Can a Containment Downflow Booth Meet ISO Conditions?

Walker Barrier Systems tests air quality in various downflow booth scenarios

The purpose behind downflow booth design is to provide operator protection during the handling of potent powders. Clean air from the ceiling plenum is distributed evenly across the whole of the work area pushing any respirable dust generated downward and away from the operator's breathing zone. As the dust moves down to a low level, the high velocity exhaust grilles direct the dust into the filters. The onboard filtration system, comprising of a minimum of fine dust filters and HEPA filters, removes the dust before returning the clean air into the ceiling plenum. A small amount of air is exhausted after the filters thereby creating a slight negative environment. Inward air movement into the booth at low level ensures containment. That is to say that potent powder cannot escape out of the booth, keeping the facility and operator safe.

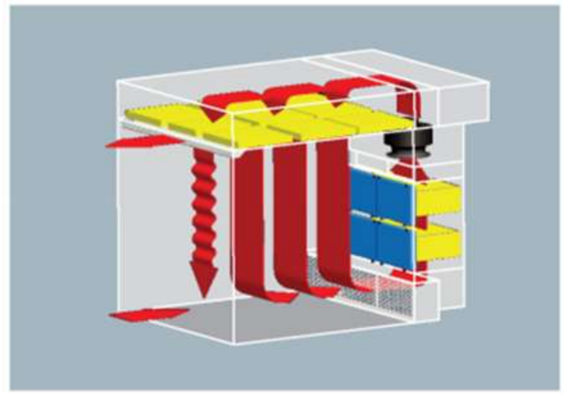

Figure 1

Figure 1 shows the air movement in a containment downflow booth. Notice the make-up air entering the booth from the outside front.

In some cases, the quality of air inside a booth during powder handling operations is important. Quality of air (or classification) is determined by obtaining particle count data. Figure 2 illustrates clean air classification typically used in aseptic processing applications using LAF benches, isolators, RABs and cleanrooms.

Clean Area Classification (US FED STD 209E)	Clean Area Classification (GMP EU)	ISO Designation	Particles ≥ 0.5 µm	Particles ≥5 µm
100	A	5	3,520	29
1000	B	6	35,200	293
10,000	C	7	352,000	2,930
100,000	D	8	3,520,000	29,300

Figure 2

We performed a series of tests to determine what air classification could be achieved by a downflow booth operating in an unclassified area. The booth was a Walker Barrier Systems 3m LX with an internal ceiling height of 108". Internal booth space was 114"W x 133"D with a safe zone of 90" from the rear wall. Booth filtration included:

(3) 24" x 24" x 12" Fine dust filters
(3) 24" x 24" x 12" HEPA filters
(12) 24" x 30" Terminal HEPA filters in the ceiling

The booth had an open front, allowing make-up air from the shop to freely enter the booth. Make-up air was approximately 500 CFM from the shop. Shop conditions at the beginning of the test included a room temperature of 70.5^0 F and an end temperature of 73.5^0 F. The booth included cooling coils, so the same temperatures were maintained inside the booth. It is important for the room temperature and booth temperature to be within 2-3^{0}F for best performance.

The shop is an unclassified area and is used for fabrication of isolators and downflow booths. Activities include welding and grinding of stainless steel (see Figure 3).

Figure 3

Test 1

Shop air samples were taken and the booth operated for 10 minutes before the first reading was taken. Readings were taken in four locations inside the booth: two near the rear wall 36" off the floor and two near the front wall 36" off the floor (see Figure 4 for the test apparatus; see Figure 5 for reading locations). The non-viable monitor samples at 1 cubic ft/minute, resulting in 36 minutes for each reading. Data was recorded after each test for both 5 micron and 0.5 micron particle sizes.

Figure 4

REAR

ZONE 2 ZONE 1

ZONE 4 ZONE 3

CONTAINMENT LINE

SHOP – ZONE 5

Figure 5

Readings of 1 cu/m (35.5 min each)	Air Flow	µ	Zone #1	Zone #2	Zone #3	Zone #4	Zone #5
Background		0.5					5,317,409
		5.0					11,557
1 10 minutes	5,000 CFM 10% Make-up Air	0.5	81,341	225,578	1,173,520	747,270	
		5.0	479	2938	10242	2566	

Particle Count Data

Based on the air classifications table (Figure 2), our test results (see Particle Count Data table) show that the booth ventilation/filtration system can provide ISO 8 quality air during powder handling operations.

Although satisfied with these results, we wondered if we could further improve air quality in the booth.

Test 2

We ran another test at a later date using the same booth but this time adding a fan filter unit (FFU) to the front of the booth and 32" side panels (see Figure 6). Make-up air of approximately 500 CFM entered the booth from the shop, but this time was mixed with HEPA filter air cascading down from the FFU.

The 2' x 4' FFU selected includes a 99.99% at 0.3 micron HEPA filter with three-speed control settings. In this case the highest setting was used, resulting in average air speed of 115 FPM. Readings were taken inside the booth as described in the previous test, again in the same locations. Results are listed in the table below.

Figure 6

Readings of 1 cu/m (35.5 min each)	Air Flow	µ	Zone #1	Zone #2	Zone #3	Zone #4	Zone #5
Background		0.5					6,859,579
		5.0					163,290
1 10 minutes	5,000 CFM 10% Make-up Air	0.5	23,218	25,456	291,109	184,639	
		5.0	222	115	1720	1090	

Particle Count Data (with FFU)

These results show that an ISO 7 can be achieved by adding one FFU in the front of the booth. This is a significant improvement considering the shop area background was nearly 7 million particles of 0.5 microns.

Test 3

Our final test looks at make-up air introduction combined with the FFU in the front of the booth. In this test, instead of having all make-up air come in through the front of the booth, 70% of the make-up air entered through the HEPA filters in the rear of the booth and 30% from the front. Readings were taken in the same locations and the same manner as before. These results are listed in the following table.

Readings of 1 cu/m (35.5 min each)	Air Flow	µ	Zone #1	Zone #2	Zone #3	Zone #4	Zone #5
Background		0.5					6,859,579
		5.0					163,290
1 10 minutes	5,000 CFM 10% Make-up Air	0.5	18,611	4,293	38,998	119,265	
		5.0	86	39	257	1149	

Particle Count Data (70/30 Make-Up)

The results show near compliance with ISO 6 conditions with only data point 4 being completely out of range. Certainly a strong ISO 7 was achieved, with 140 CFM make-up air from the front of the booth. To achieve a highly clean environment (ISO 5) in the booth without compromising make-up air flow into the booth, an airlock would be required.

The airlock would be positive pressure to the outside environment and provide make-up air to the booth. Based on the test results above, the airlock would need to meet ISO 7 requirements at a minimum, and have doors to the outside environment as well as to the booth. These doors should be interlocked so that they cannot be opened at the same time.

Conclusions

- Downflow booths can meet ISO 8 conditions even when installed in an unclassified area like a warehouse.
- Downflow booths can meet ISO 7 conditions when equipped with fan filter units.

This is especially important if some particulate control inside the booth is needed and there is no room to add an airlock.
It is important not to confuse downflow booths with cleanroom equipment. The primary purpose of a downflow booth is to keep operators and the surrounding area safe from potent airborne particles. Portable cleanrooms, such as the vertical laminar flow enclosure pictured in Figure 7, are meant to keep particulate out of product but do not keep the particulate from being breathed by operators or escaping into the room. If ISO 5 conditions are required in the downflow booth, an airlock must be added to the front of the booth.

Figure 7