



Neudorfer Engineers. Inc.
Washington - Oregon - California



Neudorfer Engineers

Cleanroom Testing & Certification

www.neudorferengineers.com

Neudorfer Engineers, Inc. provides our customer with unbiased, professional, performance testing of Cleanrooms. We are committed to providing you, our customer, with value-added expertise in an effort to ensure the best possible performance for your facility.

Our staff can test and certify a Cleanroom to either Federal Standard 209E or International Standard Organization (ISO) 14644-1 requirements. We have the instrumentation and experienced personnel to certify everything from a Class 1 Cleanroom at 0.1 micrometers, to a Class 100,000 Cleanroom at 5.0 micrometers.



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CLEANROOM TESTING & CERTIFICATION

Neudorfer Engineers specializes in the testing and certification of Cleanrooms. Our field engineers perform Cleanroom certification procedures in accordance with NEBB standards, IEST recommended practices, ISO standards, owner specifications, and our company's internal procedural standards.

We can perform this testing in your Cleanroom, laminar flow work stations and benches, fume hoods, biological safety cabinets or any other environment that you may need tested for viable particle counts and bioburden testing. Each of our clients has unique requirements; therefore, each of our testing plans is individually tailored to their specifications.

Listed below are the most common test specifications in use around the world.

ISO 14644-1 and ISO 14644-2:

The ISO standards are recognized as the international Cleanroom standards. These standards are similar in scope and requirements to the retired Federal Standard 209E. The ISO standards are metric classification only, and the particle count limits and room classifications do differ from Federal Standard 209E. The United States Government has adopted the ISO standards and has phased out FS 290E.

Federal Standard 209E:

This is by far the most commonly referenced test standard in use today. This standard was retired in December of 2002 and is no longer a United States Federal Standard, although, the FDA has acknowledged that the fundamentals are sound and should be part of a Good Manufacturing Practice (GMP). The United States Government has adopted the ISO standards, although when Federal Standard 209E was in effect the standard provided for standardized classifications for airborne particle count levels in clean environments. This standard does not specify other environmental parameters that may be required, such as air velocity, room pressures, furniture, or room furnishing specifications, etc.

NEBB Procedural Standards: (Procedural Standards for Certified Testing of Cleanrooms, 1996 Edition)

These comprehensive testing standards cover most environmental parameters. These standards expands the other standards and gives the certifiers a practical "how to" insight into certification.

IES RP-CC-0006.4:

This test standard provides test procedures for most environmental parameters that may be required. Some of these procedures include filter integrity testing, room pressurization, temperature and relative humidity, and room recovery testing, to name a few.

IES RP-CC-0034.1:

This recommended practice document covers the procedures for leak testing HEPA and ULPA filters.

User Specified Limits:

It is very common for the Cleanroom owner or contractor to create an in-house test standard that may include aspects from all three standards listed above. We are able to assist the user in the development of a comprehensive test standard that will provide a reasonable applicable test specification.

The table below describes the most common Cleanroom performance tests that we perform, and specifies the common room condition in which the test(s) are performed.

| Test Procedure | Unidirectional Airflow Room | Non-Unidirectional Airflow Room | Comments |
|-------------------------|-----------------------------|---------------------------------|---|
| Supply Volume | 1,2,3 | 1,2,3 | This test may be performed with a velocity meter or flow hood. |
| Filter Leak Test | 1,2 | 1,2 | Using an aerosol challenge of PAO or PSL, depending on product sensitivity. |
| Airborne Particle Count | 1,2 | 1,2 | Performed with an airborne particle counter with size sensitivity suitable for room classification. |
| Room Pressurization | 1,2,3 | 1,2,3 | Using digital micro- manometer. |
| Room Airflow Uniformity | 1,2 | 1,2 | Using dry ice fogger and visual, still photo, or video tape recording. |
| Room Recovery Test | 1,2 | 1,2 | Using particle generator and airborne particle counter. |
| Particle Fallout Test | 1,2,3 | 1,2,3 | Using fallout plate monitors at critical locations. |
| Room Lighting Level | 1,2,3 | 1,2,3 | Using digital photometer, per IES handbook. |
| Room Noise Level | 1,2,3 | 1,2,3 | Generally performed for contractual compliance or safety requirements. |
| Temperature & Humidity | 1,2,3 | 1,2,3 | Taken at each particle count location or long-term trend study, as required. |
| Vibration Level | 1,2,3 | 1,2,3 | Generally performed for contractual compliance or safety requirements. |
| Bioburden Test | 1,2,3 | 1,2,3 | Using RCS samplers, contract plates, or fallout plates. |

1. Indicates the test is best performed in an “as-built” condition.
2. Indicates the test is best performed in an “at-rest” condition.
3. Indicates the test is best performed in an “operational” condition.

The table above reflects the most common testing performed on Cleanrooms.

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Cleanroom Performance Testing:

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Performance testing can be done at three different levels of operation: “as-built,” “at-rest” and “operational.” In the “as-built” condition, the room is complete, with no equipment or personnel present. In the “at-rest” condition, the equipment is in the room, but not running, and there are no personnel present. In the “operational” condition, the room is operational, with equipment running and personnel present.

The only performance testing required certifying a Cleanroom by either standard is ambient particle counts, which determine the cleanliness of the area. We, however, recommend additional tests for a more in-depth understanding of the Cleanroom. These additional tests include filters scan, pressurization, airflow velocity and uniformity, airflow parallelism, temperature and relative humidity, floor conductivity, and sound and lighting testing. Each of these tests will give you a better understanding of the environment of your facility.

The filter scan test is designed to ensure that the ceiling system is installed correctly and that there are no leaks in the filter media or ceiling grid. A polystyrene test confirms that this is true.

The Cleanroom should be at a higher pressure than the surrounding, less- clean areas in order to prevent contamination from entering the Cleanroom. The pressurization test confirms that this is true.

The airflow test is done to determine the velocity and uniformity of airflow through the clean space. The airflow through each filter is measured and adjusted, as necessary, so that the air entering the room is within specifications. It sometimes is necessary to run laminar airflow and airflow parallelism tests to prove this.

The temperature and relative humidity are measured over time to determine if the air handlers in the area are able to establish and maintain uniformity.

It is necessary in a Cleanroom to avoid build-up of static electric energy. We can measure the resistance of the floor, both point-to-point and point-to-ground, to determine if the floor system meets the design criteria.

Noise level testing is used to measure the sound levels present in the Cleanrooms. Sound levels are compared to Noise Criteria (NC) Curves as a way of quantifying the actual levels to predetermined industry standards. The more noise sensitive the usage of a room, the lower the required NC level.

Light levels are measured to determine the amount of light at the working height in the Cleanroom. (The first half of this paragraph is duplication of earlier copy.) (The page needs a title.)

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Our company specializes in the testing and certification of Cleanrooms. Trained technicians perform Cleanroom certification procedures in accordance with NEBB standards, IEST-recommended practices, ISO standards, owner specifications, and our own procedural standards. The company has developed a certification program that offers customized performance evaluations, including precision filter integrity, testing using a fully computerized robotic scan, and a filter challenge using PSL spheres. Test data is presented through field and office CAD Systems.

As a certified member of the National Environmental Balance Bureau (NEBB) and a member of the Institute of Environmental Science and Technology (IEST), we work at home in the Pacific Northwest and around the world. We can help you get your facility certified, providing professional service and long-term solutions to any problem we come across, rather than quick, easy, short-term fixes.

Air Balance and Adjustment:

If we determine during testing that air balance or system adjustments are required to meet your contamination control requirements, we are often able to perform these adjustments ourselves, saving you time and money.

HEPA Filter Repair/Replacement:

We can repair most damage we find during our filter leak testing. When there is no problem that requires filter replacement, we can perform this for you without major delay.

We are able to provide bioburden (viable particle count) testing at the same time as we perform a normal Cleanroom test and certification. We use RCS samplers and contact plates to collect viable samples from various locations in your Cleanroom. The samples are then incubated in our contamination lab and the total viable particles are counted and reported to you.

Cleanroom Testing & Certification:

We can verify requisite standards in biological or microelectronic facilities for Cleanroom testing and certification ranges, from spot testing to reviewing specifications, creation of test and certification procedures for the FAB, and the deployment of test services.

We offer standard tests for certification of a Cleanroom during the commissioning and through full operation for charge, damage or failure of the environment's system components, and quality assurance.

Among tests conducted for Cleanroom certification are:

- Room pressurization testing to verify capabilities of the Cleanrooms air handler
- Airborne particle count test to compare Cleanroom classification level to cleanliness
- HEPA/ULPA filter leak scan to determine the integrity of the installed Cleanroom system
- Ultra Violet (UV) light wave spectrum analysis designed specifically for measuring light within a semiconductor lithography processing area.

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