Supplement 11

Qualification of refrigerated road vehicles

Technical supplement to 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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Abbreviations

±K	Difference in absolute temperature
ATP	Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for such Carriage
cGMP	current good manufacturing practice
EDLM	electronic data logging monitor
EN	European norm (standard)
IQ	installation qualification
OQ	operational qualification
PQ	performance qualification
SOP	standard operating procedure
TTSPP	time- and temperature-sensitive pharmaceutical product

Acknowledgements

The author of this document is Richard Lawton, Technical Director, Cambridge Refrigeration Technology, Cambridge, England.

Glossary

Electronic data logging monitor (EDLM): A small portable device that measures and stores temperature at predetermined time intervals by means of an electronic sensor. They have programmable alarm capabilities, integrated displays, and can create reports and graphs which may be permanently stored, shared and analysed via proprietary hardware, software, desktop application or through hosted databases.

Coefficient of heat transfer (The "U" value, also referred to as the "K" coefficient in the ATP Agreement): The overall heat transfer of the equipment, defined as the heating power or cooling capacity, W, per degree temperature difference, T, between the internal and external surfaces over the surface of the body, S.

The units are W/(m²K) and its formula is below.

$$K = \frac{W}{Sx\Delta T}$$

Installation qualification (IQ): The process of obtaining and documenting evidence that the premises, equipment and supporting systems have been provided and installed in compliance with their design specifications.

Operational qualification (OQ): The process of obtaining and documenting evidence, under controlled conditions, that the premises, equipment and supporting systems operate in accordance with their design specifications.

Performance qualification (PQ): The process of obtaining and documenting evidence that the premises, equipment and supporting systems, as connected together, will consistently perform in accordance with the approved process method and specifications.

Pharmaceutical product: Any product intended for human use or veterinary product intended for administration to food producing animals, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals and vaccines. Medical devices are not included.[1]

[1] Definition from WHO/QAS/08.252 Rev 1 Sept 2009. *Proposal for revision of WHO good distribution practices for pharmaceutical products – Draft for comments.*

Qualification: Documented testing that demonstrates with a high degree of assurance that a specific process will meet its predetermined acceptance criteria.[2]

Refrigerated vehicle: Road transport vehicle such as a van, truck or semi-trailer whose isolated thermostatically controlled cargo compartment is maintained at a temperature different (lower or higher) than the external ambient conditions. The environment inside the cargo compartment may be *temperature-controlled* or *temperature-modified*.

Standard operating procedure (SOP): A set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Standard operating policies and procedures can be effective catalysts to drive performance improvement and improve organizational results.

Temperature-controlled: Includes any environment in which the temperature is actively or passively controlled at a level different from that of the surrounding environment within precise predefined limits.

Temperature-modified: Includes any environment in which the temperature is predictably maintained at a level different from that of the surrounding environment, but is not actively or passively controlled within precise predefined limits.

Time and temperature-sensitive pharmaceutical product (TTSPP): Any pharmaceutical good or product which, when not stored or transported within predefined environmental conditions and/or within predefined time limits, is degraded to the extent that it no longer performs as originally intended.

Validation: Documented testing performed under highly controlled conditions, demonstrating that processes, methods, and systems consistently produce results meeting predetermined acceptance criteria.[3]

[2] Definition from Parenteral Drug Association (PDA) Technical Report No. 39: Guidance for temperature controlled medicinal products: maintaining the quality of temperature-sensitive medicinal products through the transportation environment. Bethesda (MD): Parenteral Drug Association; 2007.

[3] Parenteral Drug Association (PDA) Technical Report No. 39: Guidance for temperature controlled medicinal products: maintaining the quality of temperature-sensitive medicinal products through the transportation environment. Bethesda (MD): Parenteral Drug Association; 2007.

1. Introduction

This technical supplement 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.[4] It outlines the actions that need to be taken to qualify refrigerated vehicles equipped with active temperature-control systems which are used to transport TTSPPs. Related topics are covered in the following Technical Supplements:

- *Checking the accuracy of temperature control and monitoring devices*
- *Refrigeration equipment maintenance*
- *Transport route profiling qualification*

What is qualification?

In the context of this series of Technical Supplements, *qualification* is an inspection and testing process used to establish that a piece of equipment or a physical installation is fit for purpose in the operational context within which it will be used. There are typically three stages in the process. Each stage must be fully completed before the next one begins.

Stage 1 (for equipment): Establish by laboratory testing under tightly controlled conditions that a specific item of equipment performs in accordance with the user requirements specification (URS). This is design qualification. Although *design qualification* demonstrates compliance with the URS and associated test protocols, it does not prove that the equipment will be suitable in a specific operating environment because the URS and the test procedures are unlikely to reflect the full range of operating conditions.

Stage 1 (for installations): Establish by documented inspection and testing that an installation[5] that has been assembled in a specific location is fully in accordance with the URS and installation drawings. This is *installation qualification*.

Stage 2: Establish by further documented testing under controlled conditions that this equipment or installation is likely to perform as intended in the operating environment in which it will be used. This is *operational qualification*.

[4] http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf

[5] The installation will typically incorporate components that have a design qualification.

Stage 3: Carry out a final stage of documented testing to establish with a high degree of assurance that the equipment or installation, together with all associated systems, does indeed perform as intended under routine operating conditions. This is *performance qualification*.

1.1 Requirements

Where refrigerated vehicles are directly owned and/or operated it is important, wherever possible, to qualify each vehicle before it becomes operational. In addition, where a contract carrier service is used, the shipper has a duty to ensure that the carrier's vehicles are appropriately qualified. The qualification procedure should:

- **Demonstrate** that the temperature distribution within the payload area of the temperature-controlled compartment is maintained within the range specified for the products being transported (e.g. +2.0 °C to +8.0 °C). The qualification procedure must be able to assess actual product temperatures for commonly used load layouts. Qualification should be carried out at the ambient temperature extremes anticipated during normal operation, over known distribution routes.
- **Define** zones within the vehicle's payload area that should not be packed with TTSPPs (for example areas in close proximity to cooling coils or cold air streams).
- **Demonstrate** the time taken for temperatures to exceed the designated maximum or minimum in the event that the temperature-controlling unit fails. Similar tests should be used to validate the anticipated door-opening times that will occur during deliveries.
- **Document** the qualification exercise for internal quality assurance and external regulatory purposes.

This procedure constitutes a temperature-mapping exercise similar to that employed for fixed temperature-controlled storage facilities.

An alternative approach is to perform an initial full qualification on each trailer/ temperature-control unit type, combined with an installation qualification (IQ) for each example when a new vehicle becomes operational.

Carry out additional qualification exercises whenever significant modifications are made to the vehicle. Consider the need for requalification whenever temperature monitoring shows unexplained variability that is greater than normal.

These requirements are to ensure that TTSPPs can be safely transported within the transport temperature profile defined for each product and that

compliance can be demonstrated to the regulatory authorities and other interested parties.

1.2 Objectives

The objective of this Technical Supplement is to provide guidance on how to qualify refrigerated vehicles used for transporting TTSPPs in a way which meets the above requirements.

1.2.1 Verification

When a refrigerated vehicle is procured, the purchaser must exercise due diligence to ensure that the required performance and detailed characteristics are clearly specified so that the vehicle supplier can provide equipment that matches the needs of the operating environment. Only equipment which has been properly *verified* against industry standards and norms should be considered. If procurement is done correctly there is a high probability that the vehicle will perform well in the operating environment.

1.2.2 Qualification

Once the vehicle has been delivered it is essential that its actual performance is *qualified*. Qualification is used to demonstrate that the specified performance standards are met in the actual operating environment. This process should take place before the vehicle is used to transport valuable TTSPPs.

Qualification procedures are increasingly being seen as a requirement of current good manufacturing practice (cGMP). The qualification process applies a set of clearly defined criteria and provides documented evidence that the equipment is fit for its intended purpose. Typically this is a three-stage exercise:

Installation qualification (IQ) verifies that the equipment is installed correctly as per the original requirements and that any documentation needed for its use is in place.

Operational qualification (OQ) verifies that the equipment concerned with maintaining and ensuring product quality operates correctly over all expected ambient conditions.

Performance qualification (PQ) verifies that those parts of the equipment concerned with maintaining and ensuring product quality can perform as intended in an effective and repeatable manner over time.

1.3 Target readership

The target readership is the owners and operators of refrigerated vehicles used to transport TTSPPs, the aim being to provide sufficient information to enable them to produce a standard operating procedure (SOP) relevant to their own specific transport operations.

2. Guidance

The importance and regulatory significance of verification, validation and qualification has been outlined above. This section describes the principal steps that need to be taken to achieve these objectives.

2.1 Associated materials and equipment

The following are required:

- A sufficient quantity of electronic data logging monitors (EDLMs), qualified to European Norm (EN) 12830:1999, together with the necessary download software. WHO Performance, Quality and Safety (PQS) prequalified EDLMs may be used for this purpose.[6]
- Where possible, an ATP-approved temperature-controlled chamber should be used. The specific requirements of the cold chain for pharmaceutical products have not been ratified, but recommended guidelines have been produced.[7]
- Real, expired or dummy product.

2.2 Preliminary construction validation

The following checks should be carried out to satisfy the requirements at the IQ stage. Essentially this is an inspection procedure designed to ensure that the vehicle meets required standards; these requirements should have been stated clearly in the procurement specification.

2.2.1 Temperature-controlling equipment

The ATP agreement stipulates that refrigeration equipment should have an over-capacity of a least 1.75 times the overall heat ingress into the insulated body under operating conditions at an ambient temperature of +30.0 °C. If the predicted ambient temperature is above +30.0 °C, it would be prudent to increase the over-capacity to 2.25. In cold climates, heating capacity will also be required to provide low temperature protection if the temperature-controlled compartment needs to be maintained above 0.0 °C.

[6] See: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorypage.aspx?id_cat=35

[7] Association Francaise du Froid. Practical guidelines – cold chain for medicines. Paris: Association Francaise du Froid; 2009.

2.2.2 Thermal insulation

ATP regulations state that for frozen transport the thermal insulation of the refrigerated compartment should have a K-coefficient of heat transfer of ≤ 0.4 W/m²K, and for chilled transport a value of ≤ 0.7 W/m²K. It is recommended that all new vehicles be selected with an insulation coefficient < 0.4 W/m²K.

2.2.3 Performance checks

Before qualification, the performance of the temperature-control and the thermal insulation should be checked according to the maintenance procedure; see the companion WHO Technical Supplement: *Refrigeration equipment maintenance*.

2.3 Field shipment test

The field shipment test is designed to satisfy parts of the operational qualification (OQ) and performance qualification (PQ) stages.

2.3.1 Purpose

The purpose of this test is to demonstrate whether the product temperature distribution within the temperature-controlled compartment is maintained within the specified limits. Testing should be designed to cover commonly used load layouts at the ambient temperature extremes anticipated during normal operation over known routes.

Ideally a temperature-controlled chamber would be used for the test because this provides a consistent, monitored environment. A disadvantage of this approach is the validity of the simulated conditions; it may be difficult accurately to predict the real-world conditions of a delivery.

In most cases, a large test chamber will not be available. However, a static test at ambient temperatures may still be appropriate for an OQ.

2.3.2 Loading

When conducting a field shipment test under real operating conditions, there are two options:

- *Use real products:* In the case of a simultaneous transport and validation exercise, use actual products.
- *Use expired or dummy products:* If validation is being carried out before live operations commence, use real products that have reached their expiry date whenever possible. Otherwise use substitutes that have similar thermal properties, mass and packaging to the actual products to be transported.

Note: If expired product is shipped between countries, pay special attention to customs and security restrictions and requirements.

The vehicle should be packed according to the manufacturer's instructions and should reflect the load layout commonly used. Although the precise equipment and layout will depend on the vehicle and the products transported, general guidance can be found in the WHO guidance on *Loading and operating refrigerated vehicles*.[8]

2.3.3 Temperature probe placement

Temperature probes should be fixed within the packaging of the transported products. Ideally the temperature probes should be spread throughout the load; however, as a minimum requirement, they should be placed in the locations most vulnerable to temperature excursions. It is also informative to include less vulnerable positions (see **Annex 1**). To identify these "worst case" positions, an initial temperature mapping of the refrigerated compartment should be carried out *before* the qualification exercise. This helps ensure that vulnerable points are covered by temperature probes during qualification.

If there are multiple drop-off points along the delivery route, this should be considered when locating the temperature probes. At least two probes covering the hottest and coldest locations in the load compartment must remain attached to the payload up to the final drop-off.

2.3.4 Test procedure

A static temperature mapping exercise is recommended before conducting the mobile qualification tests. This will establish worst case positions (e.g. the hottest and coldest spots in the load compartment). These positions can be used as locations for EDLMs during the mobile tests.

As a minimum, a series of four tests should be conducted to reflect the full range of the vehicle's use.

a. test performance with maximum payload during the warmest season;
b. test performance with minimum payload during the warmest season;
c. test performance with maximum payload during the coldest season;
d. test performance with minimum payload during the coldest season.

The operator may wish to repeat these tests for statistical confirmation. See the companion Technical Supplement: *Transport route profiling qualification*.

[8] World Health Organization. EVM SOP E7-05 Loading and operating refrigerated vehicles. Geneva: WHO Effective Vaccine Management (EVM) Initiative; 2011 (http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/index2.html, accessed 10 February 2015).

During the tests, the vehicle should be operated as intended and the route should be chosen to reflect a typical worst-case scenario. The tests should preferably be conducted during an actual delivery in order to collect accurate data. If this is not possible, a representative route should be chosen. A worst-case scenario would usually include multiple drop-offs with associated door openings, with the shortest journey time between drop-offs, and overnight stops on electric standby.

Following the completion of each test, the data from the loggers can be downloaded to determine the overall performance.

Note: The need to perform warm-season and cold-season testing, as described above, means that the vehicle cannot be fully qualified until both seasons have passed, which may be as long as six months. Therefore the vehicle can only be *provisionally* qualified after completion of the first two tests. The second pair of tests must be completed satisfactorily before the vehicle is *fully* qualified for use throughout the year. If a test chamber is available, the tests for the two seasons can be simulated during a static temperature-mapping exercise, as can the effect of multiple drop-offs and overnight stops.

2.3.5 Acceptance criteria

In order to pass the OQ and PQ, the product temperatures should remain within the required temperature range during the entire route and across all four tests. For example, if the requirement is for +2.0 °C to +8.0 °C, the minimum temperature recorded should not be below +2.0 °C, −0.5 °C and the maximum should not exceed +8.0 °C, +0.5 °C.[9]

2.4 Temperature-control failure test

A temperature-control failure test is required to complete the OQ and PQ. This test determines the time in which a breakdown becomes critical.

2.4.1 Purpose

The purpose of the test is to demonstrate the time taken for temperatures to exceed the designated maximum or minimum in the event that the temperature-controlling unit fails. Note that this test cannot be carried out using real products

[9] WHO PQS specifications require EDLM devices to have an accuracy of ±0.5 °C.

during a simultaneous transport and validation test because the product would be damaged. For this reason a simulated load is recommended.

2.4.2 Loading

Do NOT use real product for this test as it will be irrevocably damaged. Instead use expired product if this is available and has been subjected to a thorough risk assessment – it is essential that expired products do not reach the market in the event of theft or mismanagement at the destination point. Alternatively, use a substitute with similar thermal properties, mass and packaging to the actual products. The chosen substitute must be suitable for the test route; for example, if a border crossing is involved, the product should be selected to avoid problems with customs. The final option is to use empty boxes which represent typical packaging type(s); this option simulates the worst case (lowest) thermal mass situation. In all cases minimal payload should be used as shown in **Annex 1**, Figure A1.1.

Again the vehicle should be packed according to the manufacturer's instructions and should reflect the load layout commonly used. Tests should be undertaken in ambient conditions reflecting the extremes of both heat and cold likely to be encountered during service.

2.4.3 Temperature probe placement

Temperature probes should be fixed within the packaging of the products being transported to ensure that the temperature of the product itself is recorded and not that of the surrounding air; air temperature within the load compartment may fluctuate outside the designated range for short periods while the product temperatures remain unchanged.

Ideally the temperature probes should be spread throughout the load; however, as a minimum requirement they should be placed in the locations most vulnerable to temperature excursion. It is also informative to include less vulnerable positions. See **Annex 1**.

2.4.4 Test procedure

The temperature-control system should be set to control the product temperatures within the standard operating temperature range. Before loading begins, make sure that the load compartment has been preconditioned to the designated temperature and check to confirm that the system has reached the set point temperature. Generally, the mid-point of the temperature range should be chosen to stabilize the products while allowing for some variation in the product temperatures. For example, if the product requires temperatures from +2.0 °C to +8.0 °C, select a set point of +5.0 °C. The system should be left to allow the

products to stabilize. The time needed for this will vary for different types of insulated equipment, although approximately 12 hours should be sufficient. A temperature sensor with a remote hand-held monitor could be attached to product nearest the doors to allow for temperature readings to be taken during the test, thereby assisting in monitoring the progress of the test.

Once stabilization is achieved, the temperature-control system should be switched off. Temperature readings can be taken periodically to provide a guide to the internal temperature. The test is complete when a single product temperature exceeds the specified maximum or minimum for the designated operating temperature classification. Following the test, the data from the loggers can be downloaded to determine the overall performance.

2.4.5 Acceptance criteria

The time taken for the product temperatures to exceed the intended maximum or minimum should be recorded in the OQ with reference to the unit being tested. These data can be used to help define contingency procedures and required response times during a transport emergency.[10]

2.5 Documentation

Comprehensive documentation is an essential part of the qualification process because it enables the long-term performance of the vehicle fleet to be monitored and it allows the operator and regulatory bodies to demonstrate compliance with good practice.

2.5.1 Designation of the vehicle

The insulated body and the associated temperature-control unit should both be uniquely identifiable. This is achieved by recording the data on the manufacturer's plate(s), which must clearly and indelibly show at least the following particulars:

- country of manufacture;
- name of manufacturer;
- model;
- serial number;
- year and month of manufacture.

[10] See: EVM-SOP-E7-06: Responding to emergencies during vaccine transport operations.

2.5.2 Results of the qualification

Appropriate documentation must be kept to ensure that there is a historical record of OQ and PQ qualification for a particular insulated body. All qualification results should be recorded, together with a list of any subsequent modifications. Instances of unexplained performance variability should be recorded; these records should be made available for future qualifications, or when there is a change of operator.

2.6 Vehicle qualification failure

In the event that a vehicle fails to meet the standard for qualification, a recommendation should be made, highlighting the reasons for the failure and any action that could be taken to improve the performance of the vehicle.

Qualification records should be stored as usual together with any recommendations or modifications made.

2.7 Calibration

The EDLMs used for qualification, as well as any on-board temperature monitoring equipment, should be recalibrated according to the procedure and time frame specified by the manufacturer, e.g. EN 13486:2003. EDLMs with non-replaceable batteries are supplied with a valid calibration certificate from the logger manufacturer; these devices do not need to be recalibrated.

If a temperature-monitoring device fails the calibration, it should be clearly marked and removed from service to be repaired or disposed of.

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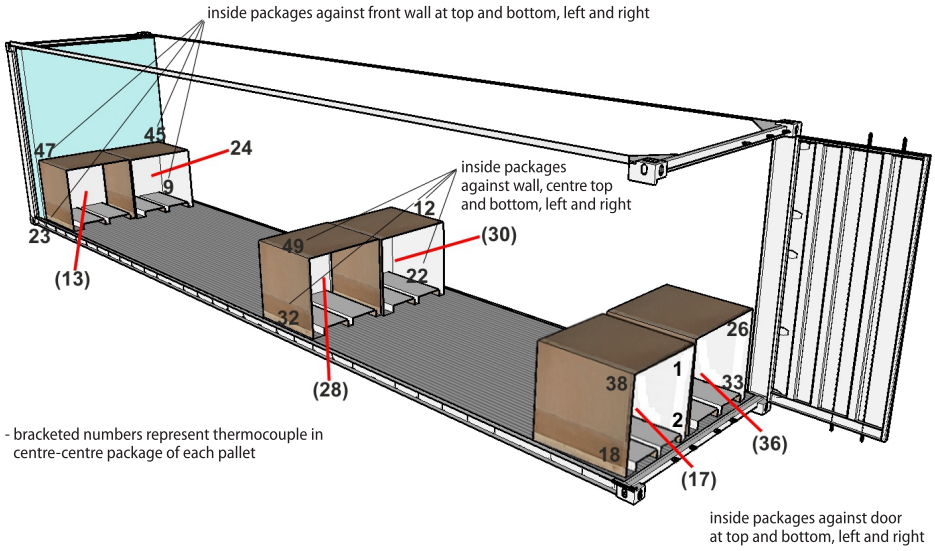
Annex 1

Placing electronic data logging monitors or temperature sensors

Electronic data logging monitors (EDLMs) and/or their sensors should be placed as shown in Figure A1.1. The minimum recording requirements for qualification testing are:

- outside ambient temperatures around the external surfaces;
- air delivery of the refrigeration unit;
- air return of the refrigeration unit;
- product close to the delivery air of the refrigeration unit;
- product in any areas likely to be deprived of airflow;
- product close to the walls;
- product close to the door.

Figure A1.1
Example layout for monitoring a part loaded trailer



Source: Cambridge Refrigeration Technologies

Note: If it is intended to double-stack pallets it is essential to validate this arrangement during the qualification process.

Revision history

Date	Change summary	Reason for change	Approved