NORTHERN ARIZONA UNIVERSITY

Department of Mechanical Engineering
Modular Sterile Cleanroom
Logan Bennett
Michelle Borzick
Gia Neve
Aaron Reynoza
ME486C Section 2 Spring 2024

To: Dr. David Willy
From: Michelle Borzick
Date: 2-2-24
Re: HW01 Self-Learning Assignment

Introduction

For my self-learning assignment, I wanted to learn how the ISO Class 7 qualification process will work for our cleanroom. Part of our team goals for our project is to qualify our cleanroom for manufacturing before graduation. I met with Dr. Becker to discuss the qualification process and he explained that we can do the qualification testing ourselves. He provided me with the relevant Aneuvas Technologies, Inc. standard operating procedures (SOPs) for the qualification process. This assignment will outline the relevant SOPs, protocols, and testing methods we will need to use to qualify the cleanroom as an ISO Class 7.

Per Operational Qualification Protocol for Anuevas Cleanroom (EQ.013.00) [1], there are three different operational tests we will need to complete: nonviable particles, surface microbial presence, and air velocity measurements. However, before we begin those tests we will need to complete the two operational testing prerequisites.

Prerequisites

The first prerequisite to testing is to have all SOPs complete for cleanroom operation, cleaning, maintenance, and calibration if applicable. For cleanroom operations we will be creating a operation manual for assembling and running the cleanroom. Dr. Becker already has gowning procedures we can use for the gowning room. The cleaning procedures for the cleanroom are going to be worked on by another teammate. Maintenance instructions will be provided in our cleanroom operations manual. Calibration will be addressed in the testing equipment attachments.

The second prerequisite is to obtain all critical instruments, ensure the instruments are calibrated, and complete the Next Equipment OQ Data Sheet – Prerequisites Form (EQ.013.00 Attachment 1) [2] shown in Figure 1. The instruments we will need to validate (or confirm validation) is the particle counter, anemometer, and potentially the incubator. Dr. Becker already has the particle counter, anemometer, and incubator available for us to use so we will need to check when they are last calibrated. If the instruments need to be calibrated we will need to use the manufacturer's manuals to determine the needed calibration steps. The incubator has a separate validation sheet per EQ.002.00 Attachment 2 [3] shown in Figure 2.

EQUIPMENT DATA SHEET – INSTRUMENT CALIBRATION

Identify all instruments to be used during the operational qualification and verify that they are in calibration.

Instrument Name	Date of Last Calibration	Date Next Calibration Due	Location/Source of Calibration Documents

Figure 1: Instrument Calibration Documentation

INCUBATOR TEMPERATURE/HUMIDITY REGULATION **LOT NUMBER:**

INCUBATOR THERMOMETER:
MODEL NUMBER: _____
SERIAL NUMBER: _____
CAL DATE: _____
DUE DATE: _____

INCUBATOR HYGROMETER:
MODEL NUMBER: _____
SERIAL NUMBER: _____
CAL DATE: _____
DUE DATE: _____

DATE	TIME	INCUBATOR TEMP (ºC)			INCUBATOR HUMIDITY (%)			ALARM TRIGGERED	INITIALS
		CURRENT	MAX	MIN	CURRENT	MAX	MIN		

Figure 2: Incubator Validation Documentation

Nonviable Particle Testing

Particle count testing will be done per Particle Counting (EQ.009.00) [4]. The materials we will need are a Met One AEROCET 831 Aerosol Mass Monitor that is calibrated, sterile gamma wipes, and 70/30 ethanol solution. EQ.009 Attachment 1 [5] has four locations where particle counting needs to be measured and recorded. The data table for the particle counting is shown in Figure 3.

PARTICLE COUNTING

DATE / TIME _____

COMMENTS _____

PARTICLE COUNTS

Site	*Acceptable Limit (0.5 µm particles)*	*Result (µg)*	*Sign/Date*
Zero	0.0 *µg*		
Inside PPC: center	0.0 *µg*		
Benchtop: lower	0.0 *µg*		
C&C Production Room	0.0 *µg*		

Figure 3: Particle Counting Documentation

Surface Microbial Testing

Surface microbial testing will be performed per Surface Contamination Testing (EQ.002.00) [6]. Agar plates will be brought into the sterilized cleanroom, touched to various surfaces outlined in EQ.002.00 Attachment 1 [7] shown in Figure 4. The plates will then be incubated for 7 days to allow for microbial growth. The microbial growth will be measured and compared back to the acceptable limits outlined in EQ.002.00 of 0 mold colonies and less than 10 colony forming units per plate.

SURFACE CONTAMINATION TESTING

DATE / TIME _____

COMMENTS _____

CONTACT PLATES

Plate #	*Site*	*Acceptable Limit (#, #M)*	*Result (#, #M)*	*Sign/Date*
	Inside PPC: RIGHT	0 , 0		
	Inside PPC: LEFT	0 , 0		
	Bench: TOP	≤ 10 , 0		
	Bench: FRONT	≤ 10 , 0		
	Clean Rm. Wall	≤ 10 , 0		
	Open Air in Cleanroom	0 , 0		
	Open Air in PPC	0 , 0		
	Positive Control	++ , 0		
	Negative Control	0 , 0		

Figure 4: Contact Plate Results

Air Velocity Measurements

Air velocity measurements will be taken per Air Velocity Measurements (EQ.011.00) [8]. The air velocity will be recorded in the center of the room horizontally and vertically and at the 8 HEPA filter zones. The individual results will be recorded on EQ.011.00 Attachment 1 [9] shown in Figure 6. The air velocities will be averaged to determine if they meet the airflow requirement of greater than 90 fpm.

AIR VELOCITY MEASUREMENT

DATE / TIME _____

COMMENTS _____

ROOM TEMP _____

AIR VELOCITY MEASUREMENTS

Site	*Maximum (fpm)*	*Minimum (fpm)*	*Sign*
Room Center/Vertical			
Room Center/Horizontal			
PPC Hepa Filter Zone 1			
PPC Hepa Filter Zone 2			
PPC Hepa Filter Zone 3			
PPC Hepa Filter Zone 4			
PPC Hepa Filter Zone 5			
PPC Hepa Filter Zone 6			
PPC Hepa Filter Zone 7			
PPC Hepa Filter Zone 8			

ROOM: AVERAGE VELOCITY: _____fpm

STDEV: ±_____fpm

PPC: AVERAGE VELOCITY: _____fpm

STDEV: ±_____fpm

Figure 6: Air Velocity Results

Moving Forward

Using all the procedures provided by Aneuvas Technologies Inc. we can determine the best way for us to qualify our cleanroom. The overall testing data gathering will only take a few hours, however there are other activities needed that may take longer. Before testing we will need to schedule time to obtain and potentially calibrate the instruments we will be using. We also will need to incubate the microbial agar plates for a week. With all this in mind, we will need to give ourselves probably 2 weeks to complete the qualification process. Knowing that will influence our build timeline. Unknowns that I still have on the process are around a required QA signature on some of the tests. If we need to have a QA present for the testing we will have to consider that when scheduling the testing. Lastly, I am unsure what we do with the testing results on all the document attachments we will have. I will need to follow up with Dr. Becker on how to complete the qualification post-testing.

References

All documents were obtained from Aneuvas Technologies, Inc.
[1] EQ.013.00 - Operational Qualification Protocol for Anuevas Cleanroom
[2] EQ.013.00 Attachment 1 - Next Equipment OQ Data Sheet – Prerequisites Form
[3] EQ.002.00 Attachment 2 – Incubator Temperature/Humidity Regulation
[4] EQ.009.00 - Particle Counting
[5] EQ.009.00 Attachment 1 - Particle Counting
[6] EQ.002.00 - Surface Contamination Testing
[7] EQ.002.00 Attachment 1 - Surface Contamination Testing
[8] EQ.011.00 - Air Velocity Measurement
[9] EQ.011.00 Attachment 1 - Air Velocity Measurement