monitoring products and/or storage facilities. A system consists of two parts: i) hardware and ii) software & web portal.

Hardware

Hardware requirements are likely to vary by segment within a country's cold chain. The four segments are based on level in the cold chain:

1. **Temperature sensor.** A device that reads the temperature at a specific location within a cold room, freezer room, refrigerator or freezer unit. Sensors may be connected individually or collectively to a logging unit or directly to a base station. Temperature sensors may also be integrated into a logging unit (internal sensor device).
2. **'Door open' sensor.** A device that detects whether a door is open or closed. This sensor is mandatory for walk-in cold rooms / freezer rooms, but optional for refrigerators.
3. **Voltage sensor (optional).** A device that records the incoming mains voltage supplying the vaccine store. This is the instantaneous voltage at the time of sampling.
4. **Sensor port.** This is the "socket" in the logging unit or base station into which the sensor cable is connected.
5. **Logging unit.** A device that records data received from individual sensor(s) to which it is connected and transmits this data to a base station. Such devices may also include a visual display and/or an audible alarm sounder. Note: the system need not include a logging unit, if all capabilities are built into the base station.
6. **Base station.** A device that receives data from individual logging units or directly from an array of sensors. The base station has its own on-board memory, power supply, and modem. The audio-visual alarm and mute button (see below) may be external to the casing of the base station, but must be located at the same site where the remote temperature monitoring system is deployed. Such devices may also include a visual display and/or an audible alarm sounder.
7. **Audio-visual alarm and mute button.** A central alarm sounder and flashing light signal that is triggered whenever a sensor records a temperature or event excursion outside programmed norms. This may be integrated into the base station, for ease of installation and greater robustness in the field. The mute button silences the alarm temporarily, and also records this "time to respond" on the part of the healthcare worker. It must also be possible to permanently turn off or temporarily mute the alarm remotely, through the web portal.
8. **Modem**. A device that automatically performs the following functions: i) transmits data periodically from the site being monitored to the server; ii) receives any remote updates, setting changes, or commands, iii) issues alerts when alarms are triggered (e.g., by sending SMSes to pre-programmed mobile phone numbers or by audio calling and leaving a

recorded voice message), iv) escalates the alert to higher-level decision-makers (e.g., through SMSes, audio calls, or emails) if the first alert is not responded to within a specified time limit. Note: The system could also be configured to transmit all SMSes and emails from the server instead of directly from the device.

9. **Display**. A screen on the base station that displays the information necessary for the user to understand the status of the monitored cold chain equipment at their site.
10. **Mode of operation.** Always on.

Software & web portal

1. **Front-end and back-end software.** The user directly interacts with the front-end software in order to control settings, access data, view visual analytics (e.g., charts, tables, maps), etc. The user does not directly interact with the back-end software, which is programmed into the device and the server.
2. **Web portal.** This website contains the user interface required to remotely control the system as well as examine datasets. The website accesses data from the server and presents reports, visualizations, alerts, and system status to the user. Any user-authorized changes to the system settings can be remotely and automatically communicated into the base station through the server.

4. Requirements

4.1 Performance

Hardware

4.1.1 Sensors

1. **Temperature sensor operating temperature range**
   Upper limit: +50°C.
   Lower limit: -30°C.
2. **Temperature sensor accuracy**. ±0.5°C or better, within the range -30°C to +20°C.
3. **Temperature sensor resolution.** ±0.2°C or better, within the range -30°C to +20°C.
4. **Temperature sensor response time.** T90 within 20 minutes maximum in accordance with EN12830:1999.
5. **Temperature sensor type.** Electronic.
6. **"Door-open" event sensor operating parameters.** Door open or door closed with a user-programmable delay function. A "door-open" event must be identified whenever the door panel is not fully seated in the closed position.
7. **Voltage sensor operating parameters.** To monitor all national standard combinations of single phase or three phase AC voltage and frequency, including the range of fluctuations encountered in the country where the equipment is installed.
8. **Sensor lead length.** Supplied as required to suit site conditions (does not apply for wireless sensors).
9. **Sensor fixings.** Remote sensors are to be supplied with fixings suitable for permanent attachment to the inside skin of a sectional cold room or freezer room or to the inside skin of a vaccine refrigerator or freezer.
10. **IP rating for all sensors and connection leads.** Protection of the product not less than IEC 60529: IP64.

4.1.2 Logging units

1. **Logging unit operating parameters.** Where logging units form part of the system they may incorporate integrated temperature sensors or they may be connected to external sensors.
2. **Logging unit power source**
   - EITHER: 110/240 volt 50/60 Hz mains operated with replaceable, rechargeable battery backup with the following minimum charge capacities and minimum 3 years operational life:

Segment 1	Segment 2	Segment 3
2 days	5 days	7 days

   - OR: non-replaceable, rechargeable battery with a minimum seven year operational life, with minimum three year warranty on battery, and same charge capacities as above.
   - OR: non-replaceable, non-rechargeable battery with a minimum seven year operational life, with minimum three year warranty on battery.

** **Note:** The potential to use DC power from solar-powered refrigerators at some of the Segment 2 and 3 sites is currently being examined. This specification may be updated accordingly.*

3. **Logging unit memory.** EPROM or equivalent non-volatile solid-state memory device capable of storing a minimum of 30 days worth of data for each sensor, assuming a 10-minute logging interval.
4. **Logging interval.** The system administrator must be able to program the logging interval at discrete periods, starting with a minimum interval of ten minutes.
5. **Logging unit casing.** Non-corrodible and robust material (e.g., plastics or treated metal).
6. **Logging unit fixings.** Loggings are to be supplied with fixings suitable for permanent attachment to the inside or outside skin of a sectional cold room or freezer room or to the inside or outside skin of a vaccine refrigerator or freezer.
7. **Logging unit IP rating.** Protection of the product not less than IEC 60529: IP64.
8. **Connection to base station.** Data transmission to the base station must be established automatically, without requiring any manual adjustment or fine-tuning other than plugging in sensors and cables, as necessary. If radio frequency links are used, they must be in accordance with ETSI EN 300-220 or the ZigBee standard[1]. In the event of interruption of power supply, the logging unit must be able to automatically reconnect with the base station once power supply is resumed.

4.1.3 Base station

1. **Base station channels.** The minimum number of temperature sensors to be supported by each base station (including the sensors from the logging units) must be at least as follows:

Segment 1	Segment 2	Segment 3
8 sensors	4 sensors	1 sensor

For Segment 1, in addition to the temperature sensors, base stations for remote temperature monitoring systems must support at least 2 door sensors.

1. **Base station memory.** Active base stations must incorporate EPROM or equivalent non-volatile solid-state memory capable of storing data from a minimum number of channels as specified above. The memory capacity must be sufficient to store 30 days worth of sensor data from all connected channels, assuming a 10-minute logging interval. The system is to be configured to overwrite data cyclically on a first-in-first-out basis when the memory is full.
   - In case of trouble with connectivity (and therefore with transmitting data to the server), the data must be stored in the base station. Upon resumption of connectivity, all the data stored during this period must be transmitted to the server.
2. **Base station power source.**
   - EITHER: 110/240 volt 50/60 Hz mains operated with replaceable, rechargeable battery backup with the following minimum charge capacities and minimum 3 years operational life:

[1] http://www.zigbee.org/en/index.asp

Segment 1	Segment 2	Segment 3
2 days	5 days	7 days

- OR: non-replaceable, rechargeable battery with a minimum seven year operational life, with minimum three year warranty on battery, and same charge capacities as above.
- OR: non-replaceable, non-rechargeable battery with a minimum three year operational life.
- * ***Note:*** *The potential to use DC power from solar-powered refrigerators at some of the Segment 2 and 3 sites is currently being examined. This specification may be updated accordingly.*

3. **Base station data connection capability.** The product must include at least a USB connection capability for downloading data to a PC. Other connection capabilities are permitted, but USB is required.
4. **Base station IP rating.** Protection of the product not less than IEC 60529: IP50.

4.1.4 Audio-visual alarm and response/mute button

1. **Alarm and mute button location.** The alarm and mute button must be at the same site as the remote temperature monitoring system, and must be capable of being positioned in an easily reachable location for the user.
2. **Sound intensity for audio alarms.** 70dB(A) at a distance of one meter from the sounder. The pattern of the signal is to be an intermittent pulse. The timing and/or pattern of the pulse should be set to ensure that it cannot be confused with the fire alarm sounder standard applicable in the country of installation. Devices with an adjustable sound profile will be acceptable provided the means for adjustment is not accessible once the device is mounted in its final position.
3. **Light intensity for visual alarms.** Flashing red colored light rated 100 mcd diffused.
4. **Alarm mode of operation.** The audio-visual alarm is to be triggered whenever an alarm event occurs for a preset time period. It is to be canceled by: i) physically pressing a "mute" button on the base station, ii) sending a remote response (e.g., through SMS) to the base station, or iii) through the web portal. Each of these responses is to be recorded by the system and used to calculate the "time of user response", which is to be transmitted to the server and displayed in the web portal.

4.1.5 Modem

1. **Modem power source**. The modem must utilize the same power source as the base station.
2. **Modem functionality**
   - Transmit data periodically from the base station to the server
   - Receive any remote updates, setting changes, or commands
   - Issue immediate alerts when alarms are triggered. E.g., by sending SMSes to pre-programmed mobile phone numbers or audio calling and leaving a recorded voice message. These alerts may be issued either directly by the modem or indirectly through the server.
   - Escalate the alert to higher-level decision-makers (e.g., through SMSes, audio calls, or emails) if the first alert is not responded to within a specified time limit.

3. **Modem connectivity.** Due to likely issues with connectivity (e.g., cellular connectivity issues), remote alerts and data transmission must automatically be possible through basic GSM standards. When available, higher-speed and more cost-efficient transmission (e.g., 3G) must be automatically utilized.

4.1.6 Display

A display should be part of the base station, and must provide the user with at least the following information:

- That the device is activated
- Battery charge level indicator OR battery replacement warning indicator activated when no less than 20% of battery life remains
- The most recently read temperature for each sensor connected directly or indirectly to the base station
- Whether or not the component is in an alarm condition
- Date, time, and cellular signal strength are optional information that could be included.

The display may show all this information together or the user may be required to access the information by means of a button mounted on the device. Logging units with more than one attached sensor must be able to show temperature and alarm data from all connected sensors.

4.1.7 Calibration

System components are to be covered by a Certificate of Traceability and Calibration. Producer-issued calibration certificates are acceptable along with a general NIST-traceable certificate for the series of logging units/base stations. However, in the case of producer-issued certification, the testing laboratory must be accredited with ISO/IEC 17025.

The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the components are traceable to an ISO/IEC 17025 accredited testing laboratory, to NIST, or to another internationally recognized standards agency. The certificate must be accompanied by a copy of the reference instrument calibration certificate.

4.1.8 Power leads

Each component connected to mains power is to be supplied with a factory-sealed plug connector to suit the mains electrical socket standard in the country of intended use (to be specified by the relevant UN-purchasing agency at the time of ordering).

4.1.9 Electromagnetic compatibility

Operation of the system and of the individual system components must be unaffected in the normal electromagnetic compatibility environment in which the system is intended to work, taking into account disturbance generated by adjacent apparatus which is compliant with relevant ISO, EN, or other internationally recognized standards. Information required to ensure uninterrupted use of the device must be contained in the user instructions.

Software

4.1.10 Front-end software and back-end software

1. **"Plug-and-play" functionality.** The base station must automatically connect and be recognized by the server when switched on. No user actions must be required to enable this, beyond the physical setup and switching on. In the event of interruption of power supply and/or cellular connectivity, the base station must automatically reconnect and be recognized by the server once power supply and/or cellular connectivity is restored. Upon reconnection, the base station must be able to transmit to the server the data that was collected during the interruption.
2. **Remote configuration.** System administrators must be able to remotely control and change settings through the web portal, including:
   - **a.** Alarm thresholds
   - **b.** Measurement and transmission frequencies of the base station
   - **c.** Alarm recipients and their details (phone numbers, email addresses, etc.)
   - **d.** Escalation tree for alarm (see Section 4.1.10.4)
   - **e.** Recipients of periodic emailed reports on the health of the cold chain,
   - **f.** Format of report (see Section 4.1.11.4)

   This user-interface must be highly visual and requiring minimal learning and effort (e.g., few mouse "clicks") to navigate.
3. **Alarm thresholds.** The system must allow different alarm settings for various types of excursions, with settings to be made by the system administrator. For example, allow 10 consecutive hours of excursions above 8 °C before alarming, allow 1 hour of excursions below -0.5 °C before alarming, immediately alarm if excursion reaches 40 °C. This type of setting must be possible through the system.
4. **Alarm escalation.** The system must allow a minimum of 3 layers of alarm escalation:
   - a. The alarm must be sent to the first recipients, as specified by the system administrator.
   - **b.** If the first recipients of the alarm do not respond within a time selected by the system administrator, then the alarm must be sent to their supervisor, as specified by the system administrator.
   - **c.** If this second recipient too does not respond within the required time, the alarm must be sent to their supervisor, as specified by the system administrator.

   The system administrator must be able to remotely specify (through the web portal) recipients at each level of this escalation tree, their preferred form of alarm (e.g., SMS, voice call, email), and the allowed time of response before the next escalation.
5. **Action-oriented alarms.** Alarm alerts (e.g., SMSes, voice calls, and emails) must be directly actionable. For example: "Refrigerator number X has been experiencing a freezing excursion for 5 hours." Escalated alarms to higher-level officials must be similarly actionable. For example: "Refrigerator X in health facility Y has been experiencing a freezing excursion for 1 hour. Please call <phone number> to talk to the relevant healthcare worker at this site."

6. **"Grouping" of sensors.** All sensors in the same appliance must be able to be "grouped" together, so that the system is aware that the same appliance is being monitored. This will prevent simultaneous alarms from different sensors for the same appliance. It will also enable users to monitor the cold chain by appliance, not by sensor.
7. **Unit of measurement.** Temperatures throughout the system must be recorded in degrees Centigrade. Calculation and display of mean kinetic temperature (MKT) must also be possible for each refrigerator/walk-in cold room.

4.1.11 Web portal

1. **Multiple layers of access privileges.** The web portal must allow the system administrator to set different access privileges and read/write privileges for various users (at least 3 levels of access privileges, customizable by the system administrator). For example, system administrators at the National level must have full privileges for the entire country, while system administrators at the State level must have full privileges, but restricted for their State. Some officials must have read/write privileges, while others must only have read privileges.
2. **Web page and map view for cold chain status.** The web portal must have a page to provide the remote user with a quick current status of all the equipment in their area of focus. A real-time map view might be available to present this visually. All appliances in alarm state must be highlighted in an obvious manner.
3. **Web page for cold chain report.** The web portal must have a page to provide the remote user with a summary report of the performance of the cold chain during a selected time period. The user must be able to select the required time period by day, week, month, and year. For the selected time period, the report must show the total time durations of heating and freezing excursions of each appliance. The sites with the greatest time durations of excursions must be displayed at the top of the list, so that they are immediately visible.
4. **Periodic emailed report.** On a monthly and annual basis, a simple, visual, and action-oriented report must be emailed to relevant officials, as specified by the system administrators. The report should summarize the health of the cold chain being monitored. Suggested information to summarize should include (but not be limited to):
   a. Since the last report, the total number of heating excursions above 8 °C for longer than 10 consecutive hours
   b. Since the last report, the total number of freezing excursions below -0.5 °C for longer than 1 hour
   c. Since the last report, a list of all the monitored cold chain equipment, in decreasing order of number of heating and freezing excursions (equipment with the most excursions on top, equipment with the least excursions at the bottom).
5. **Raw data and graphs.** The user must be able to easily access raw data from the server, and to develop graphs of the data over selected time periods.

6. **Exporting files.** The web portal must allow data to be exported in Excel/CSV, ASCII, and XML formats and images to be exported in JPEG and PDF formats.
7. **Security**. Authentication and access control of user and privileges standard not less stringent than US 21 CFR Part 11.

4.1.12 Shareable application programming interface (API)

API's are used in building software applications. In some cases, data from the remote temperature monitoring device may need to be shared with an existing in-country database (e.g., DHIS2, eVIN). In these cases, the API's must be shareable with the Employer of the system.

4.2 Robustness to environmental conditions

4.2.1 Robustness to ambient temperature range during transport and storage. -30°C to +55°C with the system components inactivated.

4.2.2 Robustness to ambient humidity range during transport, storage and use. 0 to 95% RH.

4.2.3 Robustness to voltage fluctuations. The functionality of the system and of the individual system components must not be affected by voltage fluctuations due to issues including (but not limited to) problematic power grid and intense electrical storm activity. Accordingly, the Reseller or Legal Manufacturer must enquire about the quality of power supply and, if necessary, recommend the usage of suitable voltage stabilizers to the procuring agency. If requested by the procuring agency, the Reseller or Legal Manufacturer must be able to source and supply PQS-approved voltage stabilizers.

Note: *Current specifications* can be found at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/catdocumentation.aspx?id_cat=36* .

4.3 Physical characteristics

4.3.1 Component dimensions. Not critical, as units are placed on exterior of cold chain equipment.

4.3.2 Component weight. Not critical, as units are placed on exterior of cold chain equipment.

4.4 Interface requirements

4.4.1 Software compatibility

- If the software requires an interface with a proprietary spreadsheet program, the list of compatible programs must include all releases of Microsoft Excel currently supported by Microsoft.
- The software must be compatible with all Microsoft PC operating systems currently supported by Microsoft in addition to any other operating system.

** Note that the current specification (VS01.1) is under revisions and will be published shortly*

4.5 Materials

4.5.1 Ozone depleting chemicals

During manufacture and assembly of the printed circuit boards and final assembly of the product do not use any substance included in Annex A, B or C of the Montreal Protocol.

4.5.2 Other restricted materials

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

4.5.3 Packaging

Materials used for packaging the finished product are to be free of ozone-depleting compounds as defined in the Montreal Protocol.

4.6 Warranty

All system components are to be covered by a three year warranty in the event of any component failure. On-site repair and maintenance is to be offered as an option to the purchasing party. All warranty rights are to pass from the Approved Installer to the Employer[2] after the system 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[3].

4.7 Servicing provision

The system is to be maintenance-free, apart from routine battery or sensor replacement and re-calibration. If possible, sensors that will not require replacement throughout the lifetime of the device are preferable.

4.8 Disposal and recycling

The manufacturer is to provide information to the buyer on the hazardous materials contained within the system 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.

4.9 Instructions

Each unit of the hardware must include a separate user manual and technician's installation manual in the language most appropriate to the installation site. An English version of all instruction and manuals are required to be supplied for visual inspection during application for PQS certification.

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[2] Typically the system will be installed by an Approved Installer as a component part of a cold room or freezer room installation. .

[3] Some installations will initially be purchased by one of the UN procurement agencies. In this situation, warranty rights must pass to the host government.

4.10 Training

Training in the use of the equipment will generally be given by the installer of the cold room/freezer room or refrigerator. The equipment supplier should provide the necessary training materials, and should also be able to provide in-person training to installers and system administrators.

4.11 Verification

Pre-qualification evaluation of sample systems will be carried out in accordance with PQS Verification Protocol **E006/TR03-VP.2**. Post-tender assessment and field commissioning of systems incorporating pre-qualified system components will also be carried out in accordance with PQS Verification Protocol **E006/TR03-VP.2**.

5. On-site installation and maintenance

System components are to be installed on site, and the software loaded and commissioned by personnel who have been trained to carry out these tasks. On-site maintenance of the system and the system components will be required and the legal manufacturer or reseller must provide evidence of the ability to provide this service for no less than the warranty period.

The legal manufacturer or reseller is to offer in-person training programs to personnel in each procuring country, at added cost. The training programs are to cover the physical installation and maintenance of the hardware, configuration of the software, and usage of the web portal. The legal manufacturer or reseller is also required to provide the personnel with simple and highly visual manuals for installation, usage, and maintenance.

6. Product dossier

The legal manufacturer or reseller is to provide WHO with a pre-qualification dossier containing the following. Additional

- Dossier examination fee in US dollars.
- Type examination document (please refer to product verification protocol: E006/TR03-VP.2) 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. This document must be verified and signed off by WHO PQS or an independent party authorized by WHO PQS. Section 5 in E006/TR03-VP.2 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. The

references need not be about the product being submitted for PQS approval. Rather, the references are to address and attest to the proficiency of 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.

7. Change notification

The legal manufacturer or reseller is required to advise WHO in writing of any changes which adversely affect the performance of the product after PQS pre-qualification has taken place.

8. Defect reporting

The legal manufacturer or reseller is required to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

Revision history:			
Date	Change summary	Reason for change	Approved
21 Sep, 2006	4.2.5: ‘48’ changed to ‘72’. 4.2.8: Fahrenheit option removed. 4.2.11: clause added. 4.3.1: Upper limit changed to 55°C; ‘storage’ added.. 4.3.2: ‘storage’ added. New clause 4.7.2. 4.7.3 and 4.7.4 deleted.5: ‘CFC’ changed to ‘ozone-depleting’.	Corrections. Consistency with other specifications during final review. EU RoHS Directive material restrictions incorporated.	UK (30 November 2006 - PQS Secretariat)
02 Sep, 2015	Comprehensive revision and updating of specifications to reflect new technologies in remote temperature systems	Updating specifications based on developments in technology, ensuring minimum levels of quality without restricting innovation	DM