# 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

# 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.

### Contents

# 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

# 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

# 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

# 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

# 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

# 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

# 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

# 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

# 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

# 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

# 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

# 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

# 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

# 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

# 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