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TECHNICAL BULLETIN
GENERAL INFORMATION

NU-813 Series 20 Containment Cabinet Performance Evaluation

Background

NuAire has manufactured the NU-813 Containment Cabinet since the early 1990's for particulate containment. The original design was based for more of a biological application having the blower mounted before the exhaust HEPA filter. This allowed the exhaust HEPA filter to be scan tested in place, as would be performed on a typical Class II, Type A2 Biological Safety Cabinet (BSC). The new design is based for more of a powder weighing balance, so the powder will imbed on the filter and not on the blower. The exhaust HEPA filter will be gross leak tested in place for this application.

The new NU-813 Series 20 base design and airflow pattern has also changed as illustrated on ACD-11750. The airflow is first drawn in through the access opening that has side and bottom airfoils to minimize turbulence. The airflow proceeds into the workzone in a sweeping action carrying contaminants with it into the slotted rear panel, then up the rear plenum and into the exhaust HEPA filter. As the particulate imbeds on the HEPA filter, the airflow passes through and is pulled up into the blower, then discharged out of the blower through the exhaust collar n top of the cabinet. The cabinet exhaust may either be room re-circulated or exhausted.

The NU-813 Series 20 Performance Evaluation was conducted by NuAire with the aid of independent test consultant, Mr. Gerhard Knutson, Knutsen Ventilation to quantify the cabinet's ability to provide personnel protection. Three different test methods were used to measure containment properties of potential use being tracer gas, surrogate powder and biological. The test method used for each of the above was the following:

1) Tracer Gas - ANSI/ASHRAE 110
2) Surrogate Powder - Published comparable industry test methods
3) Biological - NSF/ANSI 49 - Personnel Protection

Test Result Summary

Testing was conducted on a representative NU-813-400 (series 20) (4 foot width) model. Inflow velocity was adjusted as determined by the test method to challenge the product through out the entire range of potential operation. Additional testing information is provided in the attachments.

1) Tracer Gas Testing
   a. Smoke visualization tests demonstrated good airflow with aerodynamic entry and minimal internal turbulence with the face velocity at 50, 60, 80, and 100 fpm with no observed spillage or significant reverse flow.
   b. Traced gas tests at all tested face velocities were below the analytical limit of detection (<0.01 ppm) of the instrument.

2) Surrogate Powder (Naproxen Sodium) Testing
   a. The cabinet was set up in the recirculation mode with nominal a face velocity of 80 fpm.
   b. Tests were performed while a person conducted weighing operation at the cabinet.
   c. The surrogate testing was below the limit of detection for most samples.

3) Biological Testing
   a. The cabinet was set up in the recirculation mode with face velocities of 60, 80, and 100 fpm.
   b. Tests were performed per NSF/ANSI 49.
   c. Biological tests all passed using NSF/ANSI 49 test criteria of 5 or less Colony Forming Units (CFU's) total for the slit samplers and 10 or less CFU's for the Impingers.

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Modified ASHRAE 110 Tracer Gas Containment Tests And Surrogate Active Pharmaceutical Agent Exposures

NuAire, Inc.
Labgard Containment Cabinet

March 19, 2007

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INTRODUCTION

At the request of William Peters of NuAire, Gerhard Knutson of Knutson Ventilation Consulting, Inc. conducted a series of tests on a NuAire Labgard Containment Cabinet Model NU-813-400. The tests incorporated both tracer gas testing and surrogate power testing. The tracer gas testing used Sulfur Hexafluoride and a procedure modeled after the ANSI/ASHRAE Standard 110. The surrogate powder testing used Naproxen Sodium as a substitute for an Active Pharmaceutical Agent. The tests used standard industrial hygiene procedures to collect airborne area and personal samples while an engineer or technician conducted simulated weighing procedures using Naproxen Sodium in the Labgard Containment Cabinet.

Summary of Results

1) Tests were conducted on a Model NU-813-400 Labgard Containment Cabinet.

2) Tracer Gas testing
   a. Smoke visualization tests demonstrated good airflow patterns with aerodynamic entry and minimal internal turbulence with the face velocity at 50, 60, 80, and 100 fpm with no observed spillage or significant reverse flow.
   b. Tracer gas tests at all tested face velocities were below the analytical limit of detection (<0.01 ppm) of the instrument.

3) Naproxen Sodium Tests
   a. The cabinet was set up win the recirculation mode with nominal a face velocity of 80 fpm.
   b. Tests were performed while a person conducted weighing operation at the cabinet.
   c. The surrogute testing was below the limit of detection for most samples.

4) The combined tests demonstrate, when the cabinet has adequate face velocity in a room with controlled room air currents and the operator uses good work practices, that the cabinet provided good contaminant containment.

LABGARD CONTAINMENT CABINET

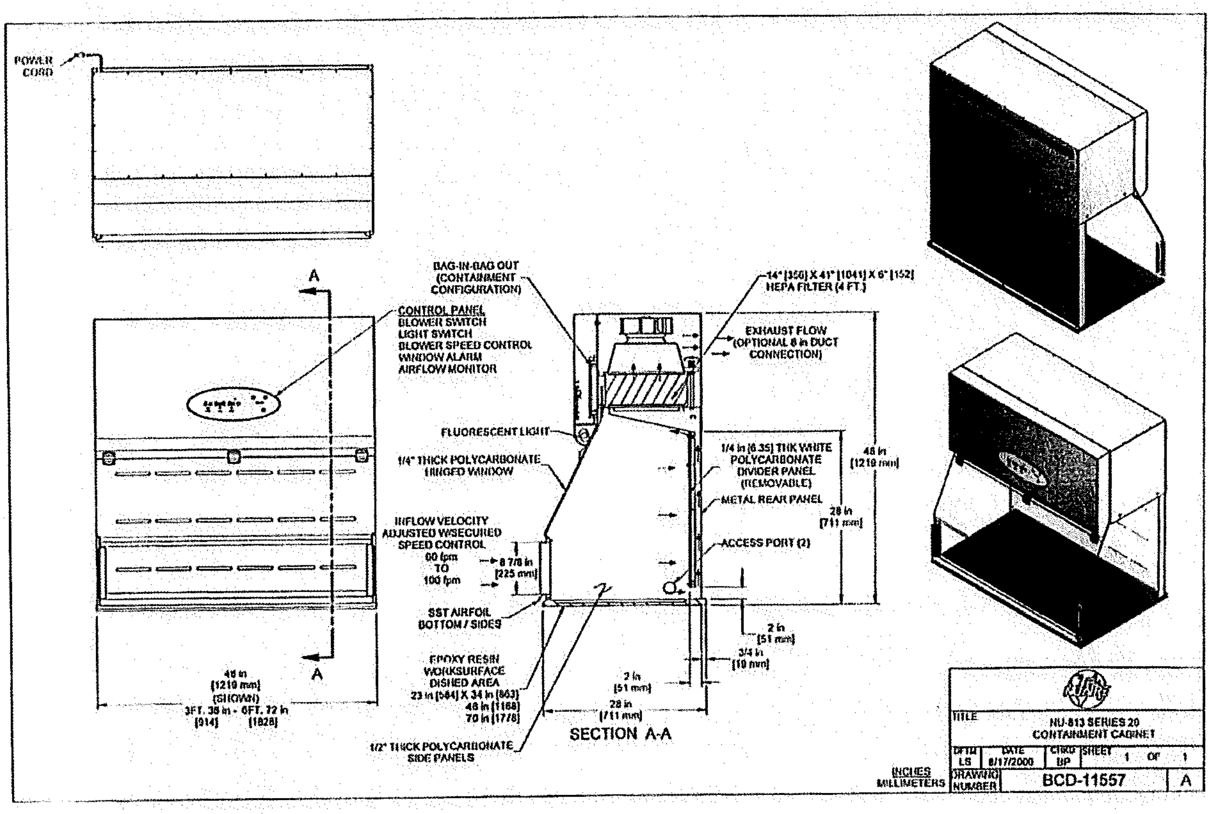
Tests were preformed on a NuAire Labgard Model NU-813-400 containment cabinet.

Test Room

The test room was a 12.5 by 12.5 by 10 foot high room. Supply air entered the room through open doors. The resulting room air currents were negligible.

Test Hood

The test hood was Labgard Model NU-813-400 Portable Bench Top Containment Cabinet. The width was a nominal 48 inches. The hood opening, with the visor closed, was 47 inches wide by 9-7/8 inches high (3.22 square feet). The unit has an integral fan with the air passing through a HEPA (High Efficiency Particulate Air) filter before discharging into the workroom. The fan is adjustable for an inflow between 60 fpm and 100 fpm. Figure 1 shows a drawing of cabinet.



The back baffle has three rows of six slots. The bottom row has six 1" by 6" slots. The center and top rows each have six ½ inch by 6 inch slots.

TRACER GAS TESTING

Hood Modifications

Since the tracer gas, sulfur hexafluoride (SF_6) is not captured by the HEPA filter, the hood was modified by closing exhaust panel, on the back of the hood, and installing the optional 8-inch exhaust duct. The exhaust was discharged through a stack on the roof of the building. This provided exhaust for the tracer gas, which would not have been collected on the HEPA filter. The arrangement did not influence the air flow patterns within the hood.

Performance Criteria

There are no performance criteria for containment cabinets. However, using laboratory hoods as a reference, the most frequently applied criteria is AM 0.05. That is, the hood while tested at the manufacturer's test site has a spillage rate of less than 0.05 ppm (50 ppb). In addition, the minimum detection level for the instrumentation is 0.01 ppm (10 ppb).

TEST RESULTS

Face Velocity Measurements.

Face velocity measurements were collected by attaching a Shortridge hood, Series 8400, with a 4 ft by 1 ft hood taped to the front of the test hood, as prescribed in NSF 49.

TABLE 1
VOLUMETRIC FLOW MEASUREMENTS
NU-813-400

Nominal Face Velocity Fpm	Cabinet Opening Width Inches	Height Inches	Area ft^2	Measured Flow cfm	Calculated Face Velocity fpm
100	47	9.875	3.22	323	100.2
80	47	9.875	3.22	257	79.7
60	47	9.875	3.22	192	59.6
50	47	9.875	3.22	162	50.3

The volumetric flow was modulated by adjusting the speed of the internal fan on the cabinet. The process was iterative since the exhaust fan was also modulated. The exhaust fan was set first, to provide a negative pressure in the exhaust plenum and to ensure no leakage from the exhaust plenum. After the negative pressure was established, the internal fan was modulated to achieve the desired flow. Four different volumetric flows were used during the tests. Table 1 shows the test results.

Smoke visualization

Airflow visualization was determined by using Regin Smoke bottles.

1) Smoke released under the airfoil turned smoothly into the hood and swept along the work surface.
2) Smoke released behind the side airfoils turned smoothly into the hood and swept along sides toward the back of the hood.
3) Smoke released on the work surface swept smoothly into the rear of the hood.
4) Smoke released high in the hood showed a moderate, slow roll with slow smoke removal.
5) Smoke released along the visor was forced back into the hood by the visor lip.
6) Smoke released in the face of the hood demonstrated a good entry profile
7) When smoke is released on the opening, most of the air enters the lower slot and the first set of slots

Tracer Gas Tests

Tracer gas tests were conducted with the standard ASHRAE ejector and with a circular array. The array was approximately eight inches in diameter and tracer gas escaped from the array through 1/16-inch holes on ¾ -inch centers. The flow rate was set at 4 lpm and the tracer gas was sulfur hexafluoride (SF_6). The detector was a Sapphire model 205. The instrument was field calibrated by injecting sulfur hexafluoride into a closed loop calibration system, as recommended by the manufacturer.

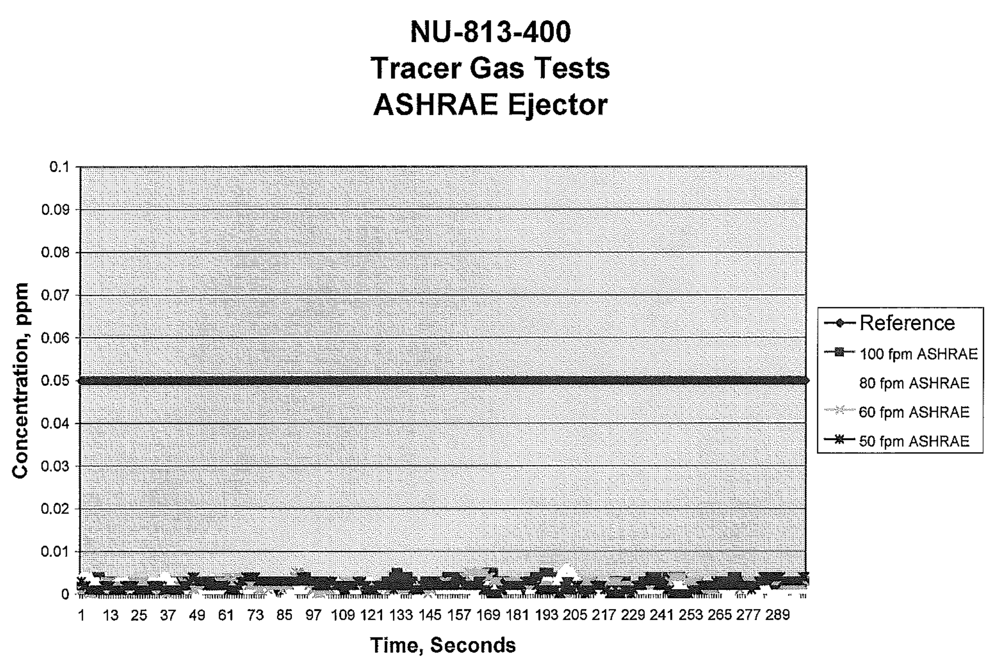
The mannequin was positioned so that the breathing zone was 45 inches off the floor. The height of the bench was 28 inches. The mannequin breathing zone was 17 inches above the work surface. The mannequin was placed in the center of the opening, with the probe piercing the lips of the mannequin to provide a sample representing a breathing zone sample. The tracer gas release rate was 4.0 lpm and the test was conducted for five minutes.

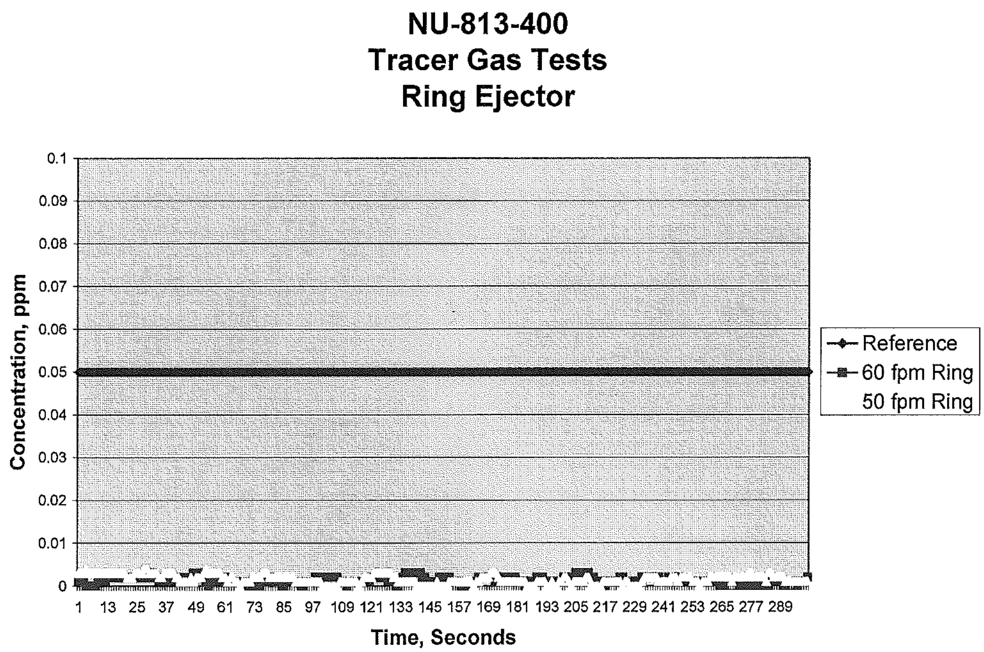
Table 2 shows the maximum and average concentrations observed during the testing. All readings were below the limit of detection for the instrument.

TABLE 2
TRACER GAS TESTS

Test	Face velocity	Position	Ejector	Average	Max
1	100 fpm	Center	ASHRAE	< 0.01	< 0.01
2	80 fpm	Center	ASHRAE	< 0.01	< 0.01
3	60 fpm	Center	ASHRAE	< 0.01	< 0.01
4	60 fpm	Center	Ring	< 0.01	< 0.01
5	50 fpm	Center	Ring	< 0.01	< 0.01
6	50 fpm	Center	ASHRAE	< 0.01	< 0.01

The test results are shown graphically in the following graphs.





Conclusion

1) The smoke visualization demonstrated aerodynamic entry into the enclosure with the face velocity ranging form 50 fpm to 100 fpm.
2) Tracer gas testing demonstrated good containment (below the limit of detection of 0.05 ppm) when the face velocity ranged from 50 fpm top 100 fpm and the enclosure was in a quiescent room.
3) The combined tests demonstrate, when the cabinet has adequate face velocity in a room with controlled room air currents and the operator uses good work practices, that the cabinet provided good contaminant containment.

SURROGATE ACTIVE PHARMACEUTICAL AGENT TESTING

Introduction

One of the major functions of the Containment Cabinet is to provide ventilation control during weighing operation of active pharmaceutical agents. To simulate these activities, three technicians performed a series of powder weighing sand transfers to scintillation jars. The procedure was conducted with a surrogate powder and industrial hygiene methods were used to determine potential exposures.

Methodology

Airborne powder (naproxen sodium) was collected using Teflon filters with pour size of 1 micrometer. The filters were housed in 25 mm cassettes. Air samples were collected at five locations with airflow rates ranging from 2.87 to 3.34 liters per minute. After samples were collected, the filters were removed from the sampling pumps, sealed and sent to an AIHA accredited laboratory for analysis.

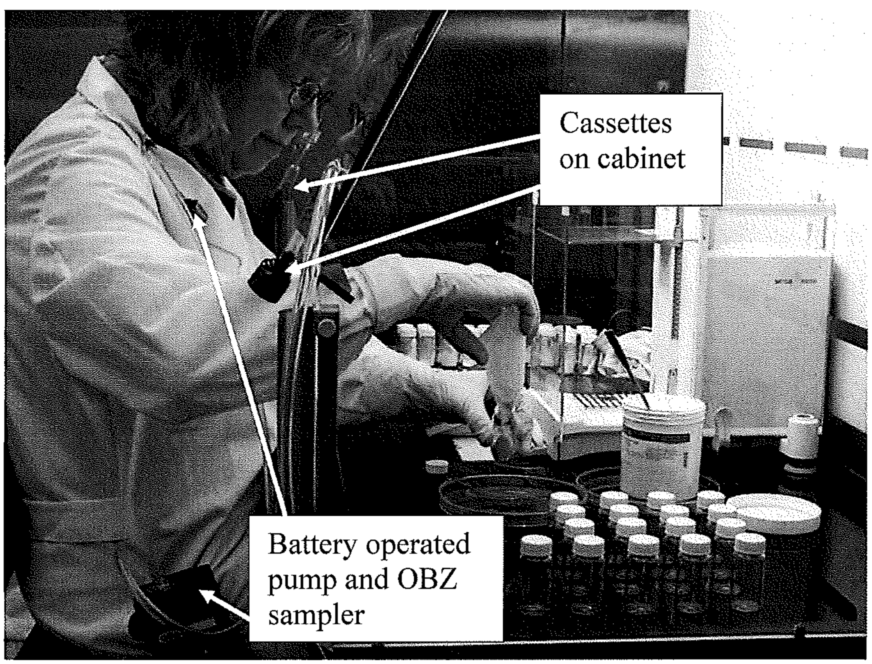


Photo 1: Sample Locations

Air samples were collected at four points near the operation and on remote point. One sample was collected in the breathing zone of the technician (OBZ) conducting the tests. Two samples were taken at the front visor of the cabinet (see Photo 1). A fourth sample was taken in the test room, about eight feet from the cabinet. A fifth sample, collected over three sample periods, ran continuously near the entrance to the test room. The purpose of this final sample was to document the general background levels in the building.

Procedure

The technician simulated a typical procedure conducted within the containment cabinet. The weighed 1 gram of powder (naproxen sodium) and palace the material is a small scintillation jar. The steps of the procedure were as follows:

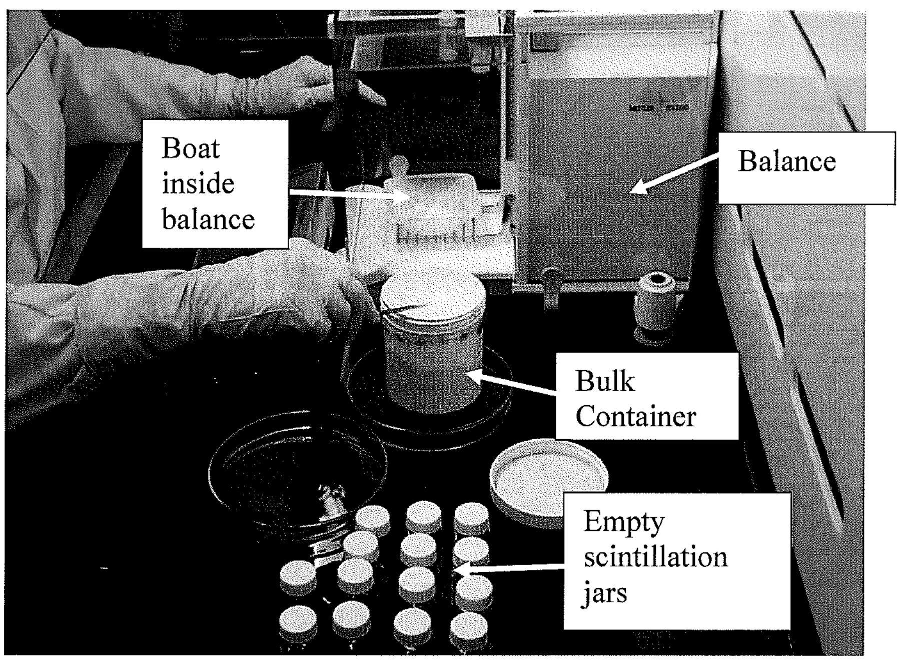


Photo 2: Material transfer to boat

1) Tare weigh the boat (balance doors closed)
2) Open balance door and transfer powder (naproxen sodium) from a bulk container to the boat by a stainless steel spatula, adjusting the material transferred until it approximates one gram (Photo 2 shows a transfer to the boat).
3) Close balance doors and weigh the boat and powder.
4) Remove lid from scintillation jar and place lid on work surface.

5) Open balance door and remove the boat from the balance and transfer the powder into a scintillation jar (Photo 1 shows a transfer into a scintillation jar).
6) Replaced lid and place the jar to the left of the scale.
7) Repeat the process twenty (20) times.

Each of three technicians performed the weighing tasks each day and the tasks were repeated on a second day.

Cabinet Exhaust

The cabinet was set up in the recirculation mode. Exhaust from the cabinet passed though a HEPA filter before discharging through a panel on the back of the hood. Because of the arrangement of the test room, a HEPA filter failure would have been detected by elevated naproxen sodium levels in the filter samples.

Face Velocity Measurements.

Face velocity measurements were collected by attaching a Shortridge hood, Series 8400, with a 4 ft by 1 ft hood taped to the front of the test hood, as prescribed in NSF 49. The volumetric flow was modulated by adjusting the speed of the internal fan. The exhaust fan provided a negative pressure in the exhaust plenum, to ensure no leakage. After the negative pressure was established, the internal fan was modulated to achieve the desired flow. A volumetric flow of 254 cfm was measured and the opening (47" by 9-7/8") was 3.22 square feet, resulting in a face velocity of 78.8 fpm.

Observations During Testing

All three technicians spilled some powder inside the enclosure. The powder caused potential contamination of the work surface, the scintillation jars, and the scale.

Since the test was to determine control capability of the hood, nothing was removed from the cabinet during the tests.

During the procedures, the technicians left their hand inside the cabinet throughout the test period. When they were done weighing powder and filling jars, they removed their gloves, leaving them inside the hood and removed their hand slowly from the cabinet. They left the room immediately after finishing the weighing operation.

Throughout the test period, the technicians worked slowly and smoothly. It was clear that their work practices optimized the performance of the cabinet.

Operator 1

1) Female, 5'-7", slight build
2) Experience laboratory technician
3) Held hands off airfoil when not required in the process
4) Added powder by tapping the spatula above the boat. This procedure required more transfers but never overfilled the boat
5) The OBZ sample cassette was lower than the opening to the cabinet
6) Operator often leaned forward, resulting in the cassette being closer to the opening of the cabinet.

Operator 2

1) Male, 6'-1/2"
2) Engineer with limited laboratory experience
3) Rested hands on airfoil when not required for the process
4) Usually overfilled the boat then removed powder to obtain the desired weight
5) Because of his height, the OBZ sample cassette was above the top of the cabinet opening.
6) Operator often leaded back, resulting in the cassette being further from the cabinet opening.

Operator 3

1) Male, 5'-11"
2) Engineer with limited laboratory experience
3) Occasionally rested free hands on airfoil
4) Appeared to have done a time and motion study to minimize movement
5) Both overfilled (as operator 2) and under filled (as operator 1) the boat
6) Tended to sit straight in chair, but would lean forward when transferring powder to a jar.

Test Results

The results for the two days of air sampling are shown in Tables 3 and 4. All three operators performed weighing operation each day of testing.

All if the sample takes near the simulated operation were below the analytical limit of detection (0.5 nanograms per sample). The only sample above the limit of detection was a background sample colleted outside the room where the procedure was conducted. There is no explanation for the elevated sample. However, it did not appear to affect the other samples.

Table 3
Naproxen Sodium Test Results
First Round

			Sample Results, ng/m^3		
	Time Minutes	**Breathing Zone**	**Left Side of Hood**	**Right Side of Hood**	**Adjacent Table**
Operator 1	37	< 4.1	< 4.6	< 4.7	< 4.4
Operator 2	40	< 3.8	< 4.3	<4.4	< 4.1
Operator 3	36	< 4.2	< 4.8	< 4.8	< 4.6

Background < 1.1 ng/m^3

Table 4
Naproxen Sodium Test Results
First Round

			Sample Results, ng/m^3		
	Time Minutes	**Breathing Zone**	**Left Side of Hood**	**Right Side of Hood**	**Adjacent Table**
Operator 1	37	< 3.3	< 3.6	< 3.8	< 3.6
Operator 2	40	< 3.5	< 3.9	<4.1	< 3.8
Operator 3	36	< 4.6	< 5.1	< 5.3	< 5.0

Background 2.3 ng/m^3

Conclusions

1) The surrogute testing demonstrated good containment for typical powder handling operations when good techniques are used.
2) Potential dust exposures resulting from work practices were not evaluated.
3) For recirculation systems, the integrity of the HEPA filter should be evaluated before using active pharmaceutical agents.
4) The surrogute dust tests demonstrate, when the cabinet has adequate face velocity in a room with controlled room air currents and good operator work practices, that the cabinet provided good contaminant containment.

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Modified NSF/ANSI 49 Personnel Protection Test For NuAire Model NU-813-400 (Series 20) Containment Cabinet

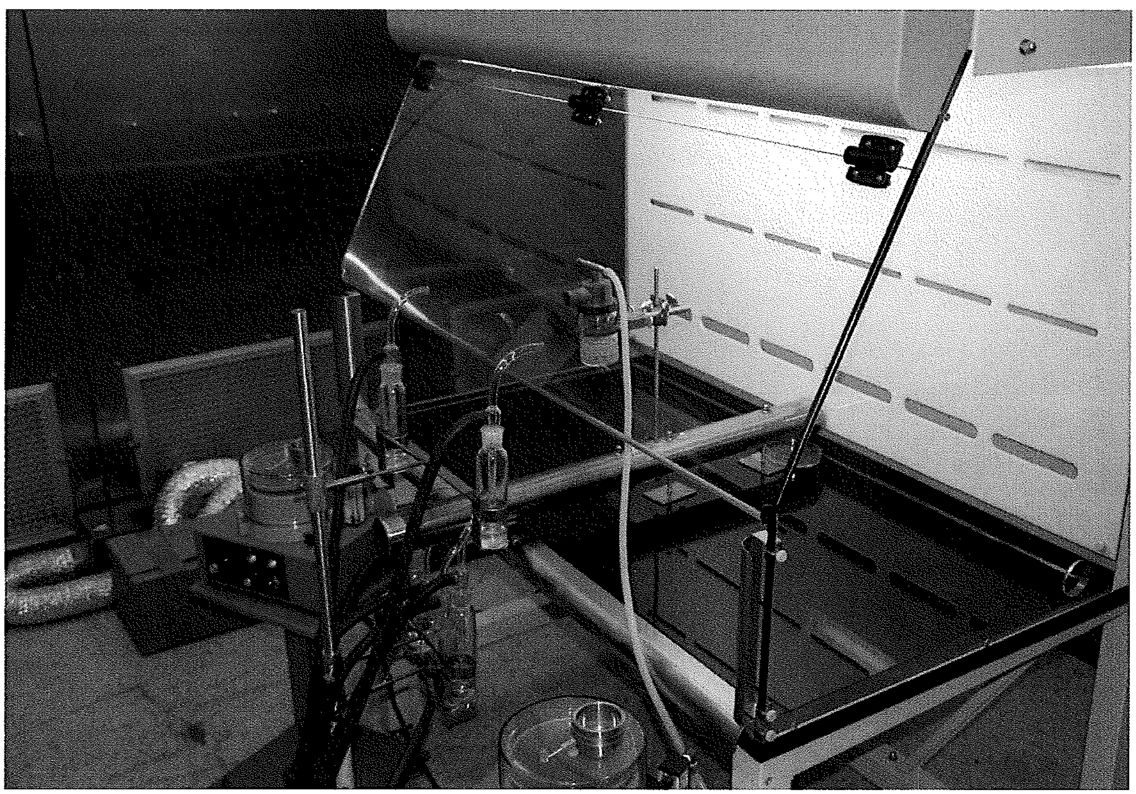
Background

To test the biological containment ability of the NU-813 Series 20 containment cabinet, the cabinet was biologically challenged for personnel protection using the NSF/ANSI 49 test procedure. The test was conducted in the NuAire clean room measuring 12.5 by 12.5 x 14 foot high. The airflow within the clean room is static per the requirements.

The cabinet was set up as being room re-circulated and the cabinets exhaust HEPA filter was gross leak tested to assure of no leaks.

The test set up was compliant to NSF/ANSI 49 except for the control plate that was moved to the back of the workzone to capture aerosolized bacteria.

Testing was conducted on a NU-813-400 (Series 20) (4 foot width) model. Inflow velocity was set at three different test values being 60, 80, and 100 fpm, using a Direct Inflow Measurement (DIM) Method. The photo below shows the personnel protection test set up in the clean room.



Test Results

General

Bacillus Concentration: 5.6 x 10^8
Dissemination Rate: 1.47 ml/5 min.
Applied PSI: 20 psi

60fpm Inflow Velocity

Initial wt. Of Nebulizer:	470.5g	469.0g	467.5g
Test Run	1	2	3
Control:	>200	>200	>200
Left Slit	2	4	1
Right Slit	0	1	2
Impingers:	1	1	1
Wt. Of nebulizer after test	469.0g	467.5g	465.8g
Sprayed Spores:	1.5g	1.5g	1.7g

80fpm Inflow Velocity

Initial wt. Of Nebulizer:	468.0g	465.9g	464.1g
Test Run	1	2	3
Control:	>200	>200	>200
Left Slit	0	2	1
Right Slit	0	0	0
Impingers:	2	6	1
Wt. Of nebulizer after test	465.9g	464.1g	462.2g
Sprayed Spores:	2.1g	1.8g	1.9g

100fpm Inflow Velocity

Initial wt. Of Nebulizer:	470.1g	468.3g	466.3g
Test Run	1	2	3
Control:	>200	>200	>200
Left Slit	1	0	0
Right Slit	0	0	0
Impingers:	3	0	1
Wt. Of nebulizer after test	468.3g	466.3g	464.7g
Sprayed Spores:	1.8g	2.0g	1.6g

Conclusion

Biological tests all passed using NSF/ANSI 49 Personnel Protection Test Criteria of 5 or less Colony Forming Units (CFU's) total for the slit samples and 10 or less CFU's for the Impingers. The NU-813 (Series 20) demonstrated good containment for biological materials.