

# Annex 5

## Technical supplements to Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products

(WHO Technical Report Series, No. 961, 2011), Annex 9

<b>1. The technical supplement series</b>	97
1.1 Topics covered	97
1.2 Target readership	98
1.3 Document development and review process	98
<b>Supplement 1</b>	
Selecting sites for storage facilities	100
<b>Supplement 2</b>	
Design and procurement of storage facilities	101
<b>Supplement 3</b>	
Estimating the capacity of storage facilities	103
<b>Supplement 4</b>	
Building security and fire protection	104
<b>Supplement 5</b>	
Maintenance of storage facilities	106
<b>Supplement 6</b>	
Temperature and humidity monitoring systems for fixed storage areas	107
<b>Supplement 7</b>	
Qualification of temperature-controlled storage areas	109
<b>Supplement 8</b>	
Temperature mapping of storage areas	111
<b>Supplement 9</b>	
Maintenance of refrigeration equipment	112
<b>Supplement 10</b>	
Checking the accuracy of temperature control and monitoring devices	114
<b>Supplement 11</b>	
Qualification of refrigerated road vehicles	115

<b>Supplement 12</b>	
Temperature-controlled transport operations by road and by air	117
<b>Supplement 13</b>	
Qualification of shipping containers	118
<b>Supplement 14</b>	
Transport route profiling qualification	119
<b>Supplement 15</b>	
Temperature and humidity monitoring systems for transport operations	120
<b>Supplement 16</b>	
Environmental management of refrigeration equipment	121

# 1. The technical supplement series

This series of technical supplements has been written to amplify the recommendations given in *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011, Annex 9).<sup>1</sup> This document sets out the principal requirements for the safe storage and distribution of time- and temperature-sensitive pharmaceutical products (TTSPPs).

The introduction to the guidance documents states that: “... supplementary materials will be developed to show how the requirements can practicably be achieved, particularly in resource constrained settings.” The technical supplements, which make up this volume, are intended to provide this additional material; each one is linked back to a specific clause or clauses in the parent document. All 16 documents are written in a standard format and each contains a reference section with hyperlinks to relevant supporting materials. Most of these materials are available free online. References to print publications are minimized to avoid the difficulties associated with purchasing books and journals.

## 1.1 Topics covered

Table A5.1 lists the titles of the supplements and the model guidance sections to which each one refers.

Table A5.1

**Titles of supplements and model guidance section to which each refers**

Title	Section(s)
1. Selecting sites for storage facilities	Section 2
2. Design of storage facilities	Section 2 to 5
3. Estimating the capacity of storage facilities	Section 3.1 to 3.4
4. Security and fire protection in storage facilities	Section 3.7
5. Maintenance of storage facilities	Section 3.10
6. Temperature monitoring of storage areas	Section 4.5.2, 4.5.4
7. Qualification of temperature-controlled storage areas	Section 4.7

<sup>1</sup> [http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/ModelGuidanceForStorageTransportTRS961Annex9.pdf?ua=1](http://www.who.int/medicines/areas/quality_safety/quality_assurance/ModelGuidanceForStorageTransportTRS961Annex9.pdf?ua=1).

Table A5.1 *continued*

Title	Section(s)
8. Temperature mapping of storage areas	Section 4.7
9. Refrigeration equipment maintenance	Section 4.9
10. Checking the accuracy of temperature control and monitoring devices	Section 4.10
11. Qualification of refrigerated road vehicles	Section 6.4, 6.5
12. Temperature-controlled transport operations by road and by air	Section 6.5, 9
13. Qualification of shipping containers	Section 6.8.1 to 6.8.4
14. Transport route profiling qualification	Section 6.8.3, 6.8.4
15. Temperature and humidity monitoring systems for transport operations	Section 6.5, 9
16. Environmental management of refrigerant gases and refrigeration equipment	Section 10.2

## 1.2 Target readership

The target readership for the model guidance, and for the technical supplements, includes regulators, logisticians and pharmaceutical professionals in industry, government and international agencies.

## 1.3 Document development and review process

The technical supplements have been written by specialist authors. All 16 supplements passed through the following editorial and public review process.

1. Each document was prepared over the course of several drafts in consultation with the series editor.
2. Acronyms and glossary definitions were harmonized throughout.
3. Public consultation drafts were posted on the WHO website in mid-2014. Review comments were received from a number of people and organizations.
4. Reviews were consolidated by the series editor and sent to the individual authors for initial comment.
5. Amended documents were prepared containing the consolidated comments categorized as “accepted”, “rejected” and “for discussion”.

These new drafts were sent back to the individual authors for further comment.

6. The series editor prepared final drafts based on the authors' responses and these drafts were checked, reviewed and signed off.
7. On the basis of these final comments, clean versions were prepared for review by the Expert Committee on Specifications for Pharmaceutical Preparations and by the Expert Committee on Biological Standardization.

On the following pages, the contents pages of the 16 technical supplements are reproduced. The full texts will be made available in electronic form on the CD-ROM of *Quality assurance of pharmaceuticals* (2015 and updates) and on the website.<sup>2</sup>

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<sup>2</sup> [http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance](http://www.who.int/medicines/areas/quality_safety/quality_assurance).

# Supplement 1

## Selecting sites for storage facilities

### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

### Contents

#### Acknowledgements

#### Abbreviations

#### Glossary

#### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target readership

#### 2. Guidance

- 2.1 Associated materials and equipment
- 2.2 Designing and costing the supply chain
- 2.3 Logistics network planning
- 2.4 Finding a potential site
  - 2.4.1 *Establish the size of the warehouse*
  - 2.4.2 *Narrow down the choices*
  - 2.4.3 *Choose a secure site*
  - 2.4.4 *Choose a future-proof site*
  - 2.4.5 *Ensure labour availability*
  - 2.4.6 *Assess flood risks*
  - 2.4.7 *Assess weather and climate-related risks*
  - 2.4.8 *Assess fire hazards*
  - 2.4.9 *Assess other natural hazards*
- 2.5 Detailed site investigation: identifying risks and opportunities
  - 2.5.1 *Ground conditions and pollution hazards*
  - 2.5.2 *Existing underground and overhead services*
  - 2.5.3 *Site survey*
  - 2.5.4 *Site clearance costs*
  - 2.5.5 *Building surveys*
  - 2.5.6 *Service connections to the site*
  - 2.5.7 *Low carbon energy potential*
  - 2.5.8 *Environmental impact assessment*

#### References

#### Revision history

## Supplement 2

### Design and procurement of storage facilities

#### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

#### Contents

##### Acknowledgements

##### Abbreviations

##### Glossary

#### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target readership

#### 2. Guidance

- 2.1 Associated materials and equipment
- 2.2 Design of pharmaceutical warehouses
  - 2.2.1 *Low-carbon design and environmental auditing*
  - 2.2.2 *Warehouse layouts*
  - 2.2.3 *Temperature-controlled storage areas*
  - 2.2.4 *Cold rooms and freezer rooms*
  - 2.2.5 *Order assembly and packing area*
  - 2.2.6 *Staging area*
  - 2.2.7 *Loading docks*
  - 2.2.8 *Other areas*
  - 2.2.9 *Temperature monitoring, mapping and qualification*
- 2.3 Design of dispensing facilities
  - 2.3.1 *Workflow*
  - 2.3.2 *Working environment and ergonomics*
  - 2.3.3 *Incoming stock*
  - 2.3.4 *Refrigerators*
  - 2.3.5 *Controlled drugs*
  - 2.3.6 *Waste and returns*
  - 2.3.7 *Location and arrangement of stock*
  - 2.3.8 *Separation of stock*
  - 2.3.9 *Patient areas*
  - 2.3.10 *Supervised consumption*
- 2.4 Building procurement
  - 2.4.1 *Preparing and agreeing the brief*

- 2.4.2 *Appointing and working with the consultant team*
- 2.4.3 *Design risk assessment*
- 2.4.4 *Choosing a procurement route for new buildings*
- 2.4.5 *Choosing a procurement route for building alterations or refurbishment*
- 2.4.6 *The client's role in tendering*
- 2.4.7 *The client's role during the construction stage*
- 2.4.8 *Commissioning and handover*

## 2.5 Procuring cold rooms and freezer rooms

### References

#### Annex 1

##### Briefing documents

- A1.1 Statement of need
- A1.2 Strategic brief
- A1.3 Project brief

#### Annex 2

##### Alternative contracts

- A2.1 Lump sum contract
- A2.2 Design and build
- A2.3 Design, build, finance and operate

### Revision history



## Supplement 3

### Estimating the capacity of storage facilities

#### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

#### Contents

Acknowledgements

Abbreviations

Glossary

#### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target readership

#### 2. Guidance

- 2.1 Associated materials and equipment
- 2.2 Inventory management concepts
- 2.3 Collecting product data
  - 2.3.1 Vaccines
  - 2.3.2 General pharmaceuticals, including non-vaccine TTSPPs
  - 2.3.3 Volume data and SKU types
- 2.4 Calculating maximum inventory volumes
  - 2.4.1 Vaccines and related supplies
  - 2.4.2 General pharmaceuticals and supplies, including non-vaccine TTSPPs
- 2.5 Calculating net storage capacity requirements
  - 2.5.1 Classifying products by storage temperature and security category
  - 2.5.2 Load support systems
  - 2.5.3 The utilization factor concept
  - 2.5.4 Pallet bay calculation
  - 2.5.5 Shelving unit calculation
  - 2.5.6 Closed shelving units and safety cabinets
  - 2.5.7 Refrigerators and freezers
  - 2.5.8 Load optimization tools

References

Tools

Revision history

## Supplement 4

### Building security and fire protection

#### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

#### Contents

##### Acknowledgements

##### Abbreviations

##### Glossary

#### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target audience
- 1.4 Associated materials and equipment

#### 2. Guidance

- 2.1 Site security and emergency access
- 2.2 General building security
- 2.3 Controlled and hazardous substances areas
- 2.4 Fire detection systems
- 2.5 Fire suppression equipment
  - 2.5.1 *Smoke ventilation systems*
- 2.6 Compartmentation
  - 2.6.1 *Sprinkler systems*
- 2.7 Fire prevention, training and control procedures
  - 2.7.1 *Risk assessment*
  - 2.7.2 *Fire prevention*
  - 2.7.3 *Fire safety training*
  - 2.7.4 *Fire control procedures*

#### References

##### Annex 1

- SOP: fire safety housekeeping
  - A1.1 Policy and objectives
    - A1.1.1 *Policy*
    - A1.1.2 *Objectives*
  - A1.2 Responsibility
  - A1.3 Associated materials and equipment

#### A1.4 Procedure

*A1.4.1 Reducing ignition sources*

*A1.4.2 Reducing fuel load*

*A1.4.3 Maintenance of fire protection measures*

#### A1.5 Related documents

### **Annex 2**

SOP: routine inspection and maintenance

#### A2.1 Policy and objectives

*A2.1.1 Policy*

*A2.1.2 Objectives*

#### A2.2 Responsibility

#### A2.3 Associated materials and equipment

#### A2.4 Procedure

*A2.4.1 Daily inspections*

*A2.4.2 Weekly inspections*

*A2.4.3 Monthly inspections*

*A2.4.4 Three-monthly inspections*

*A2.4.5 Six-monthly inspections*

*A2.4.6 Yearly inspections*

#### A2.5 Related documents

### **Annex 3**

SOP: fire drills

#### A3.1 Policy and objectives

*A3.1.1 Policy*

*A3.1.2 Objectives*

#### A3.2 Responsibility

#### A3.3 Associated materials and equipment

#### A3.4 Procedure

*A3.4.1 Conducting test evacuations*

#### A3.5 Related documents

### **Revision history**

## Supplement 5

### Maintenance of storage facilities

#### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

#### Contents

##### Acknowledgements

##### Abbreviations

##### Glossary

#### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target readership

#### 2. Guidance

- 2.1 Associated materials and equipment
- 2.2 What is maintenance and why is it important?
- 2.3 The building design and construction phase
  - 2.3.1 *The operation and maintenance manual*
  - 2.3.2 *The health and safety file*
- 2.4 Maintenance management
  - 2.4.1 *Establish an institutional or contractual framework*
  - 2.4.2 *Preventive maintenance and replacement: standards and schedules*
  - 2.4.3 *Establish a multiyear maintenance plan*
  - 2.4.4 *Planned periodic inspections*
  - 2.4.5 *Planned service inspections*
  - 2.4.6 *Curative maintenance*
  - 2.4.7 *Organizing and managing the work*
  - 2.4.8 *Inspecting and signing off the work*

#### References

##### Annex 1

Uniclass: building elements

##### Annex 2

Checklist for building weatherproofing

#### Revision history

## Supplement 6

### Temperature and humidity monitoring systems for fixed storage areas

#### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

#### Contents

##### Acknowledgements

##### Abbreviations

##### Glossary

#### 1. Introduction

##### 1.1 Requirements

*1.1.1 Temperature monitoring systems*

*1.1.2 Humidity monitoring systems*

*1.1.3 Alarm systems*

##### 1.2 Objectives

##### 1.3 Target readership

#### 2. Guidance

##### 2.1 Associated materials and equipment

##### 2.2 Related activities

##### 2.3 Choosing a monitoring system

*2.3.1 Prepare a user requirements specification*

*2.3.2 Select the basic system type*

*2.3.3 Match the system to the needs*

*2.3.4 Automated continuous monitoring*

*2.3.5 Data collection: wireless versus wired data transmission*

*2.3.6 Specific requirements for wireless networks*

*2.3.7 Web-based systems*

*2.3.8 Alarm system*

*2.3.9 User controls*

*2.3.10 Adaptability and expandability*

*2.3.11 Security and compliance*

##### 2.4 Maintenance and support

##### 2.5 System extent

*2.5.1 Number of monitoring points*

*2.5.2 Location of monitoring points*

- 2.6 Complementary services
- 2.7 Deploying the system
- 2.8 Post-installation setup and qualification activities

## References

### Annex 1

Example of form for monitoring system start-up

### Revision history

## Supplement 7

### Qualification of temperature-controlled storage areas

#### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

#### Contents

#### Acknowledgements

#### Abbreviations

#### Glossary

#### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target readership

#### 2. Guidance

- 2.1 Associated materials and equipment
- 2.2 Introduction to qualification
  - 2.2.1 *Qualification applied to temperature-controlled storage*
  - 2.2.2 *Installation qualification*
  - 2.2.3 *Operational and performance qualification*
- 2.3 Qualification protocols
  - 2.3.1 *Approval page and change control history*
  - 2.3.2 *Acronyms and glossary*
  - 2.3.3 *Description and rationale*
  - 2.3.4 *Scope and objectives*
  - 2.3.5 *Key parameters*
  - 2.3.6 *Procedures*
  - 2.3.7 *Qualification report template*
  - 2.3.8 *Approval process*
- 2.4 Installation qualification
  - 2.4.1 *Identifying critical components*
  - 2.4.2 *Checking installed systems, subsystems and components*
  - 2.4.3 *Checking electrical systems and requirements*
  - 2.4.4 *Checking environmental conditions*
  - 2.4.5 *Checking spare parts*
  - 2.4.6 *Checking auxiliary equipment*
  - 2.4.7 *Checking information needed for the preventive maintenance programme*

- 2.4.8 *Writing the IQ report*
- 2.5 Operational qualification
  - 2.5.1 *Checking installed systems, subsystems and components*
  - 2.5.2 *Calibration of controllers and sensors*
  - 2.5.3 *Standard operating procedures*
  - 2.5.4 *Control panel*
  - 2.5.5 *Alarm tests*
  - 2.5.6 *Temperature mapping – empty*
  - 2.5.7 *Power failure test*
  - 2.5.8 *Writing the OQ report*
- 2.6 Performance qualification
  - 2.6.1 *Checking installed systems, subsystems and components*
  - 2.6.2 *Temperature mapping – full*
  - 2.6.3 *Temperature recovery after door opening*
  - 2.6.4 *Writing the PQ report*
- 2.7 Specific requirements for small-scale equipment

## **References**

## **Revision history**

## **Annex 1**

Form for reporting deviations and corrective action



## Supplement 8

### Temperature mapping of storage areas

#### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

#### Contents

#### Acknowledgements

#### Abbreviations

#### Glossary

#### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target readership

#### 2. Guidance

- 2.1 Associated materials and equipment
- 2.2 The mapping protocol
  - 2.2.1 *Approval page and change control history*
  - 2.2.2 *Acronyms and glossary*
  - 2.2.3 *Description and rationale*
  - 2.2.4 *Scope*
  - 2.2.5 *Objectives*
  - 2.2.6 *Methodology*
  - 2.2.7 *Mapping report template*
- 2.3 Conducting the mapping exercise
- 2.4 Analysing the data and preparing the mapping report
  - 2.4.1 *Preliminary analysis*
  - 2.4.2 *Minimum and maximum temperatures and hot and cold spots*
  - 2.4.3 *Mean temperatures*
  - 2.4.4 *Interpreting the results and making recommendations*
  - 2.4.5 *Report auditing*
- 2.5 Implementing the mapping report recommendations

#### References

#### Annex 1

##### Test data sheets

- A1.1 Test data sheet: temperature data logger locations
- A1.2 Test data sheet: temperature distribution
- A1.3 Test data sheet: temperature distribution

#### Revision history

## Supplement 9

### Maintenance of refrigeration equipment

#### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

#### Contents

##### Acknowledgements

##### Abbreviations

##### Glossary

#### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target readership

#### 2. Guidance

- 2.1 Associated materials and equipment
- 2.2 Active and passive transport containers
- 2.3 Refrigerators and freezers
- 2.4 Freezer rooms, cold rooms and controlled ambient stores
  - 2.4.1 *Maintenance overview*
  - 2.4.2 *Maintaining the cooling system*
  - 2.4.3 *Maintaining insulated panels and vapour control sealing*
  - 2.4.4 *Condensation control outside the cold store enclosure*
  - 2.4.5 *Frost-heave control*
  - 2.4.6 *Cold store panel insulation*
  - 2.4.7 *Insulation for refrigeration pipes and other penetrations*
  - 2.4.8 *Cold store maintenance schedule*
- 2.5 Refrigerated vehicles
  - 2.5.1 *Refrigerated vans*
  - 2.5.2 *Refrigerated rigid bodies*
  - 2.5.3 *Refrigerated semi-trailer*
- 2.6 Refrigerated containers
- 2.7 Maintenance management
- 2.8 Decommissioning
- 2.9 Staff training

## **References**

### **Annex 1**

#### Checking refrigerated vehicles

A1.1 Checking insulation on a refrigerated vehicle

A1.2 Checking cooling equipment on a refrigerated van

A1.3 Checking cooling equipment on a rigid vehicle or semi-trailer

### **Revision history**

## Supplement 10

### Checking the accuracy of temperature control and monitoring devices

#### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

#### Contents

Acknowledgements

Abbreviations

Glossary

#### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target readership

#### 2. Guidance

- 2.1 Associated materials and equipment
- 2.2 Procedure
  - 2.2.1 Prerequisites
  - 2.2.2 Establishing the ice-point bath (excerpt from ASTM E563-11)
  - 2.2.3 Placing the device in the bath
  - 2.2.4 Carrying out the accuracy check, step by step
  - 2.2.5 Maintaining the bath temperature
  - 2.2.6 Actions to take following the test

References

#### Annex 1

Generic temperature accuracy check form

Revision history

# Supplement 11

## Qualification of refrigerated road vehicles

### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

### Contents

#### Acknowledgements

#### Abbreviations

#### Glossary

### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
  - 1.2.1 *Verification*
  - 1.2.2 *Qualification*
- 1.3 Target readership

### 2. Guidance

- 2.1 Associated materials and equipment
- 2.2 Preliminary construction validation
  - 2.2.1 *Temperature-controlling equipment*
  - 2.2.2 *Thermal insulation*
  - 2.2.3 *Performance checks*
- 2.3 Field shipment test
  - 2.3.1 *Purpose*
  - 2.3.2 *Loading*
  - 2.3.3 *Temperature probe placement*
  - 2.3.4 *Test procedure*
  - 2.3.5 *Acceptance criteria*
- 2.4 Temperature-control failure test
  - 2.4.1 *Purpose*
  - 2.4.2 *Loading*
  - 2.4.3 *Temperature probe placement*
  - 2.4.4 *Test procedure*
  - 2.4.5 *Acceptance criteria*
- 2.5 Documentation
  - 2.5.1 *Designation of the vehicle*
  - 2.5.2 *Results of the qualification*
- 2.6 Vehicle qualification failure
- 2.7 Calibration

## References

### Annex 1

Placing EDLMs or temperature sensors

### Revision history

# Supplement 12

## Temperature-controlled transport operations by road and by air

### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

### Contents

#### Acknowledgements

#### Abbreviations

#### Glossary

#### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target readership

#### 2. Guidance

- 2.1 Associated materials and equipment
- 2.2 Available shipping systems
  - 2.2.1 *Refrigerated vehicles – temperature-controlled*
  - 2.2.2 *Refrigerated vehicles – temperature-modified*
  - 2.2.3 *Passive shipping systems*
  - 2.2.4 *Active shipping systems for air transport*
- 2.3 Quality agreements
  - 2.3.1 *User requirements specification*
  - 2.3.2 *Service level agreements*
- 2.4 Identifying and controlling risk
- 2.5 Managing refrigerated road shipments
- 2.6 Managing passive container road shipments
- 2.7 Introduction to air transport
  - 2.7.1 *Types of air carrier*
  - 2.7.2 *Air transport labelling for TTSPPs*
- 2.8 Air transport processes
- 2.9 Managing air shipments

#### References

#### Annex 1

Packing a refrigerated vehicle

#### Revision history

## Supplement 13

### Qualification of shipping containers

#### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

#### Contents

##### Acknowledgements

##### Abbreviations

##### Glossary

#### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target readership

#### 2. Guidance

- 2.1 The three stages of qualification
  - 2.1.1 *Design qualification*
  - 2.1.2 *Operational qualification*
  - 2.1.3 *Performance qualification*
  - 2.1.4 *Requalification of reusable container systems*
- 2.2 Associated materials and equipment
  - 2.2.1 *Test equipment for design and operational qualifications*
  - 2.2.2 *Test equipment for performance qualification*
- 2.3 The performance qualification test protocol
  - 2.3.1 *Protocol title*
  - 2.3.2 *Protocol approvals*
  - 2.3.3 *Introduction*
  - 2.3.4 *Purpose*
  - 2.3.5 *Scope*
  - 2.3.6 *Acceptance criteria*
  - 2.3.7 *Responsibilities*
  - 2.3.8 *Test procedure*
  - 2.3.9 *Data analysis*
- 2.4 The performance qualification test
- 2.5 The performance qualification report

#### References

#### Revision history



# Supplement 14

## Transport route profiling qualification

### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

### Contents

#### Acknowledgements

#### Abbreviations

#### Glossary

#### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target readership

#### 2. Guidance

- 2.1 Associated materials and equipment
- 2.2 Study protocol
- 2.3 Carrying out the study
- 2.4 Data retrieval
- 2.5 Understanding temperature exposure: the degree-hour concept
- 2.6 Organizing, analysing and using the data
  - 2.6.1 *Method A for designing and testing packaging solutions*
  - 2.6.2 *Method B for passive containers with known performance characteristics*

#### References

#### Annex 1

##### Method B examples

- A1.1 Using the data
- A1.2 The warm climate case
  - A1.2.1 *Step 1: organize and analyse the route profile data*
  - A1.2.2 *Step 2: assess container suitability*
- A1.3 The cold climate case
  - A1.3.1 *Step 1: organize and analyse the route profile data*
  - A1.3.2 *Step 2: assess container suitability*

#### Revision history

## Supplement 15

### Temperature and humidity monitoring systems for transport operations

#### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

#### Contents

#### Acknowledgements

#### Abbreviations

#### Glossary

#### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target readership

#### 2. Guidance

- 2.1 Associated materials and equipment
- 2.2 Temperature and humidity monitoring devices
  - 2.2.1 *Device types*
  - 2.2.2 *Data collection, storage and retrieval*

#### References

#### Revision history

# Supplement 16

## Environmental management of refrigeration equipment

### Technical supplement to

*Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* (WHO Technical Report Series, No. 961, 2011), Annex 9.

### Contents

#### Acknowledgements

#### Abbreviations

#### Glossary

#### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target readership

#### 2. Guidance

- 2.1 Associated materials and equipment
- 2.2 Montreal Protocol
- 2.3 Selection of refrigerants and blowing agents
  - 2.3.1 *Use of chlorofluorocarbons*
  - 2.3.2 *Use of hydrochlorofluorocarbons*
  - 2.3.3 *Use of hydrofluorocarbons*
  - 2.3.4 *Use of hydrofluoro-olefin*
  - 2.3.5 *Use of hydrocarbons*
  - 2.3.6 *Ammonia and carbon dioxide*
  - 2.3.7 *Other cooling technologies*
- 2.4 Counterfeit refrigerants
- 2.5 Thermal insulation
- 2.6 CO<sub>2</sub> emissions
  - 2.6.1 *Kyoto Protocol*
  - 2.6.2 *CO<sub>2</sub> emissions from prime mover*
  - 2.6.3 *ODP and high GWP refrigerants*
- 2.7 Installation and maintenance
- 2.8 Decommissioning
- 2.9 Staff training

#### References

#### Annex 1

Montreal Protocol: non-Article 5 countries

#### Revision history

