



BSI Standards Publication

Thermal road vehicles — Temperature-controlled systems using flammable refrigerants for transport of goods — Requirements and risk analysis process

National foreword

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The UK participation in its preparation was entrusted to Technical Committee TW/1, Freight containers and swap bodies.

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English Version

**Thermal road vehicles - Temperature-controlled systems
using flammable refrigerants for transport of goods -
Requirements and risk analysis process**

Véhicules routiers réfrigérés - Systèmes sous contrôle
de température utilisant des fluides frigorigènes
inflammables pour le transport de marchandises -
Exigences et processus d'analyse des risques

Anforderungen und Risikoanalyseverfahren für
Kühlanlagen für den Straßentransport von
temperaturempfindlichen Gütern, die mit brennbaren
Kältemitteln betrieben werden

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European foreword

This document (EN 17893:2024) has been prepared by Technical Committee CEN/TC 413 “Insulated means of transport for temperature sensitive goods with or without cooling and/or heating device”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2024, and conflicting national standards shall be withdrawn at the latest by December 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Introduction

For many years, hydrofluorocarbons (HFCs) have been the preferred refrigerants used in refrigerating systems of truck and trailer road vehicles and vans (TRV). However, the use of these refrigerants is being now considered as unacceptable due to their contribution to global warming. Regulation (EU) No 517/2014 of the European Parliament and of the Council imposes provisions for the reduction of the use of HFCs, in order to reduce the emissions of these fluorinated gases and lower the impact of their use on climate change. The use of HFCs is regulated in all EU Member States, the United Kingdom and EFTA countries and these fluorinated gases are to be phased down.

The continuous improvement of refrigerating systems in terms of reduction of greenhouse gas (GHG) emissions and energy efficiency results in the deployment of technologies which has entailed the use of flammable refrigerants. The use of these flammable refrigerants in transport refrigeration units (TRU's) may raise specific safety concerns or pose additional hazards which should be considered in the design phase and during operation, correspondingly in all phases of the product life cycle. Leakage of flammable refrigerants may lead to fire, explosion, or toxicity when decomposed.

This document has been developed to enable the safe use of flammable refrigerants in TRU's. This document enables system manufacturers, owners, and operators to understand and validate the risks associated with operation, especially for maintenance and repair. This document provides requirements and methodology to an acceptable level of safety.

For TRV's this document supplements EN 378 (all parts) with specific additional requirements. It provides minimum requirements for a risk-based approach to reduce the threat to persons, assets, and the environment.

The working group which developed this document consisted of representatives from refrigerating system manufacturers, refrigerated vehicle body builder, notified body, equipment owners and other interested industry experts.

1 Scope

This document specifies requirements for the use of flammable refrigerants class A2L, A2 and A3 as defined in ISO 817 with regard to:

- design and construction of the refrigerating system (as far as not specified in EN 378-2);
- operation;
 - in all anticipated operational modes and locations;
 - including continuous idling during standstill;
- service, maintenance and decommissioning;
- for the investigation and mitigation of risk for thermally insulated means of transport, including: trucks, trailers, tanks, vans (light commercial vehicles), wagons, containers for land transport, small containers, packaging.

This document describes an Operational Mode Risk Assessment (OMRA), which uses methods such as Hazard and Operability Analysis (HAZOP), Failure Mode and Effects and Criticality Analysis (FMECA), or Fault Tree Analysis (FTA) or a combination of these methods.

The document specifies requirements:

- for the validation of possible safety concepts and protective devices within the OMRA process, including charge release tests, simulation, and function tests of the associated protective equipment;
- for tests related to the application;
- using methodologies to achieve tolerable risk values.

Mobile air conditioning systems in cars are covered in ISO 13043 and refrigerated containers conforming to ISO 20854 are excluded.

This document could be used for class “B” refrigerants providing the OMRA is adjusted to account for their specific properties.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 378-1:2016+A1:2020, *Refrigerating systems and heat pumps — Safety and environmental requirements — Part 1: Basic requirements, definitions, classification and selection criteria*

EN 378-2:2016, *Refrigerating systems and heat pumps — Safety and environmental requirements — Part 2: Design, construction, testing, marking and documentation*

EN 378-4:2016+A1:2019, *Refrigerating systems and heat pumps — Safety and environmental requirements — Part 4: Operation, maintenance, repair and recovery*

EN 1127-1:2019, *Explosive atmospheres — Explosion prevention and protection — Part 1: Basic concepts and methodology*

EN 1736:2008, *Refrigeration systems and heat pumps — Flexible pipe elements, vibration isolators, expansion joints and non-metallic tubes — Requirements, design and installation*

EN 14624, *Performance of portable locating leak detectors and of fixed gas detectors for all refrigerants*

EN ISO 7010:2020, *Graphical symbols — Safety colours and safety signs — Registered safety signs (ISO 7010:2019, Corrected version 2020-06)*

EN ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction (ISO 12100:2010)*

EN 60068-2-6, *Environmental testing — Part 2-6: Tests — Test Fc: Vibration (sinusoidal) (IEC 60068-2-6)*

EN 60068-2-75, *Environmental testing — Part 2-75: Tests — Test Eh: Hammer tests (IEC 60068-2-75)*

IEC 60079-10-1:2020, *Explosive atmospheres — Part 10-1: Classification of areas — Explosive gas atmospheres*

EN 60079-14, *Explosive atmospheres — Part 14: Electrical installations, design, selection and erection (IEC 60079-14)*

IEC 60079-15:2020, *Explosive atmospheres — Part 15: Equipment protection by type of equipment “n”*

IEC 60079-29-1, *Explosive atmospheres — Part 29-1: Gas detectors — Performance requirements of detectors for flammable gases*

IEC 60335-2-40:2018, *Household and similar electrical appliances — Safety — Part 2-40: Particular requirements for electrical heat pump, air-conditioners and dehumidifiers*

ISO 817:2014, *Refrigerants — Designation and safety classification*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1

air ventilation duct

connection between an inside compartment volume and an outside and/or other compartment volume as part of a protective device that can be used for ventilation of the compartment volume to dilute unexpected refrigerant release

3.2

alarm system

system constituting all electrical and electronic parts of the refrigerating system which monitor the correct function of the refrigerating system and the protective device(s) and may give a warning in case of malfunctioning or refrigerant leakage

3.3**authorized service facility**

service facility that is authorized by the manufacturer to repair and to maintain the TRU

3.4**compartment volume**

insulated closed space (cargo compartment) which is cooled by the refrigerating system or heated and not intended to be occupied, except periodically for loading and unloading

Note 1 to entry: The compartment volume can have several separate sections.

Note 2 to entry: The compartment volume can include the evaporator space.

Note 3 to entry: The compartment volume can also be built in a vehicle using an heat insulation kit, refer to EN 17066-1:2019, 3.1.8.

Note 4 to entry: For the definition of a compartment refer to EN 17066-1:2019, 3.1.1.6.

3.5**condenser space**

space in the outside of the TRU where condenser, condenser fan and associated pipes are located

Note 1 to entry: The air-cooled condenser section is not a confined space.

Note 2 to entry: The condenser section corresponds to control volume II described in Annex A.

3.6**control volume****CV**

theoretical volume representing a space in which a flammable atmosphere can occur as a consequence of a refrigerant leak and the ventilating condition

Note 1 to entry: It can be delimited by the internal or external space of the vehicle dimensions , and/or by specific component compartments.

Note 2 to entry: A description of CVs is included in Annex A.

3.7**enhanced tightness**

absence of refrigerant leakage in the circuit when due to the design and measures of maintenance any of the tightness tests or tightness monitoring appropriate for the application does not reveal any hazardous leaks during normal operations and expected malfunctions

[SOURCE: EN 1127-1:2019, 3.2, modified — The words “refrigerant” and “in the circuit” and the Note 1, 2, 3 to entry have been added.]

Note 1 to entry: Fugitive emissions (see 3.31.1) are regarded in this application as leaks which will not result to significant hazards according to EN ISO 12100:2010, 3.8.

Note 2 to entry: Additional information can be found in EN 1127-1:2019, Annex B.

Note 3 to entry: Clause 6, Clause 8 and especially Clause 9 provide information on design and operational aspects to maintain tightness, permanently ensured by means of enhanced maintenance and supervision.

3.8

environment ventilation

environmental condition related to the footprint of the vehicle, on which the TRU is mounted, capable of diluting releases of hazardous substances

Note 1 to entry: Defined ventilation conditions are sufficient to dilute fugitive emissions to non-hazardous concentration.

3.8.1

open air

any unenclosed space, possibly but not necessarily roofed, with, as a minimum, natural ventilation

Note 1 to entry: The environment ventilation “open air” refers to or represents areas or operating sites such as loading/unloading areas, inspection, (roofed) repair areas.

[SOURCE: EN 378-1:2016+A1:2020, 3.2.8, modified — The words “with, as a minimum, natural ventilation” and Note 1 to entry have been added.]

3.8.2

well-ventilated

area which is naturally or mechanically ventilated

Note 1 to entry: The environment ventilation “well-ventilated” refers or represent areas or operating sites such as workshops, system repair areas where ventilation requirements are established according to workplace requirements.

3.8.3

non-well-ventilated

area other than open air or well-ventilated

Note 1 to entry: The environment ventilation “non-well-ventilated” should be considered if an artificial or forced ventilation system is not in operation (due to power failures or other type of malfunction).

Note 2 to entry: For release rate and accumulation time of hazardous substances in non-well-ventilated areas or operating sites see Annex D.

3.9

evaporator space

space containing the evaporator, associated piping, connections, housing and air ducts inside the cold compartment volume

Note 1 to entry: The evaporator space corresponds to CV III (see Annex A).

3.10

external power supply

connected to grid or independent generator

3.11

type of failure

3.11.1

rare malfunction

type of malfunction which may happen only in rare instances

Note 1 to entry: Rare malfunctions could include unanticipated conditions that are not covered by the TRU design such as unexpected loose connection, or unexpected corrosion that results in a release. Where releases due to corrosion or similar conditions may or could reasonably be expected as part of the plant operations then this is not considered as a rare malfunction.

[SOURCE: IEC 60079-10-1:2020, 3.7.3 modified — NOTE 1 has been omitted and NOTE 2 has been modified]

3.11.2

catastrophic failure

reasonably unexpected occurrence which exceeds the design parameters of the TRU and control system resulting in an accidental type release of flammable refrigerant

Note 1 to entry: Catastrophic failures in the context of this standard include, for example, major accidents, crash such as the rupture of a component, equipment or piping such as total breakdown of a flange or seal.

[SOURCE: IEC 60079-10-1:2020, 3.7.4, modified — In the definition, the word “process plant” has been replaced with “TRU” and the words “an accidental type” have been added. In addition, NOTE 1 is modified.]

3.12

flammable atmosphere

mixture with air, under atmospheric conditions, of flammable refrigerant in the form of gas or vapour, which after ignition, permits self-sustained flame propagation

Note 1 to entry: For example, a mixture of flammable refrigerant fluid with air under atmospheric conditions.

[SOURCE: IEC 60079-10-1:2020, 3.2]

3.13

flammability limit

Note 1 to entry: The flammability limits are function of temperature and humidity. For refrigerants flammability, ISO 817:2014 defines test conditions of 50 % relative humidity at 23,0 °C and 101,3 kPa for burning velocity and LFL/UFL measurements. The effect of a reduced lower flammability limit and an increased upper flammability limit at higher operational humidity and temperature levels can be taken into account in the operational mode risk assessment.

3.13.1

lower flammability limit

LFL

minimum concentration of the refrigerant that is capable of propagating a flame through a homogeneous mixture of the refrigerant and air under the specified test conditions at 23,0 °C and 101,3 kPa

[SOURCE: ISO 817:2014, 3.1.24, modified — NOTE 1 and NOTE 2 have been omitted.]

3.13.2

upper flammability limit

UFL

concentration of flammable gas or vapour in air, above which the gas atmosphere is not flammable

[SOURCE: IEC 60079-10-1:2020, 3.6.13, modified — In the definition, the words “or mist” have been removed after “vapour”. Also, at the end, after “above which”, “an explosive gas atmosphere will not be formed” has been changed to “the gas atmosphere is not flammable”.]

3.14

flammable refrigerant

refrigerant with a classification of class 2L, 2 or 3 in compliance with ISO 817:2014 classification

3.14.1

auto-ignition temperature

AIT

lowest temperature of a hot surface at which, under specified conditions, an ignition of a flammable gas or vapour in mixture with air occurs

[SOURCE: IEC 60079-10-1:2020, 3.6.11, modified — In the definition, the words “/inert gas” have been removed after “air”]

3.14.2

reaction threshold temperature

RTT

lowest temperature of a substance at which a chemical can be decomposed spontaneously in a normal atmosphere, in the presence of an external source of ignition, such as an open flame, hot surface or spark

Note 1 to entry: As an estimation, the following values may be used: $RTT_{est} = AIT - 100\text{ °C}$.

3.14.3

hot surface ignition temperature

HSIT

highest temperature at which a refrigerant does not ignite when tested in accordance with Annex KK in IEC 60335-2-40:2018

[SOURCE: IEC 60335-2-40:2018]

3.15

flammable substance

substance in the form of gas, vapour, liquid, or mixtures of these, able to propagate a flame from an ignition source

3.16

hazardous area

area in which a flammable or toxic atmosphere is present, or may be expected to be present, in quantities such as to require special precautions for construction, installation or use of apparatus

[SOURCE: IEC 60079-10-1:2020, 3.3.1, modified — In the definition, the word “explosive” has been replaced with “flammable and toxic”.]

3.16.1**non-hazardous area**

area in which a flammable or toxic atmosphere is not expected to be present in quantities such as to require special precautions for construction, installation and use of equipment

[SOURCE: IEC 60079-10-1:2020, 3.3.2, modified — In the definition, the word “explosive” has been replaced with “flammable and toxic”.]

3.16.2**temporary hazardous area**

hazardous area for a short period of time as a consequence of an abnormal or accidental type leak

3.17**inside component**

component of the refrigerating system, which is located inside the insulated compartment volume (3.4)

3.18**intended use**

use of the transport refrigeration unit (TRU) in accordance with the information for use provided in the instructions

Note 1 to entry: The intended use includes all operational modes described in 5.5.2.

[SOURCE: EN ISO 12100:2010, 3.23, modified — The words “a machine” have been replaced with “the TRU” and Note 1 to entry has been added.]

3.18.1**normal operation**

situation when the equipment is operating within its designed parameters

Note 1 to entry: Failures (such as the breakdown of components or ruptures) which involve shut-down and urgent repair are not considered to be part of normal operation.

Note 2 to entry: Normal operation includes start-up and shut-down conditions, and “off”, “on”, cooling, defrost and heating, if appropriate.

Note 3 to entry: Normal operation can include occurrence of fugitive emissions. Normal operation does not include larger leaks. Normal operation of the TRU requires a certain minimum refrigerant charge.

[SOURCE: IEC 60079-10-1:2020, 3.7.1, modified — NOTE 1 and NOTE 2 have been modified and NOTE 3 to entry has been added]

3.18.2**stationary operation**

use of a TRV for cooling and storage of goods whilst not in motion

3.18.3**reasonably foreseeable misuse**

use of the TRU in a way not intended by the designer, but which can result from readily predictable human behaviour, or, in the absence of such information, by generally understood patterns of usage

[SOURCE: EN ISO 12100:2010, 3.24, modified — The words “a machine” have been replaced with “the TRU”.]

3.19

loading/unloading

action of filling/removing cargo/goods into/from the thermal insulated compartment volume, cargo space

3.20

multi-temperature compartment volume

cargo space divided by insulated partition walls in two or more insulated compartment volumes and equipped with a cooling and/or heating device for maintaining different temperatures

3.21

non-occupied space

compartment volume which is not occupied for a significant period of time by person(s)"

Note 1 to entry: For loading and unloading of goods, the doors to the insulated compartment volume(s) are open, see 8.5.

3.22

on the road operation

operation of the cooling and/or heating device using an independent power source or the mechanical or electrical power supplied by the vehicle

3.23

operating site

site or location of operation in which a vehicle with a TRU can be operated, repaired, or stored during the intended use

3.24

operational mode

combination of TRV operation (such as road transport, loading and unloading, , empty or loaded, stand still operation, repair and maintenance, and storage) and operating state of the TRU (such as idling, power ON, power OFF) during the TRU life time

3.25

operational mode risk assessment

OMRA

overall process comprising a risk analysis and risk evaluation of a TRU in different operational modes

3.26

outside component

component of the refrigerating system which is located outside the insulated body and inside the external dimensional envelope of the vehicle dimension

3.27

partition wall

bulkhead

fixed or movable, longitudinal or transversal, insulated wall between different compartment volumes

3.28

personal protective equipment

PPE

equipment to enable technicians to work safely with flammable refrigerants

3.29**power supply**

condition where the transport refrigeration unit (TRU) is powered by a source of energy, engine, generator or battery

Note 1 to entry: The battery can be part of the TRU or the vehicle, other source of power supply.

3.30**refrigerant leak detection mechanism**

system which can recognize a refrigerant leak or charge loss of the TRU

3.31**refrigerant leak type**

Tables C.1 and C.2 give additional information on leak type, size, frequencies and leak rates

3.31.1**fugitive emission**

release of refrigerant from pressurized equipment which does not result in malfunction of the cooling process in its typical operation time

Note 1 to entry: Fugitive emissions result from shortcoming of components or joints, classified as enhanced tight during operation and do not result to a malfunction and/or need for repair on the refrigerating system in a period of months to years.

Note 2 to entry: For additional information, see IEC 60079-10-1:2020, C.4.6.

3.31.2**small leak**

unexpected release of refrigerant from pressurized equipment which results in malfunction of the cooling process during longer period of time

3.31.3**large leak**

unexpected release of refrigerant from pressurized equipment which results in malfunction of the cooling process during short period of time

3.31.4**accidental rupture type leak**

catastrophic release of refrigerant from pressurized equipment caused by external events (such as accidents, fire, crash, improper service) which results in immediate malfunction of the cooling process

3.32**refrigerating system**

system to maintain a desired temperature within the insulated compartment volume(s) comprising a vapour compression refrigeration cycle using refrigerant as a working fluid dedicated for TRVs

3.33**refrigerating system repair**

repair of the TRU with intended opening of the refrigerant circuit (see 9.5)

3.34

responsible operator

person, entity or employer that has operational control of the thermal road vehicle (TRV) including the transport refrigeration unit (TRU) at any particular time including, but not limited to, driver, repair and storage operator, transport operator

3.35

safety concept

set of provisions which, together, ensure safe design and safe operation of a TRU mounted on the TRV

3.36

service access point

connection used to service the refrigerating system, that enables the refrigerant circuit to be charged, discharged, evacuated and pressure checked

3.37

service facility

building or installation where maintenance and repair of TRU or the TRV is carried out by certified personnel

3.38

shut-off device

normally closed device separating parts of the refrigerating system to reduce the maximum amount of refrigerant that can be leaked into a CV

3.39

smallest inside free volume

remaining inside volume when the compartment is packed to the maximum allowed volume; the difference between inner volume and load space

Note 1 to entry: For definition of inner volume and load space refer to EN 17066-1.

3.40

thermal road vehicle

TRV

insulated and conditioned means of transport

Note 1 to entry: Different type of vehicles are described in regulation EU 168/2013 and directive, 2007/46/EC.

3.40.1

truck

vehicle (truck/lorry) with a mounted transport refrigeration unit (TRU) and an insulated compartment volume used for temperature-controlled transport of goods, with at least one refrigerated or heated compartment

3.40.2

trailer

non-self-propelled vehicle, with a mounted transport refrigeration unit (TRU) and an integrated insulated compartment volume used for temperature-controlled transport of goods, with at least one refrigerated or heated compartment

3.40.3**LCV****light commercial vehicle**

vehicle (such as a van) with integrated insulation for the transport of goods, of which the insulated compartment volume and the load space is thermally separated from the driver's cabin

[SOURCE: EN 17066-1:2019, 3.1.1.2]

3.41**toxic atmosphere**

mixture of air, under atmospheric conditions, with toxic substances in the form of gas or vapour which can be harmful or lethal to humans

Note 1 to entry: For example, a mixture of refrigerants or decomposition products with air under atmospheric conditions.

Note 2 to entry: A toxic substance is understood to be a substance in the form of gas, vapour, liquid, or mixtures of these, which can be harmful or lethal, or can impair a person's ability to escape due to acute or chronic exposure by contact, inhalation, or ingestion.

3.42**transport refrigeration unit****TRU**

refrigerating system, consisting of a compact unit or in parts, with heat extraction from the inside of the insulated body or compartment by means of an evaporator or cooled heat exchanger and heat dissipation by a condenser or heated heat exchanger

Note 1 to entry: the refrigerating system can be a direct evaporation system or an indirect system using a secondary fluid to transfer heat.

3.43**ventilation mechanism**

means which promotes the replacement of an air volume

3.44**ventilation**

movement of air and its replacement with fresh air, i.e. without dangerous substances

3.44.1**natural ventilation**

movement of air and its replacement with fresh air due to effects of natural mixing, air movement, or temperature gradients

Note 1 to entry: For open air, ventilation is normally based on an assumed minimum wind speed of 0,15 m/s for obstructed areas and 0,3 m/s for unobstructed areas, which will be present virtually continuously (see IEC 60079-10-1:2020, Table C.1).

3.44.2**artificial ventilation****forced ventilation**

movement of air and its replacement with fresh air provided by artificial means

3.45

zone

hazardous area classification based upon the frequency of the occurrence and duration of an explosive atmosphere

[SOURCE: IEC 60079-10-1:2020, 3.3.3]

3.45.1

zone 2

area in which an explosive gas atmosphere is not likely to occur but, if it does occur, for example as a result of accidental type release of refrigerant, it can be defined as a temporary hazardous area

[SOURCE: IEC 60079-10-1:2020, 3.3.6, modified — The words “in normal operation” have been removed; the end part after “if it does occur” has been changed; and Note 1 to entry has been omitted.]

3.45.2

extent of zone

distance in any direction from the source of release to where a gas/air mixture will be diluted by air to a concentration below the lower flammability limit

[SOURCE: IEC 60079-10-1:2020, 3.3.7]

4 Symbols and abbreviated terms

For the purposes of this document, the following symbols and abbreviated terms apply.

AIT	auto-ignition temperature
CV	Control Volume
EPL	Equipment Protection Level
ETA	event tree analysis
FMECA	Failure Mode and Effects and Criticality Analysis
FTA	Fault Tree Analysis
HAZOP	Hazard and Operability Analysis
HFC	hydrofluorocarbon
HSIT	Hot surface ignition temperature
MAC	mobile air-conditioning
OMRA	Operational Mode Risk Assessment
PPE	personal protective equipment
RTT	reaction threshold temperature
SDS	Safety data sheet for chemicals (remark: SDS is equal to former MSDS)
SOI	Source of ignition
TRU	transport refrigeration units
TRV	thermal road vehicles, i.e. trucks and trailers and light commercial vehicle, vans
UFL, LFL	Upper, lower flammability limit

5 Risk assessment

5.1 General

5.1.1 General requirements

For correct function and intended operation transport refrigerating systems shall have a high level of tightness. Leakages are avoided through appropriate design rules. The fulfilment of the requirements for system tightness is realized by the manufacturers and shall represent the state of the art.

The TRU design shall be such that a high degree of tightness can be maintained throughout its life with correct supervision and maintenance. The refrigerating circuit shall be designed as enhanced tight system accomplished by leak tight design and manufacturing procedures for components, joints and connections, implemented service procedures for maintenance and operation including inspection and monitoring of leak tightness, refer to 5.7, 6.2 and 9.5.

The following sections describe the procedure for classifying leaks and performing a risk analysis related to the occurrence of leaks, the frequency of such events and to assess the consequences.

The risk assessment process is a multi-step, circular process in which different types of operational modes are reviewed and the relevant risks are estimated by the combination of the probability of occurrence of harm and the severity of that harm.

For the purpose of risk evaluation, refrigerant leaks shall be taken into account. Therefore, this document addresses the hazards associated with:

- fugitive emissions during normal operation and intended use;
- rare malfunctions and unlikely catastrophic failures that can occur due to various causes and events;
- releases due to failure of joints or components, accident, improper handling and improper service.

5.1.2 Safety principles

The safety principles and methods described in this clause cover the whole risk assessment process for the refrigerating system using flammable refrigerants in various operational modes.

NOTE ISO/IEC Guide 51:2014, Figure 2 shows a flow diagram, representing the safety principles as an iterative process for risk assessment and risk reduction.

The safety principles are based on the following:

- analyse and evaluate leak amount and frequency of leaks and characterization (5.5.3);
- analyse, evaluate and reduce risks (5.5) as much as reasonably practicable (5.6.2);
- apply appropriate protection measures against identified risks which cannot be eliminated (6.8.2);
- inform users about residual risk and indicate whether specific measures shall be taken to reduce the associated risks, where relevant (6.8.2);
- confirmation of the results of the risk assessment process with the requirements in 5.6.3.

5.1.3 Safety concept

The implementation of the safety principles results to a safety concept: design concepts, general and specific requirements for the prevention of the build-up of flammable or toxic atmospheres, protection

by design and construction as well as protective systems and implementation of a safety management system.

NOTE Establishing a safety management system and a protective system can include the consideration of PPE.

The safety concept shall include provisions for the following elements as applicable and according to results of the risk assessment for leak prevention and mechanism to mitigate risk:

- use of evaporators, valves, and related connections which represent and maintain a construction classified for enhanced tightness;
- ensuring that continuous measures are taken to reduce leakage;
- ensuring that proper ventilation is ensured and maintained if relevant for risk mitigation;
- integrated alarm system, leak diagnosis and preventive maintenance techniques for mitigation of risks;
- minimizing refrigerant charge through optimum dimensioning of the system and components;
- reduction of source of ignition: inside the compartment volume, outside electrical components and other external sources;
- comply with requirements listed in 6.8;

Annex B shows examples of possible designs and constructions.

- separation of the evaporator(s): low mass of refrigerant in the components located inside the compartment volume at power OFF;
- manual or automatic ventilation, leak detection.

5.2 Characteristics of Flammable refrigerants

The OMRA shall use the refrigerant properties specified in EN 378-1:2016+A1:2020, Annex E and ISO 817:2014 or the SDS, the most conservative values shall be used.

If different SDS for the flammable refrigerant exist, the most conservative values shall be used for the OMRA.

The flammability (and thus the LFL and UFL) are function of the concentration of flammable refrigerant in air, the operational temperature and the local humidity (see [21]). At higher humidity (e.g. > 80 % R.H.) and temperature (e.g. > 50 °C), the LFL in air can decrease and the UFL can increase. This effect shall be taken into account for such operations and in the risk assessment. It should also be considered in the estimations for the evaluation of dilution of refrigerant in air (see Annex D).

5.3 Significant hazards

The release of flammable refrigerants can lead to fire or explosion, and/or decomposition into toxic compounds.

The main hazards associated with the leakage of flammable refrigerants resulting to a temporary hazardous area include:

- fire and flame propagation: ignited leaking refrigerant, with heavy gas behaviour or homogenized in a compartment, as a flame jet or as a fireball;

- explosion: accumulation of leaked refrigerant leading to a flammable concentration and ignition in a confined space, with a significant explosion overpressure;
- toxicity as described in ISO 817:2014;
- toxicity deriving from decomposition products in case of refrigerant reaction or combustion creating toxic atmosphere.

NOTE 1 Toxic compounds or decomposition products can consist of hydrogen fluoride (HF), Carbonyl Fluoride (COF₂), AEGL values for HF can be found in the chemical data sheet CAS Nr. 7664-39-3.

NOTE 2 Potential hazards related to common refrigerating systems are described in EN 378-1:2016+A1:2020, Annex G.

NOTE 3 Possible ignition sources are listed in Annex F.

5.4 Protection against hazards

5.4.1 Protection against fire, flame propagation and explosion hazards

The protection against fire, flame propagation and explosion hazards should include different measures for prevention. A hazardous event is possible in presence of a leak where: a flammable atmosphere and a SOI occur simultaneously. The elimination of refrigerant leakage, prevention of build-up of flammable atmospheres are the primary measures for explosion protection. The elimination of SOI represent secondary measures.

5.4.2 Protection against excessive internal system pressure

The refrigerating system shall be designed according to the requirements for the pressure containment aspect as given in EN 378-2:2016.

5.5 Operational mode risk assessment

5.5.1 General

The operation of a TRU is complex as it involves various modes of operation, operators with different responsibilities, diverse ownership of the equipment and multiple intended uses.

An operational mode risk assessment (OMRA) shall be carried out by the manufacturer to analyse the risks related to the operation of the TRU in its life cycle. If necessary the manufacturer may involve TRU manufacturer and the body builder, as well as responsible operator. The OMRA shall include, but not be limited to, risks associated with maintenance, recycling or dismantling, reuse after the service life of the refrigerating system, including the second-hand market.

The OMRA shall include the intended use, reasonably foreseeable misuse, and stationary operation.

NOTE 1 EN ISO 12100 describes measures and procedures for risk determination and mitigation that need to be considered in the design phase.

NOTE 2 Information on the role and responsibility of the manufacturer can be found in the EU 2022/C247/01.

The OMRA should be carried out using one or more of the following methods or other equivalent methods as applicable to safety aspect under consideration:

- Event tree analysis (ETA) according to IEC 62502 or equivalent;
- Failure mode and effects analysis (FMCEA) according to IEC 60812 or equivalent;

- Fault tree analysis (FTA) according to IEC 61025 or equivalent;
- Hazard and operability analysis (HAZOP) according to IEC 61882 or equivalent.

Methods described in ISO 20854, SAE J2773 or ISO 13043 might be considered for the OMRA, where applicable.

The manufacturer shall provide the necessary results of the OMRA to:

- the TRU manufacturer;
- the installer of the TRU;
- the body manufacturer of the refrigerated vehicle;
- the responsible operators of different operating sites for evaluation.

Any modifications shall be evaluated and if necessary incorporated into the OMRA.

The OMRA shall include a risk assessment for flammable refrigerants as a basic part. Results shall be evaluated for all operational modes, where relevant.

The OMRA results should be discussed, evaluated, and checked by independent experts, or submitted to a competent body for review.

NOTE 3 The term independent experts includes external support as well as in-house competences. The term independent means that the expert has not participated at the OMRA execution process.

5.5.2 Operational modes

The OMRA shall consider at least the following operational modes, considering both driving and stand still, power ON and power OFF situations, and evaluate, where relevant:

- on the road operation, idling, stationary operation, interim parking or storage anywhere, passing through a tunnel;
- parking of one or more TRV in open air, garage, underground parking places;
- use of truck, trailer as food storage in public area;
- door opening processes, loading and unloading of goods, including the consideration of conditions such as:
 - use of curtains, to reduce the input of heat;
 - frequent door openings;
 - shut down of evaporator fans during door opening;
- all transport modes for the TRU or the whole TRV;
- service and repair, maintenance:
 - on the TRV (the truck, trailer, or van), and on the TRU, in professional workshops, including workpits or sewer systems;
 - functionality testing and quality of repair;

- assembly, installation, test run, commissioning and removal of parts of the TRU system, both inside the compartment volume and at the outside of the vehicle in all anticipated operational sides, including:
 - assembly of the refrigerating system and filling with refrigerant;
 - repair and opening of the TRU mounted on the TRV in small rooms, such as a van-TRU system repair in small garage;
- reasonably foreseeable misuse, such as improper loading and unloading, repair and maintenance in un-professional areas, continuous charging in the event of a leak, use of wrong or improper tools or parts;
- external events: emergency stop in tunnel, fire in tunnel, accidents, crash, fire, vibration, corrosion, mechanical damage, unauthorized intervention;
- inspections: customs, veterinarian, workers, cargo quality inspection;
- end-of-life and disposal of equipment.

The OMRA shall be performed for all intended and stationary operations including loading and unloading of transport goods and foreseeable misuse. Table 1 shows an incomplete example of possible operational modes and combination of operational states.

Table 1 — Possible states and events as result of operational modes, locations, occupancies, cargo conditions and possible combinations

	Possible events	Possible states
Vehicle	cleaning inside, accident, fire, others	stand still, moving, driving, others
Location	to be evaluated	street, repair shop, road, rail, parking, others
TRU-state	to be evaluated	OFF-no power, OFF-power, ON-Power source 1, 2, x, others
Cargo	to be evaluated	loading, loaded, empty, others
Door	to be evaluated	open, close, opening process, others
Fan(s)-state	to be evaluated	OFF, ON, idle, others
Occupancy	to be evaluated	somebody inside, nobody inside, others
NOTE The entries in Table 1 are to be understood as suggestions.		

Based on this example it is possible to generate a similar table to document and determine the probability of different states, events or situations to be used as an input for the OMRA. The complete list in 5.5.2 for the different operational modes shall be considered and assessed as a minimum.

The HAZOP, ETA and FTA methodology, or combinations thereof, can be used to analyse the different operational modes.

As ventilation is one efficient way of avoiding flammable concentrations, and therefore while performing the OMRA, all operational modes and dedicated events considered shall be at least classified according to the following types of ventilation:

- natural ventilation: occurring in places such as open air, in tunnels, during transport, open air repair area as examples;

- forced ventilation: occurring in places such as enclosed spaces in buildings, underground parking, service facilities or area as examples.

NOTE 1 8.4 provides further ventilation requirements concerning the operational sites.

The degree of dilution outside the vehicle should be considered as “high” with “fair” to “good” ventilation availability. In normal operation the CVs (see Annex A), which include the outside components and are located outside the insulated body, shall be non-hazardous areas.

The definition of ventilation degree and ventilation rate is provided in IEC 60079-10-1. To ensure that a build-up of a flammable atmosphere, caused by fugitive emissions in normal operation, inside the compartment volume is prevented, the test 6.8.3 shall be used to demonstrate that the dilution of leaking refrigerant by the naturally existing exchange of air from inside to outside is sufficient.

NOTE 2 Examples for the evaluation of a hazardous area and possible classification are given in IEC 60079-10-1:2020, Annex E. Examples of calculations to ascertain the degree of ventilation and time of persistence of a flammable atmosphere are given in IEC 60079-10-1:2020, Annex C.

Situations considering larger leaks require measures and mitigation procedures according to the OMRA.

Avoiding ignition sources is another way of eliminating hazards from leaks, and therefore while performing the OMRA, for all operational modes and dedicated events considered all potential SOI shall be listed and evaluated with regard to their ignition effectiveness.

5.5.3 Evaluation of leak rate and frequencies for characterization

Exact knowledge of the type of leakage, the processes and the causes is the fundamental basis for carrying out an OMRA. This knowledge is of great value for safe and energy-efficient operation, quality improvement and management, predictive maintenance, cost savings and other factors.

The leakages shall be characterized for the entire lifecycle of the TRU. The lifecycle includes all operational modes listed in 5.5.

The characterization of the leaks should be carried out, but not limited to, as follows:

- location of leak, causes, leak-type, -size, -history, estimation of mass flow (see Table C.1 or C.2. in Annex C), time to system failure, time to error detection (human, electronically, others);
- leak-occurrence and -frequency based on the dimension per unit per year;
- refrigerant management at service station and repair;
- supporting information might be: Literature, standards, assessments, experience reports, tests, calculations, simulation.

If precise information on leaks is not known, these shall be estimated. The mass flows can be determined with the help of Table C.1 or C.2. in such a way that meaningful assumptions for the OMRA can be made. The leakage event shall be evaluated and described for each individual case of the OMRA to estimate appropriate leak characteristics as listed above.

Leak characteristics data should be recorded and, during the OMRA process, continuously improved.

NOTE Further information on the systematic analysis and reporting of leaks can be found in [19, 20], and more specific in the SAE J2727 [11], for example.