Supplement 16

Environmental management of refrigeration equipment

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

May 2015

Contents

Abbreviations 3

Acknowledgements 4

Glossary 5

1. Introduction 7

- 1.1 Requirements 7
- 1.2 Objectives 7
- 1.3 Target readership 8

2. Guidance 9

- 2.1 Associated materials and equipment 9
- 2.2 Montreal Protocol 9
- 2.3 Selection of refrigerants and blowing agents 10
  - 2.3.1 Use of chlorofluorocarbons (CFCs) 10
  - 2.3.2 Use of hydrochlorofluorocarbons (HCFCs) 10
  - 2.3.3 Use of hydrofluorocarbons (HFCs) 10
  - 2.3.4 Use of hydrofluoroolefin (HFO) 11
  - 2.3.5 Use of hydrocarbons (HCs) 11
  - 2.3.6 Ammonia and carbon dioxide 11
  - 2.3.7 Other cooling technologies 12
- 2.4 Counterfeit refrigerants 12
- 2.5 Thermal insulation 13
- 2.6 CO_2 emissions 13
  - 2.6.1 Kyoto Protocol 13
  - 2.6.2 CO_2 emissions from prime mover 13
  - 2.6.3 ODP and high GWP refrigerants 14
- 2.7 Installation and maintenance 15
- 2.8 Decommissioning 15
- 2.9 Staff training 16

Bibliography 17

Annex 1

Montreal Protocol: non-Article 5 countries 19

Revision history 20

Abbreviations

A2L	An ASHRAE flammability class
ASHRAE	American Society of Heating, Refrigerating and Air-Conditioning Engineers
ATP	Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for such Carriage
BS EN	British Standard European Norm
CFC	chlorofluorocarbons
EN 378	European Norm (standard) on the safety of refrigerants
F-Gas	fluorinated gas
GWP	global warming potential
HC	hydrocarbon
HCFC	hydrochlorofluorocarbon
HFC	hydrofluorocarbon
HFO	hydrofluoro-olefin
MOP-19	Nineteenth Meeting of the Parties to the Montreal Protocol
ODP	ozone depletion potential
ODS	ozone depleting substance
SOP	standard operating procedure
TEWI	total equivalent warming impact
TTSPP	time- and temperature-sensitive pharmaceutical product
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme

Acknowledgements

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

Glossary

Article 5 country: The main objective of the Multilateral Fund for the Implementation of the Montreal Protocol is to assist developing country parties to the Montreal Protocol whose annual per capita consumption and production of ozone-depleting substances (ODS) is less than 0.3 kg to comply with the control measures of the Protocol. Currently, 147 of the 196 parties to the Montreal Protocol meet these criteria (they are referred to as Article 5 countries).

Non-Article 5 country: Parties to the Montreal Protocol that have an ODS consumption of greater than 0.3 kg per capita on the date of entry of the Montreal Protocol, or at any time thereafter within 10 years of the date of entry into force of the Protocol.

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]

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.

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 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.

---

[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.

[2] Definition from International Air Transport Association (IATA). 2013/2014 Perishable cargo regulations (ePCR) and Temperature control regulations (eTCR).

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 (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.

1. Introduction

This technical supplement has been written to amplify the recommendations given in section 10.2 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 gives guidance on the selection of refrigerant gases and blowing agents so that countries can minimize the environmental impact of cold chain equipment used in fixed storage and transport operations. Related topics are covered in the Technical Supplement: *Maintenance of refrigeration equipment*.

1.1 Requirements

Ensure that all new refrigeration equipment for temperature-controlled storage and transport is specified to:

- use refrigerants that comply with the Montreal Protocol;
- minimize or eliminate the use of refrigerants with high global warming potential (GWP), and;
- minimize carbon dioxide (CO_2) emissions during operation.

Select equipment to minimize whole-life environmental impact and employ best practice to eliminate leakage of refrigerant into the environment during installation, maintenance and decommissioning of refrigeration equipment.

Follow standard operating procedures (SOPs) for purchase, maintenance and end of equipment life disposal, and ensure compliance with international protocols and accords on climate change and environmental protection. Train staff to avoid excessive release of refrigerants.

1.2 Objectives

The objectives of this Technical Supplement are to provide guidance on how to meet the above requirements with regard to the environmental impact of fixed and mobile refrigeration equipment, while ensuring the efficacy of TTSPP storage and transportation.

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

1.3 Target readership

The target audience is principally the owners and operators of warehouses, pharmacies and other stores and owners and operators of refrigerated vehicles used to transport TTSPPs. Some of the content may also be useful to equipment manufacturers and suppliers.

2. Guidance

The component elements of refrigeration systems contain gases which can cause long-term environmental damage; some products may also be toxic or flammable. The principal focus of this Technical Supplement is to prevent these gases from leaking into the atmosphere where they accumulate, or into the immediate environment where they may affect occupants or become a fire hazard.

Refrigerant gases containing chlorine or bromine have a high ozone depletion potential (ODP) and damage the planet's ozone layer. These and several other gases also have a high global warming potential (GWP) and contribute disproportionately to the continuing increase in global warming.

The principal focus of the environmental impact is the refrigeration source and the prime mover. However, the thermal performance of cold room and refrigerator insulation and the insulation of the bodies of refrigerated vehicles also have an impact. Insulation limits heat transmission. This reduces the size and refrigerant charge needed for the cooling machinery, reduces energy consumption and hence limits CO_2 emissions from the refrigeration plant. However, the blowing agents used to manufacture many insulation products may have a high ODP and/or high GWP. Leakage of these agents into the atmosphere during the service life of the equipment and during end of life disposal can therefore have an adverse environmental impact.

2.1 Associated materials and equipment

Minimizing the emission of gases with high GWP requires rigorous service procedures and appropriate service equipment. Service equipment includes refrigerant recovery machines, refrigerant recovery bottles and leak detectors.

2.2 Montreal Protocol

Use of refrigerant gases and blowing agents is governed by the Montreal Protocol on Substances that Deplete the Ozone Layer. This Protocol was subsequently adjusted and/or amended in London in 1990, Copenhagen in 1992, Vienna in 1995, Montreal in 1997 and Beijing in 1999.

Under the amendments and adjustments to the Protocol, non-Article 5 parties (see **Annex 1**) were required to phase out production and consumption of: halons by 1994; chlorofluorocarbons (CFCs), carbon tetrachloride, hydrobromochlorofluorocarbons and methyl chloroform by 1996; bromochloromethane by 2002; and methyl bromide by 2005. Article 5 parties were required to phase out production and consumption of hydrobromochlorofluorocarbons by 1996, bromochloromethane by 2002, and CFCs, halons and carbon tetrachloride by 2010. Article 5 parties must still phase out production and consumption of methyl chloroform and methyl bromide by 2015. Under the accelerated phase-out of hydrochlorofluorocarbons (HCFCs) adopted at the Nineteenth Meeting of the Parties to the Montreal Protocol (MOP 19), HCFC production and consumption by non-Article 5 parties was frozen in 2004 and is to be phased out by 2020, while for Article 5 parties, HCFC production and consumption was to be frozen by 2013 and phased out by 2030 (with interim targets prior to those dates, starting in 2015). There are exemptions to these phase-outs to allow for certain uses for which feasible alternatives are lacking.

2.3 Selection of refrigerants and blowing agents

A numbering system is used for refrigerants (e.g. R-134a), developed by the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE). Prefixes can be: R, CFC, HCFC, HFC or HFO. The rightmost numeric value indicates the number of fluorine atoms in the molecule, the next value to the left is the number of hydrogen atoms plus 1, and the next value to the left is the number of carbon atoms less one (zeroes are not stated). The remaining atoms are chlorine.

2.3.1 Use of chlorofluorocarbons (CFCs)

A CFC is an organic compound that contains only carbon, chlorine, and fluorine, produced as a substituted derivative of methane and ethane. It is an ozone-depleting compound, which is highly damaging to the environment.

It is now illegal to operate refrigerated vehicles using CFCs as the refrigerating fluid or to have CFCs within the insulation in non-Article 5 countries. WHO recommends that fixed refrigeration equipment and refrigerated vehicles containing CFC's should not be purchased or operated.

2.3.2 Use of hydrochlorofluorocarbons (HCFCs)

HCFCs are similar to CFCs but contain hydrogen and have a lower ozone-depleting potential.

It is now illegal to purchase new refrigerated vehicles that use HCFCs as the refrigerating fluid or that have HCFCs within the insulation in non-Article 5 countries, although they can still be operated using recycled refrigerant. It is recommended that refrigerated vehicles containing HCFCs should not be purchased in Article 5 countries although they can and should be operated until the end of their design life.

2.3.3 Use of hydrofluorocarbons (HFCs)

HFC refrigerants are composed of hydrogen, fluorine and carbon atoms connected by single bonds; they do not deplete the ozone layer because they do not contain chlorine or bromine. However, they do have a high GWP; some higher than others. Atmospheric concentrations of these gases are rapidly increasing.

Currently most refrigerated transport solutions and most fixed refrigeration equipment depend on the use of HFCs and there is no alternative; however HFCs with lower GWP should be considered. Hydrocarbons are recommended for smaller systems.

2.3.4 Use of hydrofluoroolefin (HFO)

HFO (hydrofluoroolefin) refrigerants are the fourth generation of fluorine-based refrigerants. HFO refrigerants are composed of hydrogen, fluorine and carbon atoms, but contain at least one double bond between the carbon atoms.

These compounds have zero ODP and a very low GWP. Therefore these products offer a more environmentally friendly alternative, although there are issues with flammability.

At the time of writing, these products are in an early stage of development but are beginning to be introduced into the market. When available they would be an acceptable alternative, providing machinery is correctly designed to take into account their flammability.

2.3.5 Use of hydrocarbons (HCs)

Several hydrocarbons (HCs) have excellent refrigeration fluid properties, zero ODP, and very low GWP. The sole disadvantage of using HCs is their flammability and the risk of explosion. It is recommended that small refrigerators with refrigerant charges of less than 150 g should be preferentially purchased where an option to do so exists. Larger charges can be used, provided safety conditions are met.

The limiting factor associated with the use of HC refrigerants is the refrigerant charge size, the occupancy category and the room size. Systems with charge sizes of 0.15 kg or less may be installed in a room of any size. However, for systems with charge size of more than 0.15 kg and up to 1.5 kg, the room size should be such that a sudden loss of refrigerant does not raise the mean gas concentration in the room above the practical limit 0.008 kg/m^3. If it is proposed to use even large charges of HC, this is permitted although it is strongly recommended that European Norm (standard) EN 378 on the safety of refrigerants be consulted for safety recommendations.

2.3.6 Ammonia and carbon dioxide

Ammonia has excellent refrigerant properties and has been used for many years in larger cold stores. It is still widely used in gas and kerosene-fuelled absorption refrigerators and freezers, which provide cold chain in places without a reliable electrical supply. Ammonia is inexpensive and leaks can easily be detected by smell, it has no ODP and low GWP. Its disadvantages are that it has moderate flammability and is toxic.

Carbon dioxide (CO_2) could well be the refrigerant of the future. It has mostly good thermodynamic properties and it is starting to be used in supermarket, cold store and bottle cooler applications. It has no ODP and a GWP, by definition, of 1. Its main disadvantages are high operating pressures and a critical point (inability to condense) of 29 °C, which makes it operate less efficiently, transcritically, in hot environments.

2.3.7 Other cooling technologies

Other technologies for cooling exist that do not, in themselves, have ODP but are less common than vapour compression and absorption systems. However all passive systems such as liquid nitrogen, ice-packs and phase change material (PCM)-packs rely on a source of mechanical cooling using one of the gases described above. Examples include:

- *Liquid nitrogen:* used for cooling in some countries.
- *Liquid or dry CO_2:* liquid CO_2 is used for cooling refrigerated vehicles in some countries. Solid carbon dioxide (dry ice) is used to keep small packs cool.
- *Water-packs:* Water-based coolant-packs may either be frozen (ice-packs) or cooled (cool water-packs). They are placed in insulated containers to help maintain the temperature of the stored product.
- *PCMs:* these are coolant-packs containing waxes or other substances that are pre-cooled and placed in insulated containers like water-packs. PCMs have the specific advantage that they can be designed to change phase at a desired temperature – e.g. +5 °C.
- *Peltier effect:* Peltier cooling is an electronic system that can be used to maintain the temperature of small cool boxes.

2.4 Counterfeit refrigerants

A problem with counterfeit refrigerants has emerged in recent years in response to the restrictions put in place by the Montreal Protocol. These refrigerants are labelled as pure HFCs or HFC mixtures but in fact contain a cocktail of refrigerants including those with an ODP. Some counterfeit blends contain methyl chloride, which is toxic and can react with aluminium components, sometimes causing explosions. Counterfeit refrigerants usually contain chlorine; they are cheaper than might be expected and do not come through recognized supply channels. Refrigerants containing chlorine can be detected using a flame halide torch.

2.5 Thermal insulation

Foam insulation in cold store panels, refrigerator casings and refrigerated vehicle bodies has a considerable environmental impact. The insulation foam is expanded with a reagent that can have a GWP or ODP and the efficacy of the insulation affects the fuel consumption of the refrigeration equipment. Insulation also ages and can deteriorate by around 5% each year. As the foam deteriorates, the blowing agent leaches away; this adds to GWP and gives rise to additional fuel and electricity consumption.

2.6 CO_2 emissions

CO_2 emissions from the prime mover driving the refrigeration equipment are affected by the efficacy of the insulation and contribute to GWP via the total equivalent warming impact (TEWI). The more work the refrigeration system does, the more energy is consumed and therefore the higher the CO_2 emissions. The regulations of the Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for such Carriage (ATP regulations) for frozen transport state that the insulation should have a value of <0.4 W/m²K and for chilled transport a value of <0.7 W/m²K. It is recommended that new vehicles be selected with an insulation coefficient <0.4 W/m²K.

2.6.1 Kyoto Protocol

The Kyoto Protocol to the United Nations Framework Convention on Climate Change is an international treaty that is supposed to set binding obligations on industrialized countries to reduce emissions of GWP (greenhouse) gases. While all countries agree that GWP affects the climate, there is disagreement about accepting all of the reduction implications and therefore some countries have not signed or ratified the agreement. Nevertheless, responsible operators of fixed and mobile refrigeration equipment should take steps to minimize energy consumption and GWP gas emissions. This is also likely to be in their own long-term economic interest, because of the savings in operational cost from using more efficient equipment.

2.6.2 CO_2 emissions from prime mover

The size of the refrigeration equipment relative to the heat load has a significant effect on CO_2 emissions. The ATP agreement stipulates an over-capacity of a least 1.75 times the overall heat ingress into the insulated body under operating conditions and +30 °C ambient temperature. If the predicted ambient temperature is above +30 °C, it would be prudent to increase the over-capacity to 2.25.

2.6.3 ODP and high GWP refrigerants

When selecting fixed refrigeration systems and refrigerated vehicles, those involved in the procurement procedure should consider the ODP and GWP of the refrigerating fluid used in the cooling equipment and the blowing agent in the insulating foam. Table 1 gives the ODP and GWP of popular refrigerating fluids used in refrigeration systems. When specifying new equipment, the table can be used to help select reagents with zero ODP and the lowest technically possible GWP.

Table 1
ODP and GWP of common refrigerants and blowing agents

Refrigerant	Name	Structure	GWP	ODP
CFC-11	trichlorofluoromethane	CCl_3F	4 750	1
CFC-12	dichlorodifluoromethane	CCl_2F_2	10 900	1
CFC-502	chlorodifluoromethane chloropentafluoroethane	$CHClF_2$ $CClF_2CF_3$	4 657	0.25
HCFC-141b	1,1-dichloro-1-fluoroethane	CCl_2FCH_2	725	0.12
HCFC-22	chlorodifluoromethane	$CHClF_2$	1 810	0.05
HFC-134a	1,1,1,2-tetrafluoroethane	CH_2FCF_3	1 430	0
HFC-404a	pentafluoroethane 1,1,1-trifluoroethane 1,1,1,2-tetrafluoroethane	CHF_2CF_3 CH_3CF_3 CH_2FCF_3	3 922	0
HFC-407a	difluoromethane pentafluoroethane 1,1,1,2-tetrafluoroethane	CH_2F_2 CHF_2CF_3 CH_2FCF_3	2 107	0
HFC-410a	difluoromethane pentafluoroethane	CH_2F_2 CHF_2CF_3	2 088	0
HFO-1234yf	2,3,3,3-tetrafluoropropene	$CF_3CF{=}CH_2$	4	0
HFO-1234ze	trans-1,3,3,3-tetrafluoropropene	$CF_3CH{=}CHF$	6	0
N/A	cyclopentane	C_5H_{10}	11	0
HC-290	propane	$CH_3CH_2CH_3$	11	0
HC-600s	isobutane	$CH(CH_3)_2CH_3$	3	0
R-717	ammonia	NH_3	0	0
R-744	carbon dioxide	CO_2	1	0

CFC-11 and HCFC-141b were previously used as insulation foam blowing agents. These gases have now been mostly replaced with cyclopentane, although various HFCs are sometimes used. First-generation CFC refrigerants, such as CFC-12 and CFC-502, are no longer used. HCFC-22, and blends containing this gas, have a lower ODP and are now used less frequently; they are illegal in non-Article 5 countries. HFC-134a and HFC-404a are commonly used refrigerants. However, there is now pressure on HFC-404a because of its high GWP and alternatives are being sought. HFOs are the new generation of refrigerants currently under development, but these have flammability concerns in the form of "slow flame propagation"; they are classed by ASHRAE as A2L, low toxicity, low flammability refrigerants with a maximum burning velocity of ≤ 10 cm/s. Ammonia has been used for many years in large stores; CO_2 is now used in larger equipment and in development models of refrigerators and transport units.

2.7 Installation and maintenance

Only technicians trained in handling refrigerant gases should carry out the installation and maintenance of refrigeration equipment.

Historically, vehicle-cooling systems have high levels of gradual leakage from mechanical seals, glands, valves and mechanical joints. Generally, fixed equipment has lower leakage rates.

Regular leakage checks can identify such leaks and minimize emissions. An inventory should be maintained and an associated SOP detailing the following:

- quantity and type of refrigerant charge in each piece of equipment;
- quantities of refrigerant added at service;
- quantities of refrigerant recovered in service;
- dates and results of leakage checks;
- identity of personnel undertaking checks.

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, although it is unlikely to be in excess of 15 years, and more likely 12 years.

The following is recommended:

- 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.

- 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.
- If the insulation of the enclosure contains ODP or GWP reagents, it should, if technically feasible, be crushed so that the foaming reagents can be recovered.
- Absorption refrigerators should be disposed of with care as they are pressurized and older units contain a corrosion inhibitor (sodium dichromate). Some countries restrict the disposal of this substance in landfill.

2.9 Staff training

All employees who are involved with the handling of refrigerants should be given training. This should include:

- handling of refrigerant fluids;
- installation;
- maintenance;
- servicing.

Training should also include reference to the environmental impact of releasing high GWP refrigerants into the environment and their effect in accelerating climate change.

Bibliography

- American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE). Designation and safety classifications of refrigerants. Atlanta (GA): ASHRAE; 2010 (www.ashrae.org/File%20Library/docLib/Public/20100309_34_2007_ak_final.pdf, accessed 25 March 2015).
- Department for Environment, Food & Rural Affairs. Managing fluorinated gases and ozone-depleting substances. 2013 (https://www.gov.uk/managing-fluorinated-gases-and-ozone-depleting-substances, accessed 25 March 2015).
- International Air Transport Association (IATA). 2013/2014 Perishable cargo regulations (ePCR) & temperature control regulations (eTCR). Geneva: IATA (http://www.iata.org/publications/Pages/temperature-control-regulations.aspx, accessed 25 February 2018).
- Lawton AR, Marshall N, Clarke P. Counterfeit refrigerant in food transportation sea containers. Paris: IIR/IIF Cold Chain; 2013 (http://www.crtech.co.uk/papers/CounterfeitRefrigerantInFoodTransportationContainers.pdf, accessed 25 March 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 25 March 2015).
- Regulation (EC) no 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer. Official Journal of the European Union L 286/1 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:286:0001:0030:EN:PDF, accessed 25 March 2015).
- Regulation (EC) no 842/2006 of the European Parliament and of the Council of 17 May 2006 on certain fluorinated greenhouse gases. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:161:0001:0011:EN:PDF
- 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). United Nations; 1970 (http://www.unece.org/fileadmin/DAM/trans/main/wp11/wp11fdoc/ATP-2011_final_e.pdf, accessed 25 March 2015).

- United Nations Environmental Programme (UNEP). 2010 Report of the refrigeration, air conditioning and heat pumps technical options committee.[4] (http://ozone.unep.org/teap/Reports/RTOC/RTOC-Assessment-report-2010.pdf, accessed 25 March 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).

4 Every four years a comprehensive report is produced by UNEP on substances that deplete the ozone layer and the Montreal Protocol.

Annex 1

Montreal Protocol: non-Article 5 countries

1. Andorra
2. Australia
3. Austria
4. Azerbaijan
5. Belarus
6. Belgium
7. Bulgaria
8. Canada
9. Cyprus
10. Czech Republic
11. Denmark
12. Estonia
13. European Union
14. Finland
15. France
16. Germany
17. Greece
18. Holy See
19. Hungary
20. Iceland
21. Ireland
22. Israel
23. Italy
24. Japan
25. Kazakhstan
26. Latvia
27. Liechtenstein
28. Lithuania
29. Luxembourg
30. Malta
31. Monaco
32. Netherlands
33. New Zealand
34. Norway
35. Poland
36. Portugal
37. Russian Federation
38. Romania
39. San Marino
40. Slovakia
41. Slovenia
42. Spain
43. Sweden
44. Switzerland
45. Tajikistan
46. Ukraine
47. United Kingdom
48. United States of America
49. Uzbekistan

Revision history

Date	Change summary	Reason for change	Approved