Modular Sterile Cleanroom Finalized Testing Plan

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Design Requirements Summary

1.1 Customer Requirements

Based on the client's project requirements the team set the customer requirements as follows:

- **CR1: Modular**. Modular refers to the finished cleanroom's ability to be disassembled and reassembled with ease.
- **CR2: Transportable**. With a modular cleanroom comes a transportable one. The client requested a cleanroom that can be disassembled and transported if needed to other locations.
- **CR3: Spacious**. The client also requested a spacious cleanroom with the ability to house at least six people.
- **CR4: Safe**. The frame of the cleanroom can structurally support the weight of the necessary number of fan filter units (FFUs).
- **CR5: ISO Class 7 Compliant**. Since the cleanroom will be used for medical device manufacturing, it needs to be ISO Class 7 compliant to be certified at the end of the project.

1.2 Engineering Requirements

The engineering requirements selected by the design team were generated directly from the customer requirements. The first two customer requirements of modular and transportable are ease of construction-based requirements and will not be evaluated as engineering requirements. Instead, they will be considered during the design for manufacturing process. The customer requirement of spacious directly relates to the engineering requirement of room area. The customer requirement of ISO Class 7 compliant encompasses six engineering requirements: positive pressure, particle count, particle size, airflow, ceiling coverage, and Reynold's number. The thresholds, limits, and constraints of each engineering requirement is detailed below.

- **ER1: Spacious**. The client requested an area of 216 ft^2 to account for the customer requirement of housing at least six people. Constraints to the spaciousness of the room include support beams. The client does not want support beams in the room if possible.
- **ER2: Positive Pressure**. The positive pressure difference between the inside and outside of the cleanroom must be a minimum of 0.2 Pa. This value represents a lower limit as pressure in the cleanroom can be greater than 0.2Pa and still maintain particle count. The main constraint to the overall pressure difference is that is must be maintained with people moving in and out of the cleanroom.
- **ER3: Particle Count and Size**. Particle count and particle size must meet the ISO Class 7 requirements of a maximum of 352,000 particles of size greater than 0.5 μmμm, 83,200 particles of size greater than 1 μmμm, and 2,930 particles of size greater than 5μmμm. The particle count and size are measured as a minimum limit. The particle count and size is constrained by the FFU HEPA filter and speed. The strictest requirement for the particle count and size is the maximum of 352,000 particles of size greater than 0.5μmμm. Therefore, that constraint will be used as the main engineering requirement for particle size and count.
- **ER4: Airflow**. Airflow must meet the requirement of 0.051-0.076 m/s or 10-15 ft/s for the entire room and 60 – 90 air changes per hour [3]. Airflow like positive pressure, particle count and size will be measured as a minimum limit with the strictest requirement of 10 ft/s and 60 air changes per hour. The airflow rate is constrained by the speed of the FFUs.

- **ER5: Ceiling Coverage**. Ceiling coverage must be 15-20% covered with FFUs [2]. This design will aim to meet the minimum limit of 15% ceiling coverage. The biggest constraint on ceiling coverage is the structural supports of the ceiling frame. The frame will need to be specifically designed to support the weight of the minimum fan requirements.
- **ER6: Reynold's Number**. Reynold's number must be less than 3500 to be considered transitional flow and less than 2300 to be considered laminar flow [4].
- **ER7: Surface Contamination**. The surface contamination measured at multiple sites throughout the cleanroom must have no mold colonies and <10 colony forming units (CFUs).

2. Top Level Testing Summary

Each customer and engineering requirement will be addressed with a relevant test that are outlined in **Table 1**.

Table 1: Test Summary Table

Experiment/Test	Relevant Design Requirements
Deflection	CR4
Particle Count	CR5, ER3
Airflow	CR5, ER4, ER5, ER6
Surface Contamination	CR5, ER7
Pressure	CR5, ER2
Area	CR3, ER1
Modularity	CR1, CR2

3. Detailed Testing Plans

3.1 Deflection

Test/Experiment Summary

The deflection test will measure the distance between set points on the cleanroom roof to the floor to identify the lowest deflection points of the roof. These deflection points will be used to determine different where the vertical support beams should be located to limit deflection as much as possible. The testing will be performed without support beams and with support beams in different locations. This test will determine if CR4 is met. The equipment needed to perform the testing is only a measuring tape. The variables that will be isolated for measurement are the different deflection locations. The variables that will need to be measured are the distance from the ceiling connector to the floor. The variables that will need to be calculated are the maximum shear and moment force using a 2D free body diagram to solve. This test is to be performed on the assembled cleanroom frame without FFUs on top.

Procedure

1. Obtain a measuring tape and locate the 6 deflection points on the roof configuration.
2. For each of the support beam configurations, measure the distance from the top of the connector to the floor at each deflection point. Reference **Figures 1-3** for the deflection point locations and support beam configurations.

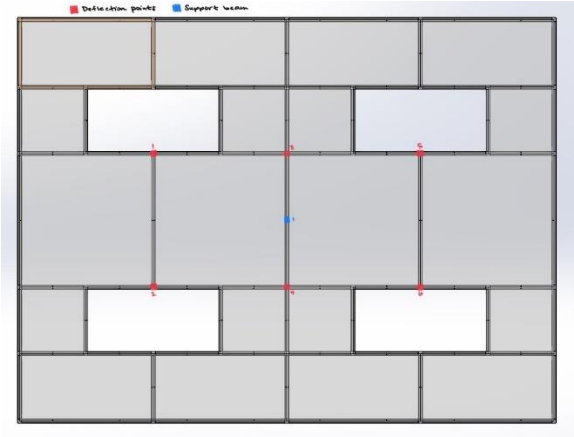

Figure 1: Configuration 1

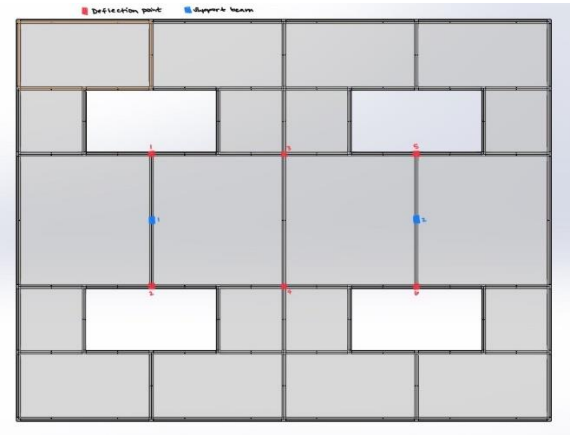

Figure 2: Configuration 2

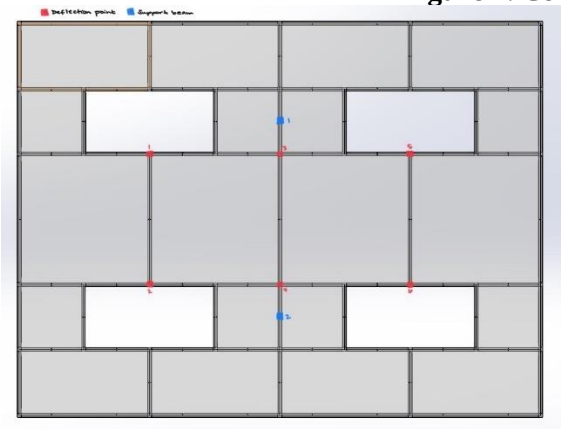

Figure 3: Configuration 3

3. Record the distances on the specifications sheet.
4. Calculate the average deflection for each support configuration.

$$Average\ deflection = \frac{\Sigma\ deflection\ measurements}{Number\ deflection\ measurements}$$

5. Create a 2D free body diagram. Calculate the maximum shear and moment force using the average deflection.

$$Maximum\ shear = \frac{\left(\frac{deflection \cdot 6 \cdot moment\ of\ inertia \cdot modulus\ of\ elasticity}{(length\ of\ force\ concentration)^2}\right)}{(3 \cdot length\ of\ maximum\ deflection - length\ of\ force\ concentration)}$$

$$Moment\ force = Maximum\ shear \cdot length\ of\ force\ concentration$$

Results

The deflection of the unsupported roof is expected to have the highest average deflection. Support beam configuration 2 is expected to have the lowest deflection since the configuration supports the closest to the FFU locations. Configurations 1 and 3 are expected to have similar slightly higher deflections compared to configuration 2.

The free body diagram of each roof section is expected to resemble **Figure 4**.

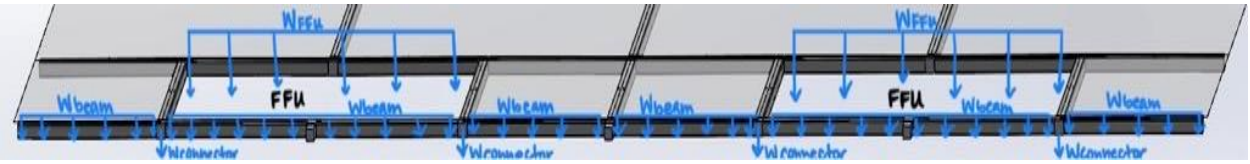

Figure 4: Free Body Diagram of 18ft Wall

With a measured deflection of 6in, moment of Inertia of $0.2127in^4$, Modulus of Elasticity $41900\ lb/in^2$, length of force concentration of 50in, and the length of max deflection being 30in, the maximum shear stress without any supports will be 32.08 lbf. For the moment force, the maximum force will be multiplied by the length of force concentration, the moment that the roof receives is 1604.18 lbf*in.

Conclusion

Deflection testing will be performed to identify the deflection points of the cleanroom roof and determine the best location for support beams to ensure CR4 was met per the client's specifications. Final deflection, maximum shear, and moment force results will be documented in the specification sheet.

3.2 Particle Count

Test/Experiment Summary

The particle count test will measure the number of particles present in the air in various locations throughout the cleanroom. This test will determine if CR5 and ER3 are met. The equipment needed to perform the testing is an aerosol mass monitor, sterile gloves, and ethanol solution. The variables that will be isolated for measurement are the locations of the measurements. The variables that will need to be measured are the number of particles. This test is to be performed on the sterile fully constructed cleanroom.

Procedure

1. Obtain calibrated aerosol mass monitor.
2. Gown up and enter the cleanroom.
3. Test particle count in all designated areas. For all measurements, measure 6ft above the ground in the center of each designated area. Reference **Figure 5** for quadrant locations.

1	3	5	7
2	4	6	8

Figure 5: Cleanroom Quadrant Layout

4. Record all particle counts on specification sheet.

Results

To have a passing testing result, any given location can have a maximum of 352,000 particles of size greater than 0.5 μm, 83,200 particles of size greater than 1 μm, and 2,930 particles of size greater than 5μm.

Conclusion

Particle count testing will be performed to verify the total number of air particles is below the acceptable limit to the ensure CR5 and ER3 were met per the client's specifications. Final particle count results will be documented in the specification sheet.

3.3 Airflow

Test/Experiment Summary

The airflow test will measure the air velocity under each FFU in the cleanroom. This test will determine if CR5, ER4, ER5, and ER6 are met. The equipment needed to perform the testing is a hot wire anemometer. The variables that will be isolated for measurement are the height and position (vertical or horizontal) of velocity measurement. The variables that will be calculated using the velocity measurements are the air changes per hour and Reynold's number of the location. This test is to be performed on the sterile fully constructed cleanroom.

Procedure

1. Obtain calibrated hot wire anemometer.
2. Gown up and enter the cleanroom.
3. Measure the horizontal and vertical velocity under the center of each FFU at a height of six feet off the ground.
4. Record the minimum and maximum measured values for each FFU location as labeled in **Figure 6**.

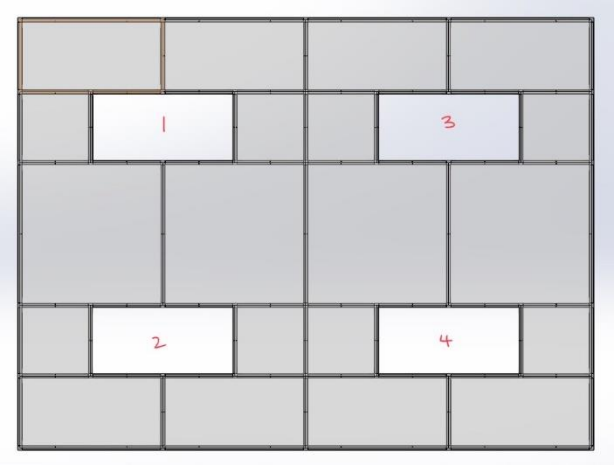

Figure 6: FFU Locations

5. Calculate the average velocity, air changes per hour, and Reynold's number at each location using the following equations:

$$Average\ velocity = \frac{\Sigma\ velocity\ measurements}{Number\ velocity\ measurements}$$

$$Air\ changes = \frac{Average\ Velocity * 60}{Cleanroom\ Volume}$$

$$Reynold's\ number = \frac{\rho V L}{\mu}$$

Results

To have a passing testing result for airflow, the average velocity at each location should be ≥ 15 ft/s (90 ft/min). The air changes per hour should be ≥ 60 changes per hour. Given the approximate cleanroom volume of $216\ ft^3$ and a minimum velocity measurement of 15 ft/s, the minimum expected air changes per hour would be:

$$Air\ changes = \frac{Average\ Velocity * \frac{60 min}{hour} * \#FFUs}{Cleanroom\ Volume} = \frac{\frac{90 ft}{min}(60)(6)}{216\ ft^3}$$
$$= 150\ air\ changes/hour$$

The Reynold's number should be $\leq 1 * 10^7$ to indicate transitional flow or ideally $\leq 5 * 10^5$ to indicate laminar flow in the empty cleanroom. Given an altitude of 7000ft, a standard air density of 0.002948 $slugs/ft^3$, a dynamic viscosity of $3.637 * 10^{-7} lbs/ft^2$, a measurement distance of 6ft, and a minimum velocity measurement of 15ft/s, the expected Reynold's number would be:

$$Reynold's\ number = \frac{\rho VL}{\mu} = \frac{\frac{0.002948 slug}{ft^3}\left(\frac{15ft}{s}\right)(6ft)}{3.637 * 10^{-7} lbs/ft^2} = 7.29 * 10^5$$

Conclusion

Air velocity testing will be performed to verify the average air velocity under each FFU is above the acceptable limit to the ensure CR5, ER4, ER5, and ER6 were met per the client's specifications. Average velocity, air changes per hour, and Reynold's number will be documented in the specification sheet.

3.4 Surface Contamination

Test/Experiment Summary

The surface contamination test will measure the number of mold and colony forming units present on various surfaces throughout the cleanroom. This test will determine if CR5 and ER7 are met. The equipment needed to perform the testing is a bacterial incubator and tryptic soy agar contact plates. The variables that will be isolated for measurement are the locations of the plates. The variables that will need to be measured are the number of mold colonies and colony forming units on the plates. This test is to be performed on the sterile fully constructed cleanroom.

Procedure

1. Obtain sealed agar plates and number each plate with the corresponding sample being taken.
2. Gown up and enter the cleanroom.
3. Invert the agar plate, remove the lid, and touch the agar plate surface to the surface being tested. Replace the plate lid. Repeat for all surfaces being tested.
4. Create a positive and negative control plate. For the negative control plate, keep the plate unopened. For the positive control plate, touch the plate with ungloved fingers.
5. Incubate all sample and control plates for 7 days in the bacterial incubator.
6. At the end of the incubation period, remove the plates from the incubator. Count and record the number of CFUs present on each plate. Record any mold colonies as an M.

Results

To have a passing testing result, the number of CFUs needs to be less than 10 on each agar plate and there needs to be no mold colonies at each location measured. The results will be recorded in the specification sheet.

Conclusion

Surface contamination testing will be performed to verify the total number of CFUs and mold colonies is below the acceptable limit to the ensure CR5 and ER7 were met per the client's specifications. Final surface contamination results are expected to be under 10 CFUs and no mold colonies and will be documented in the specification sheet.

3.5 Pressure

Test/Experiment Summary

The pressure test will measure the air pressure difference between the inside and outside of the cleanroom in various locations throughout the cleanroom. This test will determine if CR5 and ER2 are met. The

equipment needed to perform the testing is manometer. The variables that will be isolated for measurement are the locations of the measurements. The variable that will need to be measured is the pressure at each location. This test is to be performed on the sterile fully constructed cleanroom.

Procedure

1. Obtain calibrated manometer.
2. Measure ambient air pressure outside of cleanroom.
3. Gown up and enter the cleanroom.
4. Measure the pressure at the center of each FFU location shown in **Figure 7** 6ft above the ground and in the center of the wall gap height at all designated locations shown in **Figure 8**.

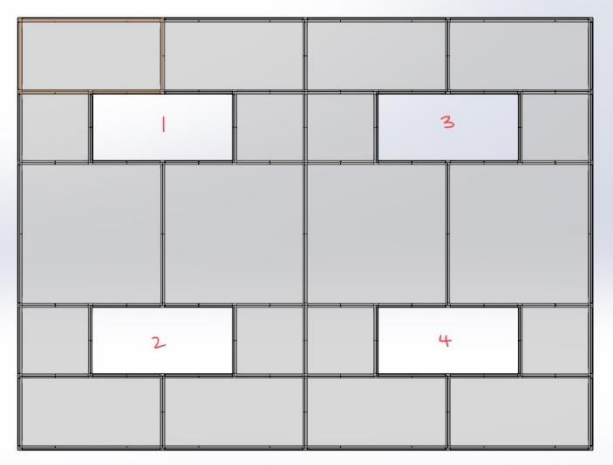

Figure 7: FFU Locations

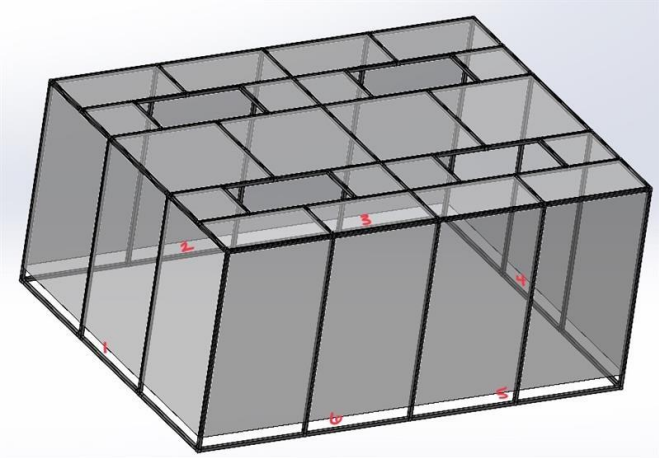

Figure 8: Pressure Wall Testing Locations

5. Record all pressures on specification sheet.
6. Calculate the average pressure under the FFUs and at the wall exits. Record the averages.

Results

To have a passing testing result, there should be a positive pressure difference of at least 0.2 Pa between the average pressure measurement under the FFU and the average measurements at the wall gap.

Conclusion

Pressure testing will be performed to verify the pressure difference is above the acceptable limit to the ensure CR5 and ER2 were met per the client's specifications. Final pressure results will be documented in the specification sheet.

3.6 Area

Test/Experiment Summary

The area testing will measure the square footage of the cleanroom. This test will determine if CR3 and ER1 were met. The equipment needed to perform the test would be a measuring tape and a calculator. The variables that will be isolated for the measurement are the length and width of the cleanroom floor in feet. The variable that will be calculated is the total area of the cleanroom.

Procedure

1. Obtain measuring tape and calculator.

2. Measure the length of the cleanroom floor from one corner to the next corner on the long side of the cleanroom. Do not include the floor beam width in the measurement. Record the measured value in inches as L.
3. Measure the width of the cleanroom floor from one corner to the next corner on the short side of the cleanroom. Do not include the floor beam width in the measurement. Record the measured value in inches as W.
4. Convert the L and W values from inches to feet. Calculate the area (A) of the cleanroom using the following equation:

$$A = LxW$$

Results

The results of this test will be an area measurement in feet slightly less than 216 ft^2 which is the area of the outside 12ft by 18ft frame of the cleanroom including the beam width. Since the beams are each 1.5in wide, the expected area for the cleanroom would be approximately 141in (11.75ft) by 213in (17.75ft).

$$A = LxW = 11.75ft\ x\ 17.75ft = 208.6ft^2$$

Conclusion

Area testing will be performed to determine the total internal square footage of the cleanroom to the ensure CR3 and ER1 were met per the client's specifications. Final area results are expected to be around $208.6ft^2$ and will be documented in the specification sheet.

3.7 Modularity

Test/Experiment Summary

Modularity testing will identify the most efficient way to assemble/disassemble the cleanroom and provide time estimates for those assemblies. This test will determine if CR1 and CR2 were met. The equipment needed to perform the test would be the assembly manual, all materials identified in the manual, a rubber mallet, a ¼" ratchet, at least one ladder, and a timer. The variable that will be isolated is the cleanroom section to be assembled. The variable that will be measured is the assembly time of each section to determine the overall assembly time.

Procedure

1. Obtain assembly manual and all required materials identified in the manual.
2. Assemble all E beams with connectors to form the perimeter of the cleanroom. Record time taken to assemble.
3. Assemble all A beams to perimeter as shown in **Figures 9-12**.

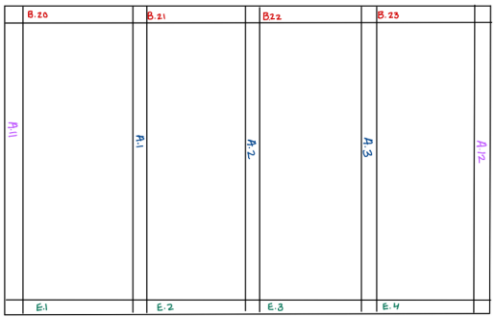

Figure 9: 18ft Wall 1

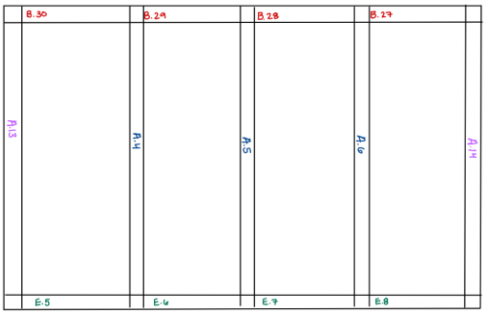

Figure 10: 18ft Wall 2

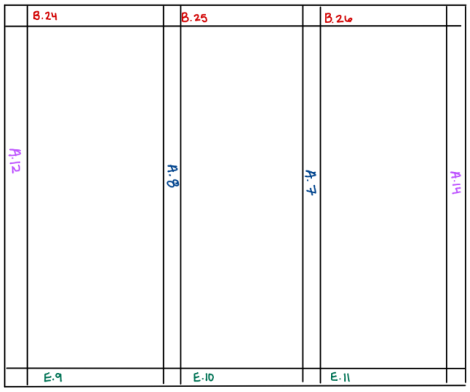

Figure 11: 12ft Wall 1

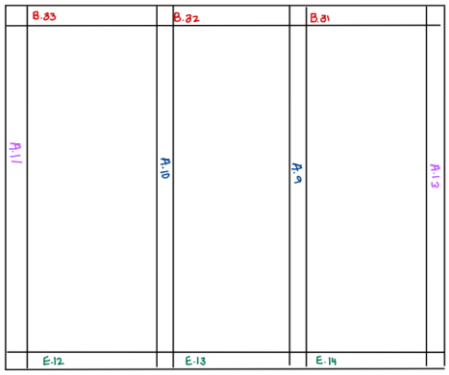

Figure 12: 12ft Wall 2

4. Assemble the ceiling in the 5 quadrants labeled in **Figure 13**. Assemble in quadrant order.

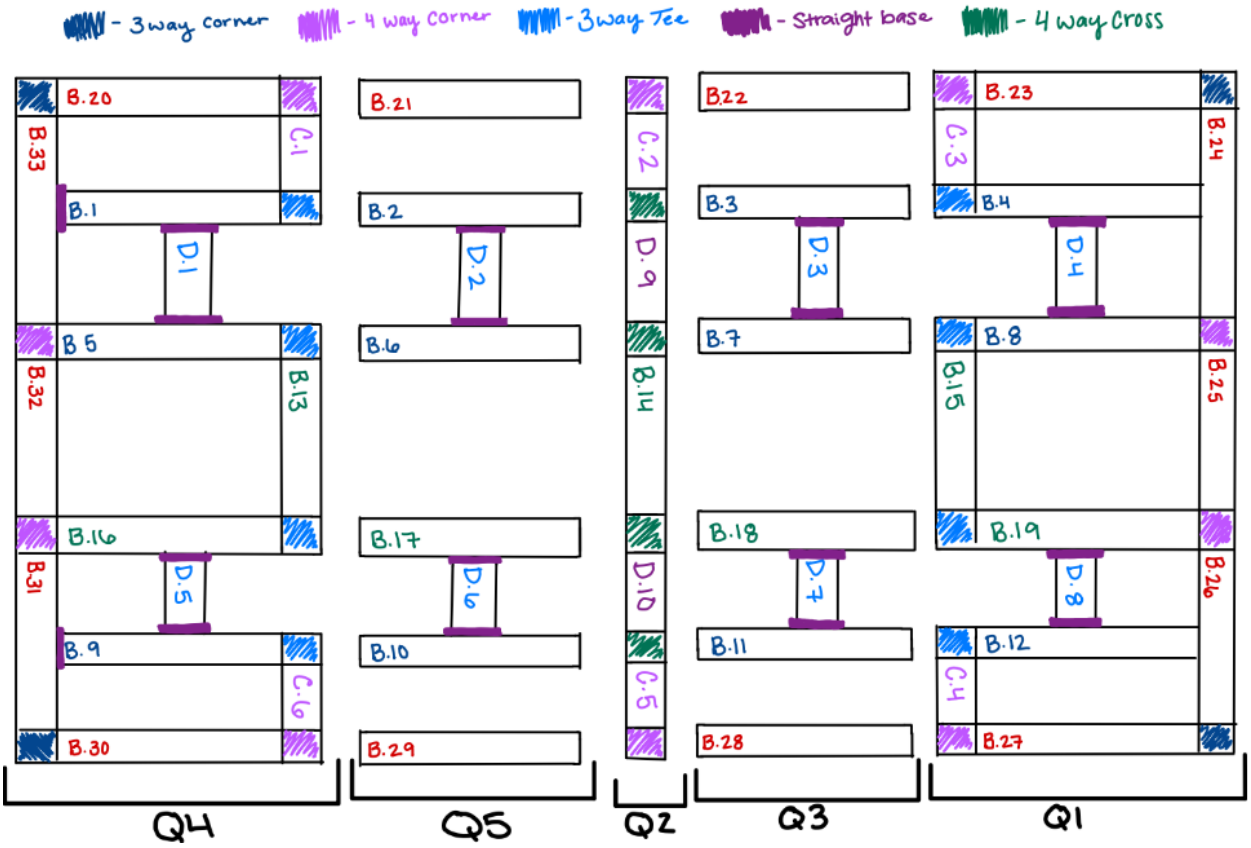

Figure 13: Ceiling Quadrants

5. Assemble all ceiling polycarbonate sheets using the required nuts and hex bolts outlined in the assembly.
6. Assemble all wall polycarbonate sheets using the required nuts and bolts outlined in the assembly.
7. Install vinyl sheets for doorway.
8. Install FFUs on ceiling. Plug in all electrical cords.

Results

To meet the customer requirements of modularity and transportable, the cleanroom needs to be able to be assembled and disassembled relatively quickly (a business day or less) and needs to be able to be disassembled into pieces that can transported to another location. Based on the assembly time the team has spent, the estimated assembly time is around 6 hours and disassembly time is around 8 hours.

Conclusion

Modularity testing will be performed to determine the total assembly and disassembly time of the cleanroom to the ensure CR1 and CR2 were met per the client's specifications. Final modularity results are expected to be around will be documented in the specification sheet.

4. Specification Sheet Preparation

4.1 Customer Requirements

The customer requirements will all need to be met to consider the design project a success. The customer requirements are outlined in Table 2 with spaces for the team to mark if the requirement was met during final testing and if the client found the result acceptable.

Table 2: Customer Requirements Summary Table

Customer Requirement	CR Met? (✓ or X)	Client Acceptable? (✓ or X)
Modular		
Transportable		
Spacious		
Safe		
ISO Class 7 Compliant		

4.2 Engineering Requirements

All engineering requirements will also need to be met to consider the design project a success. The engineering requirements will be scored based on if the measured/calculated value meets the required tolerance by the client. The overall results are shown in **Table 3**. The specific results for each test are shown in **Tables 4-9**.

Table 3: Engineering Requirements Specifications Summary

Engineering Requirement	Target	Tolerance	Measured/ Calculated Value	ER Met? (✓ or X)	Client Acceptable? (✓ or X)
Spacious	216 ft^2	± 5ft^2			
Positive Pressure	≥ 0.2 Pa	N/A			
Particle Count	< 352,000 particles > 0.5 μm	N/A			
Airflow	> 90 ft/min, > 60 air changes per hour	N/A			

Ceiling Coverage	> 15%	N/A			
Reynold's Number	$< 1 * 10^7$	N/A			
Surface Contamination	< 10 CFU	N/A			

Table 4: Deflection Testing Results

Deflection Point	Support Beam Configuration 1	Support Beam Configuration 2	Support Beam Configuration 3
1			
2			
3			
4			
5			
6			
Average Deflection			
Maximum Shear			
Moment Force			

Table 5: Particle Count Testing Results

Location	Particle Count	Acceptable Range
Corner 1		
Corner 2		
Corner 3		
Corner 4		
Center Quadrant 1		
Center Quadrant 2		
Center Quadrant 3		
Center Quadrant 4		
Center Quadrant 5		
Center Quadrant 6		
Center Quadrant 7		
Center Quadrant 8		

Table 6: Air Velocity Testing Results

FFU Location	Minimum Velocity (ft/min)	Maximum Velocity (ft/min)	Average Velocity (ft/min)	Air Changes per Hour	Reynold's Number
1					
2					
3					
4					

Table 7: Surface Contamination Testing Results

Plate #	Sample Location	Acceptable Limit (#CFU, #M)	Result (#CFU, #M)
1	Open Air Cleanroom	0, 0	
2	Cleanroom Wall 1	≤ 10, 0	
3	Cleanroom Wall 2	≤ 10, 0	
4	Cleanroom Wall 3	≤ 10, 0	
5	Cleanroom Wall 4	≤ 10, 0	
6	Positive Control	++, 0	
7	Negative Control	0, 0	

Table 8: Pressure Testing Results

Location	Pressure	Average Pressure
FFU 1		
FFU 2		
FFU 3		
FFU 4		
Wall Gap 1		
Wall Gap 2		
Wall Gap 3		
Wall Gap 4		
Wall Gap 5		
Wall Gap 6		

Table 9: Modularity Testing Results

Assembly Part	Assembly Time (Hrs)	Disassembly Time (Hrs)
Perimeter		
18ft Wall 1		
18ft Wall 2		
12ft Wall 1		
12ft Wall 2		
Ceiling Quadrants		
Polycarbonate Ceiling		
Polycarbonate Walls		
Vinyl Door		
FFUs		
Total Assembly Time:		

5. QFD (10pts)

The team developed a House of Quality (attached) to compare the customer requirements with the engineering requirements. First, the customer requirements were given weights on a scale of 1 to 5. 1 represents less important and 5 represents more important. Then, the customer requirements were directly compared against the engineering requirements on a 1, 3, 6, or 9 ranking system. 1 showed a low

correlation between the requirements, 3 and 6 a medium correlation, and 9 a high correction. Positive numbers showed a positive correlation and negative numbers show a negative correlation. Cells left blank were identified as having no correlation. Based on the rankings of the customer and engineering requirements, the absolute and relative technical importance was calculated.

Absolute technical importance was calculated by weighing the customer weight against the rankings. The relative technical importance was then determined based on the absolute technical importance ratings. Room Area ended up ranking the highest of the engineering requirements. This was because it was the only technical requirement with correlations to the modular and transportable customer requirements. The ISO Class 7 compliant requirements all ranked second and third. However, the design team will treat these requirements as more important than the room area going forward. The cleanroom cannot be certified regardless of room area unless it meets the ISO Class 7 requirements.

The first two customer requirements of modular and transportable are ease of construction-based requirements and will not be evaluated as engineering requirements. Instead, they will be considered during the design for manufacturing process. The customer requirement of spacious directly relates to the engineering requirement of room area. The customer requirement of ISO Class 7 compliant encompasses six engineering requirements: positive pressure, particle count, particle size, airflow, ceiling coverage, and Reynold's number.