

# 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

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## 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

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- 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*
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  - 2.3.3 *Incoming stock*
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  - 2.3.8 *Separation of stock*
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  - 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*
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- 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

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- 2.3 Collecting product data
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- 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

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- 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
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    - A1.1.2 *Objectives*
  - A1.2 Responsibility
  - A1.3 Associated materials and equipment

#### A1.4 Procedure

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*A1.4.2 Reducing fuel load*

*A1.4.3 Maintenance of fire protection measures*

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*A2.1.1 Policy*

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### **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.

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##### Acknowledgements

##### Abbreviations

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- 1.3 Target readership

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- 2.2 What is maintenance and why is it important?
- 2.3 The building design and construction phase
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  - 2.4.2 *Preventive maintenance and replacement: standards and schedules*
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  - 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

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- 2.2 Related activities
- 2.3 Choosing a monitoring system
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  - 2.3.2 *Select the basic system type*
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- 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

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## 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

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#### 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
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#### 2. Guidance

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- 2.2 Active and passive transport containers
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- 2.4 Freezer rooms, cold rooms and controlled ambient stores
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## **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.

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##### Acknowledgements

##### Abbreviations

##### Glossary

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- 1.1 Requirements
- 1.2 Objectives
- 1.3 Target readership

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- 2.1 Associated materials and equipment
- 2.2 Procedure
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  - 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.

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#### Acknowledgements

#### Abbreviations

#### Glossary

### 1. Introduction

- 1.1 Requirements
- 1.2 Objectives
  - 1.2.1 *Verification*
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### 2. Guidance

- 2.1 Associated materials and equipment
- 2.2 Preliminary construction validation
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- 2.3 Field shipment test
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- 2.6 Vehicle qualification failure
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## 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.

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##### Acknowledgements

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#### 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.

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#### 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.

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#### References

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- A1.1 Using the data
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#### 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.

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#### 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.

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