THE UNIVERISITY OF TOLEDO
HEALTH SCIENCE CAMPUS
CAPITAL IMPROVEMENT

HOSPITAL ENVIRONMENT CLEAN CONSTRUCTION

(H.E.C.C.) PROTOCOL

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PROJECT:_____

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DEVELOPED BY:

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Summary of Clean Construction Guidelines

1. Maintenance of ventilation is paramount.

    - All efforts should be made to achieve the following.
    - Prevent contamination of existing house ventilation by isolating supply air dampers in the construction areas to prevent a positive pressure within the construction space.
    - Maintain construction (dirty zone) in a state of negative pressurization.

2. Clean room activities (construction of ante room and soft wall)

    - Minimize dust in work area.
    - Maintain soft wall or hard wall barriers.
    - Use tacky floor step off mats at the entrance to the construction area.
    - Use appropriate cover garments.
    - All construction debris will be contained to prevent contamination of surrounding clean areas.
    - All debris will be removed in a covered and sealed container or cart.

3. Documentation of compliance will be maintained

4. Use Hepa filtered vacuums if available or by special request by University of Toledo Heath and Safety departments.

* Clean construction permit will be issued by Infection control.

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1. ESTABLISHING H.E.C.C. PROTOCOL

1.1 Background

Today's "dirty" construction practices requires that entire sensitive areas of hospitals close down and relocate their operations before starting construction and maintaining this temporary operation until after all construction is fully completed. This always results in much higher internal costs and resource strain for the medical facility above and beyond the actual construction costs. "Dirty" construction activities allow for foreign particle contamination to be deposited and built up in layers in the sensitive medical areas. These layers of contamination are very hard to eradicate after construction is completed and provide a great environment for biological growth and the opportunity for foreign particles to become airborne and contaminate other areas of the medical facility.

A clean room is defined as enclosed area that is controlled environmentally over atmospheric contamination, temperature, pressure and humidity, in which the concentration of airborne particles is controlled through specific procedures for one or more clean zones. The clean zone is a defined space in which the concentration of airborne particles is controlled to meet a specific cleanliness class. The main purpose of a cleanroom environment is to contain airborne particles, relative to size and density, and maintain containment at a consistent level. To provide an aseptic hospital environment, an effective sanitization program must also be implemented. The basis of the Cleanroom Construction Protocol is to maintain the integrity of the existing cleanroom environment before, during, and after construction in the cleanroom is completed.

The Medical College of Ohio through the consulting engineering of Benchmark Engineering Group, Inc. has developed and implemented a hospital based Cleanroom Construction Protocol for any construction work performed in the sensitive areas of the University of Toledo's Health Science Campus medical facilities know as the Hospital Environment Clean Construction (H.E.C.C.) protocol

1.2 H.E.C.C. Goal

The most obvious goal in the process of construction in a hospital environment is to maintain clean and sanitary conditions. If medical functions are being carried out in the area where the construction is necessary, the motive is obvious: not to contaminate these operations. A clean area environment consists of many surfaces, and deposition of contaminants can take place on these surfaces. These contaminants can then become re-entrained in the air stream, usually at the least convenient time.

The main focus in the medical area is to prevent airborne bacteria from infecting patients, and this is most critical in areas where bacteria can gain immediate access inside the patient's body. HEPA filters provide containment of the bacteria from the supply air, but construction in the hospital environment can cause the release of many more airborne particles and foreign bodies to contaminate the area.

1.3 H.E.C.C. Strategy

A strategy of clean construction must be established using the following steps:

1. Avoidance is the most desirable strategy. If operations can be performed without generating contaminants, then contamination problems become nonexistent. In actual operation, however, avoidance cannot always be achieved.

2. Isolation is next: keeping the contaminants from critical areas. If the first two strategies break down, as is almost always the case for some systems.

3. Containment and maintain the lowest possible level of construction particle contamination resulting from the actual construction in the cleanroom construction area.

4. Cleaning follows: this involves techniques to remove contaminants from the surface on which they have been deposited.

5. Prevention of the ingress of additional "outside" construction particle contamination from entering the actual cleanroom construction area.

6. Verification and inspection: to evaluate the effectiveness of the contamination control program. Without a method of monitoring the cleanliness of a surface, there is no way to verify the strategy of prevention or isolation, or the effectiveness of cleaning.

Overseeing the H.E.C.C. program is a philosophy of cleanliness. In all aspects of a construction program, one must *think clean*. This should be pervasive in every task, from design through construction through evaluation and startup. Involvement of the tradespeople in this philosophy is critical: they are the ones performing the work and they are the ones who can often spot problems that would pass by a more casual observer.

The H.E.C.C. Protocol provides the contractor with cleanroom construction procedures to utilize during the entire construction process. The protocol will provide for the protection of the existing clean environment, and eliminate the contamination from the construction process in the new clean area expansion. The H.E.C.C. Protocol supplies the detail and specifications on the steps to build "softwalls" and perform clean construction tasks and achieve the Protocol objectives in the clean construction envelope.

2. H.E.C.C. PREPARATION

2.1 Clean Construction Planning

The first phase of planning involves an analysis of the tasks to be performed in the installation process. Four questions must be asked in this analysis:

What tasks are involved in the installation?
It is imperative that the tradespeople who are performing the installation be involved in answering this question, as there are many "minor" tasks that are often forgotten.

How contaminating are the tasks?
If the tasks involved are relatively clean tasks, such as connecting flange-type connectors, the considerations are much different than if welding is to be performed.

Can prefabricated assemblies be created?
Some of the contamination concerns can be avoided if prefabricated assemblies are a possibility. This allows the reduction of contaminating tasks within the cleanroom, simplifying the installation concerns.

How clean does the construction environment need to be?
If the interior of utility piping is to be exposed, the cleanliness level of the construction site needs to be very clean. On the other hand, if only electrical connections are involved, the cleanliness requirements are lessened. The answer to this question has a large bearing on the way isolation of the construction area is achieved.

When the answers to these questions are established, a review of the working environment can be performed. The cleanliness needs of the construction area can be compared to the contaminating characteristics of the tasks to be performed, and to the cleanliness level of the surrounding area. This drives the cleanliness of the construction area and the amount of isolation needed between the construction area and the remainder of the cleanroom.

2.2 Isolation of Area

In isolating a construction area from a cleaner area, some sort of barrier to contaminant migration is required. This barrier may consist of rigid walls, soft walls, or air curtains, but it must inhibit the passage of airborne contaminants. Once this barrier is defined, the air movement within the isolated environment must be considered.

The more common approach is to direct airflow of specified cleanliness through this environment so that no contamination of surrounding areas occurs. To accomplish this, a review of all airflow inputs and exits is required, as well as a look at any turbulence

generating equipment that may overcome the directed airflow's. It is also important to consider the differential pressure between the isolated environment and the remainder of the hospital environment. An isolated environment with either soft or rigid walls generally has a large surface area, and a relatively small pressure differential can dislodge the walls. On the other hand, it is important to keep a slightly negative pressure in the isolation environment to minimize contaminant migration into the hospital environment through leaks in the barrier.

A significant challenge in dealing with an isolated clean construction envelope, within a hospital environment is the entrance and egress requirements for tradespeople. This is especially challenging when the isolated envelope is small. The need for exotic entrance and egress schemes becomes more critical as the difference in the cleanliness level between the hospital environment and the construction area increases.

If the size of the construction area permits, and there is a significant difference in contamination level between the hospital environment and the clean construction envelope, airlocks and a gowning/de-gowning area can be provided. This will increase the capability of the barrier to prevent contamination migration from the isolated clean envelope to the hospital environment.

When constructing an isolated environment, caution is in order. Access to nearby operating equipment must be maintained, both for operation of the equipment and maintenance of the equipment.

2.3 Safety Concerns

A final consideration in the construction of an isolated environment is the access to safety equipment. People in the isolated environment must have free access to appropriate safety equipment, based on the hazards present in the environment. How exotic the requirements for an access scheme are depends on the level of isolation. In a started, softwall environment, which allows free access through the wall, little consideration of this will be required. In a situation where an airlock is used, access to safety equipment becomes a more serious consideration.

2.4 Documentation

The next item involved in preparation is the generation of required documentation. These documents generally fall into three categories: installation documents, cleanroom protocols, and construction documentation. The two classic construction documents are the drawings and the bill of materials (BOM). It would be difficult to overstate the importance of making cleanroom protocols available and understandable to construction personnel. The "cleanroom spec" that is used for the protocol of the existing cleanroom is a necessary starting point, and from that document training documents can be generated. Finally, signs posted at various locations as reminders can be invaluable. A document that has proven critical to a number of cleanrooms is a Construction Manual. This document contains comprehensive documentation for equipment installation,

documentation of all utility systems in the cleanroom, materials requirements for each system, and the cleanroom procedures used by construction personnel.

The documentation phase of the effort ends with an installation review. This review takes place prior to the commencement of installation, and is attended by the people involved in both the design and implementation of the installation. The purpose of the review is to ensure the correctness of the installation procedure and to provide any last-minute information that has come to light.

3. CLEAN CONSTRUCTION ENVELOPE

The construction in the sensitive areas of the medical facility will be performed with H.E.C.C. Protocol procedures that apply across the entire clean construction envelope. The envelope area is defined by the following:

- Outside construction area (dirty work)
- Access to the work area from the outside (entry)
- Materials & Tools Cleaning area (cleaning)
- Clean tools & materials lay down area (pre-staging)
- Clean construction work area (clean work)

3.1 Outside Construction Area for Dirty Work

All dirty work construction that does not have to take place in the clean work area will be performed outside the clean envelope area. This includes cutting and building components subassemblies that can be taken into the clean work area and then fully assembled. This work will take place outside of the clean envelope and each subassembly will cleaned prior to entering the clean work area.

3.2 Work Area Access / Egress Area

This comprises of the hallways, stairs, elevators, and adjacent rooms near the clean work area that workers and materials will travel through in order to reach the cleaning area, clean storage area and clean work area.

3.3 Materials & Tools Cleaning Area

This is a special cleaning area that is within the clean envelope where all tools, materials and subassemblies will receive a final cleaning prior to entering the actual clean work area. Any tools that were used for construction in the clean work area will be returned daily and cleaned prior to being used again in the clean work area.

3.4 Clean Materials & Tools Lay Down Storage Area

All materials, tools and subassemblies that have been cleaned and are waiting to be used or installed will be stored within the clean envelope to maintain their clean condition.

3.5 Clean Construction Work Area

All necessary final assembly and construction work in a sensitive area will be performed inside the softwalls of the clean work area. The entire area will be cleaned each day per the clean construction procedures. No debris will be broken down or cut apart further while in the clean work area, all debris will be removed from the clean area and disposed of per approved process.

4. INFECTION CONTROL PERMIT

4.1 Construction Activity

The first step in a successful clean construction project involves project definition. This takes place prior to any construction activity, and involves defining the (Scope and Duration) that will take place:

TYPE	SCOPE	DURATION
TYPE A	Inspection, non-invasive activities - measuring & testing, minor moving of equipment and access to above ceiling and/or below floor systems – low levels of disturbance and traffic	Short duration – a few hours maximum
TYPE B	Small scale activities – minor demo and removal, drilling, mounting, small equipment or fixture installation w/ low to moderate levels of dust & debris generation, minor traffic	Short duration – less than a full work shift
TYPE C	Medium scale activity – demolition and removal, new or remodeled rooms, fixtures and equipment installation, generates moderate to high levels of dust and medium construction traffic	Intermediate duration greater than a full work shift
TYPE D	Major construction activities – large scale demolition, new and remolded rooms, structural modifications or additions, major fixture and equipment installation – generates high levels of dust and construction traffic	Long duration requiring multiple or consecutive work shifts

4.2 Risk Group

The second step involves the effect and risks involved based on the Infection Control Risk Group assessment:

GROUP	RISK	GROUP / AREA
GROUP 1	Least Risk	General commercial space not used for any medical procedures such as offices, conference rooms, classroom, lecture halls, maintenance, laundry cafeteria, etc.
GROUP 2	Medium Risk	Standard care medical facilities such as clinics, evaluation rooms, waiting rooms, standard in-patient hospital rooms, nursing stations, hallways, etc.
GROUP 3	Medium / High Risk	Research areas, Laboratories, Emergency room, Pharmacies etc.
GROUP 4	Highest Risk	Surgical rooms, Post-op, Intensive Care Units, Burn units, Delivery rooms, etc.

4.3 Permit Classification

The next step is to determine the classification and requirements necessary to perform construction in the hospital environment. Classification is determined by evaluating the Construction Activity and the Risk Group for the amount of work and sensitivity of the hospital function in the work area.

The following chart indicates the general assignment of classification based on the Risk Group verses the Construction Activity. This is just a general indication, all permits will be evaluated individually and have a classification assigned based on the individual evaluation.

	GROUP 1	**GROUP 2**	**GROUP 3**	**GROUP 4**
TYPE 1	CLASS I	CLASS I	CLASS II	CLASS II
TYPE 2	CLASS I	CLASS II	CLASS III	CLASS III
TYPE 3	CLASS II	CLASS III	CLASS IV	CLASS IV
TYPE 4	CLASS II	CLASS III	CLASS IV	CLASS IV

In general, the classifications can be described as follows:

CLASS I - Is used for minor maintenance projects, inspections and remodeling in low risk group areas.

CLASS II - Is used for small maintenance and inspection projects in high-risk areas and medium level construction projects in low risk areas.

CLASS III - Is used for small construction projects in high-risk areas and large construction projects in medium-risk areas.

CLASS IV - Is used for medium to large-scale construction in the medium to high-risk areas.

4.4 Permit Submittal

The last step is to submit the permit information to the Infection Control Department for approval of the classification and requirements necessary to perform the construction.

5. H.E.C.C CLASS REQUIREMENTS

5.1 CLASS I

Isolation:

- None

Containment:

- General execution of work by methods that minimize raising dust from construction operations
- Immediately replace any ceiling tile displaced for visual inspection or access.

Cleaning:

- General sweeping & wipe clean of any dust or debris in the area

Prevention:

- None other than standard safeguard requirements for the hospital area

5.2 CLASS II

Isolation:

- Seal any unused doors with duct tape
- Block off and seal air vents
- Turn off or isolate HVAC system in areas where work is being performed

Containment:

- Provide active means to prevent air-borne dust from dispensing into the atmosphere
- Water mist work surfaces to control dust while cutting and drilling
- Contain construction waste before transport in tightly covered containers
- Remove and seal all trash liners prior to removal from clean area

Cleaning:

- Wipe down all surfaces effected by the construction activity with disinfectant before leaving work area
- Wet mop and vacuum with HEPA filter vacuum before leaving work area
- Do not remove softwalls or barriers until complete project is thoroughly cleaned by Environmental Services Dept.

Prevention:

- Clean all tools prior to entering work area
- Place dust mat at entrance and exit of work area
- Standard safeguard requirements for the hospital area

5.3 CLASS III

Isolation:

- Seal any unused doors with duct tape
- Block off and seal air vents
- Turn off or isolate HVAC system in areas where work is being performed to prevent contamination of duct system
- Establish Clean Envelope with completely constructed softwalls prior to construction

- Maintain negative air pressure within work area utilizing HEPA equipped air filtration units

Containment:

- Provide vacuum for any drilling and cutting to prevent air-borne dust from dispensing into the atmosphere
- Water mist work surfaces to control dust while cutting and drilling
- Contain construction waste before transport in tightly covered containers
- Cover and tape up transport receptacles or carts
- Remove and seal all trash liners prior to removal from clean area
- Remove demolition materials and fixtures carefully to minimize spreading of dirt and debris
- Limit the amount of work in the clean envelope by constructing assemblies or sub assemblies outside of clean envelope as much as possible

Cleaning:

- Wet mop floor with disinfectant daily before leaving work area
- Vacuum with HEPA filter vacuum daily before leaving work area
- Wipe clean all tools after use
- Washable mats cleaned, as needed, after breaks and shift changes. Bacteria will grow under mats if not cleaned properly.
- Tack mat sheets are to be pulled as the sheets become dirty.
- Wash windows in one direction, strokes top to bottom
- Do not remove softwalls or barriers until complete project is thoroughly cleaned by Environmental Services Dept.

Prevention:

- Clean all tools prior to entering work area
- Clean all equipment and fixtures prior to entering the clean envelope
- Place dust/tack mat at entrance and exit of work area
- Observe safeguard requirements for the hospital area (University of Toledo Safety Policies)

5.4 CLASS IV

Isolation:

- Seal any unused doors with duct tape
- Block off and seal air vents
- Turn off or isolate HVAC system in areas where work is being performed to prevent contamination of duct system
- Establish Clean Envelope with completely constructed softwalls prior to construction
- Maintain negative air pressure within work area utilizing HEPA equipped air filtration units
- Construct Anteroom transition area where and all personnel area required to pass through and be vacuumed using a HEPA vacuum cleaner and change their cloth or paper coveralls each time they enter or leave the clean envelope

Containment:

- Provide vacuum for any drilling and cutting to prevent air-borne dust from dispensing into the atmosphere
- Water mist work surfaces to control dust while cutting and drilling
- Contain construction waste before transport in tightly covered containers
- Cover and tape up transport receptacles or carts
- Remove and seal all trash liners prior to removal from clean area
- Remove demolition materials and fixtures carefully to minimize spreading of dirt and debris
- Limit the amount of work in the clean envelope by constructing assemblies or sub assemblies outside of clean envelope as much as possible
- Seal all pipes, holes, conduits, and punctures appropriately

Cleaning:

- Wipe down all softwalls, existing walls, fixtures, and all surfaces with disinfectant after each shift
- Wet mop floor with disinfectant after each shift
- Vacuum with HEPA filter vacuum after each shift
- Wipe clean all tools after use
- Wash windows in one direction, strokes top to bottom
- Wash all trash receptacles inside and out with surfactant cleaner daily
- Washable mats cleaned, as needed, after breaks and shift changes.
- Tack mat sheets are to be pulled as the sheets become dirty.
- Do not remove softwalls or barriers until complete project is thoroughly cleaned by Environmental Services Dept.
- Machine scrub flooring using DI water and approved cleaning solution. (DI water mixed with 10% IPA alcohol) monthly or at end of project
- Wash all ceilings, walls, under table tops, edges of entire clean envelope and around equipment, using specified cleaning tools monthly or at end of project
- Regular P.M. on pre-filter for return air in room, vacuum/wet-wipe/re-vacuum duct, before replacing pre-filters.

Prevention:

- Clean all tools prior to entering work area
- Assigned cleaning tools never leave the clean envelope or are used in other areas
- Clean all equipment and fixtures prior to entering the clean envelope
- Place dust/tack mat at entrance and exit of work area
- Anteroom transition area where all personnel are required to be vacuumed using a HEPA vacuum cleaner before entering and leaving the clean envelope or where they can change their cloth or paper coveralls each time they enter or leave the clean envelope
- All personnel entering the work site are required to wear shoe covers and/or cloth or paper coveralls and gloves
- Standard safeguard requirements for the hospital area
- Supervision/Monitoring personnel activities monitored which might cause contamination during construction phases, i.e. smoking, eating, etc.

- Providing a clean envelope supervisor for gowning and pre-staging procedure monitoring and restricting access from outside the clean envelope.

6. CONSTRUCTION PROCEDURES FOR H.E.C.C.

The construction phase of the operation is the most visible, but will go smoothly if the proper attention was paid to the preparation phase. Discussion of the construction phase will be divided into four categories: equipment entry, equipment installation, cleanability, and safety during construction.

6.1 Construction of Softwalls

- Contractor will clean the softwall materials per the H.E.C.C. Protocol.
- Contractor will wear gowning as necessary and assemble the softwalls per the H.E.C.C. Protocol design and sketches.
- 2x4 metal framing channels will be taped into place on the floor and walls, then 2x4 metal studs will be fastened to the framing channels.
- When the framework is completed, the first section of poly film will be taped with ¾" dbl. sided tape to the stud and channel edges, starting left to right, from the bottom up to 60" on the inside and outside of the softwall.
- Outside of the first section, tape a strip with 3" dbl. sided tape 1 ½" below the top.
- The second section will overlap the first by 6", and will be taped to the first section by the 3" tape.
- The second section of poly film will be taped to the sides of the top channel will ¾" dbl. sided tape and the top of the top channel with 3" dbl. sided tape, on the inside and outside of the softwall.
- In the access doorway area, the poly film will be taped to the sides of the framing stud with ¾" dbl. sided tape and the face of the framing stud with 3" dbl. sided tape, on the inside and outside of the softwall.
- Lastly, a poly film cover will be taped to the top of the top channels, and the existing wall with 3" dbl. sided tape.
- The top cover will overhang 6" on the outside of the top channels.
- The access doorframe will be fastened through the poly film to the framing studs.
- The door will be mounted to the frame, swinging into the clean work area.

* When possible use zipper style entry from the soft wall entryway.

6.2 Tools

- All tools must be carefully cleaned prior to being brought into the clean envelope, and common tools should be dedicated for clean envelope use.
- Only tools appropriate for clean envelope use should be admitted, and no rust, flaking paint, etc., on tools are allowed.
- Tools are generally cleaned using a degreaser or ultrasonic cleaning unit for gross dirt and oil removal, followed by a wipe down with isopropyl alcohol.
- Use woven, non-shredding cleanroom wipers or lint free cloth with alcohol for tool cleaning process.
- Appropriate packaging (e.g., bagging) of the clean tools is required if the cleaning is not done in proximity to the cleanroom entry point.
- No power tools are allowed in the clean envelope area unless they are approved per the construction design, and preparation has been taken for the areas where they will be used.

- Large tools and equipment, when needed, will have an initial cleaning with a water wash or a high-pressure sprayer away from the cleanroom, with industrial cleaners used as necessary. This is followed by an alcohol wipe down upon clean envelope entry.

6.3 Demolition

- Existing demolition items in the clean work area will be removed in sections without excessive cutting and drilling.
- Any drywall will be cut by hand and removed in sections.
- All cutting and screw removal tasks will be vacuumed per the clean construction procedure.
- All debris will be covered and contained prior to the removal from the clean work area.
- The entire area will be cleaned each day per the clean construction procedures.
- No debris will be broken down or cut apart further while in the clean area, all debris will be removed from the clean area and disposed of per approved process.

6.4 Penetrations

- Special techniques for floor and wall penetration are required, generally using a double-vacuum approach.
- Dust-producing operations must be minimized, but when necessary they can be performed as long as the dust is captured prior to depositing on cleanroom surfaces.

6.5 Materials

Wood -

- Any wood material encountered or installed will be cut outside of the clean area, including the softwall area.
- If wood is to be cut (removed) from the clean area, vacuum the cut area while cutting. All cuts should be sealed immediately after cutting.

Metals –

- All metal material should be cleaned before entering the clean area.
- All fabrication, grinding, finishing, painting, etc. will be performed outside of the clean area.
- Metal components will be brought into the clean area in complete assemblies, or in bolt together sections.
- Cutting and de-burring operations are performed outside the clean area, and welding is minimized, with the vapors captured by a local exhaust.

Cement/Masonry –

- Minimize any necessary cement or masonry work in the clean area.
- If concrete or masonry cutting (demolition) is required, an additional softwall area will be constructed around the area to be cut, and only wet cutting will be allowed.
- All concrete or masonry cuts will be sealed with approved sealer immediately after cutting.

- All masonry cutting will be done outside of the building, and all masonry units will be cleaned prior to entering the clean area.
- All concrete and mortar will be mixed thoroughly outside the building.
- All new concrete and masonry will be sealed as soon as possible after it is installed.

Drywall –

- All drywall or similar gypsum wallboard will be cut outside of the clean area.
- All cuts and edges will be coated with water or dust contained surfactant.
- Any cutting (demolition) of existing gypsum wallboard will be done by hand using a utility knife or similar.
- All panels will be installed face out, do not install damaged or damp panels.
- Butt panels together with no more than a 1/16" gap.
- Locate both edge or end joints over supports.
- No power sanding will be permitted in the clean area.
- Any hand sanding performed will be vacuumed as it is sanded per the clean construction procedure.

Tile, Carpet, Trim –

- All tile, carpet, trim, & base cutting and adhesive mixing will be done outside the clean area.

Painting –

- All paint mixing and preparation will be performed outside of the clean area.

Piping –

- Wet wipe exterior of all loose dust and soiled areas.
- Rinse and newly installed piping systems.

Utilities –

- The finished installation must be cleanable from all sides.
- Flex lines should have a minimum of extra material, or must be suspended such that cleaning is not inhibited.
- An alternative is to create a utility raceway between the equipment and the utility manifold that facilitates cleaning and keeps piping neat.

6.6 New Construction

- If there is to be a time lag between the demolition and the new construction and equipment installation, where the clean area is open and not used, it is recommended that an additional temporary soft wall be constructed to seal the opening between the newly opened area and the softwall area.
- This will keep other construction contamination out of the clean area and keep the area clean while it is not being used, so daily cleaning will not be necessary.
- When construction in the area resumes, clean the area outside of the temporary softwall before removing it, then clean construction procedures will continue.

6.7 Equipment Installation

- The equipment entry process begins with unpacking the equipment, the first step in unpacking is to determine the cleanliness level of the equipment as it stands on the dock.
- Remove contained packing materials, especially wood and cardboard.
- If an inner bag exists, do not remove and proceed to clean area.
- When moving equipment into the cleanroom, be sure to clean the wheels of the movement device.
- Rack mats or tacky flooring assist in cleaning while the item is rolling.
- It is also necessary to minimize the pressure differentials during the equipment movement.

6.8 Anteroom / Airlock

- To assist in the implementation of construction protocols, prefabrication rooms exterior to the cleanroom are often constructed and kept at lower pressure than the clean area.
- These rooms are external clean zones, and may be either permanent or temporary structures.
- Provide gowning and gloving capability, with a changing area for clean area garment donning and tool storage.
- These rooms allow the construction of prefabricated assemblies in a clean environment, without all of the restrictions inherent in cleanroom practices.
- Negative pressure should be maintained with flow from clean construction area.

6.9 Safety

- An important consideration during all aspects of construction is safety.
- Many construction procedures involve the use of hazardous materials, and special considerations for those materials are required.
- For gaseous chemicals, piping status indicators are needed. These indicators communicate the leak-check status and provide a warning when the hazardous materials are present in the line.
- There also needs to be an indicator of the status of alarm systems, and the status of gas cabinets for hazardous gases.
- Appropriate safety equipment must also be installed before hazardous materials are used.

6.10 Cleaning the Clean Area

While the level of cleanliness of the clean envelop will be dictated by the Infection Control Class Rating.

Cleaning equipment needed for post-construction cleaning includes:

- Cleanroom wipes
- Dispense bottles
- HEPA-filtered Vacuum cleaners
- Mops w/ plastic handles (no wood)
- Cleaning solutions
- Ladders
- Plastic buckets w/ wringers
- HEPA-filtered floor machines

- Trash bags
- Tacky rollers
- HEPA-filtered floor buffer
- Clean non-shedding mop heads
- Squeegees
- Dispense applicator floor tools for wet-wiping procedures

Other cleaning equipment must be constructed of cleanroom-compatible materials, and must be non-contaminating.

The cleaning materials used in a cleanroom must be chosen based on the clean area requirements, compatibility with the materials used in the construction and operation, residues, dispensing methods, material degradation and shedding characteristics. Generally, sprays must be performed into a cleanroom wiper located within inches of the spray nozzle. If stored wet, the residues of the storage medium must also be considered.

Entry of cleaning materials into the cleanroom is essentially the same as all material entry. De-packaging of the material should be away from the clean envelope and storage and distribution take place inside the cleanroom.

6.11 Finish and Clean Up

Upon completion, all clean construction procedures for clean up apply to the clean area. After the clean area is cleaned, the softwalls can be removed, and the clean area should be cleaned one more time. Care must be used when removing the soft walls to ensure that any contamination trapped under or on top of the walls is cleaned up and not spread around the clean area.

7. CLEANING PROCEDURES FOR H.E.C.C.

The cleaning should begin at the most contaminant-sensitive area and proceed through the cleanroom toward the least sensitive area. Particle monitoring equipment should be used during cleaning procedures throughout the facility to maintain control of particle levels.

7.1 Ceilings

- The ceiling should be completely cleaned first.
- Vacuum the grid only on HEPA-filtered diffusers, never touch the HEPA filter media.
- Vacuuming and wet-wiping the ceiling tile and light fixture lenses should be cleaned in one direction, overlapping strokes.
- Be sure the tiles are sealed and cannot be moved before attempting to clean

7.2 Walls

- Vertical partitions, including walls, windows, and doors should be cleaned in similar manner.
- Beginning at the ceiling, and working in a vertical line toward the floor, vacuum with overlapping strokes.
- This is followed with wiping or mopping, utilizing DI water and a surfactant.
- Rinse with DI water and finally re-vacuum.

7.3 Floors

- Raised, grated, epoxy and vinyl floors can be maintained in the following manner:
- Vacuum the floor starting in the most contaminant-sensitive area, using overlapping one-directional strokes.
- Upon completion of vacuuming, wet-mop the floor in identical manner.
- Rinse with DI water and re-vacuum the entire surface of the floor.

7.4 Work Surfaces

- Using a pre-moistened cleanroom wiper, which has been folded into quarters, begin at the rear of the surface and wipe in a straight line from left to right.
- After each pass, expose a fresh area of the folded wiper and with a slight overlap, using one-directional stroke, wipe the adjacent area.
- Clean under the tabletops, legs and foot rest with a moistened cleanroom wipe.

7.5 Special Precautions While Cleaning

1. Be careful not to penetrate filters with the mop handle when removing the mop from the mop bucket.
2. Be sure to monitor the sweeper bags on the HEPA-filtered vacuum cleaners as they fill quickly and may brake, causing damage to the liners.
3. Wipe the mop buckets down inside and out, before and after use.
4. Never use the mop designated for the cleanroom outside the cleanroom area. Dedicate each area with a mop and bucket and label them to be used only in that area. (mops may be down-graded to the chase area)

5. Vacuum cleaners are to be cleaned inside and out each day, including the electrical cords, to remove particles collected from dragging on the floor.

8. PROJECT WRAP-UP

The results of a H.E.C.C. construction project can be evaluated by looking again at the original concepts. In reviewing the original goals:

- Was the clean area maintained at its desired cleanliness level?
- Was a system of clean utilities created?
- Were the clean construction methods used and adhered to?

If the answer to these questions is "yes," the construction project was successful. If the answer to one or more of these questions was "no," then an evaluation of what was compromised is in order. This will assist in the development of the plan for the next installation.

This evaluation can be performed by evaluation the strategies that were considered.

- Was contaminant generation prevented?
- Were contaminants isolated from critical areas?
- Did the cleaning methods employed effectively remove contaminants?
- What was the effectiveness of the verification and monitoring methods?

A final evaluation of the philosophy of the project may be in order.

- Was the proper priority given to the cleanliness of the utilities?
- Was a "think clean" attitude displayed by all those involved?
- Were the tradespeople actively involved in the concepts of clean construction?

Clean construction methods grow and develop as technology changes and as new methods are found for performing construction tasks. A thorough evaluation of each installation, with an eye to improvement, will allow a continuous refinement in clean construction methodology.