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.

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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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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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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.

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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.

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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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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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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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