

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*

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## Abbreviations

3PL	third-party logistics (provider)
30DTR	30-day temperature recorder
GAMP	good automated manufacturing practice
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
TTSP	time- and temperature-sensitive pharmaceutical product
URS	user requirements specification
USB	universal serial bus

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## Glossary

**3PL:** Third-party logistics provider – a firm that provides service to its customers of outsourced (or "third party") logistics services for part, or all of their supply chain management functions.

**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 stand-alone unit (e.g. valves and switches).

**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.<sup>1</sup>

**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.

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

**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 TTSP label, and within the regulatory filings, for long-term storage.

**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 predefined limits.

**Temperature excursion:** An event in which a TTSP 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 (TTSP):** Any pharmaceutical good or product which, when not stored or transported within predefined environmental conditions and/or within predefined 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 predetermined acceptance criteria.<sup>2</sup>

<sup>2</sup> Parenteral Drug Association (PDA). Technical Report No. 39: Guidance for temperature controlled medicinal products: maintaining the quality of temperature-sensitive medicinal products through the transportation environment. Bethesda (MD): PDA; 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*.<sup>3</sup> 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 TTSPs. Electronic sensors should be accurate to  $\pm 0.5^{\circ}\text{C}$  or better.<sup>4</sup> 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 TTSPs that require a humidity-controlled environment. Monitoring sensors should be accurate to  $\pm 5\%$  relative humidity (RH) and located to monitor worst-case humidity levels within the qualified

<sup>3</sup> <http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf>

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

storage volume. 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 preferably also an audible alarm, together with automatic telephone dial-up or short message service (SMS) text warnings to key personnel.

### 1.2 Objectives

The objective of this 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 are 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 a critical component of GSP in all areas, 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 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

To enable this guidance to 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 affected 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 (installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ)). See *Technical Supplement: Qualification of temperature-controlled storage areas*.
- d. Ensure that all storage areas and equipment comply 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 while minimizing the need for manual

measuring and recording. Such a monitoring system is increasingly required in facilities storing TTSPs. 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 is a document setting out the relevant compliance requirements, and the operational, technical and business needs. It also outlines the intended implementation programme. The document should be drafted by a suitably qualified person and then reviewed, revised and finalized in collaboration with all key departments such as quality management, warehousing, transport operations, and information technology (IT). 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 centralized 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 stand-alone device; typically a simple portable electronic recorder which can be directly read by the person responsible for the cold chain equipment.
- *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 and the organization has access to the data through a secure web interface. Under this arrangement, 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 provide some examples.

*Large pharmaceutical warehouses:* Large pharmaceutical warehouses typically have a 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 (radio frequency (RF)) sensor networks are a suitable technology for these types of facility. Alternatively, hard-wired sensor systems may be used. Regardless of the system chosen, 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 TTSPs, 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)<sup>5</sup> may be all that is needed – see Figure 1.

<sup>5</sup> Typically these devices have an operating life of two or three years, after which they need to be replaced.

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 1  
R30-day temperature recorders



#### 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 smallest facilities. Automated data monitoring provides reliability advantages compared to manual measurements, which rely on human intervention. Because data need 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 personal digital assistant). 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 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 (e.g. Bluetooth, Wi-Fi, RF 418/433 MHz, 900 MHz) or through a wired network (e.g. Ethernet). Both system options can be either

installed as a stand-alone system or as an SaaS. The advantage of using an SaaS solution is that the management of the system as well as upgrades and validation and qualification are outsourced. Figure 2 illustrates some typical arrangements.

Figure 2  
Monitoring system options

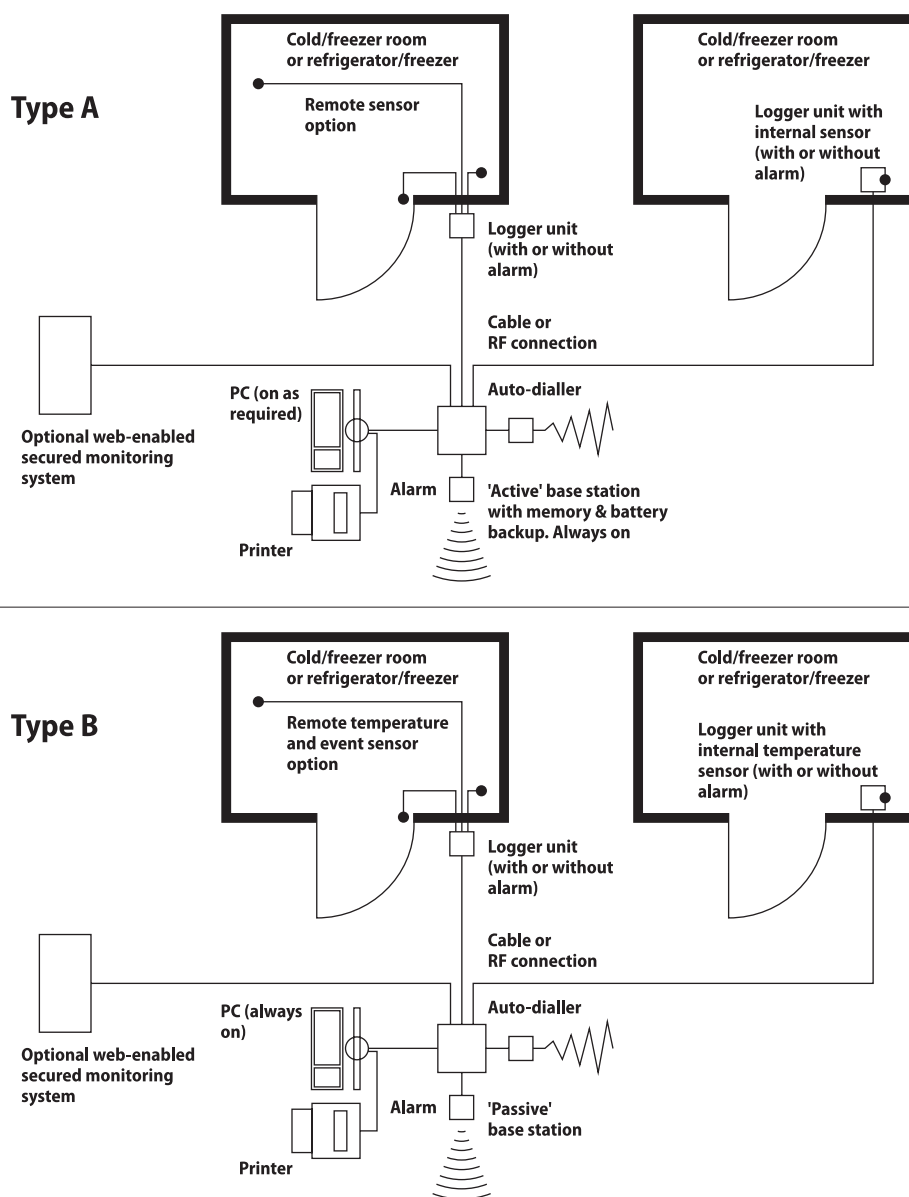
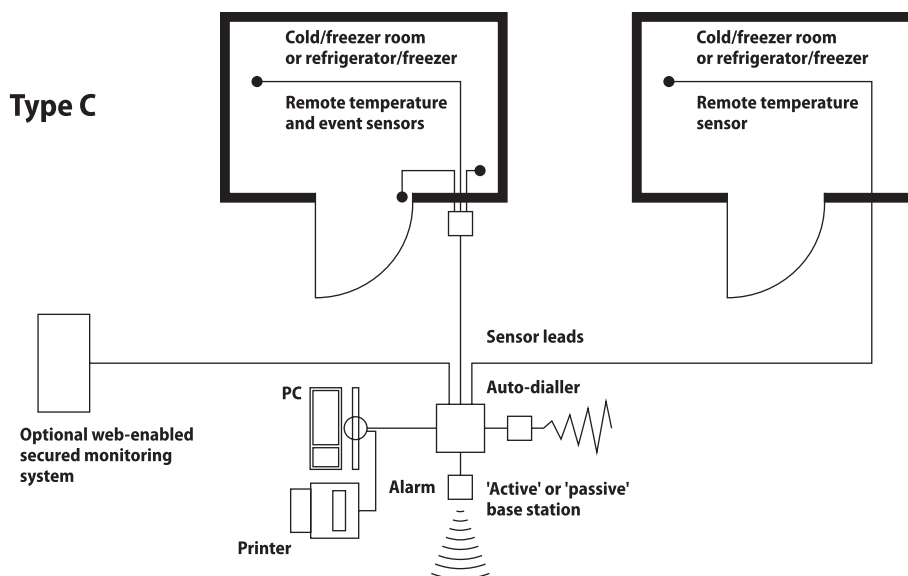


Figure 2 continued



Source: WHO/PQS

Wired sensors provide reliable data recording; however their installation can be complex and costly and this technology inhibits simple changes to the network configuration. Monitoring networks with wired sensors are also limited in terms of 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 (LAN) 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 RH sensors and sensors for logging events such as door opening.
- Sensor accuracy:  $\pm 5\%$  maximum accuracy. Generally speaking, a sensor accuracy of  $\pm 0.5\text{ }^{\circ}\text{C}$  or better should be expected.
- Sensors should be calibrated annually. An annual calibration plan for the system sensors should be drawn up 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 LANs and wide area networks (WANs), using Transmission Control Protocol/Internet Protocol (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 or qualification before 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;
- a system that allows rapid tracking of system activities; tracking could be by combinations of location, sensor, tag, document (e.g. waybill), 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 be set only by authorized users and should automatically alert responsible staff by email, text (SMS) 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 email, phone or text (SMS) message. A fully integrated system should allow the user to set an alarm schedule for different alert levels – for example workdays, weekends and holidays.

#### 2.3.9 User controls

Data need 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 triggered by events such as mains power failure or door open.

Reports should be customizable by users allowing them to choose the format (text, pdf, graph), time period and content (high and low temperature events, mean kinetic temperature (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 (e.g. airflow, pressure, flooding, movement),
  - integrated monitoring of transport systems (refrigerated and temperature-controlled vehicles or containers),<sup>6</sup>
  - automatically detecting and monitoring mobile sensors and tags (e.g. radio frequency identification device (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

Specific security and compliance requirements apply to monitoring systems and they should be installed and managed in accordance with relevant standards and regulations such as 21CFR part 11, and good automated manufacturing practice (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 also be available to users.
- Installed systems should be fully qualified by following the IQ, OQ and PQ sequence.
- The system should provide different “user levels”; each of these levels should have clearly defined authorization and access privileges.

<sup>6</sup> See Technical Supplement: *Temperature and humidity monitoring systems for transport operations*.

## 2.4 Maintenance and support

Monitoring systems are 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 round the clock 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.

## 2.5 System extent

A comprehensive monitoring system for TTSPPs should be designed to record temperature and RH for all storage areas where these products are stored or temporarily held. The system should 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 equipment used to store TTSPPs in a refrigerated or frozen condition (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 and phase change materials (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 differ 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 TTSPs 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 section 2.5.1.

Monitors 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 temperature 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 TTSPs 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 Complementary services

Implementing an effective and reliable monitoring system is a complex task; its installation, operation and maintenance involve a number of complementary linked services. The scope of these complementary services needs to be clearly defined in terms of the answers the following questions:

- *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 covered by a preventive maintenance programme?
- *Calibration:* How are sensors calibrated and by whom? How is calibration performed without disrupting the system?
- *Regulatory compliance:* What is the regulatory package provided with the system with regard to 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) must work closely with the system supplier to agree a deployment plan, and the execution of 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 set-up and qualification activities

Once the system has been installed, the system operator will need to set the system parameters; this includes defining user privileges and alarm settings and so on. 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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# Annex 1

## Monitoring system start-up form example

SECTION 1: Person in charge								
<p>Contact details:</p> <p>Name: Megapharm</p> <p>Address: Unit 10, Erehwon Industrial Estate, Erehwon City</p> <p>Tel.: +101 1234 5678</p> <p>Fax: +101 1234 7891</p> <p>Website/email: www.erewon.com</p>								
<p><b>Approvals:</b></p> <p>Determine who will be responsible for the approval of the documentation.</p>								
Type						Name	Title	Department
Contract	User requirements	Specifications	Deployment	Qualification protocol	Change control			
✓				✓	✓		Project manager	Admin
	✓	✓		✓	✓		Quality assurance	QA
			✓				IT manager	IT
<p><b>Employees in charge:</b></p> <p>Determine who will be in charge of the different activities.</p>								
<p><b>Project manager</b></p>								
Name		Title		Department		Phone/email		
Dr A. Projmann		Project Manager		Property Department				

**SECTION 1: Person in charge****IT**

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

**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 Manager	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

##### Miscellaneous

Name	Title	Department	Phone/email
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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

*Example:*

- Very crowded storage area using many different types of radio frequency (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/ power supply	Qty	Temp. sensor	Qty	Humidity sensor	Qty	Wall plate/box	Qty
Com manager	1	RF 900 MHz	28	RF 900 MHz	4	Wall mount	32
Power supply	1						

Comments

None



Revision history

Date	Change summary	Reason for change	Approved



