

Introduction to the Technical Supplements

WHO Technical Report Series, No. 961, 2011

Annex 9: Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products

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Contents

Acknowledgements	3
1. The technical supplement series	4
1.1 Topics covered	4
1.2 Target readership	5
1.3 Document development and review process	5
Revision history	6



Acknowledgements

Dr Umit Kartoglu (WHO, Geneva) has overall responsibility for the Technical Supplement series and Andrew Garnett (WHO consultant, London, England) is the series editor.

Authorship of the individual Supplements is acknowledged in each of the accompanying documents.

1. The technical supplement series

This series of technical supplements has been written to amplify the recommendations given in WHO Technical Report Series No. 961, 2011, Annex 9: *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products*.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 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
8. Temperature mapping of storage areas	Section 4.7

¹ <http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf>

Table A5.1 *continued*

Title	Section(s)
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 the following people and organizations:
 - Professor M^a Rosa Jiménez-Castellanos, Seville University Department of Pharmacy and Technology
 - FIP (International Pharmaceutical Federation)
 - IFPMA (International Federation of Pharmaceutical Manufacturers & Associations)

- Mikhail Kazanchuk (Novonordisk)
 - Dr Zvonimir Majic (Head of Quality Assurance EU Logistics)
 - Merck
 - Novartis
 - VAPI-UPIP (Belgian Association of the Pharmacists of the Pharmaceutical Industry)
 - WSMI (World Self-Medication Industry).
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 by Dr Kartoglu.
 7. On the basis of these final comments, clean versions were prepared for review by the Expert Committee on Biological Standardization.

Revision history

Date	Change summary	Reason for change	Approved

