QAS/14.598

Supplement 6

Temperature and humidity monitoring systems for fixed storage areas

Technical supplement to WHO Technical Report Series, No. 961, 2011

Annex 9: Model guidance for the storage and transport of time and temperature–sensitive pharmaceutical products

August 2014

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Acknowledgments

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Contents

Abbreviations

30DTR	30-day temperature recorder
GAMP	Good Automated Manufacturing Practices
GMP	Good Manufacturing Practice
GSP	Good Storage Practice
IQ	Installation Qualification
IT	Information Technology
LAN	Local Area Network
MKT	Mean Kinetic Temperature
OQ	Operational Qualification
PDA	Personal Digital Assistant
PDA	Parenteral Drug Association
PQ	Performance Qualification
RFID	Radio Frequency Identification Device
SaaS	Solution as a Service
SMS	Short Message Service
TCP/IP	Transmission Control Protocol (TCP) and Internet Protocol (IP)
SOP	Standard Operating Procedure
TTSPP	Time and Temperature-Sensitive Pharmaceutical Product
URS	User Requirements Specification
USB	Universal Serial Bus

Glossary

Component: Any major piece, part or assembly of the main equipment or sub-equipment that does not have its own power supply and could not operate as a standalone unit (valves, switches, etc.).

Electronic temperature monitoring and event logger system: System for recording and reporting air and/or product temperatures, with optional facilities for recording and reporting specific events such as door-opening or defrost cycles, and for issuing alarms. Such systems may be user-programmable and may also be remotely monitored via a satellite link.

Mapping: Documented measurement of the temperature and/or relative humidity distribution within a storage area, including identification of hot and cold spots.

Operational qualification (OQ): The process of obtaining and documenting evidence, under controlled conditions, that the premises, equipment and supporting systems operate in accordance with their design specifications.

Performance qualification (PQ): The process of obtaining and documenting evidence that the premises, equipment and supporting systems, as connected together, will consistently perform in accordance with the approved process method and specifications.

Pharmaceutical product: Any product intended for human use or veterinary product intended for administration to food producing animals, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals and vaccines. Medical devices are not included[1].

Qualification: Action of proving that any premises, equipment and supporting systems work correctly and actually lead to the expected results. The meaning of the word *validation* is sometimes extended to incorporate the concept of qualification.

Refrigeration equipment: The term 'refrigeration' or 'refrigeration equipment' means any equipment whose purpose is to lower air and product temperatures and/or to control relative humidity.

Standard Operating Procedure (SOP): A set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Standard operating policies and procedures can be effective catalysts to drive performance improvement and improve organizational results.

Storage temperature: The temperature range listed on the TTSPP label, and within the regulatory filings, for long-term storage.

[1] Definition from WHO/QAS/08.252 Rev 1 Sept 2009. *Proposal for revision of WHO good distribution practices for pharmaceutical products – Draft for comments*.

Temperature-controlled: Includes any environment in which the temperature is actively or passively controlled at a level different from that of the surrounding environment within precise pre-defined limits.

Temperature excursion: An event in which a TTSPP is exposed to temperatures outside the range(s) prescribed for storage and/or transport. Temperature ranges for storage and transport may be the same or different; they are determined by the product manufacturer, based on stability data.

Time and temperature sensitive pharmaceutical product (TTSPP): Any pharmaceutical good or product which, when not stored or transported within pre-defined environmental conditions and/or within pre-defined time limits, is degraded to the extent that it no longer performs as originally intended.

Validation: Documented testing performed under highly controlled conditions, demonstrating that processes, methods, and systems consistently produce results meeting pre-determined acceptance criteria.[2]

[2] PDA Technical Report No. 39: *Guidance for Temperature Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment*, 2007.

1. Introduction

This technical supplement has been written to amplify the recommendations given in Section 4.5.2 and 4.5.4 of WHO Technical Report Series No. 961, 2011, Annex 9: *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products*[3]. It covers the selection, installation and initial commissioning of temperature and humidity monitoring systems in fixed storage locations. It does not cover the routine operation of these systems. Related topics are covered in the following Technical Supplements:

- *Checking the accuracy of temperature control and monitoring devices.*
- *Qualification of temperature-controlled storage areas.*
- *Temperature and humidity monitoring systems for transport operations.*
- *Temperature mapping of storage areas.*

1.1 Requirements

The Model Guidance document defines minimum standards for temperature and humidity monitoring and alarm systems and components, and for the operational management of these systems.

1.1.1 Temperature monitoring systems

Air temperature monitoring systems and devices should be installed in all temperature-controlled rooms, cold rooms, freezer rooms, refrigerators and freezers used to store TTSPPs. Electronic sensors should be accurate to ± 0.5°C or better[4]. Sensors should be located in areas where the greatest variability in temperature is expected to occur within the qualified storage volume and they should be positioned so as to be minimally affected by transient events such as door opening.

1.1.2 Humidity monitoring systems

Humidity monitoring systems and devices should be used in temperature-controlled rooms that are used to store TTSPPs that require a humidity-controlled environment. Monitoring sensors should be accurate to ± 5% RH and located to monitor worst-case humidity levels within the qualified storage volume and they should be positioned so as to be minimally affected by transient events such as door opening.

1.1.3 Alarm systems

Temperature, and where necessary, humidity alarm systems should be linked to the monitoring system(s) with high and low alarm set points. There should be a visual alarm and also preferably an audible alarm, together with automatic telephone dial-up or SMS text warnings to key personnel.

[3] http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf

[4] Alcohol, bi-metal, gas or vapour pressure thermometers are also covered, but the focus of this Supplement is on electronic systems.

1.2 Objectives

The objective of the Technical Supplement is to provide guidance on how to protect TTSPPs from damage by the correct use of electronic temperature monitoring systems. It describes how to establish requirements and define specifications for these systems and how to assure traceability of the data that is generated.

1.3 Target readership

This document is relevant to wholesalers, warehouse operators, distributors, dispatchers and 3PLs who store TTSPPs. The specific target audience within these organizations includes those who have direct responsibility for quality management, for example, Quality Assurance (QA) Managers and Operations Managers.

2. Guidance

The ability to demonstrate compliance with Good Storage Practice (GSP) is a regulatory requirement in most countries. Effective temperature monitoring and associated record-keeping is critically important component of GSP in all stores, however small, where TTSPPs are stored. In addition, depending on the products being stored, it may be necessary to monitor and record other environmental parameters, such as relative humidity (RH). Finally, there are operational events which may also need to be logged and recorded because they can have a significant impact on environmental control – for example door opening in freezer rooms and cold rooms.

2.1 Associated materials and equipment

None

2.2 Related activities

In order that this guidance can be fully applied, the following steps also have to be completed:

a. Identify the storage areas and equipment which will be used for storing TTSPPs and their relevant temperature regimes – ambient, controlled ambient, refrigerated and frozen.

b. Map these storage areas and equipment and determine hot and cold points. For areas that can be impacted by seasonal changes, mapping should cover both cold and hot seasons. See Technical Supplement: *Temperature mapping of storage areas.*

c. Qualify the storage areas and storage equipment (IQ, OQ and PQ). See Technical Supplement: *Qualification of temperature-controlled storage areas.*

d. Ensure that all storage areas and equipment complies with applicable regulations and guidelines on the storage of TTSPPs before these products are brought into the store.

2.3 Choosing a monitoring system

In this context, a monitoring system generally refers to an automated system that simultaneously and continuously records and documents one or more physical parameters (such as temperature and relative humidity) at one or more predefined points. A monitoring system is used to record and document the conditions in various storage areas whilst minimizing the need for manual measuring and recording. Such a monitoring system is increasingly required in facilities storing TTSPPs. This section outlines the steps that need to be taken to choose a suitable system or systems.

2.3.1 Prepare a user requirements specification

The first step in the process of commissioning and installing a monitoring system is to draw up a user requirements specification (URS). This document sets out the relevant compliance requirements, the operational, technical and business needs, and also outlines

the intended implementation programme. The document should be drafted by a suitably qualified person and then reviewed, revised and finalised in collaboration with all key departments: quality management, warehousing, transport operations, information technology, etc. Once the URS has been drafted, the implementation programme must be carefully planned.

2.3.2 Select the basic system type

There are two fundamentally different design options for a centralised monitoring system. The first is a hosted system and the second is the Solution as a Service (SaaS) approach.

- *Hosted system:* The monitoring system is fully installed and hosted by the commissioning organization. The server and database are stored, managed and maintained by the organization, which is also responsible for maintaining the system and ensuring its qualification.

  For small scale facilities with limited cold chain equipment, such as primary health care facilities and small pharmacies, the most appropriate hosted system will often be a standalone device; typically a simple portable electronic recorder which can be directly read by the person responsible for the cold chain equipment.

- *Solution as a Service (SaaS):* The monitoring system hardware (sensors and readers) is installed at the organization's site, but the software, server and database are hosted by the system supplier. The data are collected, stored and managed by the supplier whilst the organization has access to the data through a secure web interface. In this scenario, the system supplier ensures the system maintenance and qualification.

Choosing between these options is a key decision, with long-term operational and financial implications.

2.3.3 Match the system to the needs

Monitoring systems should be carefully chosen to match the specific needs of the application; this could be a small pharmaceutical store, a single large-scale warehouse, or an operation with multiple warehousing sites. In addition, the type of organization is relevant; for example whether it is a 3PL, a wholesaler or a distributor. Each combination of operator and operation will have different monitoring and reporting requirements. The following sections outline a few of these.

Large pharmaceutical warehouses: Large pharmaceutical warehouses typically have complex infrastructure with a mix of storage areas. These may include primary warehousing, mezzanine floors, vaults and cages, cold rooms, walk-in coolers and refrigerators and freezers. These organizations require reliable and adaptable monitoring systems with hardware that is designed for use on industrial sites. Wireless (RF) sensor networks are a suitable technology for these types of facility. Alternatively, hard-wired sensor systems may be used. Regardless of the chosen system, it is essential that it is compatible with the storage environment and can be altered and extended as necessary to suit changing needs. A web-based system, centrally hosted and monitored by the organization, is typically used by these types of facility.

Hospitals: Pharmacies, laboratories, blood and tissue banks are typical of the hospital storage areas that need to be equipped with a monitoring system. These institutions have specific communication and technical requirements and system compatibility challenges (e.g. wireless communication) that may limit system choice.

Small-scale pharmacies and laboratories: Pharmacies and laboratories may find it cheaper and more convenient to use an externally hosted SaaS system because of the cost and complexity of the IT and operational requirements needed to support an in-house hosted system. Hardware is installed in the storage areas but the supplier hosts the software and the database, making the data accessible on-demand. This type of system generally uses wireless sensors (RF or WiFi), as they are easier to install in smaller facilities than wired systems. The size and location of the facility will determine the final choice; at the smaller end of the scale there is an overlap with small storage facilities.

Small storage facilities: These facilities also require reliable and adaptable monitoring systems. Small storage facilities typically have limited equipment for storing TTSPPs such as a small walk-in cold room and/or refrigerator(s) and freezer(s). In stores with several pieces of equipment, a small-scale version of a system suitable for large pharmaceutical warehouses may be appropriate. In peripheral stores such as health facilities or retail pharmacies a 30-day temperature recorder (30DTR)[5] may be all that is needed – see Figure 1. An SMS-enabled device can offer out-of-hours assurance because staff can receive alarm alerts on their mobile phones. A USB-enabled device allows temperature records to be downloaded and these records can then be reported to supervisory staff.

Figure 2 – 30-day temperature recorders

FridgeTag2™ with USB

LogTag® temperature recorder

2.3.4 *Automated continuous monitoring*

The monitoring system should preferably be automated and continuous. Installing a real-time or nearly real-time data recording system is clearly an advantage, except in the

[5] Typically these devices have an operating life of two or three years, after which they need to be replaced.

smallest facilities. Automated data monitoring provides reliability advantages compared to manual measurements, which rely on human intervention. Because data needs to be recorded accurately and continuously, a cost effective and efficient monitoring platform is also required.

Automated monitoring systems provide an array of analytical and reporting functions that can be accessed easily from any connected device (computer, phone, or PDA). Reports based on time, date, activity, input, event type or multiple criteria can then be generated. Data can also be compiled and analysed over longer periods of time so that trending and risk analysis exercises can be conducted.

2.3.5 *Data collection: wireless* versus *wired data transmission*

A typical monitoring system consists of a network of sensors which are linked together to form an integrated electronic temperature and event logger system. Data transmission through this network may be done through wireless communication modes (Bluetooth, Wi-Fi, Radio-Frequency (RF) 418/433 MHz, 900 MHz, etc) or through a wired network (e.g.. Ethernet). Both system options can be either installed as a stand alone system or as a SaaS. The advantages of using a SaaS solution is to outsource the management of the system as well as upgrades and validation/qualification. Figure 2 illustrates some typical arrangements.

Figure 2 – Monitoring system options

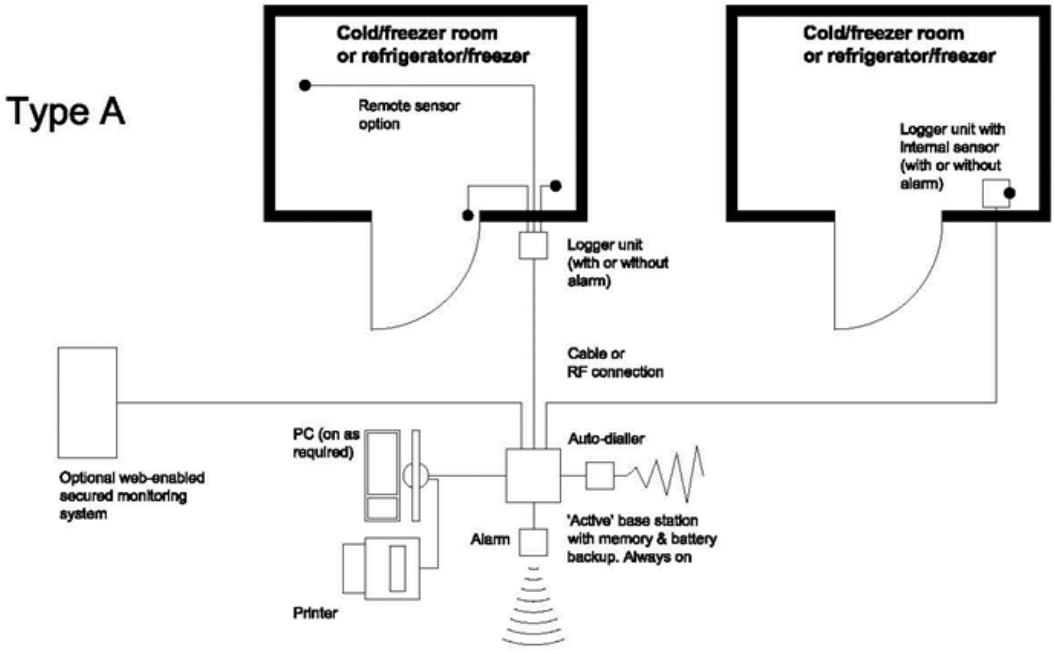
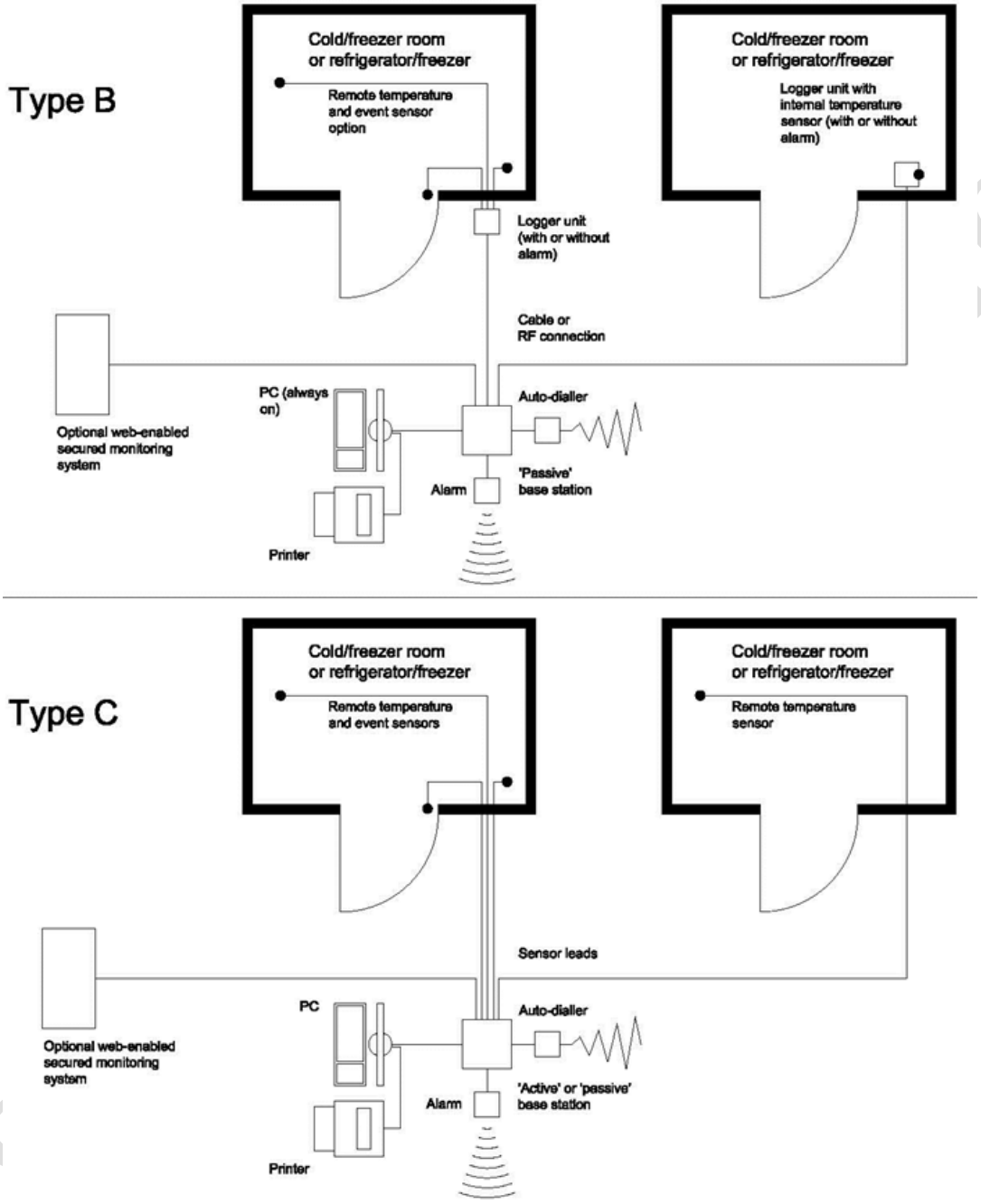


Figure 2 – Monitoring system options (continued)



Source: WHO/PQS

Wired sensors provide reliable data recording; however they can also require complex and costly installation and this technology inhibits simple changes to the network configuration. Monitoring networks with wired sensors are also limited in the adaptability of the monitoring architecture. This complicates matters when equipment needs to be moved, or a warehouse needs to be reconfigured, potentially incurring additional costs.

Wireless monitoring systems are now widely available, with different wireless transmission modes that can be adapted to suit the needs of the organization.

Wireless systems are supported on a local area network and are easier to install and use; this reduces costs and the time required for installation and maintenance.

2.3.6 Specific requirements for wireless networks

Wireless sensor networks should have the following technical characteristics:

- Sensors should continuously collect and buffer data, even during network outages and power cuts. The buffered data should then be sent to the host server when the connection is re-established. Ideally, sensors should have a built in data storage capability so that they can also act as data loggers.
- Sensors should be chosen to suit the different monitoring functions required in the network. This may include: temperature sensors for ambient and refrigerated stores, sensors with remote probes for low temperatures, temperature and relative humidity sensors and sensors for logging events such as door opening.
- Sensor accuracy: ± 5% maximum accuracy. Generally speaking, a sensor accuracy of ± 0.5 °C or better should be expected.
- Sensors should be calibrated annually. An annual calibration plan for the system sensors should be planned and designed so that it can be carried out without major disruption to the monitoring process.
- The wireless sensor network should be self-adaptable, and self-healing: sensors should also act as data transmitters within the network.
- The wireless sensor network should automatically detect and incorporate newly installed sensors.

For a wireless system, the sensor-reader subsystem should also be evaluated in terms of transmission capability, efficacy (e.g. ability to transmit through walls or doors) and power consumption. In a complex or extended monitoring scenario, wireless configurations should be tested to avoid dead zones or wireless transmission concerns.

2.3.7 Web-based systems

Web-based systems should be user-friendly, even if they are required to perform complex operations. This minimizes training requirements, reduces the time taken to deploy the system and enables the user organization to obtain maximum performance.

Monitoring systems typically operate over existing local area networks (LAN) and wide area networks (WAN), using TCP/IP, and should provide the ability to manage multiple users, buildings and sites.

Web-based systems generally emphasize ease of use, with system dashboards enabling the user to trace operations and activities, to see and follow-up all alarms, and to compile data into preformatted reports. Web-based systems also allow the data to be stored in the internet 'cloud' rather than at a specific facility. Authorized users have access to an online database via secure access arrangements. When systems of this type are adopted they should be subject to system validation/qualification before any use.

Monitoring solutions should incorporate a complete management system that includes the following features:

- User management;
- Sensor inventory management;
- Site calibration management;
- A system for reading the sensors, installed at every site;
- All sensors or tags clearly assigned to a specified location;
- Management of alarm set points;
- A system for directing alarm messages to specific individuals.
- The system that allows rapid tracking of system activities; tracking could be by combinations of location, sensor, tag, document (e.g. way bill), user or date.

2.3.8 Alarm system

The monitoring system should include an integrated alarm function that reports out-of-range events. Alarms should be managed automatically. Alarm limits should only be set by authorized users and should automatically alert responsible staff via email, SMS text message or other communication medium in case of out-of-range events or incidents.

Available equipment includes combinations of audible and visual alarms and electronic messaging systems; the latter allow authorized users to be alerted via e-mail, phone or text (SMS) message. A fully integrated system should allow the user to set an alarm schedule for different alert levels – for example work days, weekends and holidays.

2.3.9 User controls

Data needs to be recorded accurately and in real-time, and should be provided in the form of reports, charts, and graphs, which users are able to customize.

The system should allow all sensor and alarm parameters to be configured and customized by users. For instance, it should be possible to configure the sensor recording (sampling) rate or set a variety of parameters for the alarm settings. These could include:

- Low and high alarm threshold settings, triggered *before* temperature goes out of range;
- Low and high alarm settings, triggered *after* temperature goes out of range;
- Event alarms such as mains power failure or door open.

Reports should be customizable by users: format (text, pdf, graph…), time period and content (high and low temperature events, MKT analysis).

2.3.10 Adaptability and expandability

Unless the user requirement is very simple, it is wise to choose an adaptable and scalable system. A fully flexible system should support the following features:

- Ease of configuration for small-scale or large-scale facilities;

- Central monitoring of multiple remote sites;
- On-site hosting or vendor-hosting (SaaS);
- Open architecture, allowing future expansion and upgradeability. Such systems can include enhanced features such as:
  - Monitoring other parameters (airflow, pressure, flooding, movement, etc.).
  - Integrated monitoring of transport systems (refrigerated and temperature-controlled vehicles or containers)[6].
  - Automatically detecting and monitoring mobile sensors and tags (e.g. RFID)

It is important to determine both short-term and long-term needs. Making the correct initial choice makes it possible to scale appropriately if needed. Scaling possibilities can range from monitoring a specific storage area all the way up to installing a national cold chain monitoring system.

2.3.11 Security and compliance

There are specific security and compliance requirements which apply to monitoring systems and they should be installed and managed in accordance with relevant standards and regulations such as 21CFR part 11, and GAMP. Specifically:

- Audit trails should be included in the system;
- The database and the data that it holds should be secured;
- There should be a comprehensive set of Standard Operating Procedures (SOPs) covering installation, use, backup and decommissioning operations. For training purposes, a tutorial should be also available to users.
- Installed systems should be fully qualified by following the installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) sequence;
- The system should provide different 'user levels'; each of these levels should have clearly defined authorization and access privileges.

2.4 Maintenance and support

Monitoring systems are a crucial to compliance with industry regulations and any system failures have to be resolved as rapidly as possible. Whether the system is hosted or SaaS, this means that a 24/7 technical support plan should be part of the contract package. This package should include a requirement for the installer or service provider to cover maintenance, support and warranties for both hardware and software. The support period and the renewal arrangements need to be defined in the URS.

[6] See Technical Supplement: *Temperature and humidity monitoring systems for transport operations.*

2.5 System extent

A comprehensive monitoring system for TTSPPs should be designed to record temperature and relative humidity for all storage areas where these products are stored or temporarily held. The system should extend to include the following areas:

- *General warehouse areas:* All warehousing areas, including distinct zones such as mezzanines and controlled ambient stores.
- *Cages, vaults and temporary holding areas*: Cages, vaults, preparation rooms and other spaces, such as packing, loading and quarantine areas where TTSPPs are handled and stored.
- *Cold chain equipment:* This includes refrigerated or frozen storage equipment used to store TTSPPs (freezer rooms, cold rooms, freezers and refrigerators).
- *Conditioning equipment:* Refrigerators and freezers used to store and condition cold chain packaging materials should ideally be linked into the monitoring system. These materials include ice-packs, cool water-packs, gel packs or PCMs.

2.5.1 Number of monitoring points

For ambient warehousing, controlled ambient stores, preparation rooms, temporary holding areas, freezer rooms, cold rooms and other spaces that people can physically enter, the number of monitoring points depends on the size of the space and on the diurnal and seasonal temperature variations observed during the mapping studies. This may change from one facility to another. Refer to Technical Supplement: *Temperature mapping of storage areas.*

For small-scale reach-in equipment such as refrigerators and freezers, a minimum of one monitoring point or monitoring device should be installed in the storage chamber. *Note:* some national regulatory agencies require two sensors: one positioned at the coolest point and one positioned at the warmest point. The correct locations may be determined by on-site temperature mapping, or they may be determined during laboratory testing at the design qualification (DQ) stage.

2.5.2 Location of monitoring points

As previously noted, monitoring points should be located in all places where TTSPPs are stored or handled. The correct locations are established as follows:

- *Ambient and controlled ambient storage areas:* Position sensors in the places where seasonal hot and cold spots have been observed during the mapping studies.
- *Freezer rooms and cold rooms*: Position sensors in the places where operational hot and cold spots have been observed during the qualification and/or mapping studies.
- *Freezers and refrigerators*: See 2.5.1.

Monitoring points should NOT be placed in areas where transient events such as a door opening may affect the monitoring and generate an abnormally high number of alarms. If

such transient events generate out-of-range temperatures alarms too frequently and the problem cannot be resolved technically or operationally (e.g. by limiting the number of door opening events), these areas should not be used to store TTSPPs and should not be monitored.

Note: Refer to Technical Supplement: *Temperature mapping of storage areas* for further information on how to determine hot and cold spots, based on the analysis of mean temperature.

2.6 Complimentary services

Implementing an effective and reliable monitoring system is a complex task; its installation, operation and maintenance involves a number of complimentary linked services. The scope of these complimentary services need to be clearly defined in terms of:

- *Technical assistance and support:* What is the extent of the proposed technical service? What other technical assistance can the supplier provide? How will system problems (like component failure) be managed? Can spare components be kept at the site?
- *System maintenance and upgrades*: How will maintenance and system or component upgrades be managed? Is the system associated with a preventive maintenance program?
- *Calibration:* How are sensors calibrated and by whom? How is calibration performed without system disruption?
- *Regulatory compliance:* What is the regulatory package provided with the system? (Training, SOPs and Qualification).

2.7 Deploying the system

Deployment is achieved by following a step-by-step process. The relevant departments in the commissioning organization (e.g. Operations, IT, Technical, etc.) must work closely with the system supplier to agree a deployment plan, and this plan must be closely monitored as the installation and commissioning activities proceed.

To streamline implementation, a *monitoring start-up form can* be used to facilitate an exchange between the organization and the supplier and cover all the points related to the system's deployment – see **Annex 1**.

2.8 Post-installation setup and qualification activities

Once the system has been installed, the system operator will need to set the system parameters; this includes defining user privileges, alarm settings, etc. The system should then be operated for a commissioning period so that adjustments can be made and operational problems can be detected and resolved. Once the system is operating correctly it is time to perform final qualification (IQ/OQ/PQ) as described in the companion Technical Supplement: *Guidance on qualification practices for temperature-controlled storage areas.*

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- US Food and Drug Administration. *Title 21--Food and Drugs. Chapter I--Food and Drug administration Department of Health and Human Services. Subchapter A--General. Part 11 Electronic Records; Electronic Signatures 21 CFR Part 11.* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=11.
- WHO Technical Report Series No. 961, 2011, Annex 9: *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical* http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf

Annex 1 – Monitoring system start-up form example

SECTION 1: Person in charge

Contact details:

Name: Megapharm

Address: Unit 10, Erehwon Industrial Estate, Erehwon City

Tel: +101 1234 5678

Fax: +101 1234 7891

Website / email: www.erehwon.com

Approvals:

Determine who will be responsible for the approval of the documentation.

Type						Name	Title	Department
Contract	User requirements	Specifications	Deployment	Qualification protocol	Change control			
✓				✓	✓		Project manager	Admin
	✓	✓		✓	✓		Quality assurance	QA
			✓				IT manager	IT

Employees in charge:

Determine who will be in charge of the different activities.

Project manager			
Name	**Title**	**Department**	**Phone / email**
Dr A. Projmann	Project Manager	Property Department	

IT			
Name	**Title**	**Department**	**Phone / email**
Ms A. Hardrive	Systems Analyst	IT Department	

SECTION 1: Person in charge			

Employees in charge:

Determine who will be in charge of the different activities.

Quality assurance			
Name	**Title**	**Department**	**Phone / email**
Mr A. Qualman	Quality Manager	QA Department	

Instrumentation			
Name	**Title**	**Department**	**Phone / email**
Mr A. Instman	Quality Assistant	QA Department	

Maintenance			
Name	**Title**	**Department**	**Phone / email**
Ms A. Tidystore	Maintenance Mgr	Property Department	

Security			
Name	**Title**	**Department**	**Phone / email**
Mr A. Guardian	Security Manager	Security Department	

Pager/Alarm			
Name	**Title**	**Department**	**Phone / email**
n/a			

SECTION 1: Person in charge

Dr A. Projmann

Miscellaneous			
Name	**Title**	**Department**	**Phone / email**
n/a			

SECTION 2. Project description

Example:

- Installation of wireless sensors in South warehouse (12,000 square metres), including one walk-in cooler and one walk-in freezer.

SECTION 3. Technological risk

- Very crowded storage area using many different types of RF communication system.
- Energy source not always reliable.

SECTION 4 Regulatory risk

- None

SECTION 5. Data

- None

SECTION 6. Constraints

- Interference with the communication between wireless sensors and readers (antennas) may occur.

SECTION 7. Pre-installation checklist

☒ Availability of floor plan:

- South warehouse plan SW-001B

☒ Location of Ethernet Service Panel:

- 3 locations in storage area plus server room SR01

☒ Availability of power outlet in Ethernet Service Panel:

- Same as above

☒ Availability of power outlet:

- See layout SW-001B

☐ Range of IP addresses:

-

☒ Location of Server Room (also on plan):

- See layout SW-001B, room SR01

☒ All equipment is clearly identified and listed.

-

☐ Location of antenna support panel ☒ Location of server room on plan

☒ Identification of potential causes of interference:

- Care needed in placing sensors and antennae. The warehouse is very crowded and there is much equipment that can interfere with the communication between wireless sensors and readers.

Required component summary

Comm/ PSupp.	Qty	Temp. sensor	Qty	Humidity sensor	Qty	Wall plate/box	Qty
Com manager	1	RF 900MHz	28	RF 900MHz	4	Wall mount	32
Power supply	1						

Comments

None

Revision history

Date	Change summary	Reason for change	Approved