



BSI Standards Publication

**State of the art on the use of flammable
refrigerant alternatives, in particular from
class A3, in refrigeration, air conditioning
and heat pump equipment**

National foreword

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A list of organizations represented on this committee can be obtained on request to its committee manager.

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English Version

**State of the art on the use of flammable refrigerant
alternatives, in particular from class A3, in refrigeration,
air conditioning and heat pump equipment**

État de l'art sur l'utilisation de fluides frigorigènes
inflammables de substitution, en particulier de la
classe A3, dans les équipements de réfrigération, de
climatisation et de pompes à chaleur

Stand der Technik über die Verwendung von
brennbaren Kältemitteln, insbesondere der Klasse A3,
als Alternativen in Kälte-, Klima- und
Wärmepumpenanlagen

This Technical Report was approved by CEN on 20 March 2022. It has been drawn up by the Technical Committee CEN/TC 182.

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European foreword

This document (CEN/TR 17608:2022) has been prepared by Technical Committee CEN/TC 182 “Refrigerating systems, safety and environmental requirements”, the secretariat of which is held by DIN.

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Introduction

CEN and CENELEC implemented standardisation request M/555 - IMPLEMENTING DECISION of 14 November 2017 on a standardisation request to the European Committee for Standardisation and to the European Committee for Electrotechnical Standardisation as regards use of flammable refrigerants in refrigeration, air conditioning and heat pump equipment. CEN/TC 182 took the lead and established a liaison with CENELEC/TC 61.

The two European Standardization Organizations CEN and CENELEC have responded positively to standardisation request M/555 regarding use of flammable refrigerants in refrigeration, air conditioning and heat pump equipment.

CEN/TC 182 and CENELEC/TC 61 were tasked to address the standardisation request. A new working group (WG12) was set up under CEN/TC 182 with active participation of experts nominated by CENELEC/TC 61.

The technical information was gathered by six ad hoc groups two of which were led by CENELEC/TC 61 experts. The ad hoc groups analysed the current status of risk assessment in general, commercial refrigeration, transport refrigeration, industrial refrigeration, air conditioning and heat pumps, and chillers. Each of the groups finalized their summary with conclusions about existing barriers and recommendations for additional options.

The Technical Committee reviewed guidance for the risk assessment in general and for refrigeration appliances in particular. This includes reviews of guidance and standards that apply for flammable gases in general. Also, the risk assessment was reviewed of global organisations like the risk approach of the Organisation for Economic Co-operation, Development and United Nations Development Programme and United Nations Environment Programme.

The requirements of the Standardisation Request M/555 were reviewed carefully. Having reviewed the documentation, the working group agree that, responding to the standardisation request, the following deliverables were to be prepared:

- 1) A Technical Specification for the installation of refrigeration, air conditioning and heat pump equipment containing flammable refrigerants, complementing existing standards.
- 2) A Technical Specification for the operation, servicing, maintenance, repair and decommissioning of refrigeration, air conditioning and heat pump equipment containing flammable refrigerants, complementing existing standards.

The recommendations about transport refrigeration are beyond the standardisation request M/555. CEN/TC 413 will develop of a specific EN standard dedicated to transport refrigeration risk assessment.

1 Scope

This document provides the results of a comprehensive assessment of the state of the art on the use of flammable refrigerants, in particular from class A3.

Refrigerants from class B (toxic) are excluded from this scope.

This document includes the following elements:

- A segmentation of the refrigeration, air conditioning and heat pump market, making use of existing studies and research, including an assessment of safety-related barriers to the uptake of flammable refrigerants in particular from class A3 across all relevant applications;
- An assessment of the way risk assessments is used in existing standards for refrigeration, air conditioning and heat pump equipment and in other standards and a review of available risk assessment research to be taken into account including identification of potential needs for additional research;
- Analysis of:
 - the relationship between risk and increased charge;
 - the acceptability of increased risk compared to the risk presented by other technologies;
 - the options for additional mitigation methods if the risk increase is unacceptable;
- Review of existing standards and work programmes and identification of standards that should be further updated under existing or future standardisation requests based on relevant product safety legislation, in particular with regard to allowable charge sizes of flammable refrigerants, taking into account available technology as well as emerging research and development;
- Identification of options for performance based requirements that result from risk assessments to enable the use of all flammable substances;
- Identification of options for risk minimisation and for offering flexibility in application of mitigation measures.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

No terms and definitions are listed in this document.

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

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

4 Segmentation of the Industry Sector

4.1 General

The refrigeration industry produces a wide range of products and applications. Commercial and professional refrigeration, industrial refrigeration, chillers and air conditioning, transport refrigeration, and heat pumps were investigated. The main results are reflected in this clause. The complete result of the review is provided in Annex B.

4.2 Commercial applications

4.2.1 Commercial Refrigeration

Commercial refrigerated cabinets are used for storage, display, production, or sales of foodstuff. Some of these products are fixed and movable appliances.

Commercial refrigerated cabinets are cooled by a refrigerating system which enables chilled and frozen foodstuffs placed therein for display to be maintained within prescribed temperature limits. Commercial refrigerators and freezers cover a large variety of products; and they are used in diverse environments such as supermarkets, grocery stores, service stations, restaurants, hotels, pubs, and cafés. Commercial Service Cabinets are mainly horizontal refrigerated display cabinets which requires that a person serve the customer with fresh-cut or packed foodstuffs; and the appliance have one or more side facing the customer for display of fresh cut of food in a supermarket. As a sub-category some of these cabinets are also available as Self Service version.

Commercial refrigeration equipment can take many forms and combinations:

- ‘self-contained (or plug-in or integral) appliance’ means a factory made assembly of refrigerating components that are an integral part of the refrigerated equipment and consists of a storage space, one or more refrigerant compressors, refrigerant evaporators, condensers and expansion devices, eventually accompanied with additional heat exchangers, fans, motors and factory supplied accessories;
- remote display cabinets work with a remote refrigerating unit which is not an integral part of the display cabinet (e.g. condensing units, cooling packs);
- semi plug-in cabinets are cabinets with an integral condensing unit, where the heat is rejected with a secondary water or brine loop;
- refrigerating system with secondary fluid (e.g. chillers).

4.2.2 Professional Refrigerated Products

Professional refrigeration equipment can take many forms and combinations, very similar to those for commercial use. Professional service cabinets are designed for dispensing or storage, but not the sale, of chilled and frozen foodstuff like professional storage cabinets, blast chillers, cold rooms, ice cream makers, etc. A professional service cabinet is a refrigerated enclosure containing goods which are accessible via one or more doors and/or drawers. The sizes of the products are typically based on the standard tray and are used in a commercial environment. They are largely used in foodservice establishments, such as restaurants, hotels, and cafeterias. A very small fraction of “professional” service cabinets contain glass in their doors, drawers, or lids (as opposed to “commercial” service cabinets that display food and hence frequently incorporate glass).

Blast cabinets use a blast of cold air to bring down the temperature of hot food rapidly so it can be stored safely avoiding bacteria growth, and can be chilled or frozen. Blast cabinets are similar in

construction to service cabinets. However, they rely on relatively larger refrigeration systems in comparison to service cabinets, some even using up to two compressors per cabinet. Blast cabinets also contain additional fans which blast cold air over food to cool it rapidly.

4.2.3 Commercial versus professional cabinets

Both **commercial** and **professional** cabinets rely on compression technology (more than 90%): i.e. all components supporting the refrigeration cycle are included in the cabinet.

The main difference between commercial and professional is not related to installation environment, but to the user: a “commercial” refrigerator is used by a customer (shopper), and will display products, while a “professional” refrigerator is used by trained staff, and will store the products before use. Frequently existing definitions refer to “commercial” service cabinets, when in fact “professional” use of the products is done one side of the appliance, while the other side is for display or collection of product from the shopper that could access a side of the appliance. Therefore, it is noted that terminology varies for identical products.

4.3 Industrial applications

Industrial systems are characterized primarily by the size of the equipment, both physical size and heat transfer capability, and the temperature range covered by the sector. In addition to Industrial Refrigeration, this sector includes Industrial Heat Pumps (heating systems similar in scale and application to Industrial Refrigeration systems) and Industrial Air Conditioning (systems for controlling air temperature in production factories, computer centres and other process areas). Other sectors mainly focus on comfort and food, the industrial sector also includes refrigerating systems for process related activities, example temperature controls in chemical processes.

Industrial Refrigeration systems are characterized by heat extraction rates in the range 100 kW to 10 MW, typically at evaporating temperatures from $-50\text{ }^{\circ}\text{C}$ to $+20\text{ }^{\circ}\text{C}$. There is some overlap at the lower end of the capacity scale with commercial refrigeration for shops, restaurants, and institutions. Industrial systems in this sub-sector are characterized by the complexity of the design and the nature of the installation. Systems at lower temperatures, typically down to $-120\text{ }^{\circ}\text{C}$, and in capacity ranges from 1 kW to 200 kW are a specialized sub-sector including laboratory equipment for pharmaceutical, chemical, and medical applications and test stands for automotive, aerospace and space development facilities. These ultra-low temperature systems are often also required to operate at high temperatures up to $+250\text{ }^{\circ}\text{C}$ to provide a complete temperature test cycle.

Industrial Heat Pump systems have heat delivery rates from 100 kW to over 100 MW, with the heat source usually at ambient temperature or the waste heat temperature of an industrial process. These systems are usually required to deliver higher temperatures than domestic or commercial heat pumps used for space or water heating. Typical temperatures are in the range $60\text{ }^{\circ}\text{C}$ to $90\text{ }^{\circ}\text{C}$, although if the recovered heat is to be used for steam raising then it needs to be at least $120\text{ }^{\circ}\text{C}$. Heat recovered from large industrial systems is usually transferred to water or a heat transfer fluid and used for process heating or for supply to district heating systems.

Industrial Air Conditioning systems cannot be differentiated from commercial systems on size alone, as many commercial office buildings have large cooling loads. In addition to size of installation the distinguishing traits of Industrial Air Conditioning systems are that the cooling is not purely for human comfort, the load is not primarily seasonal, and the operation of the facility would be jeopardized by failure of the cooling equipment. Such systems are sometimes called “Mission Critical” and have special design requirements, including the need for uninterrupted service, which are not typically provided by traditional heating, ventilation, and air conditioning practices. In some cases, the mission-critical part of a total cooling load may be supplied in conjunction with a comfort cooling system, configured so that, in the event of partial failure of the system, the mission-critical cooling is maintained at the expense of the comfort of the occupants of the rest of the building. Other Industrial Air Conditioning systems are

primarily required to maintain acceptable processing conditions for equipment such as computer servers in data centres.

4.4 Chillers and heat pumps with water heat sink, indirect systems

Chillers and heat pumps with water heat sink are used in domestic, commercial, professional, and industrial applications. Chillers and heat pumps with water heat sink include units with a refrigerant to water heat exchanger on the use side. Capacity range is from about 1 kW up to 2 000 kW.

The units are air to water heat pumps self-contained, water to water heat pumps self-contained, brine to water heat pumps self-contained, air to water heat pumps split, chillers and domestic hot water heat pumps.

The products are used in all market segments. The overall market is 800 000 units per year.

4.5 Air to air air conditioning and heat pumps

Domestic air conditioning products and domestic heat pumps are used in households and similar locations for cooling and heating applying air conditioners and heat pumps. This application category also includes similar applications like care homes, retirement homes and other facilities with nursing services.

Air conditioners generally fall into several distinct categories, based primarily on capacity or application: small self-contained air conditioners, such as window-mounted and through-the-wall air conditioners; non-ducted split residential and commercial air conditioners; ducted, split residential air conditioners; and ducted commercial split, multi-split including variable refrigerant flow, and packaged air conditioners. In each of these categories, the term “air conditioner” includes systems that directly cool or heat the conditioned air, for instance, “air-to-air”, “water-to-air” and “ground-to-air” systems. This category does not include systems that heat or cool water or other heat transferring liquids.

NOTE For example, through the wall; whilst these products represent a small portion of the market they have nevertheless been included since they are still available and have certain construction characteristics of interest. Packaged terminal air conditioner are not usually used in Europe.

Table 1 summarizes the typical physical and installation characteristics of the different types of air conditioners.

Table 1 — Typical configurations of air conditioner types

Type		Primary configuration	System layout	Capacity range (kW)	R-410A charge range (kg)
Hermetically-sealed unit	double duct	Small self-contained	Self-contained	1 – 10	0.3 – 3
	single duct ^a	Small self-contained	Self-contained	1 – 10	0.3 – 3
Duct free split		Ducted free split	Remote	2 – 20	0.5 – 6
Multi-split		Multi-split including variable refrigerant flow	Remote	4 – 300	1 – 80
Ducted split		Residential/small cap	Remote	4 – 20	1 – 6
		Commercial/large cap	Remote	10 – 150	3 – 45
Packaged rooftop ^b		Ducted commercial	Self-contained	7 – 350	2 – 100
Exhaust air-to-air heat pump		Inside / outside	Self-contained	5 – 150	1.5 – 45
^a Single duct is used to refer to portable air conditioners.					
^b Generally these products are designed with 2 circuits. That is to say 100 kg for the complete unit 350 kW will give 50 kg per circuit.					

4.6 Transport applications

The transport applications market distinguishes between human comfort and transport of refrigerated goods. Transport applications includes mobile air conditioning systems in vehicles, railways, buses, vans, mobile homes and caravans for human comfort; and, for the transport of refrigerated goods refrigerated trucks, trailers and reefer containers land-based operation.

Transport applications have specific challenges such as shock, vibration, corrosion, and extreme operating ambient conditions. This leads to design choices different from other refrigeration applications.

Transport of refrigerated goods is typically a non-occupied area with limited access, with periodic, or non-frequent access by humans. The refrigeration units are factory built and typically mounted onto the actual vehicles, casing, or chassis.

Some systems use open type compressors with shaft seals and are driven by the main engine, for example car bus air conditioning with combustion engines. Other systems operate with hermetic or semi-hermetic compressors and electric power supply.

The United Nations Environment Programme Refrigeration and Air Conditioning Technical Options Committee (RTOC) 2018 report stated: "Light duty vehicles use from 0,3 kg to 1,4 kg refrigerant charge, while for buses the charge could be from 8 kg up to 16 kg as a function of the vehicle category (e.g. simple bus, articulated bus). Currently there are approximately 1 000 kt of refrigerant in vehicles considering that there are about 1,3 billion of road vehicles circulating¹. Assuming that 75 % of circulating vehicles is equipped with mobile air conditioning systems, and assuming a yearly renewal rate of 8 % e.g. 100 million units), the refrigerant demand (excluding service) is about 75 kt/year."

5 Current practice in the sector

All substances that exist in liquid and vapour states absorb heat during evaporation and can therefore be used as refrigerants. Refrigerants have widely varying properties and impacts and due to the significant environmental and safety impact of certain refrigerant types, can be heavily regulated during manufacture, use and disposal. There are numerous refrigerants either in use today or being proposed as alternatives. Commonly used refrigerants in refrigeration applications are the following:

- HFCs: Hydrofluorocarbons
- HCs: Hydrocarbons
- Unsaturated HFCs (also known as HFOs or Hydrofluoroolefins)
- NH₃: Ammonia
- CO₂: Carbon dioxide

Table 2 lists the various options that are currently in use or under consideration for air conditioning, along with their global warming potential and ISO 817 safety classification. Also listed are the types of air conditioner system that each refrigerant option is currently used in or is at least being considered for. All options listed are toxicity class A.

¹ <https://www.statista.com/statistics/281134/number-of-vehicles-in-use-worldwide/>.

Table 2 — Refrigerant options for air conditioning

Refrigerant	GWP (RTOCa 2018)	Flammability class	Subsector currently used in the European Union	Subsector proposed/ anticipated
R-1270	< 1	3		non ducted system
R-290	< 1	3	small self-contained, ducted split, packaged rooftop	ducted commercial split
R-1234yf	< 1	2L	small self-contained	
R-152a	148	2		non ducted system
R-32	704	2L	small self-contained, non ducted system, ducted split, ducted commercial split	multi-split, packaged rooftop
R-452B	710	2L		All
R-454A	250	2L		All
R-454B	490	2L		All
R-459A	480	2L		All
^a United Nations Environment Programme Refrigeration and Air Conditioning Technical Options Committee.				

Currently the majority of commercial plug-in or self-contained refrigeration appliances using flammable refrigerants have charge sizes of no more than 150 g of hydrocarbon (HC) such as R-600a (isobutane) or R-290 (propane) per refrigerant circuit. This is due to the charge size constraint of 150 g of flammable refrigerant within the current IEC 60335-2-89 Ed. 3. There are several millions of such units currently in use.

Horizontal standards such as EN 378 (2016) and ISO 5149 (2014) permit charge sizes of up to 1,5 kg of hydrocarbon per refrigerant circuit. Where the charge exceeds 150 g there are additional requirements for the installation site, such as certain minimum room size in which the system can be placed, a mandatory risk assessment considering the specific installation surroundings due to the potential higher charges released, a plant by plant certification.

Whilst the number of self-contained refrigeration appliances using flammable refrigerants is relatively minor compared to global populations of self-contained refrigeration appliances with non-flammable refrigerants, there is reasonably good level of experience with such self-contained refrigeration appliances and especially with products using up to 150 g per circuit. If there was a fundamental underestimation of the risk posed by the current design requirements for these self-contained refrigeration appliances, then this would become apparent to the direct stakeholders and the industry as a whole. Based on this historical data the use of flammable refrigerants with a maximum charge of 150 g per circuit in self-contained refrigeration appliances can be considered as an acceptable risk.

Recent regional and international legislation such as the European F-gas regulation, the 2016 Kigali Amendment of the Montreal Protocol and minimum efficiency regulations in USA and other countries mean that most common refrigerants used today in self-contained refrigeration appliances will no longer be applicable. Apart from R-744, the only viable refrigerants for the short to medium term are flammable, and even out of the possible options only a small number of hydrocarbons and hydrofluorocarbon/u-hydrofluorocarbon mixtures may be viable.

Based on this historical data the use of flammable refrigerants with a maximum charge of 150 g per circuit in self-contained refrigeration appliances can be considered as an acceptable risk without taking care of surrounding environment using a safety approach based on type tests.

Chillers only connected by a secondary system to the area served the appliance can be positioned outside or be equipped with ventilated enclosure / machinery room that allows to handle even high refrigerant charges safely.

Large refrigeration systems often use R-717 (ammonia) as the refrigerant. R-717 is classed as B2L by the ISO 817 safety classification. Where R-717 is considered to be unacceptable the decision is usually based on the hazards posed by toxicity in the specific location, for example if the system is located in a built up area or close to a school or hospital. The most likely alternative until recently would have been a non-flammable, lower toxicity refrigerant such as R-404A or R-507. As these are being phased out due to high global warming potential there is an increased interest in R-744 (carbon dioxide) either in cascade with R-717 or in a transcritical system configuration. There is currently virtually no use of A3 refrigerants in the industrial sector except in specialist niche markets where the flammability of the refrigerant is not an additional concern, for example in a process plant or oil refinery.

6 Design measures for flammable refrigerants

6.1 General

Products placed onto the European single market satisfy the requisite health, safety, and environmental requirements. How this is achieved is laid out in the 'Blue Guide' on the implementation of EU product rules 2016. It is necessary to meet the essential health and safety requirements of the applicable European Directive or Directives in order to place a product on the market. Detailed design measures are given in Annex D.

Following a harmonized standard is an easy way to comply with the requisite essential health and safety requirements. If other routes are used, they may be depending upon the applicable directives and the necessary conformity route. A notified body may have to verify the approach. Figure 1 gives an explanation of the routes that are appropriate for meeting the essential health and safety requirements of Directives. Provided that the essential health and safety requirements of the relevant Directives are satisfied, then following any or no European refrigeration, air conditioning and heat pump safety standards are permitted.

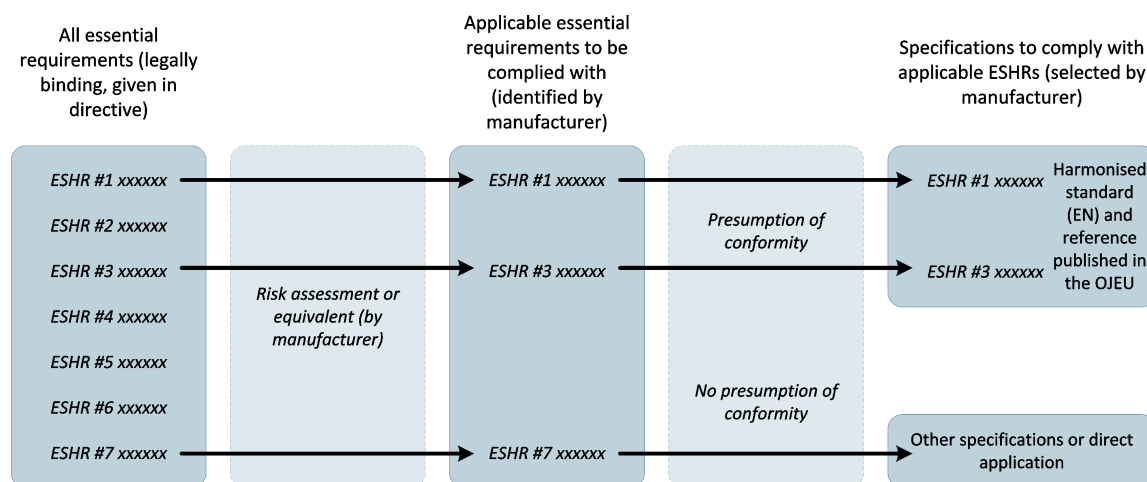


Figure 1 — The role of harmonized standards when complying with applicable essential requirements identified by a manufacturer

Regardless whether harmonized standards are followed to comply with the essential requirements of the regulations, a risk assessment of the product has to be performed as required by the regulations pertaining to safety.

6.2 Design measures

Figure 2 provides an overview of the various levels of intervention that may be applied to refrigeration, air conditioning and heat pumps systems and equipment, along with some examples of how these interventions may be practically applied. Broadly, those at the top of the list can be considered as having a higher level of reliability. As a priority, those measures that avoid the refrigerant entering into the space may be deemed more reliable, whereas those which require intervention of human occupants to initiate some action to reduce the risk may be deemed less reliable. Thus, the approaches towards the top of the list may be considered preferentially, although this can also be affected by specific circumstances and equipment type.

Reducing charge amount that could be released	• Charge amount limitation/passive methods, shut-off valves
Minimum space volume for release to be dispersed in	• Minimum room volume/area, ensuring releases to the outside
Minimising probability of leakage	• Improved tightness/enhanced tightness, regular leak checking
Effective mixing of the release	• Passive room air circulation, unit airflow circulation, housing design
Removal/exhausting of the release	• Extract ventilation, natural ventilation, buoyancy-induced outflow openings
Warning	• Alarm
Information	• Signs, instructions

Figure 2 — Overview of preventative measures and practical examples applicable to refrigeration, air conditioning and heat pump systems

The following are the basic considerations that typically apply to flammable refrigerants, all of which should be integrated into any installation:

- No sources of ignition
- Ensuring system tightness
- Limiting refrigerant charge
- Warnings/markings
- Instructions

These measures are in addition to others related to pressure and mechanical safety.

Amongst the following there are measures that are applied to A2L refrigerants but not to A2 and A3 refrigerants. The measures should be considered for all flammable refrigerants.

a) Basic measures

The following are the basic considerations that typically apply to flammables, all of which should be integrated into any one system/installation:

- No sources of ignition
- Ensuring system tightness
- Limiting refrigerant charge
- Warnings/markings
- Instructions
- Markings

A variety of other measures have recently been introduced into various refrigeration, air conditioning and heat pump safety standards.

For air conditioners, applicable measures include (either individually or in combination):

- Room size limitation
- Ventilated enclosure
- Gas detection and extract ventilation (for machinery rooms)
- Circulation airflow (continuous or initiated by gas detection)
- Improved system tightness
- Reliance upon natural ventilation openings to dilute leaked refrigerant
- Use of shut-off valves to limit charge being released
- Gas detection and alarm
- Gas detection and extract ventilation (for occupied rooms)

There are a number of other measures that are either currently in use by manufacturers or suggested within the literature or both. Many such measures could be useful for extending the safe application of flammable refrigerants across air conditioner subsectors.

- Design of enclosures or housings to better dilute releases
- Alternative means of leak detection, for example system parameters, ultrasonic, flash gas indication
- Limiting releasable charge
- Circulation airflow, either continuous or initiated by detection
- Improved system tightness
- Use of shut-off valves to limit charge being released
- Gas detection and ventilation for occupied rooms
- Surrounding concentration test

NOTE Surrounding concentration test is currently proposed for commercial refrigeration appliances under IEC 60335-2-89.

Table 3 provides an overview of protective measures within published refrigeration, air conditioning and heat pump safety standards.

Table 3 — Applicable clauses on protective measures within refrigeration, air conditioning and heat pump safety standards

Measure	IEC 60335-2-89: 2019	IEC 60335-2-40	EN 60335-2-40 ^a	EN 378	ISO 5149
No sources of ignition	22.111.1 22.112 22.113 Annex BB	22.116, 22.117	22.116	Part 2, 6.2.14	Limited
Ensuring system tightness	22.119 22.120	22.113	n/a	Part 2	Part 1 A5; Part 2
Limiting refrigerant charge	22.110	Annex GG	Annex GG	Part 1, Annex C	Part 1, Annex A

Measure	IEC 60335-2-89: 2019	IEC 60335-2-40	EN 60335-2-40 ^a	EN 378	ISO 5149
Gas detection & extract ventilation (for machinery rooms)	n/a	GG3	Annex GG	Part 3	Part 3
Warnings/markings	7	7	7	Part 2, 5.3	Part 2
Instructions	7	7	7	Part 2, 5.3	Part 2
Ventilated enclosure	22.116	GG4	GG4	Part 2	Part 2
Circulation airflow (continuous or gas detection)	22.116	GG2.2, GG9, GG10	n/a	Part 1, Annex C.3	Part 1 Annex A; Part 3, Clause 6
Natural ventilation openings to dilute leaks	n/a	GG1.3, GG8, GG11	n/a	Part 1, Annex C.3	Part 1 Annex A; Part 3, Clause 6
Shut-off valves to limit charge being released	Annex CC ^b	GG12	n/a	Part 1, Annex C.3	Part 1 Annex A; Part 3, Clause 6
Gas detection and alarm	22.116	GG13	n/a	Part 1, Annex C.3	Part 1 Annex A; Part 3, Clause 6
Gas detection & extract ventilation (occupied rooms)	n/a	GG8, Annex LL, MM	n/a	Part 1, Annex C.3, -3,	Part 1 Annex A; Part 3, Clause 6
n/a = not applicable. ^a Based on current version: EN 60335-2-40:2003+A2+A11(2004)+A12(2005). ^b Annex CC provides a test method for determining gas concentration beyond the boundary of the appliance. Shut-off valves as part of the construction can limit charge being released.					
NOTE IEC 60335-2-89 was published on 20 June 2019. At CENELEC, no parallel voting was done, the 3rd edition of IEC 60335-2-89 still needs to be implemented and voted on.					

7 Assessment of the way risk analysis is used

7.1 General

The member states of the European Union have agreed to achieve a high level of protection of health, safety and environment. Products placed onto the European market must satisfy the requisite health, safety and environmental requirements. The health, safety and environmental requirements are defined as essential requirements in the European product directives and regulations.

The European directives put the responsibility on the manufacturers, their authorized representatives, and the importers. At the workplace, the employer is responsible to inform and train their workers.

Risk assessment is part of the development process for standards. The European General Risk Assessment Methodology requests that the risk analysis is documented and included in the technical documentation. If only part of the harmonized standard is used, then the risks not covered by the standard are dealt with in the risk assessment.

The detailed assessment of risk analysis in use is given in Annex G.

The European Commission has established a system of Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health, and the environment. These Scientific Committees use the weight of evidence approach to conduct a risk assessment for stressors to which humans and/or the environment may be exposed. It is intended to complement a report on the identification of emerging issues and the work on the challenges in future risk assessment, undertaken by the European Scientific Committee on Emerging and Newly Identified Health Risks.

Scientific evidence consists of observations, experimental and model results and expert judgements that serve to support, refute, or modify a scientific hypothesis or theory. The search for relevant information and data for the Scientific Committee on Health, Environmental and Emerging Risks comprises of identifying, collecting, and selecting possible sources of evidence in order to perform a risk assessment and/or to answer the specific questions being asked (SCHEER, 2018).

Annex A reviews guidelines and standards that may be used by the refrigeration industry, and provides risk analysis information that can be used by all groups that develop standards for the refrigeration industry. Annex A analyses the current practice in the refrigeration industry sector.

7.2 Risk assessment techniques

There are several techniques which are qualitative techniques and quantitative techniques. Sometimes semiquantitative and hybrid techniques can be used as well.

a) Qualitative techniques

Qualitative assessment defines consequence, probability, and level of risk by significance levels such as “high”, “medium” and “low”, may combine consequence and probability, and evaluates the resultant level of risk against qualitative criteria. In cases where the analysis is qualitative, there should be a clear explanation of all the terms employed and the basis for all criteria should be recorded.

b) Quantitative techniques

The guidelines for developing quantitative safety risk criteria² recommend a procedure for the risk of human safety from process operations. The guidelines consider events of limited duration and acute health effects leading to fatalities. The guidelines provide a set of elements to establish quantitative risk criteria on a sound basis aligned with societal values.

All quantitative risk acceptance criteria are based on the probability of death. If the mortality rates for various levels of exposure (to toxicity, overpressure, or heat radiation) are known, the results may be summed to generate a single objective for risk.

Quantitative assessment estimates practical values for consequences and their probabilities, and produces values of the level of risk in specific units defined when developing the context. Quantitative analysis estimates practical values for consequences and their probabilities, and produces values of the level of risk in specific units defined when developing the context. Even where full quantification has been carried out, it needs to be recognized that the levels of risk calculated are estimates. Care should be taken to ensure that they are not attributed a level of accuracy and precision inconsistent with the accuracy of the data and methods employed. Levels of risk should be expressed in the most suitable terms for that type of risk and in a form that aids risk evaluation. In some instances, the magnitude of a risk can be expressed as a probability distribution over a range of consequences.

Full quantitative techniques are rarely applied for refrigeration, air conditioning and heat pump systems. An exception is The Netherlands, where standardized quantitative risk assessment techniques are embedded in national legislation for more than 30 years (Ham (1992)), applicable to all major hazards from industrial activities, including industrial ammonia refrigeration systems.

The vast majority of risk assessment studies, applied for refrigeration, air conditioning and heat pump systems and applications in Europe, is qualitative. Depending on the purpose and objective of the risk assessment, a qualitative technique can be fully adequate.

c) Hybrid and semi-quantitative techniques

Semi-quantitative methods use numerical rating scales for consequence and probability and combine them to produce a level of risk using a formula. Scales may be linear or logarithmic, or have some other relationship; formulae used can also vary. Full quantitative analysis may not always be possible or desirable due to insufficient information about the system or activity being analysed, lack of data, influence of human factors, etc. or because the effort of quantitative analysis is not warranted or required. In such circumstances, a comparative semi-quantitative or qualitative ranking of risks by specialists, knowledgeable in their respective field, may still be effective.

7.3 Risk acceptance criteria

Risk acceptance criteria are qualitative or quantitative expressions, placing limits on the acceptable risk for a given establishment. There is a large variety in risk acceptance criteria in various European countries, where several countries have embedded those in national legislation. According to Duijm (2008) [34], the first principle of risk acceptance is that all unnecessary risk should be removed. This means that the ALARA (As Low As Reasonably Achievable) or ALARP (As Low As Reasonably Practical) principle are always followed, even where the level of risk already complies with the general risk acceptance criteria.

² <https://www.aiche.org/ccps/publications/books/guidelines-developing-quantitative-safety-risk-criteria>.

The ALARA principle states that all safety precautions should be implemented that are reasonable in view of technical and economical possibilities. The ALARA principle should always be applied, and therefore it is not necessary to define separate intervals of risk where ALARA has to be used. ALARA and ALARP are normally used as synonyms. The ALARA principle involves an assessment of whether the costs of a given safety measure are disproportionately large compared to the safety gain. This assessment will be different depending on whether the level of risk is high or low in relation to risk acceptance criteria.

It should be noted that the ALARA principle is based on “reasonable in view of technical and economical possibilities”, being highly subjective qualifications. Therefore, it is important that where such qualitative techniques are applied, appropriate contents experts are involved using their expert judgement.

The individual tolerable risk of fatality for a hazardous substance is 10^{-6} annually; the risk considered as negligible is 1 % of this figure. This does vary by country and circumstance.

7.4 Assessment of the use of risk-analysis in existing standards

European directives require the manufacturer to adequately analyse and assess the risks when evaluating the electrical equipment's conformity that the product does not endanger the health and safety of persons and domestic animals. The product shall not pose risk to property, when properly installed and maintained and used in applications for which it was made.

Beside the fact that currently no specific risk assessment standard exists in land based operation of refrigeration systems or applications, parts of the transport refrigeration industry have developed risk assessment standards for the safe use flammable refrigerants. See Annex C for more details.

To meet the essential health safety and requirements of the applicable European Directive or Directives Guidance can be found in the 'Blue Guide' on the implementation of EU product rules. The Blue Guide recommends that the details for the technical solution may be specified in a standard or provided with other technical options at the discretion of the manufacturer.

The standards drafting committee is expected to perform the risk assessment for specific and known hazards for a product-specific standard that is used to demonstrate regulatory compliance. The standard user is obliged to perform the risk assessment for hazards that they identify.

Standardisation organisations provide general rules for their technical committees as orientation, advice, or recommendations for drafting international standards. These general rules are published in the form of Guides. Depending on the nature of the guide, the guides are approved at different levels. The Technical Board approves guides with information or guidance on technical work. All other guides are approved by the General Assembly or the Administrative Board. Guides are approved through a simple majority vote.

In CEN and CENELEC, the rules and guides related to safety apply to all kind of products. They are not specifically developed for the assessment risks related to refrigeration, air conditioning, and heat pumps. Many standards are developed on a global basis and implemented as European standards. IEC/ISO guides apply when global standards are developed. For this reason, IEC/ISO guides, too, are used in CEN and CENELEC standardisation.

The standards listed in Annex A are intended for application to situations involving flammable gases. Flammability characteristics of various substances are detailed in these standards. Flammability characteristics within certain standards differ from those particularly addressing refrigeration systems. It was agreed that flammability characteristics for refrigerants shall be taken from ISO 817.

Beside the fact that currently no specific risk assessment standard exists in land based operation of refrigeration systems or applications, parts of the transport refrigeration industry are developing risk assessment standards based on semi-quantitative risk assessment for the safe use flammable refrigerants.

7.5 Review of available risk assessment and potential additional research needs

The European General Risk Assessment Methodology requires that the risk analysis is documented and included in the technical documentation. If only part of the harmonized standard is used, then the risks not covered by the standard are dealt with in the risk assessment.

The standards drafting committee is expected to perform the risk assessment for specific and known hazards for a product-specific standard that is used to demonstrate regulatory compliance. IEC/ISO Guides and CEN/CENELEC Guides define procedures for the preparation of safety publications for the safety of persons, domestic animals, livestock, and property.

ISO/IEC Guide 51 distinguishes between the standards drafting committee and the user of the standard. The user of standards are manufacturers, authorized representatives, importers, distributors, and economic operators.

A series of research projects on refrigerating technology are going on in Europe, in Japan and in the USA. Only a few results are available. As soon as the results are available the respective standards committees will review the reports and decide which information should be converted into amendments to standards.

When new research results are available Technical Committees can review the factors that lead to the risk based on research and other literature. Technical Committees can do a broad comparison with increased charge.

7.6 Analysis of relationship between risk and increased charge

While it is recognized that systems can be made inherently safe by restricting the amount of flammable substance which they contain, the size and scope of most industrial systems means that this is not possible for them. Once the charge is sufficiently large to exceed the threshold to create sufficiently large local concentrations the relationship between charge size and risk is complex and non-linear.

Larger systems are not necessarily more hazardous. The risk is related more to the likely rate of leakage that can be expected in normal operations, in adverse circumstances and in worst case scenarios. It should be noted that the level of tightness against leakage required for a refrigeration system to keep it functioning efficiently and reliably is far higher than that applied to most industrial systems, including industrial gases and fuels. This is evident in the European Standard EN 1127 Part 1, *Explosive atmospheres — Explosion prevention and protection — Basic concepts and methodology*, which defines different types of joints in systems.

Almost everything used in a typical refrigeration circuit is classed under EN 1127-1 as “durably technically tight”, even for low global warming potential GWP non-flammable refrigerants such as R-744.

The options for flammability risk reduction are listed in Table 4 which was derived from Annex G of this document.

Table 4 — Options for risk reduction

Risk	Topic	Option
Leak frequency	Production stages	Enhanced stages, such as Helium leak testing Only hermetically sealed systems to be used
	Design	Only hermetically sealed systems to be used
	Leak mechanism testing	Resonance test, external impact test
	Types of joints/ connections	Eliminate detachable joints, soft solder
	Choice of system materials	High quality materials
	Protective measures	Prevent mechanical impact
Flammable volume, and persistence	Leak hole size	Minimize through improved tightness
	Leak hole location	Internal or above
	Height of leak hole	High as possible
	Leak flow path	Away from low regions
	Size and configuration of housing	Large and as open as possible
	Volume airflow rate	High as possible
	Air speed and direction	High air speed, upwards
	Size of installation area	Large as possible

When durably technically tight equipment has been used the risk of leakage is mainly restricted to releases during service work, physical damage through accident and the effect of fire or other extreme circumstances (earthquake, hurricane, terrorism). It should also be noted that refrigeration systems, even with a very large charge, do not leak indefinitely so the risk of erosion of the original leak is low, since the system operator will need to find and repair the leak to keep the system operational.

In large complex systems it is also not possible to release all of the charge into a local area within a short space of time and it is highly unlikely, even in the event of a major leak, that the total charge of a large system will be discharged. There are many good reasons for designing systems to have a low refrigerant charge, including cost of refrigerant and toxic effects, but the hazard of flammability is not relevant in this respect.

7.7 Acceptability of increased risk

7.7.1 General

Technological changes and innovations rely on public acceptance. The word acceptance has different meanings in the social sciences. In this context it is important to distinguish three levels of acceptance:

- a) Tolerance: the new exploration methods are tolerated but people may still have major concerns or even a negative attitude towards it, but the topic is not salient enough for them to go into opposition.

- b) Positive attitude: the new exploration method triggers positive attitudes towards this method and leads to a favourable position towards the method and its trial application.
- c) Positive engagement: people endorse the new methods and work actively to promote this method rather than argue for conventional invasive methods or techniques.

A quote from F. A. Manuele provides a description of the term acceptable risk in standards³:

"THE TERM ACCEPTABLE RISK is frequently used in standards and guidelines throughout the world, yet a substantial percentage of those with SH&E responsibilities are reluctant to adopt or use it. Evidence of this reluctance often arises in discussions surrounding the development of new or revised standards or technical reports. The aversion may derive from:

- *a lack of awareness of the nature of risk;*
- *concern over the subjective judgments made and the uncertainties that almost always exist when risks are assessed;*
- *the lack of in-depth statistical probability and severity data that allows precise and numerically accurate risk assessments;*
- *insufficient real-world experience in more hazardous environments where nontrivial risks are necessarily accepted every day.*

"However, in recent years, the concept of acceptable risk has been interwoven into international standards and guidelines for a broad range of equipment, products, processes and systems. This has occurred in recognition of the fact that risk-related decisions are made constantly in real-world applications and that society benefits if those decisions achieve acceptable risk levels."

Risk acceptance criteria have to fulfil requirements regarding:

- Consistency, proportionality, and transparency;
- All accident possibilities to be considered;
- Environmental damage to be considered;
- Reasonable safety distances (for land-use limitations) to be determined as well as the consequence distance for the worst-case accident (for emergency planning);
- Societal risk for land use outside the safety distances to be assessed;
- Specific safety measures at the establishment to be considered;
- It is necessary to consider the probability of events in the assessments, as probability is elementary in the notion of risk. Inclusion of probability can be either quantitatively or qualitatively.

7.7.2 Method of assessing risk in other applications

Refrigerants are also used as process chemicals for other applications. The review of other applications was restricted to risk of fire and risk of explosion. A simple approach for fire, deflagration and explosion is known as Analytical Hierarchy Method. The following steps are applied:

- Identify the hazards and consequently the risks;
- Evaluate the risk associated with each attribute of the hazard;
- Identify measures of prevention, control and mitigation of fire, deflagration, or explosion.

The IEC has developed standards for equipment in explosive atmospheres (see A.3.6).

³ PROFESSIONAL SAFETY MAY 2010, Manuele, F.A., (see www.asse.org).

7.8 Additional mitigation requirements

7.8.1 General

When prevention and protective measures fail, the company needs to have mitigation measures implemented. The aim of mitigation measures is to reduce the severity of any damage to facilities and harm to employees and public. Several examples of measures can be used to achieve this aim, such as emergency plan, evacuation planning, warning systems including alarms and flashing lights, test of emergency procedures, exercises and drills, fire-extinguishing system, or a return-to-work plan.

Ensuring that all relevant areas are adequately ventilated and protected by gas detection systems and regular leak inspections helps to reduce the probability of an ignition. Such leak testing needs to be much more frequent than that mandated for fluorinated gases by the F-gas Regulation. The use of durably technically tight joints and the elimination of non-permanent joints from occupied spaces also reduces the risk of leakage provided the permanent joints and interconnecting pipes are suitably protected from accidental damage.

7.8.2 Options for additional mitigation requirements

7.8.2.1 General

Option for additional protective measures exist for certain flammable refrigerants. In some published standards they are applied to some flammable refrigerant classes, but not to others. Most of the standards are in transition and measures are being considered.

7.8.2.2 Mitigation options for chillers

For chillers, there are different options for additional mitigation measures in general or for indoor units. For outdoor units, there are not specific changes under consideration.

A number of amendments are currently discussed in standardisation for indoor units:

- Unventilated with fan dilution for A2/A3 refrigerants in EN standards
- Measurement of refrigerant concentration outside the unit
- Enhanced tightness systems for A2/A3 refrigerants in EN standards
- Consideration of releasable charge instead of full charge

In addition, new concepts are considered or under development that can be applies in general:

- Charge minimization without affecting efficiency
- Very low concentration measurement
- Continuously (online) monitoring on performance, proactive failure detection temperatures, vibrations, propane-concentration
- Failure notification strategies

7.8.2.3 Remarks on failure modes

Within other sectors that handle flammable substances, the governing safety standards and directives refer to the fail-safe concept (A.2.5.5).

In addition, CENELEC Guide 32 (A.3.3.3) and IEC Guide 116 (A.3.3.7) advise on certain considerations for reliability of risk reduction measures, such as possible power failure (clause 8.2.2 of Guide 116) and ability to defeat or circumvent protective measures, such as interferences by the user or members of the public (clause 8.2.3 of Guide 116).

Table 5 summarizes some possible implications of the further mitigation measures being inactive due to certain failures.

Table 5 — Selected implications of failures of further mitigation measures

Further measure	Failure mode(s)	Possible implication with leak
Ventilated enclosure	Vent blocked/fan faulty	Slow exhausting
	Enclosure open	Partial release to indoor space
	Detection faulty	Slow exhausting
Gas detection and extract ventilation (for machinery rooms)	Vent blocked/fan faulty	No extract/room fills with flammable mixture
	Detection faulty	No extract/room fills with flammable mixture
Circulation airflow (continuous/initiated by detection)*	Airflow faulty	Room fills with flammable mixture
	Detection faulty	No extract/room fills with flammable mixture
Improved system tightness*	Inadequate repairs	Larger leak
Natural ventilation openings to dilute leaked refrigerant*	Openings blocked	Room fills with flammable mixture
Shut-off valves close by detection	Valve fails to close	Room fills with flammable mixture
	Detection faulty	Room fills with flammable mixture
Shut-off valves close during off-mode	Valve fails to close	Room fills with flammable mixture
Gas detection and alarm	Detection faulty, alarm faulty	Room fills with flammable mixture and occupants unaware
Gas detection and extract ventilation (for occupied rooms)*	Vent blocked/fan faulty, detector faulty	No extract/room fills with flammable mixture

8 Relevant Legislation and Standards

8.1 Relevant legislation

European legislation that is relevant for refrigerating sector was analysed. The result of the review related to the individual sector is reflected in Annex E.

8.2 European legislative framework

The Treaty on the Functioning of the European Union requires to achieve a high level of protection concerning health, safety and environmental.

The Low Voltage Directive, the Pressure Equipment Directive and the Machinery Directive are specific directives that are relevant for appliances using refrigerants.

NOTE When the product is connected through wireless communication, the low voltage directive (LVD) is not applicable anymore, and the requirements are covered by the Radio Equipment Directive.

The Directive on General Product Safety complements sector specific legislation. The Directive on General Product Safety applies to toys, electrical and electronic goods, cosmetics, chemicals and other specific product groups. The Directive on General Product Safety does not cover products, which fall under separate legislation. The EU general risk assessment methodology⁴ is intended to assist market surveillance authorities when they assess the compliance of products that are subject to Union harmonization legislation. The methodology provides builds on the Rapid Exchange of Information System Guidelines. The Directive on General Product Safety provides information about how risk is analysed by other technologies. The Directive on equipment and protective systems intended for use in potentially explosive atmospheres provides useful information about other sectors.

The process of a Formal Objection allows member states to challenge requirements in harmonized standards.

The Directive on Protection of workers potentially at risk from explosive atmospheres provides requirements for employers.

Regulations on the transport of unit systems or limit charged systems containing refrigerants by aeroplane are more restrictive than on the transportation of the refrigerant in a dedicated refrigerant gas cylinder. The time taken for delivery of unit charged systems by sea is usually not acceptable to the customer. Shipping the unit without charge and charging it locally may increase the risk of an incident due to the lack of trained personnel and correct hydrocarbon refrigerant and tools.

The IATA Dangerous Goods Regulations (DGR) prohibits the transport of charged unit systems under UN 3358 REFRIGERATING MACHINES containing flammable, non-toxic, liquefied gas. A refrigerant charge of < 100 g liquefied refrigerant is exempted but often not accepted as the type label gives the total refrigerant mass charged not the corresponding liquefied refrigerant mass. There are not such requirements for transport for UN 2857 (REFRIGERATING MACHINES containing non-flammable, non-toxic gases or ammonia solutions (UN 2672)).

8.3 Relevant standards

8.3.1 General

The European General Risk Assessment Methodology suggests that by default the risk assessment is covered by a harmonized standard that complements the essential requirements of European legislation. If only part of the harmonized standard is used, then the risks not covered by the standard are dealt with in the risk assessment. This methodology requests that the risk analysis is documented and included in the technical documentation.

The standards drafting committee is expected to perform the risk assessment for specific and known hazards for a product-specific standard that is used to demonstrate regulatory. IEC/ISO Guides and CEN/CENELEC Guides define procedures for the preparation of safety standards.

⁴ Ref. Ares(2016)2656912 - 08/06/2016.

When new research results are available Technical Committees can review the factors that lead to the risk based on research and other literature. Technical Committees can do a broad comparison with increased charge.

There is no need to develop new risk assessment standards.

8.3.2 Risk assessment standards

CEN/CENELEC Internal Regulations Part 3 state the frame for developing standards. In addition, there are guides that provide recommendations how to include safety aspects in standards. The complete review is provided in Annex A.

- CENELEC Guide 32 — Guidelines for Safety Related Risk Assessment and Risk Reduction for Low Voltage Equipment
- ISO/IEC Guide 51 — Safety aspects — Guidelines for their inclusion in standards
- ISO Guide 78 — Safety of machinery — Rules for drafting and presentation of safety standards
- IEC Guide 104 — The preparation of safety publications and the use of basic safety publications and group safety publications
- IEC Guide 116 — Guidelines for safety related risk assessment and risk reduction for low voltage equipment
- CEN Guide 414 — Safety of machinery — Rules for the drafting and presentation of safety standards

Risk assessment standards provide guidance and methodologies for the identification and assessment of hazardous situations. These standards are not specifically developed for the risk assessments related to refrigeration, air conditioning and heat pumps.

- EN 1127-1: Explosive atmospheres — Explosion prevention and protection — Part 1: Basic concepts and methodology
- ISO 10377: Consumer product safety — Guidelines for suppliers
- ISO 10393: Consumer product recall — Guidelines for suppliers
- EN ISO 12100: Safety of machinery — General principles for design — Risk assessment and risk reduction
- ISO/TR 14121-2: Risk Assessment Part 2: Practical guidance and examples of methods
- CEN/TR 14739: Scheme for carrying out a risk assessment for flammable refrigerants in case of household refrigerators and freezers
- EN 15198: Methodology for the risk assessment of non-electrical equipment and components for intended use in potentially explosive atmospheres
- EN 15233: Methodology for functional safety assessment of protective systems for potentially explosive atmospheres
- ISO 20854: Thermal container — Safety standard for refrigerating systems using flammable refrigerants — Requirements for design and operation
- EN 31010: Risk management — Risk assessment techniques
- EN 60812: Failure Mode and Effects analysis (FMEA)
- IEC 61025: Fault tree analysis

8.3.3 Safety standards

The population of safety standards for refrigerating systems consists of horizontal standards such as EN 378 (all parts) and product standards of the 60335 series. The scopes of the relevant standards are listed below.

a) EN 378

The EN 378:2016 *Refrigerating systems and heat pump — Safety and environmental requirements — Design, construction, testing, marking and documentation* includes within its scope piping, components and materials and additional equipment in direct association with those systems. It also states requirements for testing, commissioning, marking and documentation.

b) IEC 60335-2-40

IEC 60335-2-40 *Household and similar electrical appliances — Safety — Part 2-40: particular requirements for electrical heat pumps, air-conditioners and dehumidifiers* includes within its scope the safety of electric heat pumps, including sanitary hot water heat pumps, air conditioners, and dehumidifiers incorporating motor-compressors and hydronic fan coils units.

c) IEC 60335-2-89

IEC 60335-2-89 Ed. 3.0 / EN 60335-2-89:2010/A1:2016/A2:2017 *Household and similar electrical appliances — Safety — Part 2-89: Particular requirements for commercial refrigerating appliances with an incorporated or remote refrigerant condensing unit or compressor* specifies safety requirements for electrically-operated commercial refrigerating appliances that have an incorporated compressor or that are supplied in two units for assembly as a single appliance in accordance with the manufacturer's instructions (split system).

Competence of personnel

For the competence of personnel CEN has developed a standard that will be replaced by an ISO standard the same title and contents, the future EN ISO 22712⁵.

a) EN 13313: *Refrigerating systems and heat pumps — Competence of personnel*

EN 13313 provides requirements for the competence of personnel. The standard defines activities related to refrigerating circuits and establishes procedures to assess the competence of personnel that do such activities.

8.3.4 Other standards

Several standards are essential for the application of the safety standards listed in 5.3.3. These standards define fundamental parameters that are used in the safety standards.

a) ISO 817

ISO 817: *Refrigerants — Designation system and safety classification applies to refrigerants*. This standard provides requirements for assigning designations to refrigerants.

At a joint meeting of ISO/TC 86, IEC/SC 61C, IEC/SC 61D and IEC/TC 31, it was agreed that the characteristics for refrigerants shall be taken from ISO 817.

⁵ Under preparation. Stage at the time of publication: prEN ISO 22712.

- b) EN 1839: *Determination of the explosion limits and the limiting oxygen concentration (LOC) for flammable gases and vapours*

EN 1839 applies to gases, vapours and their mixtures at atmospheric pressure. This standard provides requirements for determining explosive limits of gases, vapours and their mixtures.

- c) EN 14522: *Determination of the auto ignition temperature of gases and vapours*

EN 14522 applies to gases and vapours. This standard provides requirements for determining the ignition temperature in mixtures with air or air and inert gas at ambient pressure up to a temperature of 650 °C.

- d) EN 14986: *Design of fans working in potentially explosive atmospheres*

EN 14986:2017 applies to fans intended for use in explosive atmospheres. This standard provides requirements for the design, construction and testing.

- e) EN 15198:2007, *Methodology for the risk assessment of non-electrical equipment and components for intended use in potentially explosive atmospheres*

- f) EN 50495:2010, *Safety devices required for the safe functioning of equipment with respect to explosion risks*

EN 50495 applies to electrical safety devices which are used to monitor the potential ignition sources in explosive atmospheres. This standard provides safety requirements for such devices.

- g) IEC 60079: *Explosive atmospheres*

The standards in the IEC EN 60079 series specify the form of protection to be applied to electrical (and non-electrical) components for the purpose of avoiding ignition of a flammable gas mixture that may be surrounding the component. Generally, the basic requirements applying to all cases are detailed within EN 60079-0 and thereon additional requirements specific to the type of protection chosen are detailed in the individual standards. The minimum type of protection required is broadly dictated by EN 60079-10-1.

- h) EN IEC 61508-1:2010: *Functional safety of electrical/electronic/programmable electronic safety-related systems — Part 1: General requirements; Part 2: Requirements for electrical/electronic/programmable electronic safety-related systems*

This standard stipulates the general requirements for electrical, electronic and programmable electronic safety devices. It covers the safety systems of electrical equipment and their components that could have an impact on the safety of people and the environment. has introduced a risk-based approach for determining the SIL of safety instrumented functions with a complete approach to quantifying the safety performance of electrical control systems, including the design concept, the management of the design process, operations, and the maintenance of the system throughout its lifecycle (See Annex A 3.4 for SIL details).

- i) EN ISO 13849-1:2015: *Safety of machinery — Safety-related parts of control systems — Part 1: General principles for design*

This standard provides safety requirements and guidance on the principles for the design and integration of safety-related parts of control systems (SRP/CS), including the design of software. For these parts of SRP/CS, it specifies characteristics that include the performance level required for carrying out safety functions. It applies to SRP/CS for high demand and continuous mode, regardless of the type of technology and energy used (electrical, hydraulic, pneumatic, mechanical, etc.), for all kinds of machinery. It does not specify the safety functions or performance levels that are to be used in a particular case.

- j) EN 62061:2005+A2:2015: *Safety of machinery — Functional safety of safety-related electrical, electronic and programmable electronic control systems*

This standard specifies functional safety requirements and makes recommendations for the design, integration and validation of safety related electrical, electronic and programmable electronic control systems (SRECS). It gives assurance that a safety related control system has the required integrity necessary for the level of risk. The standard was developed as a derivative of IEC 61508, which introduced the concept of functional safety and applies across all industry sectors. EN 62061 takes the provisions, rationale and SIL (safety integrity level) classification system of IEC 61508, and interprets them for machinery control systems.

- k) EN 14624:2020: *Performance of portable locating leak detectors and of fixed gas detectors for all refrigerants*, specifies in its final version the functional requirements for detectors, including specific requirements for flammable refrigerants, location of measuring points, maintenance and service.

- l) EN 50271:2018: *Electrical apparatus for the detection and measurement of combustible gases, toxic gases or oxygen — Requirements and tests for apparatus using software and/or digital technologies*

This standard is applicable to fixed, transportable and portable apparatus intended for use in domestic premises as well as commercial and industrial applications and their software-controlled safety related accessories. This is a harmonized standard to support Directive 2014/34/EU (ATEX).

- m) EN 50402:2017: *Electrical apparatus for the detection and measurement of combustible or toxic gases or vapours or of oxygen — Requirements on the functional safety of gas detection systems*

This standard is applicable to detection and measurement apparatus and systems for flammable or toxic gases or vapours or oxygen. It covers apparatus intended to measure reliably, gas concentration and to provide an output signal (alarm and/or measurement signal), the purpose of which is to give a warning of a potential hazard. This standard is a product standard which is based on EN 61508 (all parts).

- n) EN 50676:2019: *Electrical equipment used for detection and concentration measurement of refrigerant gases — Performance requirements and test methods*

This standard defines test methods and performance requirements for all electrical equipment used for the detection of the refrigerant gases as defined in EN 378-1 by means of concentration measurement.

8.4 Review of work programmes

A series of research projects are going on in Europe, in Japan and in the USA. Only a few results are available. As soon as the results are available the respective standards committees will review the reports and decide which information should be converted into amendments to standards (Annex F).

European standards are regularly reviewed and updated. CENELEC and IEC agreed that the development of technical standards is taken up by the IEC. CENELEC reviews the IEC standards and adds European common modifications if necessary. IEC is updating the following standards to include requirements for A2 and A3 refrigerants:

a) IEC 60335-2-89

The standard was published on 20 June 2019.

At CENELEC, no parallel voting was done, the 3rd edition of IEC 60335-2-89 still needs to be implemented and voted on.

b) IEC 60335-2-40

The revision is ongoing to develop additional requirements for A2L, A2 and A3 refrigerants like charge limits, dilution, circulation, ventilation requirements, additional mitigation measures. The projected publication date for the new edition is 2021.

At CENELEC, the implementation of the previous edition as harmonized standard is pending. At CENELEC, the implementation of the previous edition as harmonized standard is pending, no parallel vote was done and is now pending to go to enquiry stage.

CEN/TC 182 is updating the following standards to revise the requirements for A2L, A2 and A3 refrigerants:

a) EN 378 series

The maintenance is ongoing. Amendments are submitted when consensus is reached on requirements.

b) For the competence of personnel CEN has developed a standard that shall be replaced by an ISO standard the same title and contents, the future EN ISO 22712⁵.

c) EN 13313

CEN has offered EN 13313 to ISO as a proposal for a new project.

8.5 Identify standards that should be further developed or updated

8.5.1 General

During the review of existing standards potential improvements were identified. These improvements were categorized according to priority. The priorities are reviewed in this subclause.

National, regional and communal laws that restrict the use of flammable refrigerants may have a big impact. The review of these laws, guidelines and codes was neither in the scope of this analysis nor in the scope of European Standardisation Organisations.

8.5.2 High priority

8.5.2.1 European harmonized standards

Low speed of transforming IEC standards in a European standard is one of the biggest problems. IEC 60335-2-40, Ed. 6.0 was published end of 2018. IEC 60335-2-40, Ed. 4.2 of 2006 is the latest version taken over to CENELEC. All modifications related to flammable refrigerants in IEC standards are not implemented in the European Union. CENELEC must adopt and publish the latest edition of IEC 60335-2-40 – both with reference to the current edition and all future editions – without delay, even if the European Commission does not accept this standard as a harmonized standard.

8.5.2.2 Competence of service personnel – EN 13313

There is a lack of competence of service personnel on flammable refrigerants. EN 13313 is in modification as EN ISO 22712⁵. The proposed modification contains guidance on flammable refrigerants and is a starting point. It cannot create competence for the special risks related to flammable refrigerants. Even when new training schemes are established it will take some time to train service personnel. Following standards already propose guidance for installation and repair of systems with flammable refrigerants:

- EN 60335-2-40 Annex HH
- EN 378-4 Annex E.

8.5.3 Medium priority

The improvements listed below are important but with a medium priority.

a) IEC 60335-2-40

IEC 60335-2-40 adds limitations to the charge limits for A2L, A2 and A3 refrigerants compared to the EN 378 (all parts) and as such may create additional barriers. The concepts of IEC 60335-2-89, Ed. 3.0 should be considered for IEC 60335-2-40 in order to help reducing barriers, including potential barriers for indoor single package units using water as heat sink (brine to water, air to water... heat pumps). The concepts developed by IEC SC61D/WG21 shall be finalized and implemented in IEC 60335-2-40.

Liability of manufacturers: Even if the European Commission promotes the use of flammable refrigerants the manufacturer will remain responsible if any incident occurs. On the market there is a poor availability of components for flammable refrigerants, especially A2L refrigerant blends.

b) Transportation and storage

Transportation and Storage of products using flammable refrigerants in logistic warehouses (distributors).

c) Transport refrigeration, air conditioning and heat pumps

For the transport refrigeration sector, it is recommended to develop specific standards for the application in scope in relevant TC's, either under ISO or CEN body.

ISO 20854 — *Thermal Containers — Safety standard for refrigerating systems using flammable refrigerants — Requirements for design and operation* should be updated.

8.5.4 Low priority

Perception of the market about the risk of flammable refrigerants is unclear. There should be a study whether the market will accept flammable refrigerants.

New concepts for risk mitigation may contribute, but will not give a fast solution for the barriers related to flammable refrigerants.

9 Assessment of safety-related barriers

9.1 European Directives

The Pressure Equipment Directive (2014/68/EU) applies to the design, manufacture, and conformity assessment of stationary pressure equipment with a maximum allowable pressure greater than 0,5 bar. The directive is still defining just two type of fluid groups (I and II). All the A2L refrigerants fall in the group I, the same group of the A3 refrigerants.

Pressure Equipment Directive and associated harmonized standards currently give no guidance for checking brazed joints, which is required when a test pressure of $1,1 \times PS$ shall be used. The alternative test with a test pressure of $1.43 \times PS$ is not always possible with all components.

Annex C provides the result of an assessment of safety-related barriers to the uptake of refrigerants with lower global warming potential across all relevant applications. The segments commercial and professional refrigeration, industrial refrigerating, chillers and air conditioning and heat pumps were considered.

9.2 Competence of service personnel – EN13313

Directive 1999/92/EC is a European Directive on the minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres. This directive is implemented by member states.

Nevertheless, there are reports about lack of competence of service personnel in general and in particular on flammable refrigerants.

CEN EN 13313 provides requirements for the competence of personnel.

The standard lacks guidance for competence of service personnel working on systems with flammable refrigerants. EN 13313 is in modification as EN ISO 22712⁵. The proposed modification contains guidance on flammable refrigerants.

It cannot create competence for the special risks related to flammable refrigerants. Even when new training schemes are established it will take some time to train service personnel. Following standards already propose guidance for installation and repair of systems with flammable refrigerants:

- EN 60335-2-40 Annex HH
- EN 378-4 Annex E.

9.3 National and regional regulations

Whilst several European refrigeration, air conditioning and heat pump safety standards may be harmonized standards, harmonized standards never replace legally binding legislation. A specification of a harmonized standard is not an alternative to a national legal requirement.

Products placed onto the EU single market must satisfy the requisite health, safety and environmental requirements. How this is achieved is laid out in the applicable European Directives. The installation and the operation of products is governed by national laws and national regulations of the member states, like fire regulations und building codes.

Storage of products using flammable refrigerants in logistic warehouses is regulated in specific legislation. This category products is governed by national laws and national regulations of the member states, like fire regulations und building codes.

Transport refrigeration systems are addressed by rules on transport of dangerous goods on a global basis and by local restrictions. Recommendations are given by the United Nations⁶, the International Maritime Dangerous Goods Code⁷, the European Agreement concerning the International Carriage of Dangerous Goods by Road, ADR⁸, the U.S. Government, Code of Federal Regulations⁹, for the transport of dangerous goods including refrigeration systems with flammable refrigerants.

9.4 EN 378

In EN 378:2016 Part 1, the current requirements treat an authorized access location below ground in the same way as a supervised access location above ground, but does not make sense and is not in line with other legislation on the use of flammable gases which would require a storage or work area to be adequately ventilated but would not place different restrictions on charge based on whether the room is above or below ground. This is currently under discussion in the working group responsible for the text of EN 378. access location above ground, but this does not make sense and is not in line with other legislation on the use of flammable gases which would require a storage or work area to be adequately ventilated but would not place different restrictions on charge based on whether the room is above or below ground.

EN 378 does not present a barrier to the adoption of flammable refrigerants in the industrial sector, as shown by the widespread use of R-717. This is because most industrial systems will be installed in location class II or III as defined by EN 378:2016 Part 1 and will be in a controlled access area, usually access category C. Under these constraints there is no restriction on the charge of flammability class 2L provided the area being directly cooled or heated by the system is not a high population density area. For this purpose, high density is defined as having more than 1 person per 10 m² of floor area. For refrigerants of flammability classes 2 or 3 there is no restriction of charge if the system is location class III (for example glycol chillers serving the process area with the refrigerant all contained in a machinery room or in the open air). If the system is primarily for human comfort (which does not usually apply to industrial systems) or the population density in the space is greater than 1 person per 10 m² of floor area then the charge allowed in the system is restricted to 20 % x LFL x room volume with a cap of 25 kg for A2L refrigerants, m² for A2 refrigerants and 1kg for A3 refrigerants. The meaning of this cap for different fluids is given in Table C.1.

⁶ UN Recommendations on the Transport of Dangerous Goods - Model Regulation, Rev. 17 (2011).

⁷ International Maritime Dangerous Goods Code (IMDG-Code), 2010 Edition (incl. Amdt 35-10).

⁸ European Agreement concerning the International Carriage of Dangerous Goods by Road, ADR 2011.

⁹ U.S. Government, Code of Federal Regulations, Title 49 Transportation, Subchapter C – Hazardous Materials Regulations.

9.5 IEC 60335-2-40

IEC 60335-2-40 is currently being revised to address requirements and risk mitigation measures on appliances using flammable refrigerants. This work is taking its time. It is observed that the transition from the IEC 60335-2-40 to a harmonized European standard is not happening in an adequate timing so it is expected that for the coming revisions extensive delays will occur. The current transition from IEC to European standards is already taking 5 years.

9.6 IEC 60335-2-89

It adds limitations to the charge limits for A2L and A2 refrigerants compared to the EN 378 (all parts) and as such may create additional barriers. IEC 60335-2-89 does not consider the different ignition properties for A2L refrigerants that are accepted in other standards such IEC 60335-2-40.

The IEC 60335-2-89 Ed. 3.0 was not submitted for CENELEC parallel voting.

It happens that on IEC level a standard can be accepted but it is rejected in EU and vice versa. The transition from IEC to European standards is expected to take several years.

9.7 Transport refrigeration

In principle there is no barrier for the use of flammable refrigerants in the transport refrigeration sector (Annex H).

The transport refrigeration industry is using parts of the basic standards such as ISO 5149, EN 378 (all parts), IEC 60335-2-40 in addition to the basic requirements in EU directives. For transport applications the adoption of the basic concepts for the definition of the charge amount of refrigerants based on occupied spaces and of location only is difficult if not impossible. For this reason, the available risk-based standards for the intermodal industry and the mobile air conditioning systems Industry use other and much more application-oriented approaches to minimize risk, rather than using a conservative specification of a refrigerant charge. It is expected that this approach will also prevail in the development of risk based standards, new or extensions of existing standards.

It is also expected that the development of such extensions of or development of new risk based standards need 2 years to 4 years development time.

10 Options

10.1 Options for additional mitigation requirements

The status of developing mitigation options for refrigeration, air conditioning and heat pumps is summarized in Table 7. The information is for current and future options.

Table 6 — Status of mitigation options for refrigeration, air conditioning and heat pumps in safety standards

Mitigation options	Refrigerant class	Status of implementation in standards
Unventilated with fan dilution in EN standards (Indoor)	A2L	Already published in EN 378 (all parts) (CEN/TC 182), IEC 60335-2-40 (IEC/SC 61D)
Unventilated with fan dilution in EN standards (Indoor)	A2/A3	Under development in EN 378 (all parts) (CEN/TC 182), IEC 60335-2-40 (IEC/SC 61D)
Measurement of refrigerant concentration outside the unit (Indoor)	A2L/A2/A3	Under development in EN 378 (all parts) (CEN/TC 182), IEC 60335-2-40 (IEC/SC 61D), IEC 60335-2-89 (IEC/SC 61C)
Enhanced tightness systems in EN standards (Indoor)	A2L	Already published in IEC 60335-2-40 (IEC/SC 61D)
Enhanced tightness systems in EN standards (Indoor)	A2/A3	Under development in EN 378 (all parts) (CEN/TC 182), IEC 60335-2-40 (IEC/SC 61D)
Consideration of releasable charge instead of full charge (Indoor)	A2L/A2/A3	Under development in EN 378 (all parts) (CEN/TC 182), IEC 60335-2-40 (IEC/SC 61D)
Charge minimization without affecting efficiency (general)		Out of scope
Very low concentration measurement (general)		Potential future project
Continuously (online) monitoring of performance (general) to detect refrigerant loss	A2/A3	To be linked with mitigation measures Under development in EN 378 (all parts) (CEN/TC 182), IEC 60335-2-40 (IEC/SC 61D)
Proactive failure detection temperatures (general) to detect refrigerant loss	A2/A3	To be linked with mitigation measures Under development in EN 378 (all parts) (CEN/TC 182), IEC 60335-2-40 (IEC/SC 61D)
Proactive failure detection Vibrations (general) to avoid pipe breaks	A2/A3	To be linked with mitigation measures Under development in EN 378 (all parts) (CEN/TC 182), IEC 60335-2-40 (IEC/SC 61D)

Mitigation options	Refrigerant class	Status of implementation in standards
Continuously (online) monitoring of refrigerant-concentration (general)	A2/A3	Under development in EN 378 (all parts) (CEN/TC 182), IEC 60335-2-40 (IEC/SC 61D) Not relevant
Failure notification strategies (general)	A2/A3	Under development in EN 378 (all parts) (CEN/TC 182), IEC 60335-2-40 (IEC/SC61D) Not relevant
Ensuring that continuous measures are taken to reduce leakage	A2L/A2/A3	Already published in EN 1127-1 (CEN/TC 305)
Air-side zone separation of connections from the occupied area	A2L/A2/A3	Under consideration for transport refrigeration (CEN/TC 143)
Use of evaporators, which represent and maintain a permanently technically tight construction	A2L/A2/A3	Under consideration for transport refrigeration (CEN/TC 143)
Ensuring that proper ventilation is ensured and maintained if relevant for risk mitigation	A2L/A2/A3	Under consideration for transport refrigeration (CEN/TC 143)
Integrated leak diagnosis and preventive maintenance techniques for mitigation of risks	A2L/A2/A3	Under consideration for transport refrigeration (CEN/TC 143)
Preventive risk evaluation processes and information for users, organization of work, supervision	A2L/A2/A3	Under consideration for transport refrigeration (CEN/TC 143)
Requirements for qualification of personnel	A2L/A2/A3	Already published in EN 13313 (CEN/TC182) Under development in EN ISO 22712 ⁵ (ISO/TC 86)
Charge limits	A2L	Already published in EN 378 (all parts) (CEN/TC 182), IEC 60335-2-40 (IEC/SC 61D); revision under development
Charge limits	A2/A3	Already published in EN 378 (all parts) (CEN/TC 182), IEC 60335-2-40 (IEC/SC 61D); revision under development

a) Commercial and professional

The options for commercial and professional appliances are summarized in Table 6.

b) Industrial refrigeration

Ensuring that all relevant areas are adequately ventilated and protected by gas detection systems and regular leak inspections helps to reduce the probability of an ignition. Such leak testing however needs to be much more frequent than that mandated by the F-gas Regulations. The use of

durably technically tight joints and the elimination of non-permanent joints from occupied spaces also reduces the risk of leakage provided the permanent joints and interconnecting pipes are suitably protected from accidental damage.

c) Air conditioning and heat pumps

IEC set up working groups to specifically address requirements for A2L refrigerants and to develop additional requirements for A2 and A3 refrigerants: charge limits, dilution, circulation, ventilation requirements and additional mitigation measures. Changes for A2L refrigerants were adopted into IEC 60335-2-40 in early 2018.

d) Chillers

For chillers, there are different options for additional mitigation measures in general or for indoor units. For outdoor units, there are not specific changes under consideration.

A number of amendments are currently discussed in standardisation for indoor units:

- Unventilated with fan dilution for A2/A3 refrigerants in EN standards
- Measurement of refrigerant concentration outside the unit
- Enhanced tightness systems for A2/A3 refrigerants in EN standards
- Consideration of releasable charge instead of full charge

In addition, new concepts are considered or under development that can be applied in general:

- Charge minimization without affecting efficiency
- Very low concentration measurement
- Continuously (online) monitoring on performance, proactive failure detection temperatures, vibrations, propane-concentration
- Failure notification strategies

e) Transport refrigeration

Beside the fact that transport refrigeration application and relevant standards require shock, vibration, corrosion and other test the development of following mitigation principles for design and operation are under consideration:

- Requirement for specific application oriented risk assessment for lifetime operation and demonstration that the identified risks are tolerable and mitigated.
- Air-side zone separation of connections from the occupied area.
- Use of evaporators, which represent and maintain a permanently technically tight construction.
- Ensuring that continuous measures are taken to reduce leakage, that proper ventilation is ensured and maintained if relevant for risk mitigation.
- Integrated leak diagnosis and preventive maintenance techniques for mitigation of risks.
- Preventive risk evaluation processes and information for users, organization of work, supervision.
- Requirements for qualification of personnel.

10.2 Options for performance based requirements

Requirements in CEN and CENELEC standards are expressed in terms of performance, whenever possible, rather than design or descriptive characteristics. Performance requirements allow a maximum of freedom for technical developments and innovations. The existing set of standards is wide enough. There were no new and additional options identified for performance-based requirements.

10.3 Options for risk minimisation

There is a variety of approaches for minimisation of risk, some of which are already included within the various standards.

In general, risk is minimized by means of:

- Reducing likelihood and size of a leak;
- Dispersing a mixture arising from a leak;
- Eliminating as far as possible the presence of potential ignition sources;
- Designing equipment and installations to limit the consequences of ignition;

The status of these approaches is described in subclause 3.2.

10.4 Options for installation, operation, service, and decommissioning

10.4.1 Charge size limits

EN 378-1 is being amended to resolve, primarily considering the following:

- Address restriction for A3 refrigerant charge sizes for below ground;
- Resolve the conflict for charge limits between “other” and “human comfort”;
- To include A2 and A3 refrigerants in annex C.4 for additional risk management;
- Test procedure to determine the leak amount including when safety shut off valves are used;
- Test method to determine how much refrigerant could be leaked from a system until the room floor approaches some fraction of the refrigerants’ LFL (e.g., 50 % of LFL).

To date, considerable progress has been made on addressing these matters, however, no working draft has been issued yet.

A more general method is given in EN 1127-1 and also in ISO 20854:2019.

10.4.2 Associated risk mitigation requirements

“Mitigation measures” or “protective measures” should be reconsidered with respect to potential and obvious failure modes, such as loss of mains power and user interference.

New concepts for risk mitigation may contribute, but will not give a fast solution for the barriers related to flammable refrigerants.

10.4.3 Design of rooms

10.4.3.1 Structural requirements

The available standardisation literature related to risk assessment is wide enough, and there is no need for additional documents.

10.4.3.2 Room volume

The room volume is considered when charge size is considered.

10.4.3.3 Location of installation

Location of installation is governed by national legislation.

10.4.3.4 Ventilation

Ventilation is considered together with room volume, charge size and mitigation measures.

10.4.4 Marking of installation

Marking of installations is governed by European and national legislation and related safety standards.

10.4.5 Additional measures to ensure ongoing risk mitigation

Risk mitigation is an ongoing task for all standardisation committees that deal with refrigerants.

11 Recommendation

TC 182/WG12 recommends:

- 1) CENELEC should expedite the adoption of the latest edition of IEC 60335-2-40.

IEC 60335-2-40 is currently being revised to address requirements and risk mitigation measures on appliances using flammable refrigerants. It is proposed to consider the surrounding concentration test similar to the approach for revised IEC 60335-2-89. This work is taking its time.

It is observed that the transition of IEC standards into European harmonized standards experienced some delays due to the new European approach for the assessment of harmonized standards. Following a ruling of the European Court of Justice, the European Commission assumes more responsibility. CENELEC is working on the conversion of an IEC standard to an EN IEC standard. It is intended that IEC 60335-2-40 will be a harmonized standard by the end of 2020.

- 2) CENELEC should expedite the adoption of the latest edition of IEC 60335-2-89.

The increase of the charge limits for A2L, A2, and A3 refrigerants for single packaged units reducing barriers. It adds limitations to the charge limits for A2L, A2 and A3 refrigerants compared to the EN 378 (all parts) and as such may create additional barriers.

It is observed that the transition of IEC standards into European harmonized standards experienced some delays due to the new European approach for the assessment of harmonized standards. Following a ruling of the European Court of Justice, the European Commission assumes more responsibility. CENELEC is working on the conversion of an IEC standard to an EN IEC standard.

- 3) Establish or revise a training and competence safety standard for installation and service personnel on flammable refrigerants for the special risks related to flammable refrigerants.

Good quality competence standards for personnel working with flammable refrigerants is necessary. EN 13313 is the leading European standard for competence, where Annex F covers flammable refrigerants. This standard is currently in modification as EN ISO 22712⁵. We recognize that other standards contain valuable complementary competence elements. CEN/TC 182/WG4 should therefore review the latest version of EN ISO 22712⁵ and revise the text if and where appropriate, taking good notice of EN 60335-2-40 Annex HH and EN 378-4 Annex E. It is hoped that EN ISO 22712⁵ will provide the platform for European and national certification schemes.

- 4) “Mitigation measures” or “protective measures” should be reconsidered with respect to potential and obvious failure modes, such as loss of mains power and user interference.

“Mitigation measures” or “protective measures” should be reconsidered with respect to potential and obvious failure modes, such as loss of mains power and user interference. The need for account for such failure modes depends upon the likelihood and severity of the consequences in the event of the failure and whether the failure would ordinarily be resolved. For instance, where a system relies on integral airflow to dilute a release, if the airflow is dedicated for that purpose then there should be some means to monitor the airflow, whereas if the airflow is part of the function of the system (such as a condenser fan) then the need for an additional layer of protection is less necessary. In the event that natural ventilation openings are relied upon to protect against large flammable volumes accumulating within spaces, consideration should be given to inadvertent closing of the openings by occupants, which is foreseeable. Similarly, where remote refrigerant sensors are employed, measures should be put in place to ensure they are not inadvertently obscured (such as by painting over) by the actions of occupants.”

- 5) ISO or CEN should develop specific standards for transport refrigeration applications.

The transport refrigeration industry is using parts of the basic standards such as ISO 5149, EN 378 (all parts), IEC 60335-2-40 in addition to the basic requirements in EU directives. For transport applications the adoption of the basic concepts for the definition of the charge amount of refrigerants based on occupied spaces and of location only is difficult if not impossible. For this reason, the available risk-based standards for the intermodal industry and the mobile air conditioning systems Industry use other and much more application-oriented approaches to minimize risk, rather than using a conservative specification of a refrigerant charge. It is expected that this approach will also prevail in the development of risk based standards, new or extensions of existing standards. It is also expected that the development of such extensions or development of new risk based standards need 2 years to 4 years development time and cannot be addressed within this mandate.

Annex A (informative)

Risk analysis

A.1 General

This Annex reviews guidelines and standards that may be used by the refrigeration industry, especially for commercial refrigeration, transport refrigeration, industrial refrigeration, air conditioning and heat pumps, and chillers. This Annex collects risk analysis information that can be used by all groups that develop standards for the refrigeration industry.

This annex analyses the current practice in the refrigeration industry sector. It also reviews a selection of standards related to flammable gases or for products to be used in flammable atmospheres. There is no comprehensive review of all standards for other sectors.

A.2 Current practice in the sector

A.2.1 General

This subclause provides a general introduction about the risk assessment concept and the general practice in the sector.

A.2.2 General concept of risk assessment

Potential safety risks were identified, depending on the stage of the life cycle of the product. Table A.1 illustrates all the stages of the life cycle that should be subject to a risk assessment. It has to be noted that only installation, operation, servicing and decommissioning are in the scope of standardisation request M/555 - IMPLEMENTING DECISION of 14 November 2017 on a standardisation request to the European Committee for Standardisation and to the European Committee for Electrotechnical Standardisation as regards use of flammable refrigerants in refrigeration, air conditioning and heat pump equipment.

Table A.1 — Potential Safety Risks For Life Cycle

Life Cycle/Lifetime Stage	In scope of this assessment report	Converted by existing standards
Production	No ^a	n/a
Packaging	No ^a	n/a
Shipment	No ^a	n/a
Storage	yes	n/a
Installation	yes	n/a
Commissioning	yes	n/a
Operation	yes	n/a
Servicing	yes	n/a
Decommissioning	yes	n/a
^a Not mandated in standardisation request M/555. n/a = not applicable.		

A.2.3 Explanation of hazard arising from using flammable refrigerants

The release of a flammable refrigerant may result in a fire or decomposition products or generation of an overpressure or formation of toxic decomposition products. The consequences may include thermal damage to persons and property, overpressure damage, physiological damage to persons from toxic decomposition products or secondary fire.

Figure A.1 illustrates the sequence of events that exemplify the hazard arising from using flammable refrigerants. Initially a release or leak of refrigerant occurs and there may also be a potential ignition source present. If the refrigerant mixes with air in the requisite proportions and that mixture is present at the same location in space and time as the ignition source being active, then ignition can occur.

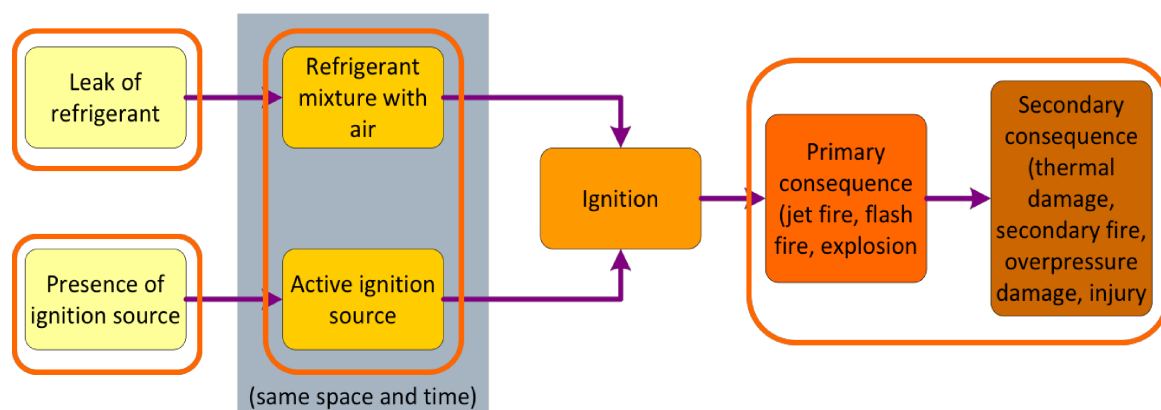


Figure A.1 — Sequence of events involving ignition of a flammable refrigerant

In order to avoid ignition and the subsequent consequences, either the leak of refrigerant or the presence of active ignition sources must be eliminated. Such elimination can never be guaranteed. A probabilistic approach to evaluating the likelihood of an ignition event and severity of subsequent consequences must be used.

A.2.4 Mandatory requirements within the single market

Products placed onto the EU single market must satisfy the requisite health, safety and environmental requirements. The health, safety and environmental requirements are defined as essential requirements in the European product directives and regulations. How this is achieved is laid out in the Guide to the implementation of directives based on the New Approach and the Global Approach (the “Blue Guide”). The Blue Guide states:

“Essential requirements define the results to be attained, or the hazards to be dealt with, but do not specify the technical solutions for doing so. The precise technical solution may be provided by a standard or by other technical specifications or be developed in accordance with general engineering or scientific knowledge laid down in engineering and scientific literature at the discretion of the manufacturer. This flexibility allows manufacturers to choose the way to meet the requirements. It allows also that, for instance, the materials and product design may be adapted to technological progress. Accordingly, Union harmonisation legislation based on essential requirements does not necessitate regular adaptation to technical progress, since assessment of whether requirements have been met or not are based on the state of technical know-how at the moment the product is placed on the market.”

The essential requirements are set out in relevant sections or annexes of a given piece of Union harmonisation legislation. Although no detailed manufacturing specifications are included in the essential requirements, the degree of detailed wording differs between different Union harmonisation acts. The wording is intended to be precise enough to create, on transposition into national legislation,

legally binding obligations that can be enforced, and to facilitate the setting up of standardisation requests by the Commission to the European standardisation organisations in order to produce harmonised standards. They are also formulated so to enable the assessment of conformity with those requirements, even in the absence of harmonised standards or in case the manufacturer chooses not to apply them.”

Thus, whilst several European refrigeration, air conditioning and heat pump safety standards may be harmonized standards, it is not necessarily mandatory to apply them. According to the EU Blue Guide:

“Harmonised standards never replace legally binding essential requirements. A specification given in a harmonised standard is not an alternative to a relevant essential or other legal requirement but only a possible technical means to comply with it.”

“Harmonised standards maintain their status of voluntary application.”

Figure A.2 gives an explanation of the routes that are appropriate for meeting the essential health safety and requirements of Directives. Provided that the essential health safety and requirements of the relevant Directives are satisfied, then following any or no European refrigeration, air conditioning and heat pump safety standards are permitted.

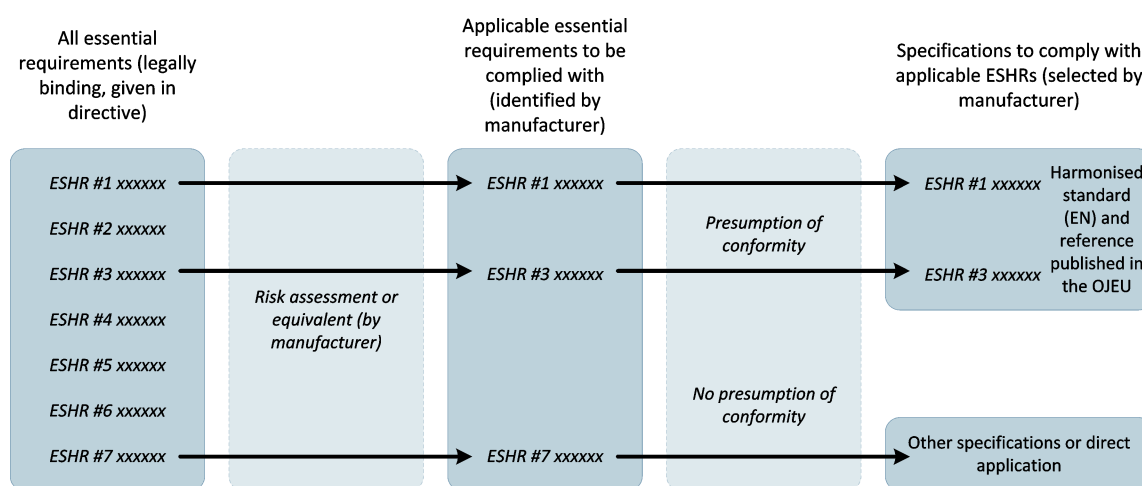


Figure A.2 — The role of harmonized standards when complying with applicable essential requirements identified by a manufacturer

If an alternative means of meeting the essential health safety and requirements is to be taken, then the appropriate means must be identified. According to the Blue Guide:

“The manufacturer can choose whether or not to apply and refer to harmonised standards. However, if the manufacturer chooses not to follow the harmonised standards, he has the obligation to demonstrate that his products are in conformity with essential requirements by the use of other means of his own choice that provide for the level of safety or protection of other interests required by the applicable legislation. These can be technical specifications such as national standards, European or international standards which are not harmonised i.e. not published in the OJEU or the manufacturer’s own specifications. In these cases the manufacturer does not benefit from the presumption of conformity, but has to demonstrate the conformity himself. This implies that he demonstrates, in the technical file of a relevant product, in a more detailed manner how the technical specifications he uses provide conformity with the essential requirements.”

It is then necessary to understand which of the relevant Directives’ essential health safety and requirements relate to the matters of concern, for instance, charge size limits. How the essential health safety and requirements are met, must be explained and documented in the applicable technical file, for example, as an internal technical specification.

Following a harmonized standard is the easier way to comply with the requisite essential health safety and requirements, but if other routes are used, they may be and depending upon the applicable directives and the necessary conformity route, a notified body may have to be used to verify the approach. Regardless whether harmonized standards are followed to comply with the essential requirements of the regulations, a risk assessment of the product has to be performed as required by the regulations pertaining to safety.

A.2.5 Requirements that apply to all products

Before placing their product on the market manufacturers should identify which regulations are applicable to their products and make a comprehensive risk assessment of their products. Manufacturers' risk assessment shall take into account all relevant product hazards. The risk analysis is documented and included in the technical documentation.

The risk assessment can be covered by a harmonized standard. There are guides that shall be followed when a Technical Committee develops a harmonized standard (A.3.3).

A.2.5.1 Design measures for systems using flammable refrigerants - Air conditioning and heat pumps

This section deals with measures that currently exist or could be integrated into refrigeration, air conditioning and heat pump safety standards to help improve flammability safety and to extend application of flammable refrigerants in refrigeration, air conditioning and heat pump systems.

Figure A.3 provides an overview of the various levels of intervention that may be applied to refrigeration, air conditioning and heat pump systems and equipment, along with some examples of how these interventions may be practically applied. Broadly, those at the top of the list can be considered as having a higher level of reliability. As a priority, those measures that avoid the refrigerant entering into the space may be deemed more reliable, whereas those which require intervention of human occupants to initiate some action to reduce the risk may be deemed less reliable. Thus, the approaches towards the top of the list may be considered preferentially, although this can also be affected by specific circumstances and equipment type.

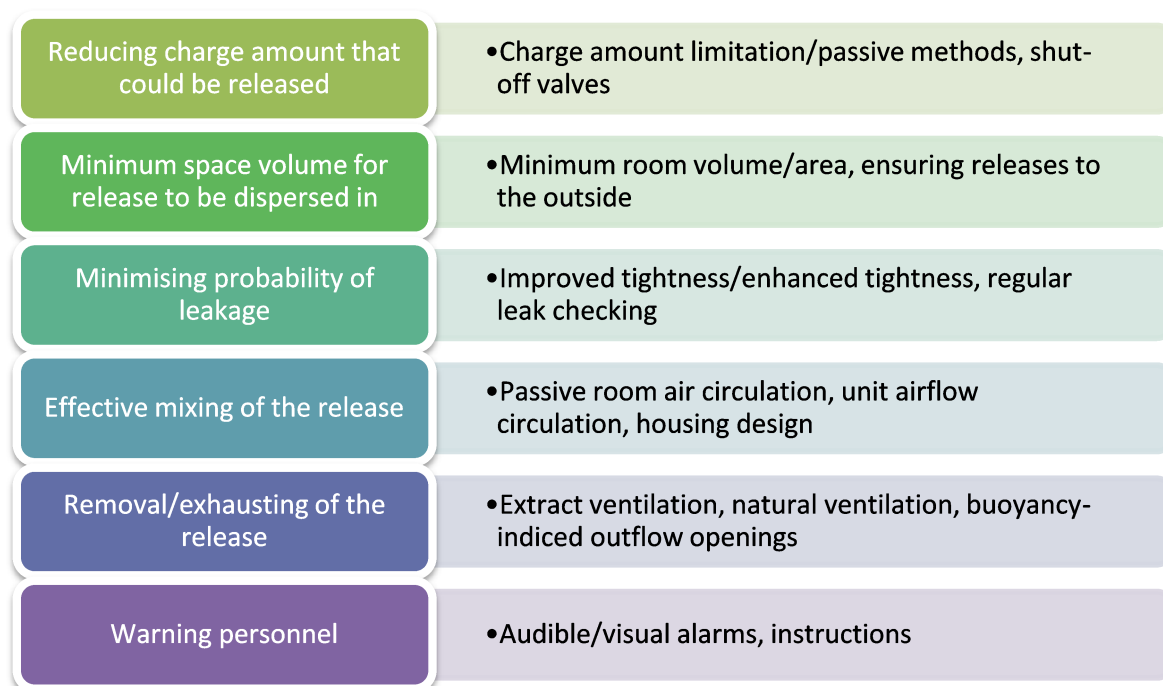


Figure A.3 — Hierarchy of flammability mitigation measures and practical examples applicable to refrigeration, air conditioning and heat pump systems

A.2.5.2 Basic measures

The following are the basic considerations that typically apply to the use of flammable refrigerants, all of which should be integrated into any one system/installation:

- No sources of ignition associated with the system that a flammable mixture could reach;
- Ensuring system tightness;
- Limiting refrigerant charge;
- Warnings/markings;
- Instructions.

Obviously, these measures are in addition to others related to pressure and mechanical safety.

A.2.5.3 Further measures currently in refrigeration, air conditioning and heat pump safety standards

A variety of other measures have recently been introduced into various refrigeration, air conditioning and heat pump safety standards, typically to offset the perceived risk of using larger charge sizes of A2L refrigerants.

For air conditioners, applicable measures include (either individually or in combination):

- Ventilated enclosure;
- Gas detection and extract ventilation (for machinery rooms);
- Circulation airflow (continuous or initiated by gas detection)*;
- Improved system tightness*;
- Reliance upon natural ventilation openings to dilute leaked refrigerant*;
- Use of shut-off valves to limit charge being released*;
- Gas detection and alarm*;
- Gas detection and extract ventilation (for occupied rooms)*.

Asterisked items (*) currently only apply to 2L flammable refrigerants.

Table A.2 displays which standards include the measures listed above.

Table A.2 — Applicable clauses within refrigeration, air conditioning and heat pump safety standards

Measure	IEC 60335-2-40	EN 60335-2-40 ^a	EN 378	ISO 5149
No sources of ignition	22.116, 22.117	22.116	Part 2, 6.2.14	x
Ensuring system tightness	22.113	n/a	Part 2	x
Limiting refrigerant charge	Annex GG	Annex GG	Part 1, Annex C	
Gas detection & extract ventilation (for machinery rooms)	GG3	Annex GG	Part 3	x
Warnings/markings	7	7	Part 2, 5.3	x
Instructions	7	7	Part 2, 5.3	x
Ventilated enclosure	GG4	GG4	Part 2	x
Circulation airflow (continuous or gas detection)	GG2.2, GG9, GG10	n/a	Part 1, Annex C.3	x
Natural ventilation openings to dilute leaks	GG1.3, GG8, GG11	n/a	Part1, Annex C.3	x
Shut-off valves to limit charge being released	GG12	n/a	Part1, Annex C.3	x
Gas detection and alarm	GG13	n/a	Part1, Annex C.3	x
Gas detection and extract ventilation (occupied rooms)	GG8, Annex LL, MM	n/a	Part1, Annex C.3, -3,	x
n/a = not applicable. x = standard includes this measure. ^a Based on current version: EN 60335-2-40:2003+A2+A11(2004)+A12(2005).				

A.2.5.4 Other possible measures not currently in refrigeration, air conditioning and heat pump safety standards

There are a number of other measures that are either currently in use by manufacturers or suggested within the literature (or both). Many such measures could be useful for extending the safe application of flammable refrigerants across air conditioner subsectors.:

- Design of enclosures/housings to better dilute releases;
- Alternative means of leak detection (system parameters, ultrasonic, flash gas indication, etc.);
- Limiting releasable charge;
- Circulation airflow (continuous or initiated by detection) (for A2 and A3 refrigerants);
- Improved system tightness (for A2 and A3 refrigerants);
- Use of shut-off valves to limit charge being released (for A2 and A3 refrigerants);
- Gas detection and extract ventilation (for occupied rooms) (for A2 and A3 refrigerants);
- Surrounding concentration test (Currently proposed for commercial refrigeration appliances under IEC 60335-2-89).

A.2.5.5 Remarks on failure modes

Amongst the various protective measures, concerns may exist with the reliability and possible failure modes arising with different technologies. Within other industry sectors that handle flammable substances, the governing safety standards and directives refer to the fail-safe concept.

In addition, CENELEC Guide 32 (A.3.3.3) and IEC Guide 116 (A.3.3.7) advise on certain considerations for reliability of risk reduction measures, such as possible power failure (clause 8.2.2 of Guide 116) and ability to defeat or circumvent protective measures, such as interferences by the user or members of the public (clause 8.2.3 of Guide 116).

Another example is within potentially explosive atmospheres (ATEX) (essential health safety and requirement 1.5.1, 1.5.2, 1.6.3, 2.0.1.1) where it is recommended to adopt fail-safe mechanisms, i.e.:

“As far as possible, failure of a safety device must be detected sufficiently rapidly by appropriate technical means to ensure that there is only very little likelihood that dangerous situations will occur.

The fail-safe principle is to be applied in general. ...

In the event of a safety device failure, equipment and/or protective systems shall, wherever possible, be secured.”

“Where equipment and protective systems can give rise to a spread of additional risks in the event of a power failure, it must be possible to maintain them in a safe state of operation independently of the rest of the installation.”

“Equipment must be so designed and constructed that sources of ignition do not become active, even in the event of rare incidents relating to equipment.

Equipment must be equipped with means of protection such that:

- *either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection;*
- *or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.*

Where necessary, equipment must be equipped with additional special means of protection.

It must remain functional with an explosive atmosphere present."

Considering these requirements, it may be observed that many of the further measures detailed in section D.2 do not necessarily account for implications associated with loss of power or failure of detection devices. Table A.3 summarizes some possible implications of the further mitigation measures being inactive due to certain failures.

Table A.3 — Selected implications of failures of further mitigation measures

Further measure	Failure mode(s)	Possible implication with leak
Ventilated enclosure	Vent blocked/fan faulty	Slow exhausting
	Enclosure open	Partial release to indoor space
	Detection faulty	Slow exhausting
Gas detection and extract ventilation (for machinery rooms)	Vent blocked/fan faulty	No extract/room fills with flammable mixture
	Detection faulty	No extract/room fills with flammable mixture
Circulation airflow (continuous/initiated by detection)	Airflow faulty	Room fills with flammable mixture
	Detection faulty	No extract/room fills with flammable mixture
Improved system tightness	Inadequate repairs	Larger leak
Natural ventilation openings to dilute leaked refrigerant	Openings blocked	Room fills with flammable mixture
Shut-off valves close by detection	Valve fails to close	Room fills with flammable mixture
	Detection faulty	Room fills with flammable mixture
Shut-off valves close during off-mode	Valve fails to close	Room fills with flammable mixture
Gas detection and alarm	Detection faulty, alarm faulty	Room fills with flammable mixture and occupants unaware
Gas detection and extract ventilation (for occupied rooms)	Vent blocked/fan faulty, detector faulty	No extract/room fills with flammable mixture

It has to be noted that all products are covered to consider failure modes regardless whether flammable refrigerants are used yes or no. These requirements are also included in the relevant standards.

The items listed here are considering that a leak happens (fault 1) and that at the same time another part of the product malfunctions (fault 2).