

Supplement 9

Maintenance of refrigeration equipment

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

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Abbreviations

ATP	Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for such Carriage
CFC	chlorofluorocarbons
ECE	See also <i>UNECE</i>
GRP	glass reinforced plastic
GWP	global warming potential
HCFC	hydrochlorofluorocarbons
LSP	logistics service provider
ODP	ozone depletion potential
PTI	pre-trip inspection
SOP	standard operating procedure
TTSP	time- and temperature-sensitive pharmaceutical product
UNECE	United Nations Economic Commission for Europe
ULD	unit load device

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

Glossary

Active systems: Externally powered or on-board powered systems using electricity or another fuel source to maintain a temperature-controlled environment inside an insulated enclosure under thermostatic regulation (e.g. cold rooms, refrigerators, temperature-controlled trucks, refrigerated ocean and air containers).

Passive systems: Systems which maintain a temperature-controlled environment inside an insulated enclosure, with or without thermostatic regulation, using a finite amount of preconditioned coolant in the form of chilled or frozen gel packs, phase change materials, dry ice or others.

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

Refrigerated container or reefer: A thermally insulated shipping container or intermodal freight container, equipped with an integrated refrigeration unit, used for the transport of TTSPPs, by road, rail or ocean freight. The refrigeration unit requires an external electrical power supply when located at a land based site, on a container ship or on a quay. During road transport electrical power is typically supplied by a diesel generator.

Refrigeration equipment: The term “refrigeration” or “refrigeration equipment” means any equipment whose purpose is to lower air and product temperatures and/or to control relative humidity.

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*.

Service level agreement (SLA): A service level agreement or contract is a negotiated agreement between the customer and service provider that defines the common understanding about materials or service quality specifications, responsibilities, guarantees and communication mechanisms. It can either be

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.*

legally binding, or an information agreement. The SLA may also specify the target and minimum level performance, operation or other service attributes.²

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.

Third-party accreditation: Accreditation or certification by an organization that issues credentials or certifies third parties against official standards as a means of establishing that a contractor is competent to undertake a specific type of work. Third-party accreditation organizations are themselves formally accredited by accreditation bodies; hence they are sometimes known as “accredited certification bodies”. The accreditation process ensures that their certification practices are acceptable, typically meaning that they are competent to test and certify third parties, behave ethically and employ suitable quality assurance.

Time and temperature-sensitive pharmaceutical product (TTSP): 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.

² Definition from International Air Transport Association (IATA). 2013/2014 Perishable cargo regulations (ePCR) & temperature control regulations (eTCR). Geneva: IATA.

1. Introduction

This technical supplement has been written to amplify the recommendations in section 4.9 of WHO Technical Report Series No. 961, 2011, Annex 9: Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products.³ It does not specifically deal with emergency maintenance or contingency planning. Related topics are covered in the following Technical Supplements:

- *Checking the accuracy of temperature control and monitoring devices*
- *Environmental management of refrigeration equipment*
- *Maintenance of storage facilities*
- *Temperature mapping of storage areas*

1.1 Requirements

Implement a maintenance programme for all temperature-controlled rooms, cold rooms, freezer rooms, refrigerators and freezers:

- Carry out regular preventive maintenance on all temperature-controlling equipment.
- Employ best practice to eliminate leakage of refrigerant into the environment during installation, maintenance and decommissioning of refrigeration equipment.

Records should be maintained to demonstrate compliance with the above requirements.

1.2 Objectives

The objective of this Technical Supplement is to provide guidance on how to meet the above requirements with regard to the maintenance of cold chain equipment for use with TTSPPs. The guidance covers all types of fixed and mobile temperature-controlling equipment.

1.3 Target readership

This technical supplement provides guidance on the maintenance of cold chain equipment aimed at more senior operations management staff. Principally these will be the owners and operators of warehouses, pharmacies and other stores, and owners and operators of refrigerated vehicles used to store and transport TTSPPs.

³ <http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf>

2. Guidance

This section provides general guidance on how to maintain the following categories of temperature-controlled equipment:

- active and passive insulated container systems used for transport;
- refrigerators and freezers;
- freezer rooms, cold rooms and controlled ambient stores;
- refrigerated vans;
- refrigerated rigid vehicles;
- refrigerated semi-trailers;
- refrigerated containers.

The sections below discuss the preventive maintenance requirements for each of these types of equipment.

2.1 Associated materials and equipment

Technicians should be appropriately equipped so that they are able to maintain temperature-controlled systems in an operable and safe condition. The basic equipment needed includes the following:

- refrigeration equipment service manuals;
- digital thermometer;
- cleaning equipment (non-solvent based);
- insulated envelope repair equipment (sealant, plating, pop riveter);
- multimeter for electrical testing;
- electronic leak detector (or sponge and soapy water);
- manifold gauges set and refrigeration tools;
- spare refrigerant;
- spare parts kits;
- refrigerant recovery machine and bottle;
- vacuum pump;
- weighing scales.

2.2 Active and passive transport containers

Reusable transportable insulated containers, such as cold boxes and the insulated unit load devices (ULDs) used for air transport,⁴ are subject to wear and tear

⁴ See: http://en.wikipedia.org/wiki/Unit_load_device

because they are handled frequently. Maintenance is likely to be limited to washing the interior and exterior with a solution of mild soapy water or a disinfectant solution containing sodium hypochlorate, 5.25% in water.

Some repairs to cold boxes may be possible, but end of life for this category of equipment will be indicated when there are holes or cracks in the internal and external covering which expose the insulating core.

Cooling elements for passively cooled containers include frozen water-packs, cool water-packs, phase-change material (PCM)-packs or eutectic plates, and possibly dry ice (solid carbon dioxide). Smaller actively cooled containers may use electronic Peltier systems. Larger actively cooled containers may have mechanical refrigeration systems. Repairs to ULDs are routinely carried out at specialist repair stations located around the world, operated by the container manufacturers.

2.3 Refrigerators and freezers

Refrigerators and freezers comprise an insulated envelope. This is normally cooled by a sealed compression-cycle refrigeration system operating on mains electricity. In remote areas with no other power supply they may use photovoltaic power systems. Gas and kerosene absorption units are also used in such places. The maintenance of these small-scale off-grid systems is outside the scope of this document, but is covered in EVM-SOP-E5-03.

The cooling system can continue to run for many years. End of life is likely to occur as a result of degradation of the insulation (especially for freezers), door hinges, door seals or cracks in the internal or external covering. Terminal degradation to the insulation of freezers is indicated by the presence of condensation on the outside, or sometimes even by the presence of ice. When this occurs the equipment should be replaced. Another indication of insulation degradation is an excessively long compressor duty cycle; the cooling equipment runs continuously with the interior never reaching the set point.

Maintenance procedures, such as those listed in EVM-SOP-E5-03, should concentrate on cleaning:

- Keep clean by regularly washing with mild soapy water solution.
- Check operation of thermostat and defrost system (if fitted).
- Keep door seals clean, avoiding build-up of material between folds and at corners.
- Remove build-up of ice (use the defrost system or a blunt scraper).
- Keep drains free of debris.
- Check appliance level – give a small fall to the rear (no more than 4 mm) to ensure door closure.
- Clean condenser coil (fins), ensure fins and cooling fan and any grilles are free of dust, fluff and debris.

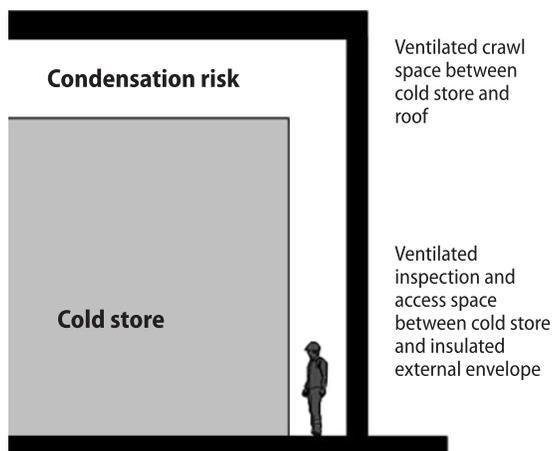
Repairs to the cooling system are likely to be uneconomical: once the pipework of a sealed mechanical system is broken into, the reliability is likely to be severely compromised. On a cost basis, where possible, it is advised that repairs be limited to electrical systems, thermostats, defrost timers and start relays; otherwise replacement of the refrigerator or freezer is recommended.⁵

In the case of absorption refrigeration systems, which are fully sealed and under relatively high pressure, repairs can only be made to the heater and thermostat, although inverting the entire refrigerator for a few hours can sometimes bring an apparently dead unit back to life.

2.4 Freezer rooms, cold rooms and controlled ambient stores

Freezer rooms, cold rooms and controlled ambient stores represent a considerable financial investment and should, with correct maintenance, last for 20–30 years. They consist of two main components: an insulated envelope constructed of preformed insulated sandwich panels and a vapour compression mechanical refrigeration system. The temperature for freezer rooms is generally -20°C or below, for cold rooms it is $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ and for controlled ambient stores it is $+15^{\circ}\text{C}$ to $+25^{\circ}\text{C}$. Figure 1 shows a typical cold store arrangement with a cold store built of insulated panels constructed inside an enclosing warehouse building. Larger cold stores may take structural support from the enclosing building; smaller units up to about 6 metres in span are generally self-supporting.

Figure 1
Layout of insulated envelope and weather enclosure



⁵ Notwithstanding these recommendations, the skill and ingenuity of competent technicians can be impressive and systems may be repaired even where spares or new units are not readily available.

2.4.1 Maintenance overview

Cold stores are delivered by the constructor in working condition, verified by commissioning tests, thermal scans and third-party accreditation. To enable the intended design life to be achieved a well-considered programme of regular inspection and preventive maintenance should be put in place. Two elements of a cold store require maintenance: the refrigeration equipment and the insulated envelope. Close attention should be paid to both of these elements. It is essential not to neglect the insulated envelope, although in the short term this might appear less important.

Owing to their size, cold stores of all three types are likely to store products with a substantial total value. To minimize the risk of product loss, most cold stores should have a duplicate refrigeration system, an emergency power supply and a sophisticated temperature monitoring and alarm system, all of which also need to be maintained.

2.4.2 Maintaining the cooling system

Cooling systems require regular maintenance; see for example the procedures set out in EVM-SOP-E5-02.

When maintaining and testing systems, it is important to remember that product losses are just as likely to be caused by exposure to too low a temperature as by exposure to a high temperature. It is therefore necessary to check that the secondary system cuts in when the temperature exceeds the allowable maximum. The operating methodology and/or the control system should be designed so that the two refrigeration systems run alternately; this ensures that a problem with either system is quickly identified. The maintenance programme should also include checking the response of the system to temperatures below the allowable minimum. In particular there should be an independent cut-off mechanism to prevent low temperature excursions. For example, if the temperature is controlled by a solenoid valve system, the low-temperature safety system should cut off the power to the compressor.

2.4.3 Maintaining insulated panels and vapour control sealing

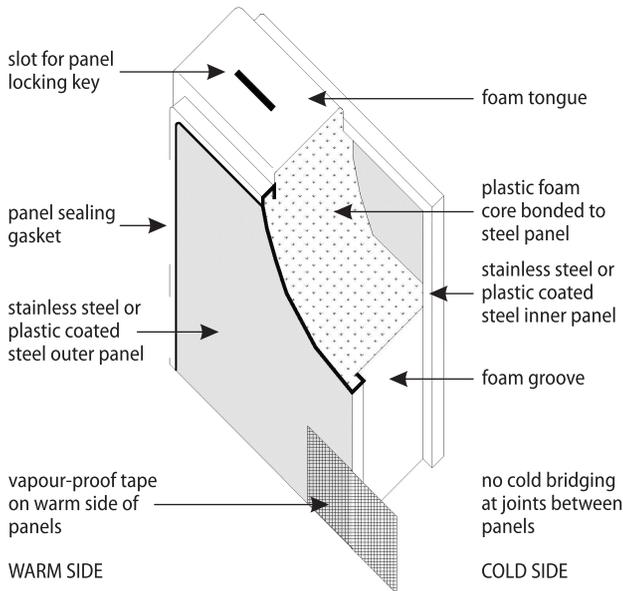
Maintenance programmes usually concentrate on the cooling equipment and the insulated envelope is frequently neglected. A badly maintained envelope will only last for 15 years; with good maintenance it can last twice as long.

Responsibility for the upkeep and the maintenance of the insulated envelope and vapour sealed panel joints should be given to a nominated person who has a clearly defined role to ensure that this work is carried out. There should be a comprehensive standard operating procedure (SOP) describing the appropriate maintenance and corrective work.

Cold store insulated envelopes are constructed from preformed insulated sandwich panels; typically corrosion-protected metal sheets with a core of foamed insulation. The insulated panels require a vapour control membrane to resist the infiltration of atmospheric water vapour into the insulation core. An impermeable barrier to prevent this happening is essential and can be likened to the hull of a ship. An ineffective vapour barrier will allow water vapour to penetrate, condense and freeze within the insulating core material or on the internal surfaces of the panels. This degrades the surfaces and leads to a loss of insulating effectiveness, panel delamination and possible structural collapse.

The metal facings of an insulating panel are themselves impermeable to water vapour transmission and effectively control the problem. The panel joints are the weak points because the joint itself must act as a vapour barrier. Continuity of the vapour control layer at the joints is achieved by incorporating a vapour seal. All joints should be sealed on the *warm* side of the enclosure, either by means of a proprietary sealing system supplied by the panel manufacturer, or with a mastic bead followed by a 100-mm wide strip of vapour-impermeable tape. Figure 2 shows a typical joint assembly.

Figure 2
Example of a cold store panel joint



Generally the panel seal only needs to be continuous on the warm side. It is not necessary to seal the joints on the inside, because permeable joints on the cold side enable vapour to pass through and to condense on the evaporator plates. However, some argue that panels should be sealed on both sides, but that the sealant on the inner panel should be permeable.

Effective vapour control sealing ensures that a barrier, impervious to water vapour, is provided around the whole of the outside of the cold store envelope and, similarly over the warm face of any intermediate walls – for example between a cold room and a smaller freezer room section located within the same volume.

Insulated envelopes by their nature are relatively flexible structures; larger units, in particular, derive much of their strength from the support provided by external, usually steel, structures. Panel fixings and joints between panels can suffer damage through thermal movement. Panels and joints therefore need to be inspected regularly and repaired or replaced as necessary. Significant movement between walls and ceilings can occur and these areas merit close inspection.

Maintenance of the vapour control sealing on the external face of the insulation panels and pipework is essential. Warm outside air has a higher water vapour pressure than air inside a refrigerated store, and water vapour will, therefore, tend to migrate through the vapour barrier into the insulation. Water vapour penetrating the vapour barrier and passing into the insulation along joint lines can condense as water or ice, depending on the temperature within the insulation, and this will impair its insulating properties and damage the joint.

For all these reasons, when designing a cold store installation it is important that the store side of the joints should be left visible and physically accessible so that regular checks for condensation or ice formation can be made, and the cause investigated and removed. The vapour seal has a finite life, which will probably be less than the life of the insulated panels themselves. It should be repaired or replaced before it deteriorates too far. In low-temperature stores, vapour seal leaks will show as a line of snow forming on the joint line where the deterioration has occurred. Repairs should be made from the outside of the store and the snow should be removed so that the effectiveness of the leak repair can be checked.

2.4.4 Condensation control outside the cold store enclosure

Condensation on the structure and in the roof voids of the building enclosing a cold store is a recurring problem. Figure 1 highlights this risk zone. Condensation occurs when air saturated with water vapour comes into contact with cold surfaces. The amount of water vapour which air can support is a function of the air temperature. As the temperature increases, the air can contain a greater and greater amount of water vapour per unit volume.

The following enclosure surfaces are particularly prone to condensation:

- the inside of roof cladding sheets;
- the inner face of wall cladding;
- the outer face of the insulated cold store wall panels;
- the upper faces of the insulated cold store ceiling panels;
- surfaces of piped services, particularly refrigerant pipes because these are very cold;
- surfaces of cold bridges penetrating the insulated enclosure of the cold store; this includes ceiling panel suspension rods and the like;
- surfaces of structural steelwork; e.g. support brackets for pipework.

To avoid condensation, it is necessary to ventilate voids with ambient air. Approximately 10 air changes per hour are needed for ventilation of the space around a cold store. Although it is possible to achieve this with natural ventilation, mechanical ventilation is often needed, although this depends on the shape of the void. Effective ventilation ensures that the dew point in the void is identical to the dew point of the external ambient air.

Condensation on the outer cladding of the store building envelope can also occur as a result of radiation, especially on clear nights. A reduction below ambient temperature of around 4 °C may occur by this means. As the dew point is typically in the order of 2 °C below dry bulb temperature, surface condensation will occur. This can usually be avoided by insulating the building envelope.

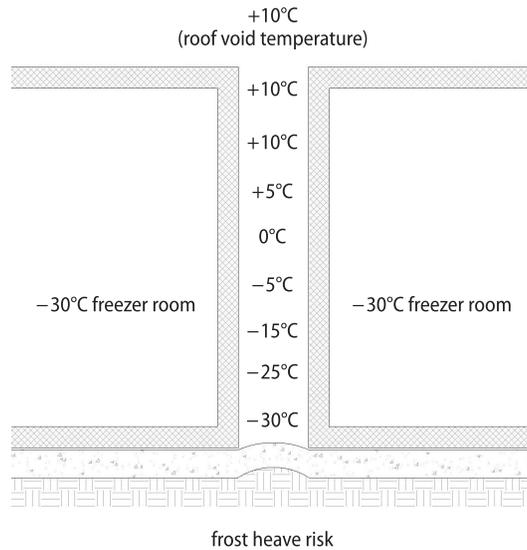
In the case of a freezer room operating at –20 °C or colder, the temperature of the ambient air immediately outside the insulated enclosure can drop below the dew point of the surrounding air, even below 0 °C; this is always a danger when there is such a large heat sink in contact with the air. This can cause condensation or ice formation on the external surface of the freezer room ceiling panels. In such circumstances, the amount of water or ice forming should be relatively small because the external relative humidity is also low. However, these accumulations need to be removed to prevent the long-term risk of panel corrosion. Safe removal requires sufficient working space, safe access and arrangements for protecting workers operating at height.

2.4.5 Frost-heave control

Frost-heave occurs when water in the subsoil beneath a continuously running freezer room freezes over time. This can occur even if the floor is insulated and the resulting expansion of the subsoil can fracture and lift the floor slab. Frost-heave is typically prevented by installing a heater mat under the freezer room floor. Ideally the mat should also extend below narrow perimeter voids outside the freezer room enclosure. Figure 3 shows the severe temperature stratification

that can occur between the roof void and floor level when two freezer rooms are placed side by side. Without good ventilation, very low temperatures may occur in the space between the rooms, leading to localized frost-heave.

Figure 3
Cross section through trapped void between freezer rooms



2.4.6 Cold store panel insulation

The recommended insulation thickness for panels with a polystyrene core is 200 mm. Polyurethane insulation is more efficient and core panels can be thinner; typically 100 to 170 mm for freezer rooms, and 100 mm for cold rooms and controlled ambient stores. A correctly specified panel insulation thickness should prevent the insulation surface temperature from falling more than 2 °C below the external air temperature, hence avoiding the dew point and resulting condensation.

2.4.7 Insulation for refrigeration pipes and other penetrations

To prevent condensation under all conditions, refrigeration pipework, electrical cables and other penetrations should be enclosed with an insulation sleeve 50–75 mm thick. These sleeves must extend for a sufficient distance beyond the cold store panel to prevent the surrounding air from cooling below the dew point. They should also be enclosed in a vapour-proof membrane to prevent condensation occurring within the insulation itself. In addition, good ventilation needs to be maintained over the surface of the sleeves.

2.4.8 Cold store maintenance schedule

Table 1 shows a suggested maintenance schedule. This can be used as a basis for developing an SOP.

Table 1
Cold store maintenance schedule

Task	Frequency
Alarm systems – heater mat	Daily
Removal of water, ice and snow from roof voids	Daily
Check operation of “trapped man” alarms	Weekly
Check operation of door seals and heaters	Weekly
Fire alarm ^a	Weekly
Check operation of emergency exits	Weekly or as required by legislation
“Walk round” inspection	Monthly
Inspection of vapour seals to ceiling panels	3-monthly
Inspection of vapour seals to wall panels	6-monthly
Mechanical installation	12 months (at least annually)
Inspection of cold store ceiling panel suspension rods and their attachments	Annually
Thermographic scan	On commissioning and every 5 years thereafter
Electrical systems	Every 5 years (ref: IEEE Code of Practice)
Professional condition survey	Every 10 years

^a See also: Technical Supplement: *Building security and fire protection*

These intervals apply only if everything is in good order; if any defects are found then checks and essential emergency repairs should be undertaken daily.

2.5 Refrigerated vehicles

Refrigerated vehicles come in various sizes but they all comprise an insulated envelope and a cooling system. The three main types are:

- refrigerated vans
- refrigerated rigid vehicles
- refrigerated semi-trailers.

2.5.1 Refrigerated vans

Refrigerated vans may either be metal skinned delivery vans that have been modified with an insulation kit, or flatbed trucks or skeletal chassis that have had a insulated box made of glass reinforced plastic (GRP) installed. These vehicles are normally 3.5 tonnes or less. The cooling equipment is a mechanical vapour compression system using power from the van's own engine. The compressor unit is typically located in the engine bay and is driven by the fan belt. Piping links the compressor to the cooling equipment inside the insulated portion of the van. The condenser unit is located either in the engine compartment or on the roof of the vehicle. Where an electric standby system is fitted, a mains-powered compressor is installed in the condenser compartment for use when the vehicle's engine is not running. An on-board electrical lead can then be connected to a suitable single-phase mains power outlet.

The vehicle operator should carry out periodic checks to confirm the condition of the insulation and cooling equipment and to verify that the maintenance procedures laid down by the vehicle body assembler and the cooling equipment manufacturer have been carried out correctly. Maintenance procedures are defined by the equipment supplier; these procedures should be obtained from the supplier and followed carefully.

Section A1.1 of **Annex 1** details the checks for the insulated body and section A1.2 describes periodic checks that should be done on the cooling equipment for refrigerated vans.

2.5.2 Refrigerated rigid bodies

Rigid vehicles have no articulation between the cab and the insulated compartment. The vehicle is supplied as a chassis to a body builder who installs the insulated structure and the refrigeration unit; these components are produced by separate manufacturers. The refrigeration unit can be a cab overhead unit, with an independent diesel and optional electric standby mode, or an underslung electrically driven unit. The power supply for the underslung refrigeration unit can be either an alternator installed on the vehicle engine or an underslung generator. Overhead cab refrigeration units can be plugged into a normal three-phase industrial supply when the vehicle is parked.

As for refrigerated vans, the vehicle operator should carry out periodic checks to confirm the condition of the insulation and cooling equipment and to verify that the maintenance procedures laid down by the vehicle body assembler and the cooling equipment manufacturer have been followed correctly.

Maintenance procedures are defined by the equipment supplier; as noted above, these procedures should be obtained from the supplier and carefully followed.

See section A1.1 of **Annex 1** for details of the checks for the vehicle body and section A1.3 for the periodic checks to be made on the cooling equipment for rigid vehicles.

2.5.3 Refrigerated semi-trailer

A semi-trailer is an articulated independent vehicle, attached and towed by a separate tractor unit. The refrigeration unit is usually nose mounted, with an independent diesel and optional electric standby mode, or sometimes an underslung, electrically driven unit. The power for the underslung refrigeration unit is supplied from an underslung generator. Nose-mounted refrigeration units can be plugged into a normal three-phase industrial supply for standby operation.

Periodic checks should be carried out by the vehicle operator as described for refrigerated rigid vehicles. Refer also to **Annex 1**, sections A1.1 and A1.3.

2.6 Refrigerated containers

Refrigerated containers (reefer containers) are likely to be the property of a carrier or shipping company and hired for a particular voyage. Refrigerated containers also sometimes appear as static stores; these could have been purchased directly from the manufacturer, but are more likely to be older seagoing units that have been made available to the aftermarket.

Refrigerated containers destined for ocean transport will already have undergone what is known as a pre-trip inspection (PTI) by the hirer. This inspection has two stages: a visual inspection of the overall condition of the insulated structure and an automatic machinery check which is performed by a PTI function on the electronic controller. The validity of a PTI, that is the time between the PTI taking place and the ocean voyage, depends on the hirer but can be between 30 and 120 days depending on the internal policies of the shipping company. It may be possible to request copies of the condition report and the electronic download of the cooling equipment PTI report from the carrier (the shipping company). It is common practice either for the logistic service provider (LSP) or the carrier to carry out the PTI before the container is delivered to the hirer for loading. The agreed procedure should be defined in a service level agreement (SLA) between the parties to the transaction.

Anyone hiring a refrigerated container has to be aware that despite the above, according to the conditions of carriage, usually documented in the bill of lading, the onus is still on the hirers to check the condition of the equipment and that it is suitable for carriage of their goods.

Checks that should be made by the cargo owner are as follows:

- check to ensure the inside of the container is clean and free of debris;
- visual check on skin integrity covering insulation;
- check on integrity of door seals and locking mechanism;
- check on drains;
- check on fresh air setting;
- check on temperature setting.

2.7 Maintenance management

Refrigeration equipment maintenance may either be carried out in-house or outsourced to suitably qualified and certified external provider(s). In both cases it is essential to establish an institutional or contractual framework with a clearly defined SLA stating the specific maintenance standards, maintenance intervals and maximum acceptable emergency response times that are required in order to protect valuable pharmaceutical products from damage or loss.

Section 2.4 of the companion Technical Supplement *Maintenance of storage facilities* outlines the necessary framework for effective maintenance management in more detail.

2.8 Decommissioning

At the end of its economic life, fixed refrigeration equipment and refrigerated vehicles need to be decommissioned. The life of a vehicle is likely to depend on the condition of the insulated body. This in turn will depend on its use, age and the effectiveness of the maintenance programme. Cold stores, if correctly maintained, can last for more than 20 years; refrigerated vehicles are unlikely to last longer than 12 years. Refrigerators and freezers are likely to have come to the end of their life when the insulation and or door seals have deteriorated to an unacceptable condition.

The following is recommended:

- a. A trained technician should remove the refrigerant from the cooling equipment. It should be incinerated in an approved plant or recycled by a refrigerant manufacturer with appropriate facilities.
- b. The insulated enclosure, if it is to be used as a store, should be made safe to ensure it is impossible for people to get trapped inside.
- c. If the insulation of the enclosure contains reagents with ozone depletion potential (ODP) or global warming potential (GWP), it should, if technically feasible, be crushed so that the foaming reagents can be recovered.

2.9 Staff training

All employees involved with the handling of refrigerants and the maintenance of insulated envelopes should be properly trained.

This training should cover:

- a. safe handling of refrigerant fluids;
- b. installation of refrigerant equipment;
- c. maintenance of insulated envelopes;
- d. servicing of refrigerant equipment.

Training should also sensitize staff to the adverse environmental impact of excessive energy consumption caused by poor management and poor maintenance procedures. Trainees also need to understand the damaging consequences of releasing high GWP refrigerants into the environment and, specifically, their effect in accelerating climate change.

Bibliography

- Economic Commission for Europe: Inland Transport Committee. Economic and Social Council. ECE/TRANS/WP.11/2011/16/Rev.1. ATP renewal tests at six and nine years for dependent equipment the refrigeration unit of which is powered by the engine of the vehicle. Economic Commission for Europe, Inland Transport Committee; 2012 (<http://www.unece.org/fileadmin/DAM/trans/doc/2012/wp11/ECE-TRANS-WP11-2011-16-Rev1e.pdf>, accessed 9 February 2015).
- Effective Vaccine Management (EVM) Initiative. EVM SOP-E5-02. Looking after cold rooms and freezer rooms. Geneva: World Health Organization; 2011 (http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/index2.html, accessed 9 February 2015).
- Effective Vaccine Management (EVM) Initiative. EVM SOP-E5-03. Installing and looking after vaccine refrigerators and freezers. Geneva: World Health Organization; 2011 (http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/index2.html, accessed 9 February 2015).
- International Air Transport Association (IATA). 2013/2014 Perishable cargo regulations (ePCR) and temperature control regulations (eTCR). Geneva: IATA (<http://www.iata.org/publications/Pages/temperature-control-regulations.aspx>, accessed 9 February 2015).
- International Association of Cold Store Contractors (European Division). Publication index (<http://www.thenbs.com/PublicationIndex/Publisher.aspx?PubID=9458&Start=1&PageSize=200>, accessed 9 February 2015).
- Lawton AR, Marshall RE. Developments in refrigerated transport insulation since the phase out of CFC and HCFC refrigerants. Beijing: International Congress of Refrigeration; 2007 (<http://www.crtech.co.uk/papers/DevelopmentsInInsulation.pdf>, accessed 9 February 2015).
- UK Institute of Refrigeration. Enclosure construction. Carshalton, Surrey: UK Institute of Refrigeration; 1996 (www.ior.org.uk/PBEM1WEIAE, accessed 9 February 2015).
- United Nations Economic Commission for Europe (UNECE). Agreement on the international carriage of perishable foodstuffs and on the special equipment to be used for such carriage (ATP). New York: United Nations; 2012 (http://www.unece.org/fileadmin/DAM/trans/main/wp11/wp11fdoc/ATP-2011_final_e.pdf, accessed 9 February 2015).

- World Health Organization. Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical pharmaceuticals. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-fifth report. Geneva: World Health Organization; 2011: Annex 9 (WHO Technical Report Series, No. 961; <http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf>, accessed 10 February 2015).

Annex 1

Checking refrigerated vehicles

The following checks should be carried out at least once every three years

A1.1 Checking insulation on a refrigerated vehicle

- a. Examine the internal and external surfaces of the bodywork for damage, corrosion and holes. Any holes or visible insulation are unacceptable and should be plated and sealed using an appropriate sealant.
- b. Check all doors and door seals. Another person should be asked to close the doors on the examiner for a few seconds; for safety reasons, ensure that the checker has a mobile phone or a third person is informed that the test is being done. Check if any daylight can be seen through the door seals; if it can, this is unacceptable and must be rectified. If the doors or their seals are damaged, repairs should be made using the correct materials.
- c. Carefully check the internal front bulkhead for damage caused by handling equipment or by cargo shifting. Specifically check that the refrigerating or air distribution systems in this area are not damaged.
- d. Check the fans and air distribution trunking, if fitted, for integrity and correct operation.

A1.2 Checking cooling equipment on a refrigerated van

- a. Equilibrate the temperature of the inside of the van to the prevailing ambient temperature.
- b. Place a temperature probe inside the vehicle in such a manner that it does not touch the floor, roof or walls.
- c. Close all doors and vents and switch on the refrigeration unit, having set its thermostat to the design temperature (e.g. +2 °C to +8 °C).
- d. Verify that the inside temperature of the empty equipment can be brought to the design temperature using either the electric standby or the diesel engine at high speed within a period of six hours. Both should be tested if they are independent systems.

- e. Verify that the inside temperature of the empty equipment can be maintained at the design temperature for a minimum period of two hours when the engine is maintained at the idle speed set by the manufacturer (where applicable) with a tolerance of about 100 revolutions per minute. This period can be reduced to one hour if the outside temperature is higher than or equal to +30 °C.
- f. Where ambient temperatures are low, verify that the design temperature can be maintained for a minimum period of two hours when the engine is maintained at the idle speed.
- g. If the unit does not achieve one or more of the above, it should be sent for servicing.
- h. Select defrost on the controller and check that the unit terminates the defrost cycle and returns to refrigeration. Check that the air circulation stops during defrosting.
- i. Again at low ambient temperatures, select a temperature setting with the thermostat between 0 °C and +5 °C, and check that the refrigeration unit heats and will control at the selected temperature.

Provided that the outcomes of the above checks are satisfactory then the unit can be approved as satisfactory for a further period in service.

A1.3 **Checking cooling equipment on a rigid vehicle or semi- trailer**

- a. Equilibrate the temperature of the inside of the trailer to the prevailing ambient temperature.
- b. Place a temperature probe inside the vehicle in such a manner that it does not touch the floor, roof or walls.
- c. Close all doors and vents and switch on the refrigeration unit, having set its thermostat to 5 °C below the design temperature (e.g. +2 °C to +8 °C).
- d. Verify that the inside temperature of the empty equipment can be brought to the design temperature within a maximum period (in minutes), as prescribed in Table A1.1.

Table A1.1
Maximum period within which temperature of the empty equipment is to be brought to the design temperature (in minutes)

Ambient °C ^a	30	29	28	27	26	25	24	23	22	21	20	19	18	17	16	15
Chilled 2–8 °C	360	350	340	330	320	310	300	290	280	270	260	250	240	230	220	210
Frozen –20 °C	180	173	166	159	152	145	138	131	124	117	110	103	96	89	82	75

^a If the ambient temperature is lower than 15 °C take the minimum time period, if higher than 30 °C take the maximum period.

- e. If the unit does not achieve the prescribed temperature change, the unit should be serviced.
- f. Select defrost on the controller and check that the unit terminates the defrost cycle and returns to refrigeration. During the defrost, check that the air circulation stops. Nose-mounted units usually have a damper which shuts off the airflow during defrost.
- g. Select a temperature setting with the thermostat between 0 °C and +5 °C, and check that the refrigeration unit heats and will control at the selected temperature.

Provided that the outcomes of the above checks are satisfactory then the unit can be approved as satisfactory for a further period in service.

Revision history

Date	Change summary	Reason for change	Approved