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This article presents a performance verification study of a downflow booth via surrogate testing.

Performance Verification of a Downflow Booth via Surrogate Testing

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Introduction

This article describes performance testing of a downflow booth in accordance with the ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment. The downflow booth was tested using lactose monohydrate in order to record the containment performance with respect to airborne particulate, when:

1. recommended operator work practices are followed
2. additional engineering controls are integrated within the downflow booth

For those not familiar with downflow booth technology, the downflow booth is an engineering control that achieves containment by air entrainment. A downflow booth achieves containment by providing unidirectional HEPA filtered airflow (Figure 1), typically 90 feet per minute when measured at approximately three feet (one meter) from diffuser screen, over the process zone. When the downflow booth is used as designed, this downward flow of unidirectional air entrains dust particulate released from the process, away from the operator. The particulate entrained in this downward flow of air is then recaptured by a low level exhaust and passed through pre-filters and HEPA filters to substantially remove the particulate. Typically this air is then re-circulated to the supply plenum resulting in a 'push/pull' system. Since the booth is an 'open front' design to allow easy access of materials and personnel, there is always a 'bleed in' of air that can potentially result in a positive pressurization of the system. To eliminate this situation, downflow booths are fitted with features to allow a 'bleed out' of air after the HEPA filter (positive pressure side of system) to maintain the design balance. This 'bleed out' of air, dependent on the application, is either re-filtered or released without further filtration. Due to the open nature of the downflow booths, they are very versatile and allow for a

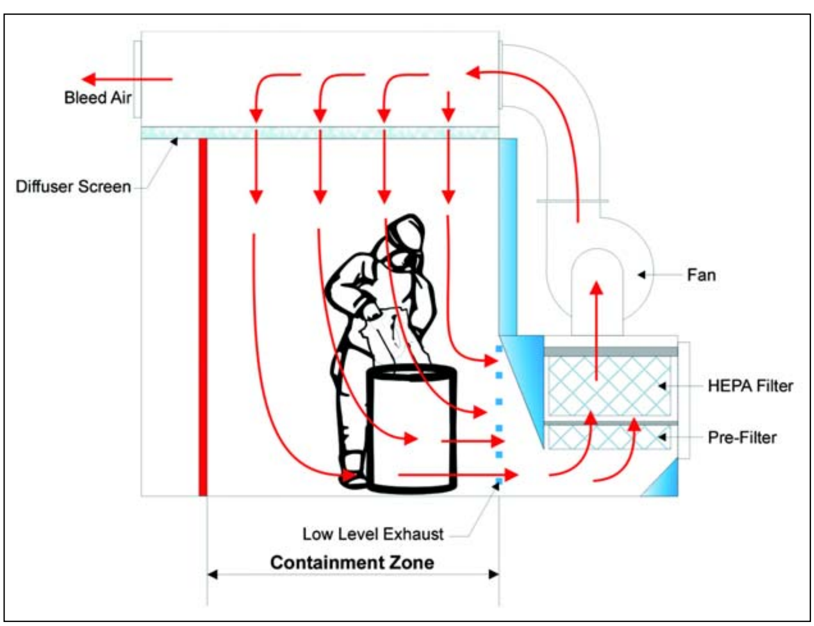

Figure 1. Unidirectional HEPA filtered airflow.

wide range of processes to be performed within them.

The downflow booth used for the performance testing was a standard re-circulating 2.0 meter wide booth. The booth's air processing system is comprised of two, rear mounted, bag-in/out filter banks arranged in parallel. Each bank consists of a high efficiency pre-filter and a HEPA filter. Polyester fabric (scrim) diffuser screens are used in the overhead supply plenum to ensure unidirectional downward airflow. Prior to surrogate testing, the downflow booth was tested to ensure it met performance specifications as defined by the downflow booth manufacturer. These tests were as follows:

- **Filter Penetration Test:** An aerosol challenge leak test was performed on each HEPA filter using a calibrated photometer and an aerosol generator that creates polydispersed particles predominantly 0.3 micron in size. The air flow through the filter was adjusted until the dP across the filter was 0.85 inches water gauge. (The differential pressure that would be seen across the filter when the downflow booth airflow is in normal running condition for new clean filter). The aerosol concentration injected upstream of the filter was 45 µg/l. The penetration of the aerosol was measured at 0.003% for the left HEPA (99.997% efficiency) and 0.002% for the right HEPA (99.998% efficiency). These measurements were within the required pass criteria for in place filter efficiency: >/= 99.97% at 0.3 micron level. Note the pre-filters were not in place during HEPA filter testing.

- **Supply Air Downflow Velocity and Uniformity**: The supply air velocity was measured with a rotating vane anemometer held three inches below the supply air scrim. Five points were measured in each of four scrim panels, for a total of 20 points. The average velocity for all 20 points was 100.5 ft/min. This met the pass criteria of average down flow velocity to be within 90 to 110 ft/min. The average velocity for each panel also was confirmed to be within 10% of the composite average down flow velocity. In addition, none of the individual points deviated more than 12% from the average velocity of the panel in which it was measured. These measurements met the specifications for the downflow booth. The total supply airflow was calculated and confirmed by measurement as 3360 cfm.

- **Bleed Air Volume:** In order to measure the bleed airflow from the downflow booth, a transition piece was placed over the bleed air outlet. It gradually channeled the air from the large rectangular bleed air diffuser into a 1 ft. square outlet, where the airflow was measured with a rotating vane anemometer. The measured bleed airflow was 430 cfm, equating to 11.4% of the total airflow (3360 cfm). This was within the required specification of five to 15% of the total airflow.

- **Return Air Flow Uniformity:** The return airflow was measured with a rotating vane anemometer held one inch away from the face of the grille. Four points were measured in each section of the return grille – left, center, and right – for a total of 12 points. The average velocity for each panel was within 10% of the composite average and none of the individual points deviated more than five percent from the average velocity of the panel in which it was measured. These measurements met the required pass criteria.

- **Smoke Tests:** Smoke tests were performed to demonstrate the airflow characteristics of the booth. The tests were video taped for record. The tests showed that:

  - The containment boundary or safe work zone extended 52" forward from the rear wall of the booth.
  - Within the safe work zone, the air flowed uniformly from the air supply scrim in the booth ceiling down to the return air grille in the rear wall of the booth.
  - The air moved in "plug flow" fashion, without back-mixing or diffusion.
  - Disturbances in the air stream caused by obstacles in the booth (equipment, people, etc.) were quickly resolved and did not cause air to flow back up into the operator's breathing zone.

The results of this performance verification testing demonstrated that the 2.0 meter wide downflow booth was operating within the defined performance criteria.

Surrogate Testing Protocol

The task to be performed in the booth was designated as drum-to-drum transfer of 25 kg of Lactose. This task was selected based on the following criteria:

- Drum-to-drum transfers by hand scooping or direct discharge from a drum liner are common tasks that are performed at the majority of pharmaceutical facilities.
- It is an 'open' and manual process, reliant on operator technique, so it would challenge the equipment to a reasonable level and provide suitable parallel for 'real world' tasks.
- The equipment and materials required to perform the task are readily available.
- Lactose is the recommended surrogate of the ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment, (Appendix G) and is readily available. The surrogate material was sourced to be in compliance with the Good Practice Guide. [Lactose-313, NF Monohydrate; Product No. 661550, Batch 8506060313]. The Lactose used had a particle size distribution of 75% (by weight) less than 37 micrometers with 24% between 75 and 37 micrometers, and one percent larger than 75 micrometers. Although not a crystalline material, lactose has physical characteristics, such as particle size and dustiness, similar to the products typically handled in a pharmaceutical environment. Additionally, it is detectable at very low concentrations in air.

Due to the space limitations within the booth, the testing protocol was developed for one operator to perform out all of the required tasks. To reduce the risk of potentially contaminating the test area and thereby raising the background levels, we arranged the tasks from those expected to release the least amount of contamination to those expected to release the most, as follows:

1. Downflow Booth with Additional Controls:

The manual transfer of lactose (25 kg) from the bulk drum to one receiving drum (in all instances the drums to be fitted with double liners) within the downflow booth with the addition of a ventilated charging collar to improve dust containment and a drum handler to improve ergonomics. Note that the ventilated charging collar provides additional control only via additional containment by air entrainment and this is still considered an open process.

1.1 Transfer the drums (bulk product and receiving) into the downflow booth.
1.2 Stage the bulk drum on the drum handler and the receiving drum in front of it. De-lid the drums.
1.3 Locate the ventilated collar on to the opening of the receiving drum and stage the liners. The operator should use the drum handler to position the opening of the bulk drum as close as possible to the receiving drum. The operator shall use the drum handler to angle the bulk drum to allow direct liner to liner transfer by pouring/scooping to the receiving drum. The operator also shall ensure that the opening of the liner containing the bulk lactose is kept below the extraction slots of the ventilation collar during liner opening and material transfer.
1.4 The bulk drum liner is verified empty by slowly pulling it out of the bulk drum over the top of the ventilated collar; being careful to ensure that the liner opening remains below the extraction slots. Residual material encountered during this process is worked free and transferred into the receiving drum. Once empty, the bulk liner is carefully balled up (within the collar) and passed into a sleeved trash chute that is incorporated into the ventilated collar.
1.5 Tie off the liners for the receiving container and re-lid the drum. Remove one layer of gloves and place into bulk receiving drum and re-lid the bulk drum.

2. Downflow Booth with No Additional Controls:

The manual transfer of lactose (25 kg) from the bulk drum to one receiving drum (in all instances the drums to be fitted with double liners) within the downflow booth with no additional controls or ergonomic aids.

2.1 Transfer the drums (bulk product and receiving) into the downflow booth.
2.2 Stage the drums to the rear of the booth and de-lid drums and stage liners. The operator should hand scoop the lactose until sufficient material is transferred to allow the liner containing the remaining material to be lifted out of the drum to allow direct discharge from the liner by pouring into the receiving drum.
2.3 When liner is empty, place it back into the now empty bulk product drum. Tie off the liners for the receiving container and re-lid the drum. Remove one layer of gloves and place into bulk receiving drum and re-lid the bulk drum.

3. Downflow Booth Ventilation System Disabled:

The same procedure as described in item two (downflow booth). The purpose for this test would be to establish the magnitude of airborne dust levels for a drum to drum transfer if no engineering controls were employed. This data was considered useful as it would allow us to ascertain the amount of protection provided by the downflow booth technology

As per the recommendations of the ISPE Good Practice Guide (Section 4.5 Clothing), the clothing for the operator was as follows:

3.1 Tyvek® one-piece disposable suit
3.2 Several layers of impermeable gloves, a layer of gloves is to be removed after each task is completed and discarded. A layer of gloves also should be removed after conducting a task that results in a high level of dust on the gloves.

The hairnet/cover was excluded as there were no cGMP requirements since the testing was performed in a non-GMP area.

An operator was selected and trained on the simulation. Attention to good work practices to reduce airborne particulate generation was stressed. As a result of the training it was determined that each task required an average duration of 20 minutes, when performed following the operator procedures as outlined previously. Based on this data and to ensure that the testing yielded a relevant number of samples, each task would be repeated a total of three times. To further ensure that a sample representative of all the dust emitted from the task was collected, the sampling was extended for an additional 15 minutes at the end of each iteration with the operator remaining in the booth for that period (as recommended by the ISPE Good Practice Guide – 'Equipment Specific Test Protocols,' page 32). As per the protocol, following the completion of the task and extended sampling period, all air sampling pumps were stopped and the filter cassettes removed and changed before proceeding with the subsequent process iteration.

Since very high concentrations of airborne lactose were expected during the test with the downflow booth disabled, there was concern that this task would contaminate the downflow booth and testing area to a point that the raised background levels would affect any future testing. For this reason, only a single iteration of this test was performed. Also, the 15 minute sample extension period was reduced to five minutes. Given the high airborne concentrations expected, it was felt that the shortened duration of the extension period would have no significant impact on reported airborne concentration obtained by these samples.

Air Sampling Method

Operator Breathing Zone (OBZ) air samples were collected during this study to quantify the typical exposures for the operator while performing the designated tasks. The operator wore a calibrated air monitoring pump attached to his belt and a sample collection device (25 mm, 1.0 μm PTFE filter in two-piece blank, conductive cassette) attached to his collar. The filter cassette was attached to the pump with Tygon® tubing.

Area air samples also were collected in fixed locations inside and outside of the downflow booth - *Figure 2*. This included three area air samples inside the booth and just outside the "safe working zone." Three area air samples also were collected outside the booth in order to assess the potential for particulate migration out of the booth during the surrogate operation. All the area air samplers were oriented to face into the downflow booth The sample locations were in accordance with the recommendations of ISPE Good Practice Guide, 'Equipment Specific Test Protocols', (page 34) and were as follows:

- Inside booth: eight inches off left side wall and eight inches outside safe work zone
- Inside booth: in the center of the booth and eight inches outside safe work zone
- Inside booth: eight inches off right side wall and eight inches outside safe work zone
- Outside booth: eight inches outside booth in front of left side wall
- Outside booth: five feet outside and in the center of the booth
- Outside booth: eight inches outside booth in front of right side wall

Planning and careful field techniques were required when air sampling to ensure that meaningful data was collected and that the samples are not cross-contaminated during collection, resulting in false positives. With this in mind, the following field techniques were employed:

- Pre- and post- monitoring verification of sample pump's airflow calibration. This is done by a comparison to a secondary, NIST traceable, calibrated standard for three trials, that were then averaged.
- The lower of the pre- or post- monitoring calibration averages were used to calculate the sample volume for a given pump.
- Careful observation and recording of sample pump run times in order to determine an accurate total sample volume.
- Over-handling of filters was avoided as much as possible.
- Filters were always handled with clean powder-free gloves.
- Filters were stored in sealed plastic "zip-lock" bags with separate bags for clean and used filters. If the filter cassettes were seen to be dusty (pump casing was examined for evidence), the cassettes were wiped off after capping before placing the used filters into the plastic bag.
- Filter cassette tips were stored in separate clean plastic "zip-lock" bag during air monitoring. The colors were reversed on used filters (red tip on inlet) to distinguish from clean filters (blue tip on inlet). Touching of the filter cassette inlet opening and the filter cassette tip pointed ends were avoided as much as possible.
- Tips were placed on filters after turning pumps off.

As previously stated, the air sampling was extended by 15 minutes at the end of each task iteration with the operator remaining in the booth for that period. At the end of this 15 minute 'rest period,' all air sampling pumps were stopped and the filter cassettes removed and changed before proceeding with the subsequent process iteration.

Background area air samples also were collected prior to conducting any work to determine if the surrogate material was detectable in workplace air, either from pre-existing operations or other sources of contamination, such as preparation for this testing.

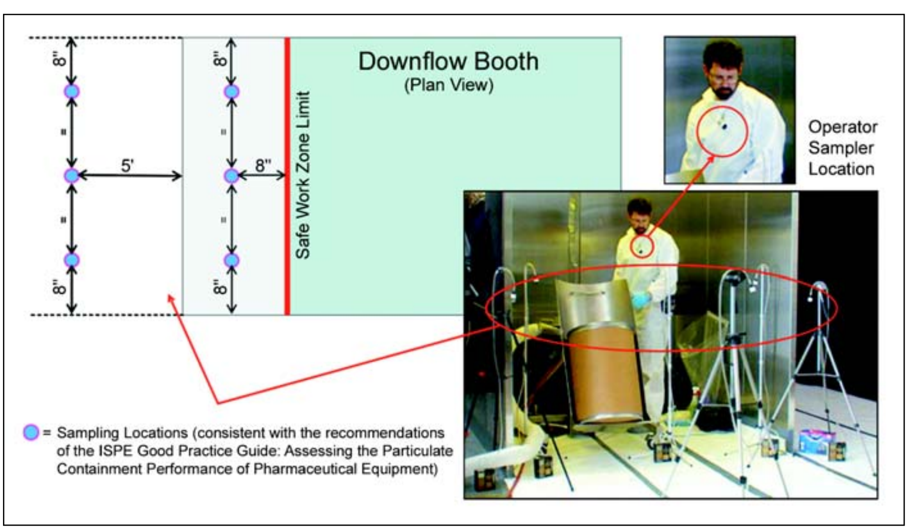

Figure 2. Downflow booth (plan view).

Test Equipment

The test equipment used was as follows:

- Air Monitoring Pumps were operated at a flow rate of approximately 2.0 liters per minute. These pumps were calibrated before and after sampling by an airflow meter calibrated to the National Bureau of Standards (NBS).
- Sample collection device (25 mm, 1.0 μm PTFE filter in two-piece blank, conductive cassette).

Analysis

All air samples were submitted to an

independent laboratory for sample analysis for lactose. Each sample was identified using a unique number and stored and shipped the samples in refrigerated containers to minimize the potential for sample degradation. The field blanks were handled in the same manner as the other air samples, except that no air was drawn through the filter cassettes.

The samples were analyzed using High Performance Liquid Chromatography (HPLC) with Pulsed Amperometric Detection (PAD). The sample was extracted from each PTFE filter using in situ methodology with a suitable solvent for lactose. The analytical reporting limit for lactose using this method is two nanograms per air sampling filter.

It also should be noted that the test results were not time weighted and reflect the actual average concentration over the sample time.

Background Testing

Two days were taken to complete the testing and prior to beginning work on each day of this performance verification study, two background area air samples were collected in the testing area both inside and outside the booth in locations that would subsequently be used for the static area air samples. The results of these samples were as follows:

Background Area Air Samples Collected on Day One

- Inside: <0.01 µg/m^3
- Outside: <0.01 µg/m^3

Background Area Air Samples Collected on Day Two

- Inside: 0.05 µg/m^3 (Elevated reading, assumed to be due to moving of potentially contaminated bulk containers into the downflow booth prior to background sampling on day two.)
- Outside: <0.01 µg/m^3

Additionally, one field blank was submitted for analysis for approximately every 10 air samples collected. Since a total of 53 air samples were collected in this study, five field blanks were submitted for analysis. The results of these field blank samples were all reported as less then <2ng per filter.

Observations During Testing of Booth with Additional Controls

The first test required that the downflow booth be tested with a ventilation sleeve containment system and drum handler as an additional engineering control - *Figure 3*. This system was selected as it has the following features:

- Provides high-velocity ventilation 360 degrees (425 cfm) around the perimeter of the localized working area, creating a cross-sectional plane of exhaust. Exhaust HEPA filter prior to discharge.
- Integrated bag out port
- Integrated drum handler to improve ergonomics

The ventilation sleeve containment system was connected to a stand alone Air Handling Unit (AHU) fitted with a HEPA filter in order to generate the required airflow (425 cfm). This stand alone AHU was located outside the downflow booth. It should be noted that the downflow booth was not rebalanced at this stage to assess the effect of the additional 425 cfm of air exhausted by the ventilation sleeve out of the booth. Differential pressure measurements across the polyester air diffusers did not appreciable change when the collar was in use, indicating that the additional 425 cfm make up air most likely entered the booth through the booth's open front. A localized disruption of the typical unidirectional airflow within the booth can be expected adjacent to the ventilated collar. The collar exhaust flow rate was monitored for the duration of the testing and was held constant.

Figure 3. Ventilation sleeve containment system and drum handler.

In order to achieve the transfer, the open end of the liner containing the lactose was extended through the opening of the ventilated collar and into the receiving drum. The lactose was then transferred from the bulk drum by 'massaging' the contents slowly through the liner into the receiving drum - *Figure 4*. As soon as the liner was nearly empty, it was removed from the bulk container by the operator and carefully inverted to fully discharge the contents into the receiving container, all the time ensuring that the open discharge side liner was never raised above the high velocity exhaust slot of the ventilated collar. Once empty, the liner was disposed of by posting it into the sleeved waste port on the ventilated collar (located below the velocity exhaust slot of the ventilated collar). The ventilated collar was then lifted off of the receiving container and placed on the floor of the downflow booth. The liner containing the lactose in the receiving drum was then tied off and the drum re-lidded.

Figure 4. Lactose transfer from bulk drum by 'massaging' the contents slowly through the liner into the receiving drum.

The waste out bag containing the waste liner and all used gloves were placed within the bulk drum and sealed re-lidding it.

It also was recorded that due to space limitations in the booth created by the drum handler, in order to remove the empty bulk drum and to replace it with a new one an individual outside of the booth was needed. The bulk drum containing the waste was first transferred to this individual and then the new receiving drum with liners was transferred to the operator, at the safe work line. This task was accomplished as carefully as possible to not disturb or unintentionally contaminate the static area air samplers

Results for Booth with Additional Controls

A total of 21 air samples were collected for all the task iterations using this configuration as follows:

- Operator Breathing Zone Air Samples: The exposure of one operator was assessed for three iterations (three samples) of the transfer process; each iteration took between 32 and 35 minutes to complete (including the 15-minute extension period)

  Results Range: <0.03 to 0.04 µg/m^3
  Mean: 0.03 µg/m^3

- Area Air Samples: A total of 18 area air samples were collected at three locations within and three locations outside the downflow booth.

  Results Inside - Range: <0.03 to <0.03 TR* µg/m^3
  Inside - Mean: 0.03 µg/m^3
  Outside - Range: <0.03 to 0.05 µg/m^3
  Outside - Mean: 0.03 µg/m^3

**TR = Trace amount detected on sample. A trace amount indicates an analytical peak that shows the presence of lactose on the sample, but at a level below the reporting limit for the air volume collected. It is used to indicate that the results show that lactose was present on the sample, but an amount below the two nanogram lower limit of quantification.*

Observations during Testing of Booth without Additional Controls

For the second test, the only engineering control used was the downflow booth. As per the recommendations for operating in a downflow booth, the operator positioned the drums as close as possible to the low level exhaust located at the back of the booth. The bulk drum also was placed as close as possible to the receiving container to minimize the distance required to scoop the lactose. The operator then carefully transferred by hand scooping the lactose from the bulk drum to the receiving drum, at times ensuring that the scoop was placed entirely inside the receiving container before dispensing the contents - *Figure 5*.

As soon as the liner was nearly empty, it was removed from the bulk container by the operator and carefully inverted to fully discharge the contents into the receiving container. The receiving liner was then tied off and the drum re-lidded. The waste liner and all used gloves were placed into the bulk drum and sealed by re-lidding it.

Results for Booth without Additional Controls

A total of 21 air samples were collected for the drum to drum transfer of lactose using the downflow booth as the only engineering control as follows:

- Operator Breathing Zone Air Samples: The exposure of one operator was assessed for three iterations (three samples) of the transfer process; each iteration took between 37 and 39 minutes to complete (including the 15-minute extension period)

  Range 0.64 to 1.54 µg/m^3
  Mean: 1.01 µg/m^3

- Area Air Samples: A total of 18 area air samples were

Figure 5. An operator carefully transfers; by hand scooping the lactose from the bulk drum, to the receiving drum, ensuring the scoop is placed entirely inside the receiving container before dispensing the contents.

collected at three locations within and three locations outside the downflow booth.

Range Inside - Range: <0.02* to 0.06 µg/m³
Inside - Mean: 0.03 µg/m³
Outside - Range: <0.02 to 0.05 µg/m³
Outside - Mean: 0.02 µg/m³

** Note that due to the variation of total sampled air volumes (a function of both sample rate and sample time), a lower reportable airborne concentration of 0.02 µg/m³ was achievable for this test as compared to the 0.03 µg/m³ limit indicated in the result of the booth with additional controls*

Observations during Testing of Booth with Ventilation Disabled

For the third and final test, the downflow booth air handling system was disabled. The tasks performed by the operator were exactly the same as those conducted for the test two with the downflow booth operating, except that the operator was slightly quicker in completing the product transfer. As previously stated since there was a concern with lactose contamination of the booth and the testing area, only one iteration of this test was performed and the 15 minute extension of the sampling period used in the previous tests was shortened to five minutes.

Results of Booth with Ventilation Disabled

Total of seven air samples were collected for this test:

- Operator Breathing Zone Air Sample: The exposure of one operator was assessed for a single iteration (one sample) of the transfer process; the iteration took 24 minutes to complete (including a 5-minute extension period)

  Results 2,250 µg/m³

- Area Air Samples: A total of six area air samples were collected at three locations within and three locations outside the downflow booth.

  Results Inside - Range: 51.6 to 177.0 µg/m³
  Inside - Mean: 123.5 µg/m³
  Outside - Range: 10.0 to 32.3 µg/m³
  Outside - Mean: 20.0 µg/m³

Conclusion

Historical data shows that downflow booths typically control operator exposures to between 100 and 50 µg/m³ based on eight-hour time weighted averages. The results of this study indicate that even greater control is possible when good operating procedures and transfer technique are rigidly followed by an operator.[3,4,5,6] The results (Tables A, B, and C) show that downflow booth technology is highly effective in reducing and controlling high levels of airborne lactose dust and the potential exposure to the operator when procedures and techniques are applied precisely. The results show that when coupled with good technique, the downflow booth provided exposure control to 1 µg/m³ for lactose for the period of

	Booth with Additional Controls	Booth with No Additional Controls	Booth with Ventilation Disabled
Operator Breathing Zone Range	< 0.03 to 0.04 µg/m³	0.64 to 1.54 µg/m³	2,250 µg/m³
Operator Breathing Zone Mean	0.03 µg/m³	Mean: 1.01 µg/m³	Only one sample collected
Area Air Samples Inside Range	< 0.03 to < 0.03 µg/m³	< 0.02 to 0.06 µg/m³	51.6 to 177.0 µg/m³
Area Air Samples Inside Mean	0.03 µg/m³	0.03 µg/m³	123.5 µg/m³
Area Air Samples Outside Range	< 0.02 to 0.05 µg/m³	< 0.02 to 0.05 µg/m³	10.0 to 32.3 µg/m³
Area Air Samples Outside Mean	0.03 µg/m³	0.02 µg/m³	20.0 µg/m³

Table A. Showing summary of results.

Date	Sample #	Type of Sample	Activity	Time(min)	Air Volume (L)	Conc. (μg/m³)
8/25/06	082506-01	Background	Background area air sample (inside)	76	167.6	0.05
8/25/06	082506-02	Background	Background area air sample (outside)	76	167.6	< 0.01
8/25/06	082506-03	OBZ	Drum-to-drum transfer of 25 Kg lactose by hand scooping (iteration #1)	37	83.1	1.54
8/25/06	082506-04	Area (in)	Static area air sample inside booth; LEFT side (iteration #1)	37	80.5	< 0.02
8/25/06	082506-05	Area (in)	Static area air sample inside booth; CENTER (iteration #1)	37	81.6	< 0.02
8/25/06	082506-06	Area (in)	Static area air sample inside booth; RIGHT side (iteration #1)	37	79.6	< 0.03
8/25/06	082506-07	Area (out)	Static area air sample outside booth; LEFT side (iteration #1)	37	80.8	< 0.02TR
8/25/06	082506-08	Area (out)	Static area air sample outside booth; CENTER (iteration #1)	37	81.6	< 0.02
8/25/06	082506-09	Area (out)	Static area air sample outside booth; RIGHT side (iteration #1)	37	83.3	< 0.02
8/25/06	082506-10	Field Blank #1	N/A	N/A	N/A	< 2 ng
8/25/06	082506-11	OBZ	Drum-to-drum transfer of 25 Kg lactose by hand scooping (iteration #2)	37	83.1	0.64
8/25/06	082506-12	Area (in)	Static area air sample inside booth; LEFT side (iteration #2)	37	80.5	0.06
8/25/06	082506-13	Area (in)	Static area air sample inside booth; CENTER (iteration #2)	37	81.6	< 0.02
8/25/06	082506-14	Area (in)	Static area air sample inside booth; RIGHT side (iteration #2)	37	79.6	< 0.03
8/25/06	082506-15	Area (out)	Static area air sample outside booth; LEFT side (iteration #2)	37	80.8	< 0.02TR
8/25/06	082506-16	Area (out)	Static area air sample outside booth; CENTER (iteration #2)	37	81.6	< 0.02
8/25/06	082506-17	Area (out)	Static area air sample outside booth; RIGHT side (iteration #2)	37	83.3	< 0.02
8/25/06	082506-18	OBZ	Drum-to-drum transfer of 25 Kg lactose by hand scooping (iteration #3)	39	87.6	0.86
8/25/06	082506-19	Area (in)	Static area air sample inside booth; LEFT side (iteration #3)	39	84.8	< 0.02
8/25/06	082506-20	Area (in)	Static area air sample inside booth; CENTER (iteration #3)	39	86.0	< 0.02
8/25/06	082506-21	Area (in)	Static area air sample inside booth; RIGHT side (iteration #3)	39	83.9	0.03
8/25/06	082506-22	Area (out)	Static area air sample outside booth; LEFT side (iteration #3)	39	85.2	< 0.02TR
8/25/06	082506-23	Area (out)	Static area air sample outside booth; CENTER (iteration #3)	39	86.0	0.05
8/25/06	082506-24	Area (out)	Static area air sample outside booth; RIGHT side (iteration #3)	39	87.8	< 0.02
8/25/06	082506-25	Field Blank #2	N/A	N/A	N/A	< 2 ng

Table B. Results of lactose surrogate air sampling downflow booth (only).

operation.

Further, the combination of a ventilated collar and drum handler with the downflow booth successfully demonstrated exposure control well below 1 μg/m³ for lactose for the period of operation. There was only one detectable reading from the sample taken in the operator's breathing zone (0.04 μg/m³) and one detectable reading among all the static area air samples collected (0.05 μg/m³).

The case for the use of engineering controls such as the downflow booth for open transfer operations also was confirmed by the high levels of lactose dust measured when no engineering controls are employed (2,250 μg/m³). This information is of further value as it gives a reasonable indication of the protection factor (the ratio of observed concentration without protection to that when protective measures are used) that can be provided by the use of downflow booth type technology; in excess of 2000.

The data collected also provides good evidence that the air sampling results in this study were not adulterated by background levels of lactose or from any other source. Three of the four results collected for the four background area air samples submitted for analysis were below the analytical reporting limit for the sample collection period (greater than 60 minutes). The one detectable reading on Day 2 was likely due to moving of bulk containers into the downflow booth, which occurred after the air samplers were started. In addition, the five field blanks showed no reportable levels of lactose.

As previously stated, throughout the study the operator always removed his outer gloves after handling the receiving container and wiped down the downflow booth's exhaust

Date	Sample #	Type of Sample	Activity	Time(min)	Air Volume (L)	Conc. (μg/m³)
8/25/06	082506-26	OBZ	Drum-to-drum transfer of 25 Kg lactose by hand scooping (w/out vent.)	24	53.9	2250.0
8/25/06	082506-27	Area (in)	Static area air sample inside booth; LEFT side (iteration #1)	24	52.2	142.0
8/25/06	082506-28	Area (in)	Static area air sample inside booth; CENTER (iteration #1)	24	52.9	177.0
8/25/06	082506-29	Area (in)	Static area air sample inside booth; RIGHT side (iteration #1)	24	51.6	51.6
8/25/06	082506-30	Area (out)	Static area air sample outside booth; LEFT side (iteration #1)	24	52.4	17.6
8/25/06	082506-31	Area (out)	Static area air sample outside booth; CENTER (iteration #1)	24	52.9	10.0
8/25/06	082506-32	Area (out)	Static area air sample outside booth; RIGHT side (iteration #1)	24	54.0	32.3
8/25/06	082506-33	Field Blank #3	N/A	N/A	N/A	< 2 ng

Table C. Results of lactose surrogate air sampling downflow booth (without ventilation).

plenum where a distinct ring of particulate contamination was noted. When the additional engineering controls were utilized, the operator ensured that his technique did not allow the material being transferred to leave the local exhaust ventilation zone during the transfer process, and the operator removed his outer gloves after handing the receiving container and wiped down the drum lift after each iteration.

However, we also must state that these results are specifically for airborne lactose and while they provide a valuable benchmark, actual containment characteristics for alternate compounds can only be known by testing with those compounds. Additionally, in the process environment where the pace of work is accelerated and operators may not always use good technique, the exposure levels experienced by the operator are likely to be higher, perhaps by as much as an order of magnitude dependent on the material being handled and the process operation.

Based on the results of this study, we can conclude:

- The performance of a downflow booth can be significantly enhanced by the use of a double lined drum and a ventilated collar integrated with a drum handler to improve ergonomics.
- Operator technique and strict adherence to procedures can significantly improve the performance of a downflow booth with no additional controls.
- Similar results may be achieved and repeated by a well trained and conscientious operator, rigidly following recommended procedures in combination with a downflow booth.

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