NuAire Laboratory Equipment Electrical Safety
UL 61010-1:2012 listing and the application of NFPA 99:2015

Summary
NuAire manufactures and provides products that are used in Health Care Facilities (HCF's). Typical applications are BioSafety Cabinets (BSC's) in pharmacies and diagnostic/pathology rooms. To assure customers that NuAire products are safe, they are evaluated and listed by Underwriters Laboratory (UL) for electrical and mechanical safety. However, some HCF personnel are misinterpreting the NFPA 99:2015 code for testing requirements of non-patient care equipment. Specifically, they are conducting an electrical leakage test and applying the patient care room requirements to a non-patient care application. This technical bulletin is intended review both UL and NFPA requirements and clarify the requirements for non-patient care equipment.

Background
NuAire Products being primarily used in life science laboratories meet and are listed to the electrical and mechanical safety requirements of the UL 61010-1 (Electrical Equipment for Measurement, Control and Laboratory Use). This standard based on the internationally harmonized IEC 61010-1. Countries can then adopt the harmonized standard and apply it as their national standard, for the US, this is through Underwriters Laboratories (UL).

The UL 61010-1 has three basic electrical tests that must be performed. These are ground bond, die-electric withstand and electrical leakage. The requirements for these tests are based on normal laboratory use. Other industries like the patient care medical equipment industry, tests to a standard using the same tests, but has stricter requirements typically based on the type and amount of potential contact with people. The NFPA 99:2015 for HCF's uses the tighter requirements because of increased patient contact. The key then is the interpretation of what equipment in a HCF is required to be reviewed and tested to the NFPA 99:2015 code. The NFPA 99:2015 also provides a handbook that has additional clarification comments from the authors of the standard.

The NFPA 99:2015 is a code that covers Health Care facilities states its purpose and application as follows:

1.2 Purpose.
The purpose of this code is to provide minimum requirements for the installation, inspection, testing, maintenance, performance and safe practices for facilities, material, equipment, and appliances, including other hazards associated with primary hazards.

1.3 Application.
This code shall apply to all health care facilities other than home care and veterinary care.

1.3.1.1 This document is intended for use by those persons involved in the design, construction, inspection and operation of HCF and in the design, manufacture, and testing of appliances and equipment used in *patient care rooms* of health care facilities.

In review of the above statements, if products are located in patient care rooms, they are subject to the code. If it is not in a patient care room, they are not subject to the code. NuAire products are not used in patient care rooms and thus not subject to the code.

Further in the code, it also does reference the term Laboratories and states the following:

3.3.85 Laboratory.
A building, space, room or group of rooms intended to serve activities involving procedures for investigation, diagnosis, or treatment in which flammable, combustible, or oxidizing materials are to be present.

A.3.3.85 Laboratory.
These laboratories are not intended to include isolated frozen section laboratories; areas in which oxygen is administered; blood donor rooms in which flammable, combustible, or otherwise hazardous materials normally used in laboratory procedures are not present; and clinical service not using hazardous materials.

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The handbook states that "Diagnostic and/or therapeutic areas of health care facilities are often referenced to as laboratories. For purposes of this document, however, only those areas with the hazards indicated in the definition are considered laboratories. The safety reference for these laboratories is the NFPA 45, Standard for Fire Protection for Laboratories Using Chemicals." So in this case, application is directly referenced to fire protection. NuAire products used in health care facilities are restricted from using flammable materials by our UL listing and labeled as such directly on the product, and thus not subject to the code.

Further in the code, chapter 10, Electrical Equipment.

10.1 Applicability.

An appliance that yields erroneous data or functions poorly is potentially harmful. Quality assurance of full appliance performance is not covered, except as it relates to direct electrical or fire injury to patients or personnel.

The handbook states" Section 10.1 clearly delineates the scope of chapter 10 as being related to the prevention of direct electrical or fire injury *to patients* through the proper performance, maintenance, and testing of electrical equipment in health care facilities."

Further in section 10, the term laboratory is used. However, as stated in the definition section 3.3.85 and discussed above, the use of the term laboratory is for locations which flammable, combustible, or oxidizing materials are to be present. Again, NuAire products used in health care facilities are restricted from using flammable materials by our UL listing and labeled as such directly on the product, and thus not subject to the code.

Conclusion

The application of the NFPA 99:2015 clearly states in the first chapter "testing of appliances and equipment used in patient care rooms of health care facilities". It is followed by the term Laboratory in which flammable, combustible, or oxidizing materials are to be present. And lastly, the chapter 10 handbook references the scope as "prevention of direct electrical or fire injury to patients".

In review of NuAire products used within HCF's, our equipment is not used in patient care rooms, is not used with flammable, combustible, or oxidizing materials present and has no contact with patients. NuAire products are used in pharmacies, diagnostic/pathology rooms and are not within the intended scope of the NFPA 99:2015 code.

Additional Electrical Leakage Information from the NFPA 99:2015 Handbook

The term touch current is defined (in 3.3.163) as the electrical "leakage current flowing from the enclosure or from parts thereof, excluding patient connections, accessible to any operator or patient in normal use, through an external path other than the protective grounding (earth) conductor to earth or to another part of the enclosure." This definition specifically excludes normal patient connections for the appliance.

The term touch current is used in lieu of the term chassis leakage current (used in NFPA 99 prior to the 2012 edition) or other terms to provide consistency with international standards such as ANSI/AAMI ES60601-1. Theoretically, insulation covering the power conductors should be perfect; there should be no leakage (or touch) current and all current used to power electrical appliances should flow through the power conductors. Realistically, however, insulation is not perfect and some of the current flowing through the power conductors "leaks" through the insulation because of capacitance across the insulation and between conductors. Similarly, stray capacitance within the appliance itself allows some additional unwanted current to flow from conductors internal to the device to the appliance chassis or enclosure.

NFPA 99 requires that patient care–related electrical appliances (with the exception of double insulated appliances) have a dedicated grounding conductor to bring all of this unwanted current on the chassis or enclosure back to ground (called "protective earth" in international standards) without harm to anyone. If the grounding conductor is "broken" in some manner, this unwanted current is available on the appliance chassis or enclosure, and it will flow to ground through any other available circuit. Any person, including a patient, touching the appliance chassis or enclosure when the grounding conductor is broken will complete that circuit, and the touch current will flow through their body. When the grounding conductor is intact, it is parallel with the person, so almost all of the touch current flows through the grounding conductor.

Subsection 10.2.6 specifies a touch current limit of "500µA with normal polarity and the ground wire disconnected (if a ground wire is provided)." The 500µa limit was lower in NFPA 99 editions prior to 2012. The primary rationale for raising the limit to 500µA beginning with the 2012 edition was to harmonize with international standards, which had specified a touch current limit of 500µA for decades without any report of an electrical injury rate higher than that in the United States, even though the United States had a lower limit.

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International standards (such as ANSI/AAMI ES60601-1) require manufacturers to design their equipment to comply with a 500-µA touch current limit, with both normal and reversed polarity. Although the touch current will commonly be higher when the power conductor polarity is reversed, NFPA 99 only specifies the limit with normal polarity because the effort and risk to measure touch current with reversed polarity was felt to not be worth the patient safety benefit in user facilities. The 500-µA limit is specified with "the ground wire disconnected," because a disconnected or broken ground wire (conductor) is the most common single fault condition. When the ground wire is connected, which is presumably the most common state of the appliance; the touch current will nearly always be close to zero. Previous editions of NFPA 99 did include a specification for a touch current limit with the ground wire intact. For the 2012 edition, the committee decided to remove the intact ground wire touch current specification, since it afforded minimal benefit for the amount of effort required to conduct the test.

The above handbook references the 60601-1 standard (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance). Medical equipment or equipment that contacts people is as stated above required to have lower touch current in a single fault condition (ground removed). Limits are stated as 100µA (ground connected)/500µA (ground removed).

Electrical equipment, such as refrigerators, freezers, incubators, centrifuges and Biosafety cabinets meet the 61010-1 (Electrical Equipment for Measurement, Control and Laboratory Use) and is allowed to have a higher touch current in a single fault condition (ground removed). Limits are stated as 500µA (ground connected)/3500µA (ground removed).

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