Annex 5

Technical supplements to
Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products

1. The technical supplement series 97
   1.1 Topics covered 97
   1.2 Target readership 98
   1.3 Document development and review process 98

Supplement 1
   Selecting sites for storage facilities 100

Supplement 2
   Design and procurement of storage facilities 101

Supplement 3
   Estimating the capacity of storage facilities 103

Supplement 4
   Building security and fire protection 104

Supplement 5
   Maintenance of storage facilities 106

Supplement 6
   Temperature and humidity monitoring systems for fixed storage areas 107

Supplement 7
   Qualification of temperature-controlled storage areas 109

Supplement 8
   Temperature mapping of storage areas 111

Supplement 9
   Maintenance of refrigeration equipment 112

Supplement 10
   Checking the accuracy of temperature control and monitoring devices 114

Supplement 11
   Qualification of refrigerated road vehicles 115
Supplement 12
Temperature-controlled transport operations by road and by air 117

Supplement 13
Qualification of shipping containers 118

Supplement 14
Transport route profiling qualification 119

Supplement 15
Temperature and humidity monitoring systems for transport operations 120

Supplement 16
Environmental management of refrigeration equipment 121
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). 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 practically 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

<table>
<thead>
<tr>
<th>Title</th>
<th>Section(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Selecting sites for storage facilities</td>
<td>Section 2</td>
</tr>
<tr>
<td>2. Design of storage facilities</td>
<td>Section 2 to 5</td>
</tr>
<tr>
<td>3. Estimating the capacity of storage facilities</td>
<td>Section 3.1 to 3.4</td>
</tr>
<tr>
<td>4. Security and fire protection in storage facilities</td>
<td>Section 3.7</td>
</tr>
<tr>
<td>5. Maintenance of storage facilities</td>
<td>Section 3.10</td>
</tr>
<tr>
<td>6. Temperature monitoring of storage areas</td>
<td>Section 4.5.2, 4.5.4</td>
</tr>
<tr>
<td>7. Qualification of temperature-controlled storage areas</td>
<td>Section 4.7</td>
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</table>

### Table A5.1 continued

<table>
<thead>
<tr>
<th>Title</th>
<th>Section(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Temperature mapping of storage areas</td>
<td>Section 4.7</td>
</tr>
<tr>
<td>9. Refrigeration equipment maintenance</td>
<td>Section 4.9</td>
</tr>
<tr>
<td>10. Checking the accuracy of temperature control and monitoring devices</td>
<td>Section 4.10</td>
</tr>
<tr>
<td>11. Qualification of refrigerated road vehicles</td>
<td>Section 6.4, 6.5</td>
</tr>
<tr>
<td>12. Temperature-controlled transport operations by road and by air</td>
<td>Section 6.5, 9</td>
</tr>
<tr>
<td>13. Qualification of shipping containers</td>
<td>Section 6.8.1 to 6.8.4</td>
</tr>
<tr>
<td>14. Transport route profiling qualification</td>
<td>Section 6.8.3, 6.8.4</td>
</tr>
<tr>
<td>15. Temperature and humidity monitoring systems for transport operations</td>
<td>Section 6.5, 9</td>
</tr>
<tr>
<td>16. Environmental management of refrigerant gases and refrigeration equipment</td>
<td>Section 10.2</td>
</tr>
</tbody>
</table>

### 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

Supplement 1

Selecting sites for storage facilities

Technical supplement to


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

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 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
      2.3.9 Patient areas
      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
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

Revision history
Supplement 3

Estimating the capacity of storage facilities

Technical supplement to


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 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
      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


Contents

Acknowledgements

Abbreviations

Glossary

1. Introduction
   1.1 Requirements
   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
      A1.1.1 Policy
      A1.1.2 Objectives
   A1.2 Responsibility
   A1.3 Associated materials and equipment
Annex 5

A1.4 Procedure
   A1.4.1 Reducing ignition sources
   A1.4.2 Reducing fuel load
   A1.4.3 Maintenance of fire protection measures

A1.5 Related documents

Annex 2
SOP: routine inspection and maintenance
   A2.1 Policy and objectives
       A2.1.1 Policy
       A2.1.2 Objectives
   A2.2 Responsibility
   A2.3 Associated materials and equipment
   A2.4 Procedure
       A2.4.1 Daily inspections
       A2.4.2 Weekly inspections
       A2.4.3 Monthly inspections
       A2.4.4 Three-monthly inspections
       A2.4.5 Six-monthly inspections
       A2.4.6 Yearly inspections
   A2.5 Related documents

Annex 3
SOP: fire drills
   A3.1 Policy and objectives
       A3.1.1 Policy
       A3.1.2 Objectives
   A3.2 Responsibility
   A3.3 Associated materials and equipment
   A3.4 Procedure
       A3.4.1 Conducting test evacuations
   A3.5 Related documents

Revision history
Supplement 5

Maintenance of storage facilities

Technical supplement to

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 What is maintenance and why is it important?
   2.3 The building design and construction phase
      2.3.1 The operation and maintenance manual
      2.3.2 The health and safety file
   2.4 Maintenance management
      2.4.1 Establish an institutional or contractual framework
      2.4.2 Preventive maintenance and replacement: standards and schedules
      2.4.3 Establish a multiyear maintenance plan
      2.4.4 Planned periodic inspections
      2.4.5 Planned service inspections
      2.4.6 Curative maintenance
      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


Contents

Acknowledgements
Abbreviations
Glossary

1. Introduction
   1.1 Requirements
      1.1.1 Temperature monitoring systems
      1.1.2 Humidity monitoring systems
      1.1.3 Alarm systems
   1.2 Objectives
   1.3 Target readership

2. Guidance
   2.1 Associated materials and equipment
   2.2 Related activities
   2.3 Choosing a monitoring system
      2.3.1 Prepare a user requirements specification
      2.3.2 Select the basic system type
      2.3.3 Match the system to the needs
      2.3.4 Automated continuous monitoring
      2.3.5 Data collection: wireless versus wired data transmission
      2.3.6 Specific requirements for wireless networks
      2.3.7 Web-based systems
      2.3.8 Alarm system
      2.3.9 User controls
      2.3.10 Adaptability and expandability
      2.3.11 Security and compliance
   2.4 Maintenance and support
   2.5 System extent
      2.5.1 Number of monitoring points
      2.5.2 Location of monitoring points
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


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 Introduction to qualification
      2.2.1 Qualification applied to temperature-controlled storage
      2.2.2 Installation qualification
      2.2.3 Operational and performance qualification
   2.3 Qualification protocols
      2.3.1 Approval page and change control history
      2.3.2 Acronyms and glossary
      2.3.3 Description and rationale
      2.3.4 Scope and objectives
      2.3.5 Key parameters
      2.3.6 Procedures
      2.3.7 Qualification report template
      2.3.8 Approval process
   2.4 Installation qualification
      2.4.1 Identifying critical components
      2.4.2 Checking installed systems, subsystems and components
      2.4.3 Checking electrical systems and requirements
      2.4.4 Checking environmental conditions
      2.4.5 Checking spare parts
      2.4.6 Checking auxiliary equipment
      2.4.7 Checking information needed for the preventive maintenance programme
2.4.8 Writing the IQ report

2.5 Operational qualification

2.5.1 Checking installed systems, subsystems and components
2.5.2 Calibration of controllers and sensors
2.5.3 Standard operating procedures
2.5.4 Control panel
2.5.5 Alarm tests
2.5.6 Temperature mapping – empty
2.5.7 Power failure test
2.5.8 Writing the OQ report

2.6 Performance qualification

2.6.1 Checking installed systems, subsystems and components
2.6.2 Temperature mapping – full
2.6.3 Temperature recovery after door opening
2.6.4 Writing the PQ report

2.7 Specific requirements for small-scale equipment

References

Revision history

Annex 1

Form for reporting deviations and corrective action
Supplement 8

Temperature mapping of storage areas

Technical supplement to


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 The mapping protocol
      2.2.1 Approval page and change control history
      2.2.2 Acronyms and glossary
      2.2.3 Description and rationale
      2.2.4 Scope
      2.2.5 Objectives
      2.2.6 Methodology
      2.2.7 Mapping report template
   2.3 Conducting the mapping exercise
   2.4 Analysing the data and preparing the mapping report
      2.4.1 Preliminary analysis
      2.4.2 Minimum and maximum temperatures and hot and cold spots
      2.4.3 Mean temperatures
      2.4.4 Interpreting the results and making recommendations
      2.4.5 Report auditing
   2.5 Implementing the mapping report recommendations

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


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 Active and passive transport containers
   2.3 Refrigerators and freezers
   2.4 Freezer rooms, cold rooms and controlled ambient stores
      2.4.1 Maintenance overview
      2.4.2 Maintaining the cooling system
      2.4.3 Maintaining insulated panels and vapour control sealing
      2.4.4 Condensation control outside the cold store enclosure
      2.4.5 Frost-heave control
      2.4.6 Cold store panel insulation
      2.4.7 Insulation for refrigeration pipes and other penetrations
      2.4.8 Cold store maintenance schedule
   2.5 Refrigerated vehicles
      2.5.1 Refrigerated vans
      2.5.2 Refrigerated rigid bodies
      2.5.3 Refrigerated semi-trailer
   2.6 Refrigerated containers
   2.7 Maintenance management
   2.8 Decommissioning
   2.9 Staff training
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


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 Procedure
      2.2.1 Prerequisites
      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


Contents

Acknowledgements

Abbreviations

Glossary

1. Introduction
   1.1 Requirements
   1.2 Objectives
      1.2.1 Verification
      1.2.2 Qualification
   1.3 Target readership

2. Guidance
   2.1 Associated materials and equipment
   2.2 Preliminary construction validation
      2.2.1 Temperature-controlling equipment
      2.2.2 Thermal insulation
      2.2.3 Performance checks
   2.3 Field shipment test
      2.3.1 Purpose
      2.3.2 Loading
      2.3.3 Temperature probe placement
      2.3.4 Test procedure
      2.3.5 Acceptance criteria
   2.4 Temperature-control failure test
      2.4.1 Purpose
      2.4.2 Loading
      2.4.3 Temperature probe placement
      2.4.4 Test procedure
      2.4.5 Acceptance criteria
   2.5 Documentation
      2.5.1 Designation of the vehicle
      2.5.2 Results of the qualification
   2.6 Vehicle qualification failure
   2.7 Calibration
References

Annex 1
   Placing EDLMs or temperature sensors

Revision history
Supplement 12

Temperature-controlled transport operations by road and by air

Technical supplement to


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 Available shipping systems
      2.2.1 Refrigerated vehicles – temperature-controlled
      2.2.2 Refrigerated vehicles – temperature-modified
      2.2.3 Passive shipping systems
      2.2.4 Active shipping systems for air transport
   2.3 Quality agreements
      2.3.1 User requirements specification
      2.3.2 Service level agreements
   2.4 Identifying and controlling risk
   2.5 Managing refrigerated road shipments
   2.6 Managing passive container road shipments
   2.7 Introduction to air transport
      2.7.1 Types of air carrier
      2.7.2 Air transport labelling for TTSPPs
   2.8 Air transport processes
   2.9 Managing air shipments

References
Annex 1
   Packing a refrigerated vehicle

Revision history
Supplement 13

Qualification of shipping containers

Technical supplement to

Contents
Acknowledgements
Abbreviations
Glossary
1. Introduction
   1.1 Requirements
   1.2 Objectives
   1.3 Target readership
2. Guidance
   2.1 The three stages of qualification
      2.1.1 Design qualification
      2.1.2 Operational qualification
      2.1.3 Performance qualification
      2.1.4 Requalification of reusable container systems
   2.2 Associated materials and equipment
      2.2.1 Test equipment for design and operational qualifications
      2.2.2 Test equipment for performance qualification
   2.3 The performance qualification test protocol
      2.3.1 Protocol title
      2.3.2 Protocol approvals
      2.3.3 Introduction
      2.3.4 Purpose
      2.3.5 Scope
      2.3.6 Acceptance criteria
      2.3.7 Responsibilities
      2.3.8 Test procedure
      2.3.9 Data analysis
   2.4 The performance qualification test
   2.5 The performance qualification report

References
Revision history
Supplement 14

Transport route profiling qualification

Technical supplement to

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 Study protocol
   2.3 Carrying out the study
   2.4 Data retrieval
   2.5 Understanding temperature exposure: the degree–hour concept
   2.6 Organizing, analysing and using the data
      2.6.1 Method A for designing and testing packaging solutions
      2.6.2 Method B for passive containers with known performance characteristics

References

Annex 1
Method B examples
   A1.1 Using the data
   A1.2 The warm climate case
      A1.2.1 Step 1: organize and analyse the route profile data
      A1.2.2 Step 2: assess container suitability
   A1.3 The cold climate case
      A1.3.1 Step 1: organize and analyse the route profile data
      A1.3.2 Step 2: assess container suitability

Revision history
Supplement 15

Temperature and humidity monitoring systems for transport operations

Technical supplement to


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 Temperature and humidity monitoring devices
      2.2.1 Device types
      2.2.2 Data collection, storage and retrieval

References

Revision history
Supplement 16

Environmental management of refrigeration equipment

Technical supplement to


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 Montreal Protocol
   2.3 Selection of refrigerants and blowing agents
      2.3.1 Use of chlorofluorocarbons
      2.3.2 Use of hydrochlorofluorocarbons
      2.3.3 Use of hydrofluorocarbons
      2.3.4 Use of hydrofluoro-olefin
      2.3.5 Use of hydrocarbons
      2.3.6 Ammonia and carbon dioxide
      2.3.7 Other cooling technologies
   2.4 Counterfeit refrigerants
   2.5 Thermal insulation
   2.6 CO₂ emissions
      2.6.1 Kyoto Protocol
      2.6.2 CO₂ emissions from prime mover
      2.6.3 ODP and high GWP refrigerants
   2.7 Installation and maintenance
   2.8 Decommissioning
   2.9 Staff training

References
Annex 1
   Montreal Protocol: non-Article 5 countries

Revision history