Application of IEC 61010-2-011:2016/2019 and IEC 61010-2-012:2016 to address refrigerated systems in laboratory equipment

Executive Summary

The IEC 61010 family of standards focuses on laboratory equipment. The 2-011:2016 and 2-012:2016 distinctions of the IEC 61010[1] go in-depth to specifically address refrigerated systems in laboratory equipment. This paper will explore the differences between the two standards and the specifics required for laboratory equipment to become compliant.

Differentiating the two standards

Similar in application, the IEC 61010-2-011:2016 and 61010-2-011:2016 have distinct differentiations for refrigerated systems in laboratory equipment.

IEC 61010-2-011

This version of the standard falls under the scope of IEC 61010-1 that employ a refrigeration system, whether integral or external, provided the equipment is under direct control of the refrigeration system. When flammable refrigerants are used, this version only applies to equipment that employs 150g or less per stage of a refrigeration system. Equipment incorporating trans-critical refrigerant systems are excluded.

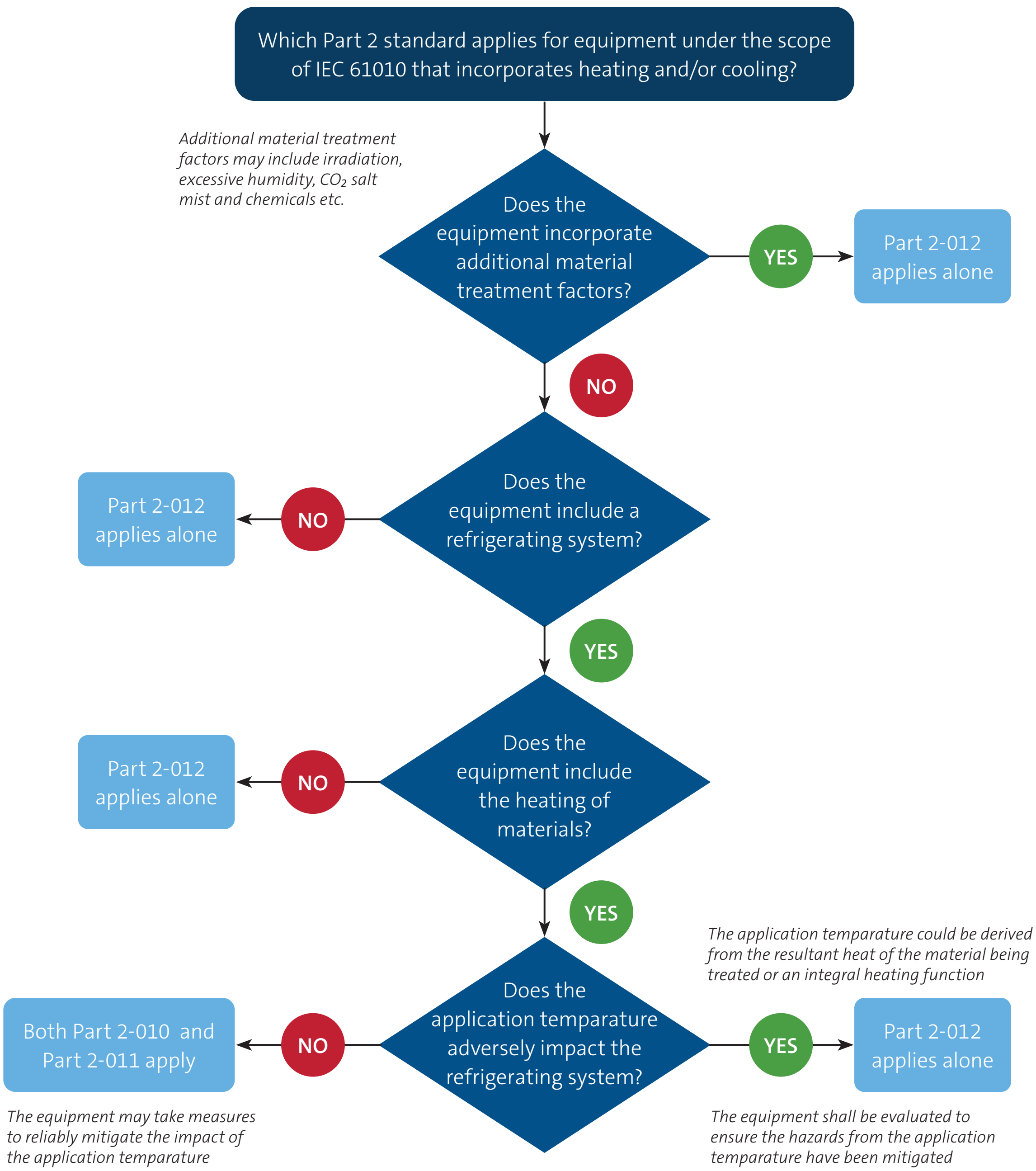
IEC 61010-2-012

The IEC 61010-2-012 standard pertains to climatic and environmental testing and other temperature conditioning equipment. This equipment specifically employs both a heating function and refrigeration system where the combination of the two introduces additional or more severe hazards than if treated separately.

**Note: If the system does not introduce additional or more severe hazards when treated separately, then IEC 61010-2-010 and IEC 61010-2-011 apply. Refer to Figure 01 of IEC 61010-2-011 or IEC 61010-2-012 for the flow chart.*

The standard also examines irradiation function for the materials being treated that present additional hazards. This also includes functions that expose the materials being treated to excessive humidity, carbon dioxide, salt mist, or other substances which may result in additional hazards. Mechanical movements that present additional hazards and a provision for walk-in units to the operating area to load or unload treated materials are included, as well.

Figure 01 – Flow chart illustrating the selection process



Guidance for the application of the correct Part 2 standard(s)

When the equipment includes only a material heating system, and no refrigerating system or other environmental factors apply, then Part 2-010 applies without needing Part 2-011 or Part 2-012. Similarly, when the equipment includes only a refrigerating system, and no material heating system or other environmental factors apply, then Part 2-011 applies without needing Part 2-010 or Part 2-012. However, when the equipment incorporates both a material heating system and a refrigerating system or the materials being treated in the intended application introduce significant heat into the refrigerating system, a determination should be made as to whether the interaction between the two systems will generate additional or more severe hazards than if the systems were evaluated separately (controlled temperature, see flow chart of figure 102 for selection process). If the interaction of the heating and cooling functions yields no additional or more severe hazards then both Part 2-010 and Part 2-011 apply for their respective functions. Conversely, if additional or more severe hazards result from the combining of the heating and cooling functions, or if the equipment incorporates additional material treatment factors, then Part 2-012 applies, but not Part 2-010 or Part 2-011.

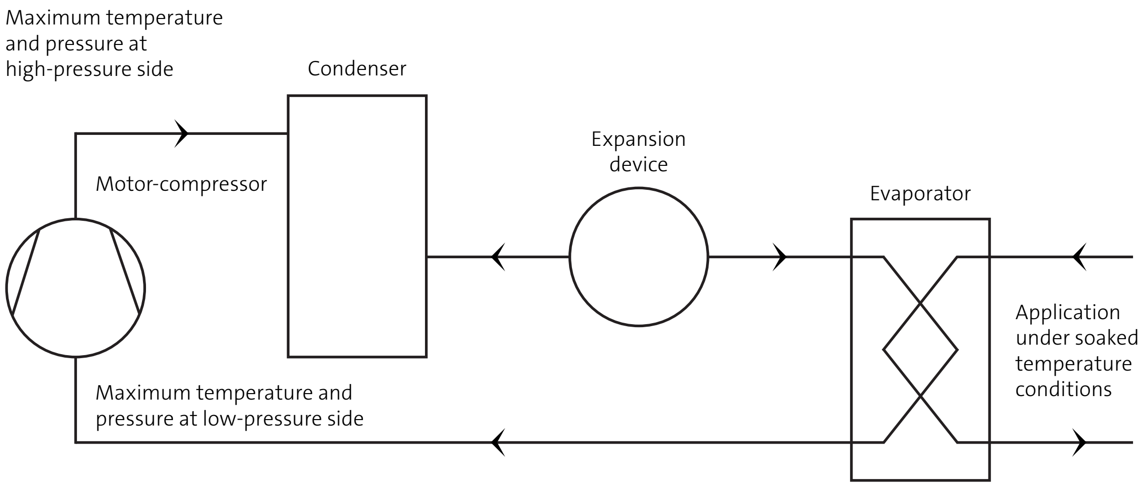
What hazards are applicable for a refrigerating system?

The typical hazards for a refrigerating system (see Figure 02) consisting of a motor compressor, a condenser, an expansion device and an evaporator include but are not limited to:

- The excess of temperature of the low-pressure side (return temperature) to the motor compressor is higher than admissible. A motor-compressor incorporates a refrigerant cooled motor and it should be established that the maximum temperatures of the low-pressure side under least favorable condition do not exceed the insulation ratings within the motor.
- The excess of pressure of the low-pressure side at the inlet to the motor-compressor is higher than admissible. The housing of the motor-compressor is exposed to this pressure and so the design rating of the motor-compressor housing should accommodate the worst-case pressures while providing the correct safety margin for a pressure vessel.
- The excess of temperature of the high-pressure side to the condenser is higher than admissible. The temperatures of the high-pressure side under the most unfavorable hazard if insulation is degraded.
- The excess of pressure of the high-pressure side to the condenser is higher than admissible. The refrigerant components downstream of the motor-compressor up to the expansion device are exposed to this pressure and so the design rating of these components should accommodate the worst-case pressures whilst providing the correct safety margin for a pressure vessel.
- The maximum controlled temperatures where the heat is being extracted from, may impact the maximum temperature of the low-pressure side to the motor-compressor as well as present a temperature hazard if the operator is exposed, or an electrical hazard if insulation is degraded. Whether this controlled temperature is derived from an integral heating function of the device or the heat dissipated from the material being cooled, the impact under worst-case conditions should be evaluated.

The current draw of the equipment should be established when including the worst-case running conditions of the refrigerating system including any defrost cycles that may apply.

Figure 02 – Typical refrigerated single-stage system



Unique terms, definitions and concepts

Refrigerating system – Combination of interconnected refrigerant-containing parts constituting one closed refrigerant circuit in which the refrigerant is circulated for the purpose of extracting and rejecting heat.
Redefined in 2nd Ed (2019). (IEC 61010-2-011, 3.102)

Flammable refrigerant – Refrigerant with a flammability classification of group 2 or 3 in accordance with ISO 5149-1 and ISO 817. (IEC 61010-2-011, 3.103)

Maximum allowable pressure PS – Maximum pressure for which the equipment is designed, as specified by the manufacturer.
Redefined in 2nd Ed (2019). (IEC 61010-2-011, 3.105)

Soaked temperature condition – Environmental temperature condition when all the temperatures in the equipment under test (EUT) equal to ±2 degrees Celsius of the test room ambient. (IEC 61010-2-011, 3.106) this is based on the maximum rated ambient for which the equipment is designed as referenced in the instructions for use (IFU).

Refrigerant – Fluid used for heat transfer in a refrigerating system, which absorbs heat at a low temperature and a low pressure of the fluid and rejects heat at a higher temperature and a higher pressure of the fluid, usually involving changes of state of the fluid.
New for 2nd Ed (2019).(IEC 61010-2-011, 3.108)

Controlled temperature – Temperature where the evaporator is located and to which the low-pressure side of the equipment is exposed, as a result of heat transfer either by active heating or from the application system or specimen.
New for 2nd Ed (2019). (IEC 61010-2-011, 3.109)

Lower explosive limit (LEL) – concentration of flammable gas or vapor in air, below which an explosive gas atmosphere will not be formed.
New for 2nd Ed (2019). (IEC 61010-2-011, 3.110)

Motor-compressor – Refrigerating subassembly consisting of the mechanical mechanism of the compressor and the motor, both of which are enclosed in the same sealed housing, with no external shaft seals, and with the motor operating in a refrigerant atmosphere with or without oil. New for 2nd Ed (2019). (IEC 6101-2-011, 3.111)condensing unit - specific refrigerating subassembly combination for a given refrigerant, consisting of one or more motor-compressors, condensers, liquid receivers (when required) and the regularly furnished accessories.
New for 2nd Ed (2019). (IEC 61010-2-011, 3.112)

Hydrofluorocarbon (HFC) refrigerants – Non-flammable refrigerants, are known greenhouse gases. Banned in certain parts of the world, e.g. Europe (R-134 – Tetrafluoroethane; R-22 - Freon).

Hydrocarbon (HC) refrigerants – Flammable refrigerants, are natural, non toxic, non-ozone depleting. (R-600 - Butane; R-290 - Propane)

Transcritical refrigerant system – A HFC-free refrigeration system that uses Co_2 or Ammonia (NH_3) as the refrigerant.

Cascade system – Refrigerating system consisting of two or more independent refrigeration circuits where the condenser of one system rejects heat directly to the evaporator of another (IEC 61010-2-012, 3.2.103)

Condenser – Heat-exchanger in which vaporized refrigerant is liquified by removal of heat (IEC 61010-2-012, 3.2.105)

Condensing unit – Specific refrigerating subassembly combination for a given refrigerant, consisting of one or more motor-compressors, condensers, liquid receivers (when required) and the regularly furnished accessories (IEC 61010-2-012, 3.2.106)

Evaporator – Heat-exchanger in which liquid refrigerant is vaporized by absorption of heat (IEC 61010-2-012, 3.2.107)

High-pressure side – Part of a refrigerating system operating at approximately the condenser pressure. Also known as discharge pressure. (IEC 61010-2-012, 3.2.108)

Low-pressure side – Part of a refrigerating system operating at approximately the evaporator pressure. Also known as suction pressure. (IEC 61010-2-012, 3.2.109)

Additional marking and documentation requirements[2]

The following markings need to be marked:

- The total mass of refrigerant for each refrigeration circuit (IEC 61010-2-011, Cl. 5.1.2; IEC 61010-2-012, Cl. 5.1.101)
- The chemical name(s), formula(s) or refrigerant(s) for each component refrigerant. Blends shall also include the proportions for each refrigerant components (IEC 61010-2-011, Cl. 5.1.2; IEC 61010-2-012, Cl. 5.1.101)
- The maximum allowable (PS) for each high and low stage. Also known as the Design Pressures. (IEC 61010-2-011, Cl. 5.1.2; IEC 61010-2-012, Cl. 5.1.101)

Table 01 – New referenced warning symbols:

Number	Symbol	Reference	Description
101		ISO 7010 - W010 (2011-06)	Warning: Low temparature/freezing conditions, frostible hazard
102		ISO 7010 - W021 (2011-06)	Warning: Flammable material/flammable liquid
103		ISO 7010 - W009 (2011-06)	Warning: Biological hazard
104		ISO 7010 - W027 (2011-06)	Warning:Optical radiation
105		ISO 7010 - W011 (2011-06)	Warning: Slippery surface
106		ISO 7010 - W024 (2011-06)	Warning: Crushing of hands

a. (IEC 61010-2-012, Table 01)

- Symbol 101 of Table 1 is used where easily touched cold surfaces exceeds the value of - 30 degrees Celsius (IEC 61010-2-011, Cl. 10.101; IEC 61010-2-012, Cl. 10.1)
- The symbol 102 of Table 1 shall be placed on the nameplate of the unit near the declaration of the refrigerant type and charge information when flammable refrigerants are used. (IEC 61010-2-011, Cl. 5.2)

b. The perpendicular height for warning symbols need to be at least 15 mm. The height of the text needs to be at least 1.8 mm. (IEC 61010-2-011, Cl. 5.2; IEC 61010-2-012, Annex DD.1.7 and Cl. 5.2)

Maximum pressure in a refrigerating system (2-11, 11.7.101-11.7.103; 2-12, 11.7.1-11.7.2.101)

The rated maximum working pressure of a component is determined either by its rating (if an approved/certified component) or by design if it passes the test of 11.7.102 (Pressure and Fatigue testing). The maximum allowable pressure (PS) is determined by test or by applying the saturated vapor pressure at the minimum specified temperatures of Table 02:

Table 02 – Minimum temparature for determination of saturated vapor pressure of refrigerant

Ambient conditions	≤ 43 °C	≤ 55 °C
High pressure side with air cooled condenser	63 °C	67 °C
High pressure side with water cooled condenser or water heat pump	Maximum leaving water temparature + 8 K	
High pressure side with evaporative condenser	43 °C	55 °C
Low pressure side with heat exchanger exposed to the outdoor ambient temparature	43 °C	55 °C
Low pressure side with heat exchanger exposed to the indoor ambient temparature	38 °C	38 °C
Note 1: For the high pressure side, the specified temparatures are considered the maximum which will occur during operation. These temparatures are higher than the temparatures that would occur if the compressor had been running and then turned off. For the low pressure side, it is sufficient to base the calculation of pressure on the expected temparature of the compressor after it has been running and then turned off. These temparatures are minimum temparatures and thus determine that the system will not be designed for maximum allowable pressure lower than the saturated refrigerant pressure corresponding to these minimum temparatures.		
Note 2: The use of specific temparatures does not always result in saturated refrigerant pressure within the system, for example a limited charge system or a system working at or above critical temparature, CO_2 in particular.		
Note 3: For zeotropic blends the maximum allowable pressure (PS) is the pressure at the bubble point.		

Determining PS by applying the saturated vapor pressure is the worst-case scenario. Most applications involve a limited-charge system, in which case saturated vapor pressures would never been seen in a practical application. In most cases, PS will be determined by test and considered the highest of the following:

- **The maximum pressure developed during the temperature runs as defined by 10.4.1**

  This test is performed at the maximum rated temperature ambient (typically 40 degrees Celsius by default) per manufacturer's specification as noted in instructions for use. When measuring pressures, the tests are to be started from a soaked temperature condition when all pressures have fully equalized in the maximum rated ambient. These are often referred to as the "soaked pressures". For systems that incorporate both air-cooled condensers and water-cooled condensers, the testing of the air-cooled condensers is typically considered worse-case due to the lack of influence the elevated ambient has on a water-cooled system with respect to its ability to effectively remove heat. Once the soaked pressures have been determined for a given system, the EUTs are run at ±10% of the maximum rated voltage unless the manufacturer specifies a wider voltage rated tolerance.

  At the termination of the test, the monitoring needs to continue after the unit is switched off until the pressures from each refrigerant stage have equalized or clearly demonstrate that maximum values have been reached. These are often referred to as post-test equalization pressures.

- **The maximum pressure developed during the condenser fan stall test (4.4.2.10d) for an air-cooled refrigeration system and the condenser water failure test (4.4.2.10e) for a water-cooled refrigeration system.**

  These tests are run in the worst-case voltage as determined by the Normal Temperature and Pressure runs, as stated above, and are run in a 25 degrees Celsius ambient for pressures. The temperatures are still normalized to 40 degrees Celsius or the maximum rated ambient temperature, whichever is higher.

For air-cooled refrigeration systems, testing includes a stalled condenser fan test and a blocked condenser fins test. For water-cooled systems, this would involve a condenser water failure test. This is done completely blocked off and restricted-flow until maximum temperatures are attained. The latter portion is best done incrementally starting completely open and then gradually restricting the water flow while allowing temperatures/pressures to stabilized until such time the HPCO functions or test terminates by some other means.

For all refrigeration systems in cases where the maximum rated ambient is less than 40 °degrees Celsius, an extreme operating ambient abnormal test is run. As for systems employing a temperature control system, the equipment under test (EUT) is subjected to an uncontrolled cooling test where the control is bypassed. In many cases EUTs may be run in a bottom–out temperature (BOT) mode during normal temperature/pressure runs. In these cases, this test is not necessary.

- **The maximum pressure developed during the test of 4.4.2.101 if applicable**

  This testing is required where the rated ambient is less than 40 degrees Celsius. Protective devices can operate during this test.

- **The maximum pressure developed during the test of 11.7.104.8**

  Known as the Transport Temperature Test, it is intended to simulate pressures a refrigeration system is subject to during transport. These values can be derived by several different ways. The simplest means is to use saturated refrigerant pressures at 55 degrees Celsius for normal transport or 70 degrees Celsius for transport under tropical conditions. Systems involving flammable refrigerants are always to be at 70 degrees Celsius.

Transport temperature test method 1:

- Calculate the total volume of the refrigerating system in question;
- Calculate the charge to volume ratio for the design charge
- Take a charging cylinder of known volume and charge it to give the same volume to mass ratio as the system to be simulated place the cylinder with a pressure gauge or transducer in a controlled ambient defined by the storage and/or transport ambient temperature and allow the cylinder to soak
- Record the maximum pressure and use this value as the test pressure for the refrigerating system

Transport temperature test method 2:

- Measure the pressure of the refrigerating system under soaked temperature condition
- Use an evacuated cylinder and heat it up to soaked temperature condition
- Charge the cylinder with the same refrigerant used in the refrigerating system under soaked temperature condition until it has the same pressure as the refrigerating system in soaked temperature condition
- Place the cylinder with a pressure gauge or transducer in a controlled ambient defined by the storage and/or transport ambient temperature and allow the cylinder to soak
- Record the maximum pressure and use this value as the test pressure for the refrigerating system

Transport temperature test method 3:

Methods 1 or 2 are to be used when using blended refrigerants. However, most refrigerants are considered ideal gases.
As such you can also use the ideal gas law when the refrigerant is an ideal gas. This will not work on blended refrigerants.
To find the pressure from the ideal gas law as:

$$P = (nRT) / V$$

- Where P, V and T are the pressure, volume and absolute temperature, n is the number of moles of gas and R is the ideal gas constant
- This is often the most convenient way to determine the transport pressure. The chemical amount (n) (in moles) is equal to the total mass of the gas (m) (in grams) divided by the molar mass (M) (in grams per mole)

- **Leakage and rupture at high pressure (2-11, 11.7.102)**

  For components subject to the high-side or low-side pressure of the refrigerating system, the structural strength of the fluid containing parts shall comply with 3 × PS, as defined by 11.7.101 for the high-side or low-side of the refrigerating system.

  For evidence of conformity with national regulations in the USA, Canada and some other countries, the structural strength of components is identical but the design rating of the component is different based on the safety margin required in the national regulations. For example, in the USA the design rating for a component complying with ASME boiler code is one-fifth of the structural strength of the component.

  The minimum structural strength rating of refrigerant containing components in the USA and Canada is five multiples the maximum pressure measured during normal pressure tests and three multiples maximum pressure measured during abnormal pressure tests. The selection of certified components from North America based on testing conducted in this standard shall take into consideration these certification differences.

  Conformity is checked by inspection of the ratings of the components exposed to this pressure and, if a hazard could arise, by the following pressure test in Item c) below. Components that are certified to the component requirements of 14.101 and are used within their RATINGS (component pressure rating ≥ PS) are deemed to comply with this requirement without test. Keep in mind that for piping/tubing, you will need to refer to Table 03 for the minimum wall thickness for copper and steel tubing using standard soldering and brazing. The tubing subject to pressure on either the suction or discharge pressure sides needs to comply with these thicknesses in order to waive testing.

Table 03 – Minimum wall thickness for copper and steel tubing

Outside diameter		Copper				Steel	
		Protected within refrigerator		Unprotected			
inches	(mm)	inches	(mm)	inches	(mm)	inches	(mm)
1/4	(6.35)	0.0245	(0.623)	0.0265	(0.673)	0.025	(0.635)
5/16	(7.94)	0.0245	(0.623)	0.0265	(0.673)	0.025	(0.635)
3/8	(9.53)	0.0245	(0.623)	0.0265	(0.673)	0.025	(0.635)
1/2	(12.70)	0.0245	(0.623)	0.0285	(0.724)	0.025	(0.635)
5/8	(15.88)	0.0315	(0.799)	0.0315	(0,799)	0.032	(0.813)
3/4	(19.05)	0.0315	(0.799)	0.0385	(0.978)	0.032	(0.813)
7/8	(22.23)	0.0410	(1.041)	0.0410	(1.041)	0.046	(1.168)
1	(25.40)	0.0460	(1.168)	0.0460	(1.168)	–	–
1-1/8	(28.58)	0.0460	(1.168)	0.0460	(1.168)	0.046	(1.168)
1-1/4	(31.75)	0.0505	(1.283)	0.0505	(1.283)	0.046	(1.168)
1-3/8	(34.93)	0.0505	(1.283)	0.0505	(1.283)	–	–
1-1/2	(38.10)	0.0555	(1.410)	0.0555	(1.410)	0.062	(1.575)
1-5/8	(41.28)	0.0555	(1.410)	0.0555	(1.410)	–	–
2-1/8	(53.98)	0.0640	(1.626)	0.0640	(1.626)	–	–
2-5/8	(66.68)	0.0740	(1.880)	0.0740	(1.880)	–	–
Nominal wall thickness of tubing will have to be greater than the thickness indicated to maintain the minimum wall thickness.							

- **Pressure Test (2-11, 11.7.102.2)**

  The pressure of the component or assembly (equipment under test, EUT) is raised, by air or non-hazardous gas or via a hydrostatic pressure test, gradually to the specified test value and is held at that value for 1 min. Examples include:

  - If the continuous operating temperature for the EUT is less than or equal to 125 degrees Celsius for copper or aluminum, or 200 degrees Celsius for steel, the test temperature of the EUT during this test is at least 20 degrees Celsius
  - If the continuous operating temperature for the EUT exceeds 125 degrees Celsius for copper or aluminum, or 200 degrees Celsius for steel, the test temperature of the EUT during this test are at least 150 degrees Celsius for copper or aluminum and 260 degrees Celsius for steel
  - For other materials or higher temperatures, the effects of temperature on the material fatigue characteristics are evaluated

  The EUT is considered to have complied with the requirements of this test if it withstands the pressure test without rupture. If the EUT does not comply, then an alternate method to demonstrate compliance is to subject the EUT to the fatigue test.

- **Fatigue Test (2-11, 11.7.102.3)**

  If the continuous operating temperature of the EUT exceeds 125 degrees Celsius for copper or aluminum, or 200 degrees Celsius for steel, the fatigue test temperature of the parts or assemblies that are at these temperatures, are at least 10 K above the continuous operating temperature.

  The static test pressure needs to be increased by the ratio of allowable stress of material at room temperature to that at the highest continuous operating temperature. For other materials, the effects of temperature on the fatigue characteristics will be evaluated to determine the test conditions.

  Three of the test samples will be filled with fluid and connected to a pressure-driving source. The pressure will be raised and lowered between the upper and lower cyclic values at a rate specified by the manufacturer for a total number of 250k cycles. The entire specified pressure excursion should occur during each cycle.

  The following test pressures shall be applied:

  - For components at the low-pressure side, maximum PS for the low-pressure side shall be applied the for the first cycle.
  - For components at the high-pressure side, maximum PS for the high-pressure side shall be applied for the first cycle
  -

  The pressure for the test cycles shall be as follows:

  - Upper pressure value shall not be less than 0.7 x PS and the lower pressure value shall not be greater than 0.2 × PS
  - For the final test cycle, the test pressure shall be increased to 1.4 × PS (2 x 0.7 × PS)
  - The component shall not rupture, burst or leak during this test
  - A strength pressure test at 2 × PS is to be performed on three samples, other than the samples used for the fatigue test. The component shall not rupture, burst or leak during this test.

Additional pressure requirements for flammable refrigerants (2-11, 11.7.104)

This standard addresses the requirements for refrigerating equipment which uses flammable refrigerant when the amount of refrigerant is limited to a maximum of 150g in each separate refrigerant circuit. For equipment that uses a refrigerant charge or flammable refrigerant that exceeds this amount, additional requirements shall apply.

The ISO 5149 or EN 378-1, EN 378-2, 378-3, and 378-4 are standards that address requirements for refrigerating systems that utilize greater than 150g of flammable refrigerant and can be used to identify what the additional requirements may be. Equipment containing flammable refrigerants that comply with this standard may not meet the requirements for the US – See informative Annex DD for additional warning markings required for the US.

There are two different types of systems employing flammable refrigerants addressed, one is a protected cooling system and the other an unprotected cooling system.

Refrigerating equipment with a protected cooling system are those:

- Without any part of the cooling system inside an operator access compartment
- Where any part of the cooling system which is located inside an operator access compartment is constructed so that the refrigerant is contained within an enclosure with at least two layers of metallic materials separating the refrigerant from the operator access compartment, each layer having a thickness of at least 0.1 mm. The enclosure has no joints other than the bonded seams of the evaporator where the bonded seam has a width of at least 6 mm
- Where any part of the cooling system which is located inside an operator access compartment has the refrigerant contained in an enclosure which itself is contained within a separate protective enclosure. If leakage from the containing enclosure occurs, the leaked refrigerant is contained within the protective enclosure and the refrigerating equipment will not function as in normal use. The protective enclosure shall also withstand the test of 11.7.102. No critical point in the protective enclosure shall be located within the operator access compartment.

Some additional considerations would include the following:

- Separate compartments with a common air circuit are considered to be a single compartment.
- Refrigerating equipment with a protected cooling system and which use flammable refrigerant shall be so constructed as to avoid any fire or explosion hazard in the event of leakage of the refrigerant from the cooling system.
- Separate components such as thermostats that contain less than 0.5 g of flammable refrigerant are not considered to cause a fire or explosion hazard in the event of a leakage from the component itself.
- For refrigerating equipment with a protected cooling system, no additional requirements apply to electrical components located inside operator access compartments.
- A piece of equipment with a protected cooling system which, when tested, is found not to comply with the requirements specified for a protected cooling system, may be considered as having an unprotected cooling system if it is tested in accordance with 11.7.104.5 and found to comply with the requirement for an unprotected cooling system.

Validation of a protected cooling system is determined by the Leakage Test for flammable refrigerant (2-11, 11.7.104.3) and the Scratch Test for protected cooling systems (2-11, 11.7.104.4).

Leakage test for flammable refrigerant - Critical points are only considered to be the interconnecting joints between parts of the refrigerant circuit, including the gasket of a semi-hermetic motor-compressor. Welded telescopic joints of the motor-compressor, the welding of the pipes through the compressor housing and the welding of the hermetic glass-to-metal seals (fusite) are not considered critical points.

Scratch test for protected cooling systems - All accessible surfaces of protected cooling systems, including accessible surfaces in intimate contact with protected cooling systems, are subject to this test. Once the scratches are made to the appropriate parts of the refrigerating equipment they will then need to withstand the pressure test of 11.7.102 with the test pressure reduced by 50%.

Refrigerating equipment with an unprotected cooling system are those:

- where at least one part of the cooling system is placed inside an operator accessible compartment or those which do not comply with 11.7.104.2.

For a refrigerating equipment with an unprotected cooling system and which uses flammable refrigerant, any electrical component located inside the operator accessible compartment, which during normal condition or single fault condition produces arcs or sparks, and luminaries, shall be tested and found at least to comply with the requirements of Annex AA for group IIA gases or the refrigerant used.

This requirement does not apply to:

- non-self-resetting protective devices necessary for compliance with 4.4
- intentionally weak parts that become permanently open-circuited during the tests of 4.4, even if they produce arcs or sparks during operation

Refrigerant leakage into operator accessible compartments shall not result in an explosive atmosphere outside the operator accessible compartments in areas where electrical components that produce arcs and sparks during normal operation or abnormal operation, or luminaries, are mounted, when doors or lids remain closed or when opening or closing doors or lids unless these components have been tested and found at least to comply with Annex AA for group IIA gases or the refrigerant used.

Separate components such as thermostats that contain less than 0.5 g of flammable gas are not considered to cause a fire or explosion hazard in the event of a leakage from the component itself. Other types of protection for electrical apparatus for potentially explosive atmospheres covered by the IEC 60079 series are also acceptable. For guidance on this topic, UL 471: Standard for Commercial Refrigerators and Freezers, 10th Ed[3]. SB5.2.2 provides the following guidance:

SB5.2.2 The protection shall comply with one of the following protection techniques and associated standards references:

a. **Enclosed break device**
    - IEC 60079-15:2010, Clause17; or
    - UL 60079-15:2013, Clause 17

b. **Non-incendive component**
    - IEC 60079-15:2010, Clause17; or
    - UL 60079-15:2013, Clause 17; or
    - ISA 12.12.01:2013, Clause 12

c. **Hermetically sealed device**
    - IEC 60079-15:2010, Clause18; or
    - UL 60079-15:2013, Clause 18; or
    - ISA 12.12.01:2013, Clause 3

d. **Sealed device**
    - IEC 60079-15:2010, Clause19; or
    - UL 60079-15:2013, Clause 19; or
    - ISA 12.12.01:2013, Clause 13

e. **Non-icendive circuit (spark ignition compliance)**
    - IEC 60079-11:2011, Clause 5.5 (for "ic" applications); or
    - UL 60079-11:2013, Clause 5.5 (for "ic" applications); or
    - ISA 12.12.01:2013, Clause 7

Changing of a lamp is not considered a potential explosion hazard, because the door or lid is open during this operation.

Stagnation of leaked flammable refrigerant

Refrigerating equipment which uses flammable refrigerant needs to be constructed so that leaked refrigerant will not stagnate and thus cause a fire or explosion hazard in areas outside the operator accessible compartment where components producing arcs or sparks or luminaires are mounted.

This requirement does not apply to areas where:

- Non-self-resetting protective devices necessary for compliance with 4.4
- Intentionally weak parts that become permanently open-circuited during the test of 4.4 are mounted, even if they produce arcs and sparks during operation

Separate components such as thermostats that contain less than 0,5 g of flammable gas are not considered to cause a fire or explosion hazard in the event of a leakage of the component itself. Compliance is checked by the following test unless luminaires and components that produce arcs and sparks during normal operation and which are mounted in the areas under consideration have been tested and found at least to comply with the requirements in Annex AA for group II A gases or the refrigerant used. Irrespective of the requirements given in IEC 60079-15:2010, 5.1, surface temperature limits are specified in 11.7.104.7. Other types of protection for electrical apparatus for potentially explosive atmospheres covered by the IEC 60079 series are also acceptable. (See reference to UL 471 SB5.2.2 above for guidance).

Surface temperature limits

Temperatures on surfaces that may be exposed to leakage of flammable refrigerant shall not exceed the ignition temperature of the refrigerant as specified in Table 04, reduced by 100 K.

Compliance is checked by measuring the appropriate surface temperatures during the tests specified in Clause 10 and 4.4. The temperatures of non-self-resetting protective devices that operate during the tests specified in 4.4 or intentionally weak parts that become permanently open-circuited during the tests specified in 4.4 are not measured during those tests specified in 4.4 that cause these devices to operate.

Table 04 – Refrigerant flammability parameters

Refrigerant number	Refrigerant name	Refrigerant formula	Refrigerant AUTO IGNITION temperature [a c]	Refrigerant lower explosive limit [b c d e]
			°C	% V/V
R50	Methane	CH_4	645	4,9
R170	Ethane	CH_3CH_3	515	3,1
R290	Propane	$CH_3CH_2CH_3$	470	1,7
R600	n-Butane	C_3H_8	365	1,5
R600a	Isobutane	C_4H_{10}	460	1,8
R1150	Ethene	$CH(CH_3)_3$	425	3,1
R1270	Propylene	C_2H_4	455	2,3

[a] Values for other flammable refrigerants can be obtained from IEC 60079-20 and IEC 60079-20-1.

[b] Values for other flammable refrigerants can be obtained from IEC 60079-20 and ISO 5149.

[c] IEC 60079-20 is the reference standard. ISO 5149 may be used if the required data is not contained in IEC 60079-20.

[d] Concentration of refrigerant in dry air.

[e] In some standards, the term "flammability limit" is used for "explosive limit".

Additional information and marking requirements for flammable refrigerants (2-11, Annex DD)

These requirements are informative, however, for the US/CAN these requirements are essentially normative to align with UL 471, Annex SB.

Table DD.1 – Quantity of Group A2/A3 refrigerant per occupied space

Refrigerant number	Chemical name	Formula	Quantity of refrigerant per occupied space[a]		
			lb./1000 ft³	ppm by vol	g/m³
R-142b	1-Chloro-1,1-difluoroethane	CH_3CClF_2	3,7	14000	60
R-152a	1,1-Difluoroethane	CH_3CHF_2	1,2	7000	20
R-170	Ethane	CH_3CH_3	0,50	6400	8,0
R-290	Propane	C_3H_8	0,50	4400	8,0
R-600	Butane	C_4H_{10}	0,51	3400	8,2
R-600A	2-Methly propane (Isobutane)	$CH(CH_3)_3$	0,51	3400	8,2
R-1150	Ethene (Ethylene)	C_2H_4	0,38	5200	6,0
R-1270	Propene (Propylene)	C_3H_6	0,37	3400	5,9
Note: Listed equipment for use in laboratories with more than 100 ft² (9,3m²) of space per person are exempt from this limit provided the eqipment is installed in accordance with the listing and with the manufacturer's installation instruction.					
[a] Values for refrigerants are from ANSI/ASHRAE 15-2013, Table 01					

- (DD.1.2) When a flammable refrigerant is used, the markings as outlined in DD.1.3 to DD.1.6, or the equivalent are in letters no less than 6.4mm (1/4 inch) high and permanently marked on the refrigerating equipment in the indicated locations

- (DD.1.3) operator markings are to be provided on or near any evaporators that can be contacted by the user:
  - Danger - Risk of fire or explosion
  - Flammable refrigerant used
  - Do not use mechanical devices to defrost refrigerating equipment
  - Do not puncture refrigerant tubing

- (DD.1.4) Service markings - For self-contained refrigerating equipment, the following markings shall be located near the machine compartment. For a remote condensing unit, the following markings shall be located by the inter-connecting refrigerant tubing connections and by the nameplate:
  - Danger - Risk of fire or explosion. Flammable refrigerant used. To be repaired only by trained service personnel. Do not puncture refrigerant tubing.
  - Caution - Risk of fire or explosion. Flammable refrigerant used. Consult repair manual / owner’s guide before attempting to install or service this equipment. All safety precautions must be followed.

- DD.1.5) Disposal
  - Caution - Risk of fire or explosion. Dispose of properly in accordance with federal or local regulations. Flammable refrigerant used. This marking shall be provided on the exterior of the refrigerating equipment.

- (DD.1.6) Exposed tubing
  - Caution - Risk of fire or explosion due to puncture of refrigerant tubing. Follow handling instructions carefully. Flammable refrigerant used. This marking shall be provided near all exposed refrigerant tubing.

- (DD.1.7) Accessing the refrigerant circuit
  - Refrigeration tubing or other devices through which the refrigerant is intended to be serviced shall be painted, colored, or labeled red, Pantone® Matching System (PMS) No. 185. This color shall be present at all places where service puncturing or otherwise creating an opening in the refrigerant circuit might be expected.
  - In the case of a process tube on a MOTOR-COMPRESSOR, the color mark shall extend at least 2.5 cm (1 inch) from the motor-compressor

- (DD.1.8) Symbol for warning of flammable materials
  - The marking in item DD.1.4 a) shall also contain symbol 102 of Table 1 for warning of flammable materials.
  - The color and format of the symbol shall be the same as shown. The perpendicular height of the triangle shall be at least 15 mm (9/16 in).

- (DD.1.9) Equipment containing a remote condensing unit - For equipment containing a remote condensing unit, the following marking shall be located near the tubing intended for the connection of the field supplied refrigerant tubing:
  - Caution - This equipment is intended for use with flammable refrigerant. Install in accordance with the flammable refrigerant requirements specified in the ANSI/ASHRAE 15

- (DD.1.10) Refrigerating equipment intended for laboratory use - Refrigerating equipment intended for laboratory use that contains an A3 refrigerant shall be marked:
  - This unit is intended for use in commercial, industrial, or institutional occupancies as defined in the Safety Standard for Refrigeration Systems, ANSI/ASHRAE 15

- (DD.2.1) Handling and moving
  - Installation and operating instructions shall be provided with cautionary statements concerning the handling, moving, and use of the refrigerating equipment to avoid either damaging the refrigerant tubing or increasing the risk of a leak

- (DD.2.2) Packaging markings - The shipping carton of refrigerating equipment that employs a flammable refrigerant shall be marked:
  - Caution - Risk of fire or explosion due to flammable refrigerant used. Follow handling instructions carefully in compliance with U.S. government regulations
  - The warning marking of symbol 102 of Table 01 shall also appear on the shipping carton

- (DD.2.3) Replacement components and servicing
  - The installation and operating instructions shall indicate that component parts shall be replaced with like components and that servicing shall be done by the manufacturer's authorized personnel, so as to minimize the risk of possible ignition due to incorrect parts or improper service

- (DD.2.4) Installation instructions for equipment containing a remote condensing unit
  - In addition to the above, the installation instructions for equipment containing a remote condensing unit shall contain the following:
    a. Information for spaces where pipes containing flammable refrigerant are allowed, including statements that (1) the pipework shall be protected from physical damage and, (2) compliance with the installation requirements of ANSI/ASHRAE 15 shall be observed
    b. The minimum necessary room volume per refrigerating system charge allowed. Refer Table DD.1. This may be in the form of a table indicating minimum room volume per refrigerant charge amount, but shall not reference a formula
    c. Information for handling, installation, cleaning, servicing and disposal of refrigerant
    d. A warning that the equipment shall not be installed in a room with continuously operating open flame or ignition sources

Summary and Conclusion

Laboratory refrigerators are used to cool samples or specimens for preservation. They include refrigeration units for storing blood plasma and other blood products, as well as vaccines and other medical or pharmaceutical supplies. Laboratory refrigerators that comply with regulations from agencies such as the U.S. Food and Drug Administration (FDA) are designed to provide specific levels of temperature control and a uniform temperature throughout the chamber. These instruments allow the storage of reagents and samples over an extended period of time. Refrigerators are widely used for the storage of enzymes, buffers, dyes etc., and prevent them from temperature-associated degradation. Freezers maintain temperatures below 0 degrees Celsius and are used for the storage of cell cultures and in blood banks to store samples in a frozen from over a span of several days. These refrigerators and freezers are equipped with a robust temperature monitor and control system that allows maintenance of a constant desired temperature.

Refrigeration plays a vital role in the laboratory environment. To help ensure safety from materials through operation, the IEC 61010 examines complete refrigeration environments that could present performance or hazard related issues. Understanding the IEC 61010 family of standards and how they apply to equipment and systems will prove valuable to compliance preparation.

For more information about UL's testing and certification services and the challenges of IEC 61010-2-011 / 2-012, email medical.inquiry@ul.com or visit UL.com/healthcare.

End Notes

1. "Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-011: Particular requirements for refrigerating equipment." https://webstore.IEC.ch/publication/62079
2. “ISO 7010:2011 prescribes safety signs for the purposes of accident prevention, fire protection, health hazard information and emergency evacuation." https://www.ISO.org/standard/54432.html
3. " UL 471: Standard for Commercial Refrigerators and Freezers" https://standardscatalog.UL.com/standards/en/standard_471_10