

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).¹ 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

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.²

² 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.

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Acknowledgements

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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

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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.

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- 1.2 Objectives
- 1.3 Target readership

2. Guidance

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- 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*
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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
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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

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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.

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- 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
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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.

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- 2.3 Controlled and hazardous substances areas
- 2.4 Fire detection systems
- 2.5 Fire suppression equipment
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 - 2.6.1 *Sprinkler systems*
- 2.7 Fire prevention, training and control procedures
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 - 2.7.2 *Fire prevention*
 - 2.7.3 *Fire safety training*
 - 2.7.4 *Fire control procedures*

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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*
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 - A1.4.3 *Maintenance of fire protection measures*
- A1.5 Related documents

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- A2.2 Responsibility
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- A3.1 Policy and objectives
 - A3.1.1 *Policy*
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Maintenance of storage facilities

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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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Temperature and humidity monitoring systems for fixed storage areas

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Qualification of temperature-controlled storage areas

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Temperature mapping of storage areas

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Supplement 9

Maintenance of refrigeration equipment

Technical supplement to

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Checking refrigerated vehicles

- A1.1 Checking insulation on a refrigerated vehicle
- A1.2 Checking cooling equipment on a refrigerated van
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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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Supplement 11

Qualification of refrigerated road vehicles

Technical supplement to

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Supplement 12

Temperature-controlled transport operations by road and by air

Technical supplement to

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Qualification of shipping containers

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Supplement 14

Transport route profiling qualification

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Temperature and humidity monitoring systems for transport operations

Technical supplement to

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