FLORIDA CLEANROOM SYSTEMS

ISO Class Cleanroom Manufacturing, Design, Build, Certification

CLEAN BUILD PROTOCOLS

ISO Class Cleanroom Environments

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Section 1: Preparation of Clean Zone Construction Site Preliminary Cleaning

1.1 Construction Personnel Training Meeting

All supervisory personnel involved in the construction of the cleanroom environment will be required to attend a Clean Zone Construction Site training meeting to be orientated in the protocols of cleanroom construction and working in the cleanroom environment. It will then be your responsibility to assure all your construction trades persons are orientated before entering and working in the Clean Zone Construction Site.

1.2 Designation of Clean Zone Construction Site

The clean zone construction site will be designated as the final floor plan of the cleanroom environment, existing facility floor to the bottom of existing facility roofing system, plus 48" outside final cleanroom floor plan drawings. If a mechanical equipment room is remotely located from cleanroom final floor plan it to will be designated as part of the Clean Zone Construction Site. Entry, egress, and assembly protocols are to be administered the same as the designated Clean Zone Construction Site.

1.3 Preparation of Clean Zone Construction Site Preliminary Cleaning

The preparation of the Clean Zone Construction Site will be performed per the following protocols:

1.3.1 Clean Zone Construction Site Barrier Installation

A. A 4 mil vinyl barrier is to be installed 48" outside of the final cleanroom floor plan. Barrier should extend from the existing facility floor to the bottom of the existing facility roof decking structure. Penetrations through the barrier are to be sealed with aluminum tape utilizing aluminum tape as an air tight method. Barrier is to have 1 – 10' high zippered opening.

B. A 4 mil vinyl barrier, no less than 10' x 13' x 12' high with a 10' high zippered opening, will be attached to the main Clean Zone Construction Site barrier to be utilized as an entry / egress / ante room. All trades people, construction tools, construction equipment, lift equipment, and construction materials are required to enter through this entry / egress barrier observing all entry / egress protocols at various stage of construction.

C. If a remote mechanical equipment room is included in the Clean Zone Construction Site it is to be prepared and entered as specified for the Clean Zone Construction Site.

D. 3 sets of the final cleanroom construction drawings will be maintained in the Clean Zone Construction Site ante room. No other drawings or paper products are to enter the Clean Zone Construction Site.

1.3.2 Cleaning of Clean Zone Construction Site Overhead Structures

A. Overhead structure is defined as the bottom of the existing facilities roof decking, support joist, sprinkler piping, electrical, piping, existing HVAC units and distribution systems, and any other chases, cabling or items located directly above the Clean Zone Construction Site.
B. All overhead structure is to be first vacuumed with a HEPA filtration vacuum system capable of removing existing build up of particulate from all overhead structure. All overhead structure is then to be wiped down with a detergent solution and with lint free cleanroom cloths. Any exposed fibrous material such as the ends of existing insulation coverings or tears to existing covering are to be thoroughly sealed with aluminum tape.
C. All vacuuming and wiping of existing surfaces is to be accomplished from the top down. Bottom of existing roof deck first then utility chases in appropriate order dependent on elevation.

1.3.3 Cleaning of Clean Zone Construction Site Existing Wall Surfaces

A. Existing masonry block or drywall surfaces located in the Clean Zone Construction Site, which will be buried behind modular cleanroom wall systems, are to be thoroughly HEPA vacuumed and wiped down with a detergent solution and lint free cleanroom cloths. All vacuuming and wiping is to be accomplished from the top of the wall down to the bottom of the wall.

1.3.4 Cleaning of Clean Zone Construction Site Existing Flooring Surfaces

A. Existing flooring systems located in the Clean Zone Construction Site will be cleaned after completion of all overhead and wall surfaces sanitization. Existing flooring surface is to be vacuumed with HEPA filtered vacuum and mopped with a lint free mop with detergent based solution.

Section 2: Entry / Egress Protocol Stage 1

2.1 Entry / Egress Protocols Stage 1

After final vacuuming and mopping of Clean Zone Construction Site entry and egress to Clean Zone Construction Site will be upgraded to Stage 1 Entry / Egress Protocols to be defined as follows:

A. Clean Zone Construction Site ante room floor is to have 50% of the flooring area on the main Clean Zone Construction Site side covered with tack mat cleanroom flooring material. It is to be refreshed on requirement should any foot prints be noticed in main Clean Zone Construction Site area.

B. After air wash all personnel, construction materials, construction equipment, and lift equipment is to enter or egress the Clean Zone Construction Site only through the ante room barrier moving slowly across tack mat surface to assure clean entry into the main Clean Zone Construction Site. The zippered opening to leading into the ante room is to be fully closed before opening of zippered opening into main Clean Zone Construction Site.

2.2 Gowning Protocols Stage 1

Entry / Egress Protocol Stage 1 will now include gowning of bouffant under hard hat, mustache or beard cover if applicable, coverall, and boot covers.

A. Cleanroom garments should be donned from the top down. Bouffant first, hard hat next, coverall next and boot covers last. Tops of boot covers are to cover bottom of coverall. It is recommended that sweat bands be worn under bouffant and hard hat.

B. Safety Items such as eye or hearing protection are to be worn on the outside of the cleanroom garments. The coverall is not to be unzipped while in the main Clean Zone Construction Site.

2.3 Contraband Items

Items not allowed in the ante room or main Clean Zone Construction Site is as follows:

- Paper, Wood, or Fibrous Materials
- Non Cleanroom Rated Cloths
- Wood Pencils Lead Products
- Sharpie Markers

- Aerosol paints or Propellants
- Circular Saws
- Reciprocating Saws
- Ferrous Metal Cutting Blades
- Grinding Wheels

2.4 Enforcement

Enforcement of cleanroom protocols will be 3 verbal warnings, warning to direct supervisor, then expulsion from Clean Zone Construction Site.

Section 3: Receiving and Cleaning of Cleanroom Construction Materials

3.1 Unloading Area

No materials will be unloaded directly into the Clean Zone Construction Site without being unpacked and cleaned per the following protocols.

3.2 Packaging Removal

Packaging Removal of cleanroom construction materials will be required as follows:

A. Removal of all fibrous packaging materials such as all paper, cardboard, foam, and bubble packagings. Adhesive protective vinyl coatings may be left in place.
B. All films, oils, or manufacturing residues should be removed with detergent based cleaning solution.

3.3 Air Wash

All materials will be required to be air washed with compressed air before entering the Clean Zone Construction Site ante room. Air washing is to be from the top in a downward pattern.

Section 4: Staging of Construction Materials to Clean Zone Construction Site

4.1 Staging Tools and Construction Equipment

A. Tools and construction equipment required for use in the Clean Zone Construction Site is to be air washed outside the Clean Zone Construction

Site ante room then thoroughly wiped down with a detergent based solution inside the ante room.

B. Tool boxes, work pouches, parts bags, and containers must either be emptied, air washed and sanitized or left outside the Clean Zone Construction Area.
C. Construction equipment such as forklifts, man lifts, or material handling equipment must be air washed and wiped down before entering main Clean Zone Construction Site. All rolling equipment is to be supplied with non marking tires.

4.2 Staging Construction Materials Handling

A. Structural steel components arriving at job site with manufactures primer are to receive 1 coat of white epoxy based paint before being staged to Clean Zone Construction Site.
B. Modular components and wall panels with aluminum honeycomb, polystyrene or isocyanurate cores are to be thoroughly air washed before entering Clean Zone Construction Site.
C. Ceiling tiles with non sealed edges are to be sealed with aluminum taping before entering main Clean Zone Construction Site. Any cut tiles or tiles requiring penetration are to be modified and taped outside the main Clean Zone Construction Site.
D. Coatings requiring mixing of powders or resins are to be mixed outside of the Clean Zone Construction Site and inserted only when in liquid form.
E. Flooring compounds require the mixing of quartz silica particulates for color are to be mixed outside the Clean Zone Construction Site.

4.3 Contraband Tools, Equipment, or Materials

Any tools, equipment, materials not meeting the above protocols or releasing fibrous materials or outgassing into Clean Zone Construction Site will be removed. If in doubt about a tool, product or material get pre approval before ordering or renting.

Section 5: Clean Zone Construction Assembly Protocols

5.1 Allowable Fastening Methods

A. Masonry fasteners may only be utilized with HEPA filtration vacuum assist.

B. Self Tapping fasteners may only be utilized with HEPA vacuum assist.

C. Welding or soldering may only be utilized with fume vacuum and fire watch. Hot Work Permits Required.

D. Propellant based fasteners such as Ramset Fast Track Systems.

E. Powder based systems such as Hilti with Operators Permit Only.

5.2 HEPA Vacuum Maintenance

HEPA vacuums utilized in Clean Zone Construction Area are to be cleaned with compressed air and detergent solution after each construction shift or day.

5.3 Continual Cleaning Protocols Construction Stage 1

Continual cleaning of all cleanroom components is required on as clean as you go method. Components are to be wiped down with detergent solution and lint free cloths as installed.

5.4 Daily Cleaning Protocols Construction Stage 1

Daily cleaning or Clean Zone Construction Site will be accomplished at the end of shift activities.

A. All materials inside the Clean Zone Construction Site are to be stocked on rolling scaffolds or carts off the floor. No materials are to be stocked or left on floor at end of shift.

B. Clean Zone Construction Site flooring is to be HEPA vacuumed and mopped with lint free mop and detergent solution including 48” buffer zone outside floor plan.

C. Cleanroom Garments are to be disposed of at end of shift in proper container in ante room.

D. Zippered openings are to be closed and taped at end of shift.

Section 6: Cleanroom Component Assembly Protocols Stage 1

6.1 Prefabricated Cleanroom Wall Systems

Prefabricated cleanroom wall systems may be assembled per manufacturer's specifications with the following exceptions.

A. Base channel sections must be fastened per Clean Zone Construction Site Protocols
B. Post Sections with electrical, plumbing, or process piping are to have the covers left off till after building department inspections. Covers are to be stored inside Clean Zone Construction Site on rolling scaffold off the floor.
C. Door Panels are to be installed without knobs or pneumatic closers and taped back to the wall panel to be fully open. Frames are to be protected by taping metal framing base channel to upright jambs both sides.
D. Windows and pass through devices are to be installed per manufacturers' specifications and thoroughly cleaned with detergent solution as installed.
E. Manufacturers' top channels are to be instead with splices on butt ends to hold channels in alignment.
F. Low level return air plenums are to be thoroughly wiped with detergent solution before and after assembly. If assembled on unfinished concrete flooring the interior floor of the plenum is to have sheet steel covering concrete. Filter Grill is to be covered with visqueen and closed. Top is to be sealed with visqueen while awaiting air distribution connection.
G. Structural Steel support columns and beams, typically shipped with primer coat only, are to be coated with one coat white epoxy before assembly.
H. There will be no cutting, welding, or modifications resulting in particulate intrusion on any prefabricated components. Should a prefabricated component require alteration in the field it will be removed from the Clean Zone Construction Site, modified, then be reinserted while observing all entry / egress protocols.
I. No touch up of prefabricated components is to be accomplished with aerosol paints typically supplied by manufacturer. Any touch up of prefabricated components will be accomplished with low VOC brush enamels or epoxies.

6.2 Prefabricated Cleanroom Roofing Systems

Prefabricated panelized roof systems are to be installed while observing all prefabricated wall assembly protocols with the following additions.

A. Roofing panels are typically supplied with 5" self tapping screws for attachment to supporting steel structure and perimeter wall system top channel. Self tapping screws will require two trades' people to install with HEPA vacuum assist. The trades' person on top the panel inserting the screw will install additional neoprene gasket under screw head. The trades' person under the panel is to vacuum any metal, polystyrene or aluminum shavings while attaching to structural steel member.
B. Panels supplied with H-Mull style connectors are to have gasketing material installed into the H-mull channel before assembly. Tongue and Groove type panels are to have gasket installed per manufacturers' specifications.
C. Roof panel fascia trim is to be installed with gasket material on both horizontal and vertical edges.
D. Roof panels are to be cleaned with detergent solution both top and bottom on a clean as you go method.

6.3 Modular Electrical Systems

Modular electrical systems are to be installed per manufacturer's specifications with the following exceptions.

A. Modular electrical whips penetrating panelized roofing system will require appropriate sized rubber grommets for seals.
B. Modular whips are to be suspended by independent wires per local code compliance. No modular electrical whips are to lie on top of ceiling tiles or be in contact with suspended ceiling grid components.
C. Modular electrical junction boxes must be mounted on threaded rod assemblies.
D. Modular electrical connectors are supplied with their own mounting sleeve to be fastened to underside of roofing system.
E. No modular electrical system is to be energized while being assembled. Upon initial energy start up of modular electrical systems no trades persons are to be on roof of cleanroom environment or in contact with metal surfaces.
F. Electrical subcontractor will be responsible for above protocols and safety compliance.

6.4 Conventional Electrical Systems

A. Some prefabricated modular wall systems come with 2" x 4" x 1 ¼" handi boxes that are not code compliant for other than 120v wiring systems. It is the deepest box that will fit in their post systems. 240v process equipment will require either a corded strain relief type connection into a ceiling box or an additional box placed on top of the 2" x 4" x 1 ¼" handi box. Should an additional box be required to be surface mounted it should a beveled cover such as Wiremold Series 5000 series. The concept of a beveled surface is to minimize particulate entrapment areas. The electrical engineer should consult with the electrical plans reviewer for a solution that will satisfy local electrical codes.

6.5 Low Voltage Wiring Systems

A. Some prefabricated modular wall systems come with post systems with cavities that can accommodate low voltage wiring for control and monitoring systems. They must be UL rated per system to be accepted by most local building departments' electrical review engineers. If no UL documentation or rating is supplied most low voltage wiring can be run in ¾ " conduits but require the knock out on the supplied handi box to be punched out to a ¾" fitting. Low voltage face plates and sensors should be of a flush design.

6.6 HVAC Air Distribution Systems

A. HVAC air distribution systems are to be assembled and cleaned on an as you go method. Joint ceiling mastic must be covered with aluminum faced tape. The ends of air distribution systems are to be capped with visqueen during lunch breaks and at the end of the shift to avoid any ambient particulate from settling in the air distribution system before start up.
B. All supplied thermostats, humidistats, or control panels are to be of a locking design as flush to the wall system as possible.
C. Insulation blankets are to be installed in a particulate free method as possible. Standard sizes may be taped together with aluminum tape. Cut sizes must be modified outside the Clean Zone Construction Site. Edges of all blankets should be sealed with aluminum tape before entering Clean Zone Construction Site.

6.7 Piping Systems

Drainage systems requiring the cutting and trenching of the Clean Zone Construction Site flooring system will adhere to the following protocols.

A. Floor cutting and trenching for drains will be completed before initial preparation of the Clean Zone Construction Site.
B. Visqueen barriers will be erected to contain dust in area to be cut.
C. A negative air pressure device will be utilized to exhaust dust during cutting and excavation. Negative pressure will be required till all trenching is back filled and floor is patched and resealed.

Fire Suppression Systems will require the following installation protocols be observed.

A. Recessed distribution heads with flush white covers must be utilized in the ceiling system.
B. All penetrations through ceiling tiles must be sealed with approved gasketing materials.

All other piping systems will require approved gasketing on all wall, ceiling, or roofing system penetrations.

6.8 Gasketed Cleanroom Suspended Ceiling Systems

A. Gasketed cleanroom ceiling systems are to be installed per manufacturers' specifications.
B. Tape on gasket material is not to be removed till lighting fixture, HELPA / ULPA filtration module, or ceiling tile is ready to be placed into position.
C. All ceiling system components are to be wiped clean with a detergent solution on an as you go method.
D. Vinyl covered tiles with mineral or gypsum cores are to have all four edges sealed with aluminum tape before installation.
E. Cut Tiles for perimeter and special sized opening are to be cut with a cutting device that will leave a square edge. No scoring and snapping of tiles will be permitted.
F. All devices penetrating ceiling tiles will be installed with the penetration opening sealed with aluminum tape and an approved gasket material between the device and the vinyl surface of the ceiling tile.

6.9 Cleanroom Flooring Systems

A. All epoxy resin flooring systems are to be of an antimicrobial technology, giving protection against the growth of bacteria, fungi and mould.
B. Mixing of all powders, quartz silica, or other particulate producing application methods are to be accomplished outside the Clean Zone Construction Site.
C. All flooring systems are to be installed with either an integrated radius cove base with the same finish characteristics of the flooring system or vinyl base system.
D. Flooring systems installations will require the use of negative pressure machines exhausting fumes and particulate to the outside of the existing facilities building envelope from the floor preparation stages though the manufacturers full cure specification. Negative air flow is to be adequate enough where no residual odors from adhesives or epoxy solutions are detectable in surrounding areas and particulate is not allowed to settle on horizontal cleanroom surfaces.
E. Flooring systems will be allowed to cure fully to manufactures specifications before process equipment installation.

Section 7: Entry / Egress Protocols Stage 2 Intermediate Cleaning

7.1 Entry / Egress Protocols Stage 2

Intermediate cleaning of Clean Zone Construction site will consist of a total wipe down of all installed components with a detergent based solution and then a wipe down with 3% hydrogen peroxide and 2% sodium hypochlorite (bleach). Entry and egress to Clean Zone Construction Site will be upgraded to:

Stage 2 Entry / Egress Protocols to be upgraded to include:

A. Clean Zone Construction Site ante room floor is to have 50% of the flooring area on the main Clean Zone Construction Site side covered with tack mat cleanroom flooring material. It is to be refreshed on requirement should any foot prints be noticed in main Clean Zone Construction Site area.
B. After air wash all personnel, construction materials, construction equipment, and lift equipment is to enter or egress the Clean Zone Construction Site only through the ante room barrier moving slowly across tack mat surface to assure clean entry into the main Clean Zone Construction Site. The zippered

opening to leading into the ante room is to be fully closed before opening of zippered opening into main Clean Zone Construction Site.

7.2 Gowning Protocols Stage 2

Entry / Egress Protocol Stage 2 will now include gowning of bouffant under hard hat, mustache or beard cover if applicable, coverall, boot covers and latex gloves with top of

A. Cleanroom garments should be donned from the top down. Bouffant first, hard hat next, coverall next and boot covers last. Tops of boot covers are to cover the bottom of coverall. It is recommended that sweat bands be worn under bouffant and hard hat.
B. Safety Items such as eye or hearing protection are to be worn on the outside of the cleanroom garments. The coverall is not to be unzipped while in the main Clean Zone Construction Site.

Section 8: Cleanroom HVAC Air Handling System Startup

Cleanroom HVAC air handling systems are to be started and run for 24 hours as follows:

8.1 Pre-Filter Rating and Installation

A. 1” x 24” x 24” pre-filters with a MERV 11 rating according to ASHRAE 52.2 standards by independent test laboratory shall be installed in all low level return grills within the cleanroom environment.
B. The appropriate sized pre-filter for the air handling unit with a MERV 14 rating shall be installed in the air handling unit. Depending on filter size metal spacers may be required in the air handling unit.

8.2 Cleanroom HVAC Air Handling System Burn in

A. Air handling equipment will run continuously for 24 hours before installation of HEPA /ULPA Filtration modules.

Section 9: HEPA / ULPA Filtration Modules Installation

9.1 Unpacking and Staging to Clean Zone Construction Site

A. HEPA / ULPA filtration modules are to be removed from cardboard packaging outside of the Clean Zone Construction Site. They are to be left in the plastic packaging bag. Care is to be taken not to touch the filter face.

B. HEPA /ULPA filtration modules are to be air washed with compressed air to remove any fibrous material from plastic bag packing and moved into Clean Zone Construction Site through ante room entry.

9.2 HEPA / ULPA Installation

A. HEPA / ULPA filtration modules will be installed into suspended ceiling filter opening and connected to air distribution system while in plastic packaging bag. Top of bag will be slit to accommodate connection of air distribution connection to collar of HEPA / ULPA filtration module.

B. Face of HEPA / ULPA filtration module shall remain protected by plastic covering till final start up of cleanroom air handling systems.

Section 10: Stage 3 Final Cleaning and Sanitizing at Rest

10.1 Stage 3 Final Cleaning and Sanitizing Protocols

A. Final cleaning of cleanroom environment at rest will be performed with air handling units fully operational but with no process equipment installed. All visqueen barriers shall be removed at this time. Cleanroom environment will be wiped down with 3% hydrogen peroxide and 2% sodium hypochlorite (bleach) solution.

10.2 Gowning Protocols Stage 3

Entry / Egress Protocol Stage 3 will now include gowning of bouffant under hard hat, mustache or beard cover if applicable, coverall, boot covers and latex gloves with top of latex glove overlapping the bottom of coverall sleeve.

A. Cleanroom garments should be donned from the top down. Bouffant first, hard hat next, coverall next and boot covers last. Tops of boot covers are to cover bottom of coverall. It is recommended that sweat bands be worn under bouffant and hard hat. Latex gloves are to be donned after hand washing.

Safety Items such as eye or hearing protection are to be worn on the outside of the cleanroom garments. The coverall is not to be unzipped while in the main Clean Zone Construction Site.

Section 11: Final Clean Zone Cleaning and Sanitizing Operational

11.1 Final Surface Cleaning and Sanitizing

A. All cleanroom process equipment and furniture will be installed following entry / egress protocols sate 3.

B. Final cleaning and sanitizing of cleanroom environment will be performed with all furniture and process equipment in place. All surfaces starting with the ceiling system will be wiped down with 3% hydrogen peroxide and 2% sodium hypochlorite (bleach) solution.

Section 12: Air Flow Testing and Certification

12.1 Testing Standards

The cleanroom environment air flow and particulate counts will be certified by an independent certification agency licensed by the National Environmental Balancing Bureau (NEBB). Testing is to comply with ISO standards 14644-1 though 8. Testing is to include:

- Airflow volume / velocity readings - assures that both unidirectional and non-unidirectional flow areas are properly balanced and unidirectional zones are maintaining proper air patterns
- Room air exchange rates - states if the area is meeting its design airflow
- Cleanroom Recovery Time – states the time it takes the cleanroom to recover from shut down.
- HEPA filter integrity testing - tests HEPA filters and system for leaks
- Non-viable particle counting - reports the amount of airborne particulate of a specified size in the clean zone
- Temperature / relative humidity testing - examines whether the air HVAC controls are functioning properly and uniformly
- Pressure cascade monitoring - verifies that room differential pressures are operating according to design

12.2 Testing Reports

- GMP/CFR 211 and ISO compliant technical report
- Certificates of Compliance (Cleanrooms, Clean Devices, Filters)
- Equipment and Instrument Calibration Report (with NIST Traceability)

Section 13: Systems Validations IQ

Validation of all cleanroom environmental equipment, controls systems, and monitoring systems will be documented to required cGMP standards.

13.1 HVAC Air Handling Systems

A. HVAC Air Handling Systems IQ Objective - To demonstrate that the HVAC systems installed in the cleanroom environment conforms to the purchase specifications and the manufacturers' literature, and to document the information that the equipment meets specifications.

B. Scope - For new installation, modification, replacement, or relocation of any component of the HVAC air handling systems.

C. Responsibility – Mechanical engineer of record is responsible for writing the protocol, supervising the performance of the IQ, verifying the data and writing the IQ report.

13.2 HEPA / ULPA Filtration Systems

A. 2 HEPA / ULPA Filtration Systems IQ Objective - To demonstrate that the HEPA / ULPA filtration systems installed in the cleanroom environment conforms to the purchase specifications and the manufacturers' literature, and to document the information that the equipment meets specifications for air cleanliness rating per ISO 14644

B. Scope - For new installation, modification, replacement, or relocation of any component of the 2 HEPA / ULPA Filtration Systems.

C. Responsibility – Certification Contractor of record is responsible for writing the protocol, supervising the performance of the IQ, verifying the data and writing the IQ report.

13.3 HVAC Controls Systems

A. HVAC IQ Objective - To demonstrate that the HVAC controls system installed in the cleanroom environment conforms to the purchase specifications and the manufacturers' literature, and to document the information that the equipment meets specifications.

B. Scope - For new installation, modification, replacement, or relocation of any component of the HVAC control system.

C. Responsibility – Controls engineer of record is responsible for writing the protocol, supervising the performance of the IQ, verifying the data and writing the IQ report.

13.4 Environmental Monitoring Systems

A. Environmental Monitoring Systems IQ Objective - To demonstrate that the Environmental monitoring system installed in the cleanroom environment conforms to the purchase specifications and the manufacturers' literature, and to document the information that the equipment meets specifications.

B. Scope - For new installation, modification, replacement, or relocation of any component of the environmental monitoring systems.

C. Responsibility – Environmental monitoring systems engineer of record is responsible for writing the protocol, supervising the performance of the IQ, verifying the data and writing the IQ report.

13.5 Reports Inventory

- HVAC Air Handling Systems
- HEPA / ULPA Filtration Systems
- HVAC Controls Systems
- Environmental Monitoring Systems

13.6 Reports Requirements

For each Air Handling Unit (AHU) installed, engineer of record will describe the units and prepare a list of the units, the rooms and quality of air they supply is entered in an HVAC room matrix:

HVAC IQ
Room No.
Room Name AHU No.
ISO Classification Area (sq. ft.)
Ceiling Height
ST. Pressure (In. WG)
Temp. (+/- 5 F)
Humidity RH (+/- 5 %)
Process Exhaust (cfm)
Pressure Exhaust (cfm)
Supply Air Flow (cfm) Rm. Ave.
Velocity Air Changes AC/HR +/- 20%b)

Typical components for each AHU are:

- Condenser Units
- Fan Units
- Heater
- Dehumidifying Systems
- Pre-filters
- Reheat coil
- Cooling coil
- HEPA / ULPA filters

Describe any required supporting utilities: electrical, water, air inlets, etc.

Procedure For each AHU, fill in the prepared checklist with the detailed mechanical and electrical specifications, drawings, etc. (as itemized in the IQ format) for each component as listed in the IQ format. The individual component checklist includes a space to record the information plus any deviations found during the installation check. Reporting Responsible person verifies that the information is complete, prepares the deviation report and the Installation Qualification Report and, submits to clients QA person.

Section 14: Cleanroom Closeout Journal

14.1 Closeout Journal Inventory

- Architectural Engineered Design Drawings
- As Built Drawings
- Operational Manuals
- Equipment Warranty's from OEM
- Installation Warranty's from General Contractor and Subcontractors
- IQ Reports from Engineers of Record

Section 15: Cleanroom Systems Maintenance Journal

15.1 Required Maintenance Scheduling

- Air Handling Systems
- HEPA / ULPA Filtration Systems
- Control Systems
- Monitoring Systems