Environmental Challenges of Clean Room and Containment Area Light Fixtures

Protecting people, product and processes from particulates, pathogens, EMI, fires and explosions
Clean rooms are controlled environments designed to eliminate particulates and contaminants that can potentially compromise R&D, products or processing of pharmaceutical compounds. Clean room environments are sealed and the air is filtered to maintain specific levels of particulate-free air. Clean rooms maintain positive pressure to assure that any leakage will be directed away from the clean room space.

Containment areas are controlled environments designed to protect people and the outside environment from pathogens and other substances that might be harmful to human beings (example: Ebola, Lassa) and/or the environment (example: genetically modified crops) that are present in these rooms – research areas, isolation rooms or vaccine manufacturing facilities. These areas are often referred to as biosafety labs (BSL). The higher level biosafety labs (BSL3 and BSL4) are sealed and maintain negative pressure to assure that any leakage of dangerous elements will be directed towards the containment area.

Both clean rooms and containment areas are sealed/controlled environments designed to protect people, product and processes. Clean room and containment areas have strict protocol for personnel entering/leaving the spaces, activities performed in the spaces and cleaning procedures. The guidelines for these protocols and procedures are found in ISO 14644 for cleanrooms (Federal Standard 209E is no longer in effect but still is referenced) and Biosafety in Microbiological and Biomedical Laboratories (BMBL) – 5th Edition for containment areas and biosafety labs. Federal Standard 209E, ISO14644 and BMBL were not intended to provide standards or testing procedures for lighting fixture leakage, cleanability, corrosion resistance or interface with the ceiling; therefore, lighting manufacturers have been forced to make inferences from these publications and consult other universally accepted standards for guidance in the design and manufacturing of lighting fixtures for these applications. Fortunately we now have National Sanitation Foundation’s Protocol P442 “Controlled Environment Light Fixtures” (2015) to provide standards and testing procedures for lighting fixture leakage, cleanability, corrosion resistance, toxicity and interface with the ceiling in clean room and containment area applications.

In addition to leakage, cleaning and corrosion resistance challenges, lighting fixtures installed in these controlled environments must operate safely in hazardous locations (explosive vapors and dust) and maintain safe levels of conducted and radiated electromagnetic interference (EMI). Both of these areas, hazardous locations and EMI, have universally accepted standards and testing procedures intended for lighting fixtures.

**CONTROLLED ENVIRONMENT AND LIGHTING FIXTURE INTEGRITY**

In order to utilize ISO14644 and BMBL for evaluation of clean room and containment area lighting fixtures it is helpful to consider the lighting fixture as a controlled enclosure that interfaces with a controlled environment. If the clean room or containment area is designed and built to resist leakage, facilitate cleaning, resist corrosion, provide hazardous location protection and be free of dangerous levels of EMI; the lighting fixture must provide the same protection. If not, the lighting fixture will compromise the integrity of the clean room/containment area.

**PERFORMANCE STANDARDS/TESTING PROCEDURES**

**For Leakage, Interface with Ceiling Structure, Cleanability and Corrosion Resistance**

National Sanitation Foundation’s Protocol P442 “Controlled Environment Light Fixtures” establishes minimum requirements for the design, construction and performance of light fixtures for use in controlled environments (pharmaceutical processing, bio-tech research, biosafety labs, surgical suites, clean room manufacturing, food processing, horticulture, etc.). These light fixtures are installed and used in environments where leakage, interface with the ceiling structure, cleanability and corrosion resistance are critical.

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1. PRESSURE DECAY

Pressure Decay is leakage from the lighting fixture into the room (clean room application) and pressure leakage from the room into the lighting fixture (containment area application).

**LEAKAGE FROM LIGHTING FIXTURE TO ROOM ENVIRONMENT – NSF P442 “CONTROLLED ENVIRONMENT LIGHT FIXTURES”**

Section 6.2.1.3 of NSF P442 describes the 6-step testing procedure for: Pressure Decay – leakage from light fixture to room environment.

1. Prepare the light fixture as a sealed system.
2. Remove any obstructions, where necessary, to expose the outer hull of the fixture.
3. Attach a manometer, pressure gauge, or pressure transducer system to the outer hull of the light fixture with plastic or rubber hosing to indicate the interior pressure. A viable penetration point may need to be installed.
4. Pressurize the light fixture with a regulated air pressure source to a reading of 2 in w.g. (500 Pa) +/- 10%, turn off the pressurizing air, and wait 5 minutes.
5. Repeat step 4 as needed until air pressure has stabilized. Turn off the pressuring air and wait 30 min.
6. Measure the pressure after 30 min. A change in pressure within 10% of the original value is allowable.

**LEAKAGE FROM ROOM ENVIRONMENT FIXTURE TO LIGHT FIXTURE – NSF P442 “CONTROLLED ENVIRONMENT LIGHT FIXTURES”**

Section 6.2.1.4 of NSF P442 describes the 6-step testing procedure for: Pressure Decay – leakage from room to the light fixture.

1. Prepare the light fixture as a sealed system.
2. Remove any obstructions, where necessary, to expose the outer hull of the fixture.
3. Attach a manometer, pressure gauge, or pressure transducer system to the outer hull of the light fixture with plastic or rubber hosing to indicate the interior pressure. A viable penetration point may need to be installed.
4. Pressurize the light fixture with a regulated vacuum source to a reading of -2 in w.g. (500Pa) +/- 10%, turn off the pressurizing air, and wait 5 minutes.
5. Repeat step 4 as needed until air pressure has stabilized. Turn off the vacuum and wait 30 min.
6. Measure the pressure after 30 min. A change in pressure within 10% of the original value is allowable.

2. INGRESS PROTECTION

Ingress Protection is solid object or dust particulate leakage into the lighting fixture and water/moisture leakage into the lighting fixture.

**DUST/PARTICULATE AND WATER/MOISTURE LEAKAGE INTO LIGHTING FIXTURE INTERIOR – IEC60598 (Ingress Protection for Lighting Fixtures)**

According to NSF P442 IP65 is the minimal acceptable rating for leakage into the fixture interior. NSF references ISO60598 (Ingress Protection for Lighting Fixtures) as a universally accepted standard and testing procedure publication for rating lighting fixtures’ ability to withstand water and solid object penetration. Ingress Protection (IP) ratings are listed with two consecutive numbers (example: IP65). The first number (6_) refers to solid object ingress protection (6 indicates no ingress of dust) and the second number (_5) refers to water ingress protection (5 indicates that water projected by a nozzle (6.3mm) against enclosure from any direction shall have no harmful effects.). See the following two charts for a complete description of ingress protection ratings.

**IMPORTANCE OF INDEPENDENT LABORATORY AND FACTORY TESTING FOR DECAY PRESSURE LEAKAGE**

Independent laboratory testing for decay pressure leakage provides assurance that the product has been successfully designed to resist leakage. Factory testing for decay pressure leakage provides assurance that the product has been successfully manufactured. Both independent laboratory testing of design and factory testing of manufactured product are necessary to assure that the installed product will perform as intended.
### INGRESS PROTECTION – SOLID OBJECTS

<table>
<thead>
<tr>
<th>LEVEL</th>
<th>OBJECT SIZE PROTECTED AGAINST</th>
<th>EFFECTIVE AGAINST</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Not protected</td>
<td>No protection against contact and ingress of objects</td>
</tr>
<tr>
<td>1</td>
<td>50mm</td>
<td>Any large surface of the body, such as the back of the hand, but no protection against deliberate contact with a body part.</td>
</tr>
<tr>
<td>2</td>
<td>&gt;12.5mm</td>
<td>Fingers or similar objects.</td>
</tr>
<tr>
<td>3</td>
<td>&gt;2.5mm</td>
<td>Tools, thick wires, etc.</td>
</tr>
<tr>
<td>4</td>
<td>&gt;1mm</td>
<td>Most wires, screws, etc.</td>
</tr>
<tr>
<td>5</td>
<td>Dust Protected</td>
<td>Ingress of dust is not entirely prevented, but it must not enter in sufficient quantity to interfere with the satisfactory operation of the equipment; complete protection against contact.</td>
</tr>
<tr>
<td>6</td>
<td>Dust Tight</td>
<td>No ingress of dust; complete protection against contact.</td>
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### INGRESS PROTECTION – WATER

<table>
<thead>
<tr>
<th>LEVEL</th>
<th>OBJECT SIZE PROTECTED AGAINST</th>
<th>EFFECTIVE AGAINST</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Not protected</td>
<td>–</td>
</tr>
<tr>
<td>1</td>
<td>Dripping water</td>
<td>Dripping water (vertically falling drops) shall have no harmful effect.</td>
</tr>
<tr>
<td>2</td>
<td>Dripping water when tilted up to 15°</td>
<td>Vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.</td>
</tr>
<tr>
<td>3</td>
<td>Spraying water</td>
<td>Water falling as a spray at any angle up to 60° from the vertical shall have no harmful effect.</td>
</tr>
<tr>
<td>4</td>
<td>Splashing water</td>
<td>Water splashing against the enclosure from any direction shall have no harmful effect.</td>
</tr>
<tr>
<td>5</td>
<td>Water jets</td>
<td>Water projected by a nozzle (6.3mm) against enclosure from any direction shall have no harmful effects.</td>
</tr>
<tr>
<td>6</td>
<td>Powerful water jets</td>
<td>Water projected in powerful jets (12.5mm nozzle) against the enclosure from any direction shall have no harmful effects.</td>
</tr>
<tr>
<td>7</td>
<td>Immersion up to 1m</td>
<td>Ingress of water in harmful quantity shall not be possible when the enclosure is immersed in water under defined conditions of pressure and time (up to 1 m of submersion).</td>
</tr>
<tr>
<td>8</td>
<td>Immersion beyond 1m</td>
<td>The equipment is suitable for continuous immersion in water under conditions which shall be specified by the manufacturer. Normally, this will mean that the equipment is hermetically sealed. However, with certain types of equipment, it can mean that water can enter but only in such a manner that it produces no harmful effects.</td>
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CLEANABILITY, CORROSION RESISTANCE AND INTERFACE WITH CEILING STRUCTURE

NSF/ANSI 2 (splash zone) establishes minimum food protection and sanitation requirements for the materials, design, fabrication, construction and performance of food handling and processing equipment including light fixtures. NSF requires that all lighting fixture materials be considered suitable (non-toxic, corrosion resistant, durable, etc.) for food/splash zone applications by the FDA, that the design is devoid of gaps and crevices that might harbor bacteria, mold or pathogens and all openings are sealed and/or gasketed. The NSF label is recognized by life science and healthcare regulators.

NSF P442 acknowledges that all NSF/ANSI 2 standards are applicable in NSF P442. Additionally NSF P442 requires that lighting fixtures are fabricated of materials, designed and constructed so soil and other debris anticipated in its end use environment are removed by normal non-mechanical cleaning methods and that the lens frame produces a progressive, uninterrupted surface with the ceiling structure that is devoid of both gaps and abrupt 90° returns.

HAZARDOUS LOCATIONS – CLASS I, DIVISION 2 AND CLASS II, DIVISION 2

Class I, Division 2 classification usually includes locations where volatile flammable liquids or flammable gases or vapors are used, but which would become hazardous only in case of an accident or of some unusual operating condition. The quantity of flammable material that might escape in case of accident, the adequacy of ventilating equipment, the total area involved, and the record of the industry or business with respect to explosions or fires are all factors that merit consideration in determining the classification and extent of each location.

Class II, Division 2 classification includes locations where dangerous concentrations of suspended dust would not be likely but where dust accumulations might form on or in the vicinity of electric equipment. These areas may contain equipment from which appreciable quantities of dust would escape under abnormal operating conditions or be adjacent to a Class II Division 1 location, as described above, into which an explosive or ignitable concentration of dust may be put into suspension under abnormal operating conditions.

ELECTROMAGNETIC INTERFERENCE – (RADIATED AND CONDUCTED)

It is imperative that lighting fixtures do not produce radiated or conducted emissions (EMI) that can negatively affect the performance of sensitive electronic equipment used in clean room and containment area environments. Military Standard 461F provides standards and testing procedures that will assure EMI protection (conducted and radiated) for these applications. Testing of radiated emissions should be conducted at one meter per Air Force/Navy Fixed specifications.
METHODS OF PRODUCT SPECIFICATION

In most cases facility engineers, or consulting architects/electrical engineers/lighting designers will select the lighting fixtures installed in controlled environments. The selected lighting fixtures will be specified in Section 26 5000 of the construction documents. The specified lighting fixtures can be identified by manufacturer/catalog number, product features, standards/testing procedures documents or a combination of these methods. Unless the specification process includes standards/testing procedures, verified by independent laboratories, there is no assurance that the integrity of the lighting fixture will be compatible with the integrity of the controlled environment. Additionally it is important that product features be qualified.

**Features must be qualified**

- Unless stainless steel lens frame is qualified by “free of room side welding” you will risk corrosion because welding destroys the chromium content’s ability to resist corrosion.

- Unless closed cell gasketing is qualified as “extruded closed cell gasket with vulcanized corners” you will risk open cells that collect contaminants and leakage at gasket joints.

- Unless triple gasketing is qualified as “must be tested for leakage at factory” you will risk pressure decay and ingress leakage.

Lighting fixtures used in clean room and containment area applications must be sealed against leakage (NSF P442 and IEC60598 IP65), constructed of non-corrosive materials (NSF P442 and NSF2), designed for ease of cleanability (NSF P442 and NSF2), produce a progressive surface with the ceiling structure (NSF P442), operate safely in hazardous locations (UL Standard 844 Class I, Division 2 and Class II, Division 2) and be compatible with sensitive electronic equipment used in these spaces (MIL STD 461F Air Force/Navy Fixed).

Lighting fixtures used in clean room and containment area applications should be specified by performance standards, tested according to standardized procedures by independent laboratories and factory certified that the manufactured product does not leak.

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