



CLEANROOM PROTOCOL

LEVEL 1

Level 1 protocol begins with the completion of building “Dry-in”. “Dry-in” implies that the external building shell is complete and sealed against the outside world. Level 1 requires it. Level 1 will end with the completion of cleanroom related internal building shell partitions prior to painting. The internal shells are physical barriers isolating future cleanrooms and related areas (service corridors, air returns, access corridors, etc.) from the general building environment. The cleanliness level maintained in Level 1 is unclassified, but better than a normal construction level.

It is important to activate one or more makeup air handlers as early as possible in order to provide positive pressure in the building. Portable exhaust capabilities are required for removal of fumes and to minimize spread of contamination.

Work to be performed includes installation of the make-up and recirculation air units including piping and equipment, ductwork, general building plumbing, electrical and painting. A minimum level of extra effort is required to keep the area cleaner than the outside world. All internal air handling surfaces, including pre-cleaned ducts and components, which cannot be thoroughly cleaned later, will require protection to Level 3 conditions.

There are no staging or gowning requirements except that shoes or boots and clothing are to be clean. All materials, tools, and equipment are to be kept clean. This means free of gross dust, dirt and grease.

Rules for Level 1:

You must:

- **Have Level 1 training.**
- **Have a badge indicating you have Level 1 training.**

Your tools and material must:

- **Be free of gross dust, dirt and grease.**

You must meet minimum dress requirements:

- **Your shoes or boots and clothing must be clean.**

Environments To Enhance Your Business Results

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When you enter the cleanroom:

- You must enter through a clearly marked personnel entry.

You may not take into the cleanroom:

- Any tobacco product.
- Any food, drink or chewing product.

While in the cleanroom you may not:

- Spit, eat, drink, or chew.
- Use any unapproved chemicals, solvents, or cleaning materials.
- Put trash on the floor.
- Store more than a one day material supply.

When working in the cleanroom you may not:

- Use any gasoline or diesel powered equipment.

While in the cleanroom you must:

- Clean up all spills and messes.

When cleaning in the cleanroom:

- Use only approved materials and tools.

Level 1 Cleaning Requirements:

Level 1 cleaning is that performed routinely during course construction and preliminary preparation for clean environments. A minimum of this level of cleaning should continue to be performed in all areas adjacent to clean environments after more progressive cleaning procedures have begun in more critical areas.

Remove all trash and debris daily. Conventional garbage cans and dumpsters are satisfactory containers, and no restrictions apply to the methods of emptying containers. Floors are to be cleaned daily. Dry mops are preferable, with brooms acceptable where required. The floors are also to be wet mopped daily, or more frequently if necessary to prevent dust from migrating to more critical areas. Conventional wet mopping tools and procedures are satisfactory at this level since the objective is not to remove the contamination, but only to prevent its transfer to other areas. This includes conventional housekeeping detergents, if required.

Vacuuming of floors and other surfaces which have obvious buildup of dirt may be required if the above procedures are not adequate to prevent the spread of dirt to more critical areas. Conventional housekeeping vacuuming systems, including the entire array of brushes and attachments, may be used. The Cleanroom Supervisor will indicate if this procedure is required.

Spills and leaks of liquid materials should be cleaned up as soon as they are detected, primarily for safety reasons. Mops, wet vacuums, and absorbent wipers may be used without restrictions, provided they are compatible from a safety consideration.

CLEANROOM PROTOCOL

LEVEL 2

Level 2 protocol begins with the completion of cleanroom related internal building shell partitions prior to painting. These shells include walls intended to be a physical barrier isolating future cleanrooms and related areas (service corridors, air returns, access corridors, etc.) from the general building environment. Level 2 ends just prior to the start of installation of any cleanroom surface. The cleanliness level maintained in Level 2 is unclassified, but counts should be in the 100,000 – 300,000 particles of 0.5 μ and larger per cubic foot range.

Activate the house vacuum clean system. Activate the makeup air handler on a 24 hour status to provide a positive pressure in the building. Portable exhaust or permanent capabilities are required for removal of fumes and to minimize spread of contamination. Provide DI water service as early as possible.

Work to be performed includes installation of additional mechanical equipment, ductwork, piping systems, process piping and electrical distribution systems. Extra effort is required to keep the area cleaner than the outside world. All internal air handling surfaces, including pre-cleaned ducts and components, which cannot be thoroughly cleaned later, will require protection to Level 3 conditions.

Staging areas of Level 1 quality are required. If the surrounding areas are not of Level 1 quality, a temporary enclosed staging area of Level 1 quality should be provided. The staging area may serve as both an equipment and personnel entry rooms. A boot cleaner, tacky mats, HEPA filtered vacuum cleaner, hand washing facilities and drinking water are required.

Rules for Level 2

You must:

- **Have Level 2 training.**
- **Have a badge indicating you have Level 2 training.**
- **Enter from an official Level 1 staging area.**

Your tools and material must:

- **Be free of gross dust, dirt and grease and cleaned.**

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- Be inspected for Level 2 condition.
- Unpacked prior to entering the cleanroom.

You must meet minimum dress requirements:

- Your shoes and clothing must be clean.
- You may be required to change shoes or clothes if not of cleanroom quality.

When you enter the cleanroom:

- You must enter through a clearly marked personnel entry.
- You must use the shoe cleaner and walk on the tacky mat.

You may not take into the cleanroom:

- Any tobacco product.
- Any food, drink or chewing product.
- Any foam, shredded or wrapping paper, cardboard, or other contaminating packing materials.

While in the cleanroom you may not:

- Spit, eat, drink, or chew.
- Use any unapproved chemicals, solvents, or cleaning materials.
- Put trash on the floor.
- Store more than a one day material supply.

When working in the cleanroom you may not:

- Use any gasoline or diesel powered equipment.
- Use any air tools.
- Use any brooms or similar sweeping type cleaning tools.

While in the cleanroom you must:

- Clean up all spills and messes.
- Have the Cleanroom Supervisor inspect clean-up.

When cleaning in the cleanroom:

- Use only approved materials and tools.
- Do not use any brooms or other sweeping type of device.
- Use only house vacuum or portable vacuum.

Level 2 Cleaning Requirements:

All trash and debris should be removed and all surfaces in the entire area should be vacuumed, using central house vacuum or a portable vacuum cleaner, wet wiped and sealed and painted prior to the start of any work in this area.

Trash and debris are to be kept in a container with lid and removed at least once each shift. Trash and debris shall not be allowed to fall on the floor. The floors should be vacuum cleaned or wet mopped when contaminated and at the end of each shift.

Surfaces of material and equipment being installed should be wiped clean with absorbent wipes wetted with clean water. Oil and greases should be solvent wiped with approved solvents. Wipes should be replaced and disposed of as soon as they develop any discoloration other than what might be caused by the solvent being used (or according to manufacturer's recommendations). Wipes should not be used more than once. Water and solvent should not be used in situations where they might cause damage to the surfaces being cleaned.

At the end of Level 2, the area will require a complete top down clean prior to being upgraded to Level 3. The cleaning procedures will be the same as those used during the Level 2 protocol.

CLEANROOM PROTOCOL

LEVEL 3 CLEANROOM RULES

Level 3 protocol begins after the final Level 2 cleaning is completed and just prior to the installation of the first clean room surfaces. It ends when the re-circulating handlers are turned on and the final top-down cleaning prior to the HEPA filters being un-bagged is complete (typically called "blow down). The cleanliness level maintained in Level 3 is unclassified, but counts should be in the 5000 – 20,000 particles of 0.5 μ and larger per cubic foot range with peaks in the 50,000 – 100,000 range.

Operate the makeup air handlers on a 24 hour status to provide a positive pressure in the building and clean areas. House exhaust capabilities are required. DI water service must be provided.

Work to be performed includes the installation of cleanroom surfaces including walls, ceilings, flooring, doors, and built-ins such as pass-throughs. Concentrated effort is required to maintain the area in a clean condition, well above the outside world.

Staging areas of level 2 quality are required. If the surrounding area is not of Level 2 quality, a temporary enclosed staging area of Level 2 shall be provided. The staging area may serve as both equipment and personnel entry rooms. Provisions for shoe and cleanroom garmenting storage shall be included. A shoe cleaner, tacky mats, HEPA filtered vacuum cleaner, hand washing facilities, dryer, and drinking water are required.

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Rules for Level 3

You must:

- **Have Level 3 training.**
- **Have a badge indicating you have Level 3 training.**
- **Gown and enter from an official Level 2 staging area.**
- **Use the shoe cleaner when entering staging area.**

Your tools and material must:

- **Be free of gross dust, dirt and grease and cleaned.**
- **Be inspected for Level 3 condition.**
- **Unpacked prior to entering the cleanroom.**

You must meet minimum dress requirements:

- **Your shoes or boots and clothing must be clean.**
- **You must be wearing cleanroom approved shoes.**
- **You must wear undamaged gloves at all times.**
- **You must wash and dry your hands before putting on gloves.**
- **You must wear face masks, hat/hood, gloves, coveralls, & booties.**

When you enter the cleanroom:

- **You must enter through a clearly marked personnel entryway.**
- **You must take a drink of water before entering.**
- **You must walk across the tacky mat.**

You may not take into the cleanroom:

- **Any tobacco product.**
- **Any food, drink or chewing product.**
- **Any foam, paper, cardboard, or wrapping and packing material.**
- **Any wooden tool boxes, sawhorses, or other wood products including wooden handled tools.**
- **Any pencils, felt tips, magic markers, or erasers.**

While in the cleanroom you may not:

- **Spit, eat, drink, or chew.**
- **Use any unapproved chemicals, solvents, or cleaning materials.**
- **Touch any filter surface.**
- **Touch any cleanroom surface unless necessary and then only when wearing gloves.**
- **Put trash on the floor.**
- **Store more than shift's supply of materials.**

When working in the cleanroom you may not:

- **Use any lp, natural gas, gasoline or diesel powered equipment.**

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- Use any air tools.
- Use any cartridge fired tools.
- Do not saw, drill, use abrasives, weld, paint or engage in any activity which would cause particles, dust, grit, fiber, vapor, fumes, smoke or other contaminating material without a written permit and proper containment measures.

While in the cleanroom you must:

- Clean up all spills and messes.
- Report any and all damage to the Cleanroom Supervisor. When in doubt, report!

When cleaning in the cleanroom:

- Use only approved materials and instruments.
- Use only house vacuum or HEPA filtered vacuums.
- Do not use any brooms or other sweeping type of device.
- You must clean all floors daily with house vacuum or HEPA filtered vacuum cleaners.
- Wipe installed cleanroom surfaces with low-particulate wipes and clean DI water or approved solvent.

Level 3 Cleaning Requirements:

Trash and debris shall not be allowed to accumulate. It shall not be stored in the cleanroom. Floors shall be vacuumed with house vacuum or 99.99% HEPA filtered vacuum cleaners when contaminated and at the end of each shift. Subsurfaces over which succeeding work is to be installed shall be carefully inspected and wiped clean by using low-particulate wipers wetted in approved solvent to preclude the entrapment of contamination in the final work. Wipes shall be replaced and disposed of as soon as they develop and discoloration other than that caused by the solvent being used. A complete top-down clean of all surfaces is required as a part of transition to level 4.

CLEANROOM PROTOCOL

LEVEL 4 CLEANROOM RULES

Level 4 protocol begins when recirculating handlers have been turned on and after the final Level 3 top-down cleaning prior to the HEPA filters being unbagged is complete, typically called “blow down”. Do not expose any HEPA filters until top-down clean is complete. Level 4 ends when the cleanroom is complete and ready for “As-Built” certification. The Cleanroom Supervisor shall inspect the cleanroom for contamination sources prior to releasing it for Level 5 certification. Contamination sources not allowing

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the room to meet the designated class of cleanroom (1, 10, 100, or 1000) shall be removed with no exceptions. The typical level of cleanliness maintained is Class 1000 in the early stages progressing to a Level close to the final design classification as the room is completed.

Operate all makeup air handlers on a 24 hour status. Operate recirculating air handlers to keep areas positive to surrounding areas. Convenient DI water, house vacuum, nitrogen, and process air are typically required.

Work to be performed consists primarily of HEPA filter installation. Any remaining floor, wall, ceiling grid, electrical and mechanical work is to be completed. All cleanroom entry room work is to be completed during this phase, including installation of all decontamination equipment, storage equipment, drinking fountain, mirrors, etc.

A staging area of Level 3 quality is required. If the surrounding area is not of Level 3 quality, a temporary enclosed staging area of Level 3 shall be provided. The staging area shall serve as both equipment and personnel entry rooms. Provisions for shoe and cleanroom garment storage is necessary. A shoe cleaner, tacky mats, HEPA filtered vacuum cleaner, hand washing facilities, HEPA filtered hand dryer, and drinking water are required.

All access doors to the cleanroom except main entrance should require a key in order to be opened from the outside. The Cleanroom Supervisor, his designated surveillance officer, or Site Construction Manager should be the only persons authorized to unlock these doors. "Clean" trash containers should be maintained outside of the cleanroom, adjacent to each access point.

Rules for Level 4

You must:

- **Have Level 4 training.**
- **Have a badge indicating you have Level 4 training.**
- **Gown and enter from an official Level 3 staging area.**
- **Use the shoe cleaner when entering staging area.**

Your tools and material must:

- **Be free of gross dust, dirt and grease and cleaned.**
- **Be inspected for Level 4 condition.**
- **Unpacked prior to entering the cleanroom.**

You must meet minimum dress requirements:

- **Your shoes and clothing must be clean.**
- **You must be wearing cleanroom approved shoes.**
- **You must wear undamaged gloves at all times.**
- **You must wash and dry your hands before putting on gloves.**

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- You must wear face masks, hat/hood, gloves, coveralls, & booties.
- Clean garments are required at start of each shift.
- Damaged garments must be replaced immediately.

When you enter the cleanroom:

- You must enter through a clearly marked entryway.
- You must take a drink of water before entering.
- You must walk across the tacky mat.
- Use the “sign-in/sign-out” log.

You may not take into the cleanroom:

- Any tobacco product.
- Any food, drink or chewing product.
- Any foam, paper, cardboard, or wrapping and packing material.
- Any wooden tool boxes, sawhorses, or other wood products including wooden handled tools.
- Any pencils, felt tips, magic markers, or erasers.
- Any paper except cleanroom or properly encased paper.

While in the cleanroom you may not:

- Spit, eat, drink, or chew.
- Use any unapproved chemicals, solvents, or cleaning materials.
- Touch any filter surface.
- Touch any cleanroom surface unless necessary and then only when wearing gloves.
- Put trash on the floor.
- Store more than shift’s supply of materials.

When working in the cleanroom you may not:

- Use any lp, natural gas, gasoline or diesel powered equipment.
- Use any air tools.
- Use any cartridge fired tools.
- Do not saw, drill, use abrasives, weld, paint or engage in any activity which would cause particles, dust, grit, fiber, vapor, fumes, smoke or other contaminating material without a written permit and proper containment measures.

While in the cleanroom you must:

- Clean up all spills and messes immediately.
- Report any and all damage to the Cleanroom Supervisor. When in doubt, report!

When cleaning in the cleanroom:

- Use only approved materials and instruments.

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- **Use only house vacuum or HEPA filtered vacuums.**
- **Do not use any brooms or other sweeping type of device.**
- **You must clean all floors daily with house vacuum or HEPA filtered vacuum cleaners when contaminated and at the end of each shift.**
- **Wipe installed cleanroom surfaces with low-particulate wipes and clean DI water or approved solvent.**

Level 4 Cleaning Requirements:

A complete top-down clean is required after adequate “blow-down” of air handling systems and prior to exposure and installation of the HEPA filters during the Level 3 to Level 4 transition.

While Level 4 protocol rules are in effect, all surfaces shall be cleaned as often as required to pass the solvent wipe test at any time. The surfaces shall be cleaned either by vacuuming with house vacuum or HEPA filtered vacuum cleaners (99.99% efficient, minimum) or by wiping with low-particulate wipes wetted with solvent. Wipes shall be replaced and disposed of as soon as they develop any discoloration other than what might be caused by the solvent being used (or according to manufacturer’s recommendations). Wipes shall under no circumstances be used more than once.

Trash and debris shall not be allowed to accumulate. It shall not be stored in the cleanroom. Floors shall be vacuumed with house vacuum or 99.99% HEPA filtered vacuum cleaners when contaminated and at the end of each shift. Upon completion of Level 4 work, just prior to certification, the area shall undergo a final cleaning. At this time all floor and wall protective coatings shall be removed and Level 5 rules shall be enforced.

CLEANROOM PROTOCOL

LEVEL 5 CLEANROOM RULES

Level 5 protocol begins when the cleanroom is complete, running, and ready for “As-Built” certification. It stops when the cleanroom has been certified. The typical level of cleanliness maintained is a class close to the required “as-built” class at the beginning of certification and progressing to the required class by the completion of certification. All cleanroom systems should be operating on a normal basis.

Work to be performed is certification and the installation of any process equipment required prior to turning over the cleanroom to owner. During the FS209 particle counting portion of the certification process, no other work should be performed. Process

equipment installation is typically done under Level 5 or Level 6 (Operational) protocol requirements.

An equipment staging area of Level 4 quality is required. If the surrounding area is not of Level 4 quality, a temporary enclosed staging area of Level 4 shall be provided. The equipment staging area may serve as both equipment and equipment related personnel entry room. Provisions for shoe and cleanroom garmenting storage shall be included. A boot cleaner, tacky mats, HEPA filtered vacuum cleaner, hand washing facilities, HEPA filtered hand drier, and drinking water shall be provided.

All personnel not directly involved with moving equipment or materials into the cleanroom shall enter through the regular entry room which shall be completed by this point. The personnel entryway shall not be used for equipment or material entry unless specifically designed for that purpose. The personnel entry room shall be complete with all specified cleanroom preparation equipment installed.

The access doors to the cleanroom shall require a key in order to be opened from the outside. The Cleanroom Supervisor or his designated surveillance officer shall be the only person authorized to unlock these doors. The doors shall remain locked at all times, even when personnel is working inside cleanroom. "Clean" trash containers shall be maintained outside of the cleanroom entry room and adjacent to each equipment access point,

Rules for Level 5

You must:

- **Have Level 5 training.**
- **Have a badge indicating you have Level 5 training.**
- **Gown and enter from an official Level 4 staging area.**
- **Use the shoe cleaner when entering staging area.**

Your tools and material must:

- **Be free of gross dust, dirt and grease and cleaned.**
- **Be inspected for Level 5 condition.**
- **Unpacked prior to entering the cleanroom.**

You must meet minimum dress requirements:

- **Your shoes and clothing must be clean.**
- **Bulky clothes, furs, angora, linty stockings or similar types of clothes are not allowed in the cleanroom.**
- **Clothing minimizing amount of bare skin are required.**
- **No cosmetics of any kind permitted.**
- **Adequate personal hygiene required.**

- Personnel suffering from flaking skin problems shall not enter the cleanroom.
- Personnel suffering from colds, flu, allergies, and similar illnesses shall not enter the cleanroom.
- You must be wearing cleanroom approved shoes.
- You must wear undamaged gloves at all times.
- You must wash and dry your hands before putting on gloves.
- You must wear face masks, hat/hood, gloves, coveralls, & booties.
- Clean garments are required at start of each shift.
- Damaged garments must be replaced immediately.

When you enter the cleanroom:

- No person, whether authorized or not, shall enter the cleanroom unless their physical presence is absolutely necessary.
- You must enter through a clearly marked entryway.
- You must take a drink of water before entering.
- You must walk across the tacky mat.
- Use the “sign-in/sign-out” log.

You may not take into the cleanroom:

- Any tobacco product.
- Any food, drink or chewing product.
- Any foam, paper, cardboard, or wrapping and packing material.
- Any wooden tool boxes, sawhorses, or other wood products including wooden handled tools.
- Any pencils, felt tips, magic markers, or erasers.
- Any paper except cleanroom or properly encased paper.
- Any cleanroom paper previously removed from the cleanroom.
- Any service attaches or general toolboxes.

While in the cleanroom you may not:

- Spit, eat, drink, or chew.
- Use any unapproved chemicals, solvents, or cleaning materials.
- Touch any filter surface.
- Touch any cleanroom surface unless necessary and then only when wearing gloves.
- Put trash on the floor.
- Store more than shift’s supply of materials.
- Except in case of emergency, exit the cleanroom except through cleanroom entryways.

When working in the cleanroom you may not:

- Use any lp, natural gas, gasoline or diesel powered equipment.

- Use any air tools.
- Use any cartridge fired tools.
- Use abrasives such as steel wool, emery cloth or sandpaper in the cleanroom.
- Perform contaminating work of any kind during certification.

While in the cleanroom you must:

- Clean up all spills and messes immediately.
- Report any and all damage to the Cleanroom Supervisor. When in doubt, report!

When cleaning in the cleanroom:

- Use only approved materials and instruments.
- Use only house vacuum or HEPA filtered vacuums.
- Do not use any brooms or other sweeping type of device.
- You must clean all floors daily with house vacuum or HEPA filtered vacuum cleaners when contaminated and at the end of each shift.
- Wipe installed cleanroom surfaces with low-particulate wipes and clean DI water or approved solvent.

Level 5 Cleaning Requirements:

All surfaces shall be cleaned as often as required to pass the solvent wipe test at any time. The surfaces shall be cleaned either by vacuuming with house vacuum cleaner or by wiping with low-particulate wipes wetted with solvent. Wipes shall be replaced and disposed of as soon as they develop any discoloration other than what might be caused by the solvent being used (or according to manufacturer's recommendations). Wipes shall under no circumstances be used more than once. Trash and debris shall be removed as soon as generated. It shall not be stored in the cleanroom. Floors shall be vacuumed with house vacuum cleaner when contaminated and at the end of each shift. Upon completion of work at this level the area shall undergo a final complete cleaning.