# A SMEPAC-Based Case Study on Airflow Entrainment, Human Factors, and the Gap Between Engineering Capability and Operational Reality in Downflow Booth Operations

Lessons Learned from Containment Performance Verification Activities

## Contents

# 1. Executive Summary

Containment equipment is frequently specified, purchased, and validated as though containment were a fixed property of the equipment itself. This paper argues, and demonstrates with field data, that this framing is incomplete and can be misleading. Containment performance is an emergent property of the complete containment system: equipment design establishes the engineering capability, but the exposure an operator actually experiences depend equally on process design, operator's behavior, workspace configuration, material characteristics, and the validated operating procedures that govern how the equipment is used. A downflow booth (DFB) that is fully capable of achieving Occupational Exposure Band (OEB) 3 containment on a manufacturer's factory acceptance test can still produce a personal breathing-zone result of several thousand micrograms per cubic meter at a customer site if the working envelope is crowded, the operator works outside the validated safe working zone, or an unplanned handling step is introduced.

This paper uses Standardized Methodology for the Evaluation of Pharmaceutical Airborne Particle Emissions from Containment Systems (SMEPAC) verification of a customized Esco Downflow Booth Generation 2 (DFBG2) as a case study to move beyond simple pass/fail reporting. Three operators handled 30 kg of lactose monohydrate surrogate powder inside a compact, client-customized booth. Two of three operators produced personal exposure results that exceeded the OEB 3 acceptance range, despite the booth itself meeting its engineering containment specification. We use fluid dynamics, ergonomics, and occupational hygiene literature to explain the mechanisms responsible: disruption of the downflow airstream by operator movement, the wake and thermal plume generated by the human body, the influence of drum geometry on capture efficiency, and turbulence generated by an unplanned bag-shaking step. We then discuss what these findings mean for how SMEPAC data should be interpreted, and how the hierarchy of controls and human factors engineering can be applied to close the gap between engineering capability and operational capability.

# 2. Introduction

SMEPAC initially stands for the *Standardized Measurement of Equipment Particulate Airborne Concentration,* a methodology originally published by the International Society for Pharmaceutical Engineering (ISPE) in 2005, which then revised as second edition in 2012 as ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment, and reissued in its third edition in 2024 under the new title of *SMEPAC Standardized Methodology for the Evaluation of Pharmaceutical Airborne Particle Emissions from Containment Systems,* reflecting the name the industry had already adopted informally [1,2,3]. The methodology is applied when potent bulk powders are weighed and dispensed in quantities large enough that airborne powder clouds may form and pose a hazard to operators, particularly within the breathing zone while working at a Primary Engineering Control (PEC). This is especially important when handling hazardous drug substances or potent Active Pharmaceutical Ingredients (APIs), where even brief exposure above the occupational exposure limit (OEL) are hazardous. Engineering controls are selected based on powder quantity, potential exposure risk, and specific physical hazards (e.g., dustiness). For moderate-risk scenarios, operator exposure is mitigated by performing weighing and dispensing operations inside a Downflow Booth (DFB).

A downflow booth is an open-front containment workstation designed to control airborne particulate generated during powder handling operations such as weighing, dispensing, and sampling. The system operates by drawing room air through a high-efficiency particulate air (HEPA) filter located at the ceiling of the booth and directing it vertically downward as a uniform airflow curtain. This downward airflow captures dust generated at the work surface and transports it toward low-level exhaust grilles positioned behind or beneath the working zone. The contaminated air is then filtered before being either recirculated within the booth or discharged through the facility exhaust system. By establishing a controlled airflow path from clean supply to filtered exhaust, the booth reduces particulate dispersion into the surrounding room while maintaining operator visibility and ergonomic access to the process area.

*Figure 1. Esco Downflow Booth G2*

Potent powders are classified according to their allowable occupational exposure concentration averaged over an 8-hour workday, expressed as an Occupational Exposure Band (OEB). Since OEB banding systems are organization-specific, the relationship between an OEB category and its corresponding OEL range may vary across different organizations. Therefore, OEL values should be considered the more definitive parameter when describing occupational exposure limits. Nevertheless, to facilitate discussion and provide contextual reference, Table 1 summarizes the conventional OEB classification structure utilized by Esco.

*Table 1. Occupational Exposure Band (OEB) classifications*

| | OEB 1 | OEB 2 | OEB 3 | OEB 4 | OEB 5 | OEB 6 | OEB 7 |
|---|---|---|---|---|---|---|---|
| OEL range | >1000–5000 µg/m³ | >100–≤1000 µg/m³ | >10–≤100 µg/m³ | >1–≤10 µg/m³ | <1.0–0.01 µg/m³ | 0.01–0.001 µg/m³ | <0.001 µg/m³ – <1 ng/m³ |

SMEPAC is performed when a user needs to demonstrate the containment performance of a specific weighing and dispensing process under a specific PEC, while simultaneously evaluating the adequacy of the associated Standard Operating Procedure (SOP) and the competency of the operators executing it. Testing is normally conducted with a surrogate powder that safely mimics the dustiness and handling characteristics of the actual hazardous material. Airborne samples are collected at defined static locations within and around the booth and at the operator's breathing zone, alongside surface swab samples, to characterize both containment and residual contamination.

The conventional way this data is reported, and often the only way it is read by non-specialist audiences, is as a binary outcome: did the measured concentrations fall inside or outside the OEB acceptance range. That framing is defensible for a go/no-go decision on a specific test run, but it obscures the more important engineering and occupational hygiene question: why did the result come out the way it did, and what does that tell us about the containment system as a whole. This paper develops that second question using a real SMEPAC verification project as its evidentiary base. The project involved a compact, small-size customized DFBG2 booth, three operators of differing size, handedness, and experience, and a surrogate powder trial that produced out-of-specification personal exposure results alongside an otherwise compliant equipment performance profile. Sections 3 through 5 develop the underlying engineering and human factors principles; Sections 6 through 8 present the case study, results, and root cause investigation; Sections 9 through 12 discuss the implications for containment engineering practice, contamination control strategy, and end-user operations.

## 3. Why Containment Performance Is Frequently Misunderstood

Containment equipment is typically procured against a single performance number, most commonly a guaranteed containment value expressed in µg/m$^3$ at the operator's breathing zone, derived from a SMEPAC test during factory acceptance test (FAT) or site acceptance test (SAT) conducted under controlled, idealized conditions. It is natural, but incorrect, to treat that number as an intrinsic property of the equipment that will transfer unchanged into routine production. In practice the FAT/SAT number describes the containment capability of the equipment under the specific process, operator, material, and workspace configuration used during that test. Change any one of those variables and the achieved exposure can change by an order of magnitude or more, even though the physical booth, its airflow design, and its filtration have not changed at all.

This misunderstanding is reinforced by how containment claims are commonly communicated in commercial literature and internal validation summaries, where a single guaranteed value is presented without the operating envelope that produced it. The equipment supplier is responsible for engineering capability: the airflow rate, velocity profile, filtration efficiency, and physical geometry of the enclosure. The end user is responsible for operational capability: the process design, the specific SOP, operator training and technique, the layout of ancillary equipment inside the working zone, and the discipline with which the safe working zone is respected during routine use. A containment performance verification exercise, whether a FAT, SAT, or full SMEPAC study, measures the combined result of both. When a result is out of specification, the reflexive question is often *"is the booth underperforming,"* when the more useful question is *"which element of the combined system deviated from the conditions under which capability was established."*

A second source of confusion arises from a failure to distinguish between statistical variability and actual equipment failure. SMEPAC data sets are typically sparse, often comprising three or fewer replicate runs per operator, and reflect a process subject to significant inherent variability driven by technique, timing, and material behavior. Accordingly, a single elevated result cannot be definitively interpreted as an engineering control failure; it may simply reflect a localized process execution that exceeded the validated operating envelope. Resolving this ambiguity requires the systematic root-cause investigation described in Section 8, rather than a rudimentary assessment against the acceptance criterion.

## 4. SMEPAC Beyond a Pass-or-Fail Test

### 4.1 The relationship between SMEPAC and Containment Performance Assessment (CPA)

SMEPAC is best understood as a standardized data-generation methodology, not as an assessment in itself. It defines how samples are collected, where they are located, what surrogate materials are appropriate, and how results should be reported so that data are comparable across facilities, equipment vendors, and time [1]. A Containment Performance Assessment (CPA) is the broader risk-based evaluation that consumes SMEPAC data, together with process knowledge, material toxicology, facility design information, and operator competency records, to reach a judgment about whether operator exposure is adequately controlled for a specific product and process. In other words, SMEPAC generates the numbers, while CPA interprets what the numbers mean in the context of the actual risk being managed.

### 4.2 Risk-based interpretation of SMEPAC data

A risk-based reading of SMEPAC data looks well past the pass/fail line. It examines the pattern across sampling locations, not just the personal breathing-zone result, to identify where elevated concentrations originated in the process. It considers the exposure duration recorded against each result, since the same integrated mass captured on a filter represents a very different hazard if it occurred over 20 minutes than over two hours. It looks at surface swab data as a leading indicator of chronic secondary exposure risk through touch contamination, not only through inhalation. It considers operator-to-operator variability as data about the robustness of the SOP, not noise to be averaged away. And it weighs an out-of-specification result against the specific deviation from validated practice that accompanied it, distinguishing a result produced under strict SOP adherence, which implicates the engineering control, from one produced during an unplanned or off-procedure activity, which implicates process and behavioral controls instead.

### 4.3 Why does worst-case testing intentionally stresses the system

A recurring point of confusion among end users is the discovery that a SMEPAC protocol was deliberately designed around worst-case conditions rather than typical operating conditions: full batch quantities, larger drum sizes, minimum ergonomic clearances, and operators representing a range of experience, stature, and dominant hand. This is not a flaw in the test design; it is the entire point of the exercise. A containment system validated only under best-case conditions provides no assurance about what happens on a difficult day, with an inexperienced operator, a larger-than-typical batch, or a workspace that has been reconfigured to accommodate an unusually

sized container. Worst-case testing intentionally probes the edges of the operating envelope so that the resulting SOP, training program, and workspace design can be established with the true limits of the system in view, rather than the limits observed under ideal conditions. An out-of-specification result under a deliberately stressed test condition is therefore not necessarily evidence that the equipment is inadequate for routine use; it may be evidence that the worst-case scenario needs to be excluded from routine use through procedural or layout controls, which is itself a valuable and actionable finding.

## 5. Engineering Principles Governing Downflow Booth Performance

A downflow booth achieves containment by establishing a unidirectional airstream, typically directed from the ceiling of the enclosure toward a perforated or grated floor or a low-level exhaust plenum, that sweeps particulate matter generated during handling away from the operator's breathing zone and into the exhaust and filtration system before it can disperse. This principle works reliably under undisturbed conditions. It is far more fragile than it appears once a moving human body, an open container, and manual handling activity are introduced into the airstream. This section develops specific mechanisms that determine whether the theoretical downflow capture pattern survives contact with real operating conditions.

### 5.1 Airflow disruption around operator movement

Downflow velocities in dispensing booths are deliberately kept low, typically in the range of 0.45 ± 20% m/s, to avoid re-entraining settled powder or generating turbulence of their own. This means the downflow airstream is aerodynamically weak relative to the airflows an operator's own body and movements generate nearby. Reaching, bending, turning, and walking within the booth all displace air at velocities that can exceed the downflow velocity by a wide margin, and that displaced air entrains the surrounding downflow, distorting its trajectory and locally reversing or redirecting flow that would otherwise carry particulate toward the floor. Computational fluid studies of human movement in controlled airflow environments have shown that a walking or turning human body generates a low-pressure recirculation region immediately behind it, strong enough to draw clean air from the working zone into that recirculation and carry it upward and rearward, opposite to the intended downflow direction [4]. In a small-sized booth, where the operator's movement envelope occupies a large fraction of the total working volume, there is very little undisturbed airflow left for the entrainment effect to average out against, so the distortion is felt directly at the breathing zone rather than being diluted before it arrives.

### 5.2 Wake effects generated by the human body

A related but mechanistically distinct effect is the wake generated by the human body itself, independent of movement. The human body is an obstruction to the downflow airstream, and any bluff body placed in a moving airstream generates a wake, a region of separated, recirculating flow on its downstream side. As the body walks or moves, the forward motion displaces air and causes flow separation around the torso, limbs, and head. This generates an irregular, turbulent downwash of air that follows the body.

In a downflow booth this wake forms behind and around the operator's torso and head, and it is where particulate generated at hand height during weighing or transfer tends to be drawn upward toward the breathing zone rather than swept downward toward the floor. This wake effect is added by the operator's thermal plume: the human body continuously sheds a buoyant layer of warm air that rises along the body surface from foot level, accelerating as it ascends, and this convective boundary layer has been shown experimentally to persist even in the presence of an imposed ventilation airflow, effectively creating a local upward current that can oppose or override a weak downflow field [5,6,7]. Because most inhaled air in a calm indoor microenvironment is drawn from this boundary layer rather than from the bulk room air, particulate entrained into the thermal plume near floor or waist level has a disproportionately high probability of reaching the breathing zone compared to particulate released elsewhere in the booth. This same mechanism has been documented directly in fume hood containment study, where body heat dissipation was shown to measurably degrade hood capture performance by influencing the airflow distribution at the hood face [8]. The practical implication for downflow booths is that containment performance is not solely a function of exhaust and supply airflow design; it is a function of how that airflow interacts with the wake and thermal plume of the specific person standing in it.

### 5.3 Influence of drum geometry on downflow capture

The geometry of the container being handled has a direct and often underappreciated effect on local capture efficiency. A tall drum with a narrow open mouth, of the kind used to store and transfer bulk powder, creates a partially enclosed volume above the settled powder surface where the downflow airstream cannot penetrate uniformly. Air entering the drum mouth accelerates and can generate localized turbulence inside the drum as it displaces the air already present, particularly as the drum empties and the internal headspace above the remaining powder increases. This internal turbulence can dislodge fine particulate from the powder surface and eject it

back out through the drum mouth in a plume that the surrounding downflow field, oriented vertically rather than radially, is poorly positioned to capture. The effect becomes more pronounced as the fill level drops, meaning the containment challenge posed by a given drum is not constant through a dispensing operation but increases as the batch nears completion, exactly when an operator may be tempted to reach further into the drum or manipulate its liner to recover the last of the material. Drum height, mouth diameter, and orientation relative to the downflow centerline should therefore be treated as containment-relevant process design variables, not simply as material handling logistics.

### 5.4 Effect of turbulence created by bag shaking

Powder is commonly supplied or transferred inside plastic liner bags nested within a drum, and it is common practice, when the bulk of the material has been dispensed, to shake or manipulate the liner to bring residual powder down to where it can be scooped or poured. This is a fundamentally different aerodynamic event from steady-state weighing and pouring. Shaking a flexible bag imparts rapid, chaotic acceleration to any fine particulate adhering to its interior surface, releasing it as a short-duration, high-concentration aerosol burst rather than the comparatively steady low-level dust generation associated with pouring. Because this burst is brief and intense, the local particulate concentration can transiently exceed the containment capacity of a downflow field designed around a continuous, moderate generation rate, particularly if the shaking motion also displaces air in a way that interacts with the operator's wake as described in Section 5.2. Because bag shaking is often not identified as a discrete step in the original process design, it is frequently absent from the SOP against which a booth's containment capability was originally established, meaning that when it is introduced during actual operations, whether by design or by operator improvisation, the system is being asked to perform outside its validated envelope.

### 5.5 Engineering capability versus operational capability

The mechanisms above make clear why a single guaranteed containment value cannot be treated as portable across every combination of operator, process step, and container geometry. Engineering capability is the containment performance the equipment can deliver under a specified, controlled set of conditions, typically the conditions present during FAT or SAT: a trained test operator, a defined material and container, and a process sequence that excludes off-procedure activity. Operational capability is the containment performance actually achieved during routine production, where operator population, technique, container condition, and process discipline vary. The gap between these two capabilities is not a defect to be engineered away entirely; some gap is inevitable in any real operation. The purpose of a well-designed containment program is to keep that gap small and predictable through the layered controls and to use verification data such as SMEPAC results to actively measure the size of the gap rather than assuming it does not exist.

### 5.6 The safe working zone concept

Downflow booths are typically designed with a defined safe working zone: a bounded volume, usually specified as a horizontal depth measured from the exhaust grille toward the front opening of the booth, within which the downflow field has been engineered and validated to provide effective capture. Outside this zone, airflow velocity and direction become progressively less predictable as the operator moves closer to the open front face of the booth, where room air can be drawn in and mix with the controlled downflow, and where the vertical downflow trajectory has less distance to establish itself before reaching the working surface. The safe working zone is not a nominal convenience; it is the physical envelope inside which the equipment's guaranteed containment value is valid. Positioning process equipment, containers, or the operator's own working position outside this zone, even by a modest margin, removes the basis for assuming the engineering capability demonstrated during qualification still applies.

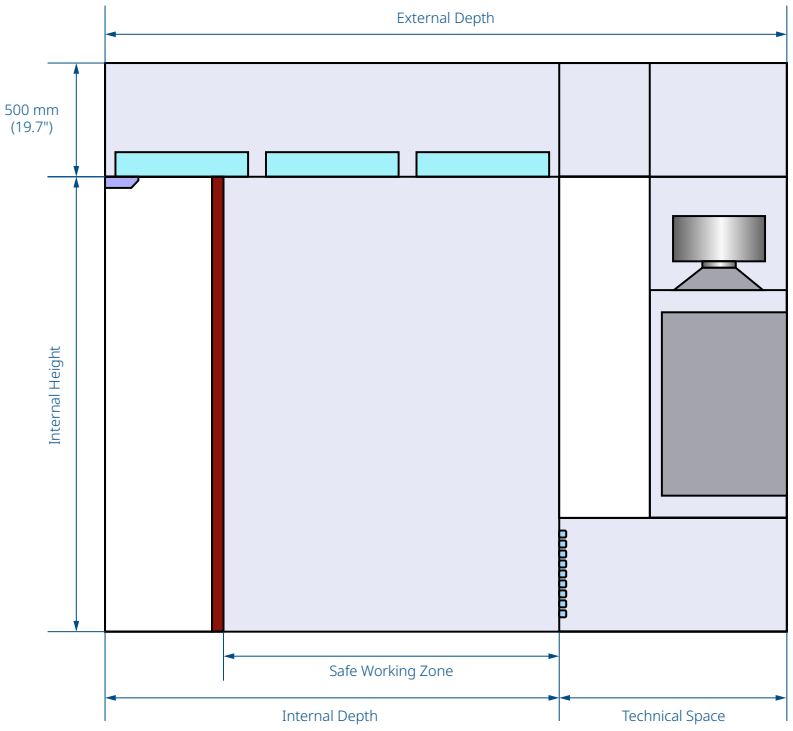



*Figure 2. Safe Working Zone in Downflow Booth*

### 5.7 Influence of workstation ergonomics

The safe working zone concept only functions if the operator can physically complete the required task while remaining inside it, which makes workstation ergonomics a containment-relevant design parameter rather than a separate occupational health consideration. Working height, reach distance, and the placement of ancillary equipment such as balances, receiving containers, and tooling all determine whether an operator naturally stays within the validated zone or is forced to lean, reach, or step forward to complete the task comfortably. An operator of below-average stature working at a fixed height designed around an average anthropometric assumption may need to reach further into the booth to see the balance display or manipulate the drum, unconsciously extending their working position toward or past the boundary of the safe working zone. Left-hand or right-hand dominance similarly affects natural working posture and can shift an operator's effective position relative to the exhaust grille depending on which side of the booth ancillary equipment is placed. None of these factors are captured by a containment specification expressed purely in airflow terms, yet each of them directly determines whether the engineering capability of the booth is actually accessible to the specific person performing the task.

## 6. Case Study: SMEPAC Verification of a Customized Downflow Booth

The principles developed in Section 5 are illustrated here using a SMEPAC verification project conducted on a customized Esco DFBG2 project. The powder handled in the represented process was an Active Pharmaceutical Ingredient classified as OEB 3, with an allowable occupational exposure limit of >10 to ≤100 µg/m$^3$ over an 8-hour workday with about 30-kg powder weighing load. Based on this classification, a Downflow Booth was selected as the appropriate PEC.

### 6.1 Booth configuration

The booth was customized to fit the available installation footprint at the end user's facility, with internal dimensions of 1740 mm width, 1200 mm depth, and 2100 mm height, placing it at the compact, small-size configuration end of the standard DFBG2 size range. The booth incorporated a defined safe working zone extending 800 mm from the exhaust grille toward the front opening, within which all weighing and dispensing activity was intended to be performed. Table 2 summarizes and Figure 3 visualizes the booth configuration.

*Figure 3. Booth layout and visualization during SMEPAC test*

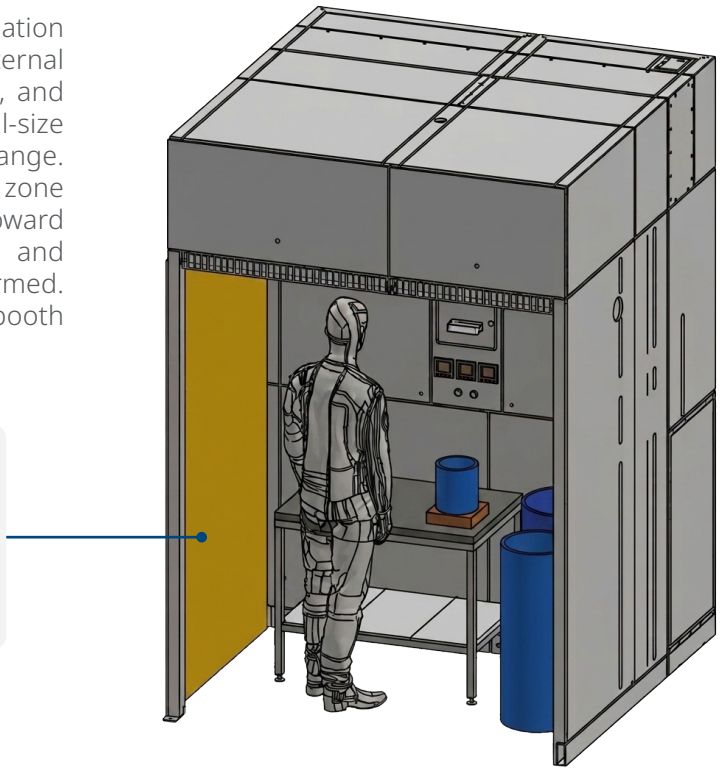



*Table 2. Customized configuration of the Esco DFBG2 used in this study*

| Parameter | Description |
|---|---|
| Model | DFBG2 |
| Internal dimensions (W × D × H) | 1740 × 1200 × 2100 mm |
| External dimensions (W × D × H) | 1800 × 1800 × 2600 mm |
| Safe working zone | 800 mm depth, measured from exhaust grille to front opening |

## 6.2 Surrogate material and test methodology

Lactose monohydrate was selected as the surrogate material for its dustiness characteristics, which are representative of the OEB 3 API used in the actual process, and for its status as an inert, well-characterized material commonly used in SMEPAC studies. The verification simulated handling and weighing of a 30 kg drum of lactose monohydrate, from which 25 kg was transferred to a bulk receiving drum and 5 kg to a secondary receiving drum, using an appropriately sized scoop. Table 3 summarizes the materials and equipment used.

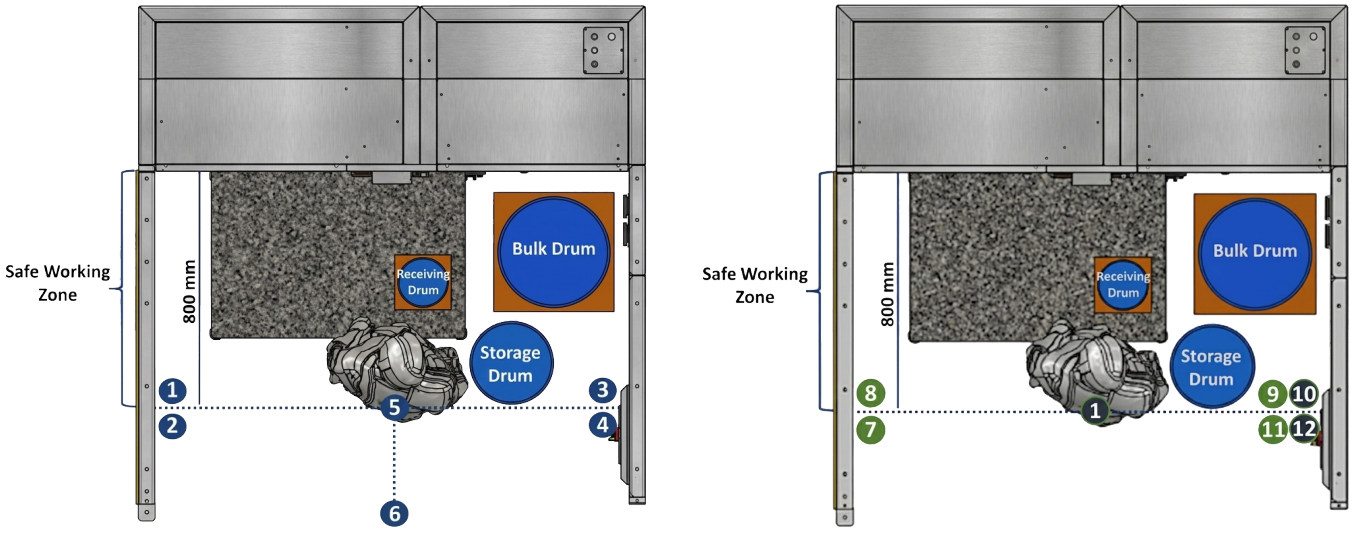
*Table 3. Materials and equipment used for the surrogate powder test*

| Materials for operation | Materials for sampling | Equipment |
|---|---|---|
| 30 kg lactose monohydrate in a storage drum, contained inside double bags | 25 mm PTFE, 1.0 µm filter cassettes | Air sampling pumps |
| Appropriately sized scoop | Sampling tubes | Flow meter |
| Two receiving drums (25 kg and 5 kg) | Cotton swabs, deionized water, 100 $cm^2$ template, zip-lock bags, labels | Stopwatch |

Two categories of sample were collected. Surface swab samples characterized residual surface contamination before and after the operation. Air samples, collected continuously through the operation, characterized both area (static) concentrations at defined locations and personal exposure at the operator's breathing zone. Table 4 summarizes the sampling matrix, which followed the static and personal sampling point configuration described in the SMEPAC methodology [1].

*Table 4. Sampling points based on the SMEPAC approach*

| Qty | Location and purpose |
|---|---|
| 1 | Blank / control |
| 1 | Pretest background, 1200 mm outside the safe working zone line |
| 3 | Static Point 1 — 200 mm from the transverse line at the inner edge of the support stands, toward the rear wall, inside the safe line |
| 3 | Static Point 2 — as above, outside the safe line |
| 3 | Static Point 3 — 200 mm from the right wall, inside the safe line |
| 3 | Static Point 4 — 200 mm from the right wall, outside the safe line |
| 3 | Static Point 5 — midway between the sides of the booth, level with the safe working zone line |
| 3 | Static Point 6 — 2000 mm from the safe working zone line |
| 3 | Personal sampling — operator breathing zone |
| 6 | Surface Points 7–12 — inside/outside the safe working zone line, left and right walls, at working height and at 1500 mm |




*(a)* *(b)*

*Figure 4. Air Sampling (a) and Surface Sampling (b) Points Visualization*

*Figure 5. Operating Breathing Zone*

### 6.3 Operators

Three operators performed the verification sequentially, each opening a fresh 30 kg storage drum of lactose monohydrate. Operator 1 was a female validation specialist and pharmacist with prior experience in powder weighing, right-hand dominant, 166 cm in height. Operator 2 was a female validation specialist with a bioprocess engineering background, basic powder-weighing skill, left-hand dominant, 153 cm in height. Operator 3 was a male welding operator with no prior experience in weighing API-type powders, right-hand dominant, 160 cm in height. This operator population was deliberately heterogeneous with respect to experience, stature, and hand dominance, consistent with the worst-case testing rationale discussed in Section 4.3, and it allows the results to be interpreted, in part, in terms of the ergonomic and human factors mechanisms described in Sections 5.2 and 5.7.

## 7. Results

All three operators produced a complete set of area and personal exposure results across their respective test durations. The acceptance criterion for this study was the OEB 3 exposure range of 0.01–0.1 mg/m$^3$ (10–100 µg/m$^3$). Results are summarized by operator in Tables 5 through 7.

*Table 5. Summary of results: Operator 1 (exposure duration 38 min 17 s)*

| Parameter | Description |
|---|---|
| Personal exposure (breathing zone) | **204 µg/m$^3$ (exceeds OEB 3)** |
| Area, Point 1 | 39 µg/m$^3$ |
| Area, Point 2 | 9.2 µg/m$^3$ |
| Area, Point 3 | Below Quantification Limit |
| Area, Point 4 | 0.473 µg/m$^3$ |
| Area, Point 5 | **225 µg/m$^3$ (exceeds OEB 3)** |
| Area, Point 6 | 21.3 µg/m$^3$ |

Two of Operator 1's seven results fell outside the OEB 3 acceptance range: the personal breathing-zone sample (204 µg/m$^3$) and Static Point 5 (225 µg/m$^3$), both roughly double the upper band limit of 100 µg/m$^3$.

*Table 6. Summary of results: Operator 2 (exposure duration 30 min 20 s)*

| Parameter | Description |
|---|---|
| Personal exposure (breathing zone) | **17,250 µg/m$^3$ (exceeds OEB 3)** |
| Area, Point 1 | 0.615 µg/m$^3$ |
| Area, Point 2 | 1.745 µg/m$^3$ |
| Area, Point 3 | 0.735 µg/m$^3$ |
| Area, Point 4 | 0.367 µg/m$^3$ |
| Area, Point 5 | Below Quantification Limit |
| Area, Point 6 | 5.05 µg/m$^3$ |

Operator 2 produced the highest personal exposure result recorded in the study, 17,250 µg/m$^3$, despite every area (static) sample remaining well within, or far below, the acceptance range. This pattern, a single extreme personal result against an otherwise clean area sample field, is a signature worth returning to in Section 8, since it points toward a highly localized, operator-proximate event rather than a general failure of the booth's downflow field.

*Table 7. Summary of results: Operator 3 (exposure duration 20 min 56 s)*

| Parameter | Description |
|---|---|
| Personal exposure (breathing zone) | **9,300 µg/m³ (exceeds OEB 3)** |
| Area, Point 1 | Below Quantification Limit |
| Area, Point 2 | 2.82 µg/m³ |
| Area, Point 3 | Below Quantification Limit |
| Area, Point 4 | 0.27 µg/m³ |
| Area, Point 5 | 46.1 µg/m³ |
| Area, Point 6 | 6.65 µg/m³ |

Operator 3, the least experienced operator in the study, produced a personal exposure result of 9,300 µg/m³, roughly 93 times the upper OEB 3 limit, again against a set of area samples that were individually compliant. Across all three operators, three of twenty-one total results exceeded the OEB 3 acceptance range, and all three exceedances involving the personal breathing-zone sample were substantially more severe, in relative terms, than the single area exceedance recorded for Operator 1. The equipment itself, evaluated purely on its ability to maintain low static concentrations throughout the booth volume, performed within its engineering specification in the large majority of locations and across all three operators.

## 8. Root Cause Investigation

The pattern described in Section 7, elevated personal exposure against largely compliant area data, is consistent with a localized, operator-proximate containment failure rather than a systemic deficiency in the booth's engineered downflow field, and the root cause investigation for this project focused accordingly on the conditions specific to the operator's immediate working position.

### 8.1 Limited working space and intrusion on the safe working zone

The primary contributing factor identified during root cause investigation was workspace configuration. The actual test setup placed large ancillary equipment, including the weighing table and receiving drums, in a configuration that occupied a substantial portion of the booth's available safe working zone. This was the intended worst-case configuration for this verification, but it consequently required operators to perform some handling activities near, or occasionally beyond, the 800 mm safe working zone measured from the exhaust grille as the boundary within which the downflow field had been engineered and validated for effective capture. When powder-generating activity occurred outside this zone, airborne particulate was no longer reliably entrained by the downward airflow and conveyed toward the exhaust; instead, localized recirculation increased the likelihood of particulate migrating toward the operator's breathing zone.

This finding is consistent with NIOSH experimental work on downflow booth performance, which found that particle release occurring near or beyond the edge of the safe working zone caused a sustained rise in worker breathing-zone concentration, because the ventilation system could no longer capture contaminant at the source once generation moved outside the validated airflow field [13]. That study reinforces the same point this case study makes: containment performance is governed as much by where particulate is generated relative to the validated zone as by the equipment's underlying capability.

It is worth being direct about what this means here: the arrangement was not created solely for testing, but rather represented the actual operational constraints. Fitting the balance, both receiving drums, and the scoop within an 800 mm working depth left little margin for the operator to remain fully inside the validated zone while completing the task. This is a design-integration gap rather than a simple behavioral one, closing it means either enlarging

the safe working zone at the design stage, if the site footprint allows, or reducing how much equipment and material sit inside the zone at any one time (e.g., staging sub-batches, or relocating the secondary receiving drum outside the zone). Both are legitimate engineering responses; neither was available as a retrofit once the booth was already installed at this footprint, which is why equipment-footprint and ergonomic modeling belongs at the pre-installation design stage (Section 11.2), not the post-verification corrective-action stage.

### 8.2 An unplanned bag-shaking step

During the verification, the end user requested that operators shake the plastic liner bags inside the drum to bring residual powder at the top of the bag down to where it could be recovered. This step was not part of the original process design or SOP against which the booth's containment capability had been established. As discussed in Section 5.4, bag shaking generates a short, high-intensity aerosol burst that is aerodynamically distinct from steady-state pouring, and its introduction as an improvised, off-procedure activity is a reasonable driver of at least some of the elevated personal exposure results, particularly given that this kind of transient, close-proximity release is exactly the scenario in which the operator's own wake and thermal plume, described in Section 5.2, are best positioned to carry material directly into the breathing zone.

### 8.3 Non-perforated work surface

The weighing table used in the study had a solid granite worktop without perforations. Where a weighing surface is positioned near the exhaust panel, a perforated work surface is generally preferable, since it allows the downflow airstream to draw airborne powder through the surface and into the exhaust path rather than requiring it to travel laterally around a solid obstruction before capture. The solid worktop used in this study represents a local aerodynamic obstruction that may have contributed to reduced capture efficiency immediately at the point of powder generation.

### 8.4 Post-test decontamination practice

Wet wiping with isopropyl alcohol (IPA) was performed only on the primary working equipment, such as the table and balance, between test runs. Thorough wet wiping of booth walls and equipment surfaces is a standard decontamination step, and residual surrogate powder left on surfaces between runs could reasonably have contributed to elevated surface swab results and to resuspension during subsequent operator activity, although this factor is considered secondary to the working-zone and process-deviation factors described above, given the operator-proximate signature of the personal exposure exceedances.

Because the test was deliberately conducted under worst-case conditions, as discussed in Section 4.3, these findings should not be read as evidence that the booth's engineering capability is inadequate for OEB 3 handling. They are, instead, exactly the kind of actionable root cause information that a worst-case SMEPAC study is designed to surface: specific, identifiable deviations from the validated operating envelope that can be closed through procedural, layout, and behavioral controls, as developed in Sections 10 and 11.

## 9. Discussion: Why Personal Exposure Can Exceed Equipment Capability

**HIGHLIGHT**

Containment performance is an emergent property of the complete containment system. Equipment design establishes the engineering capability, but actual exposure depends equally on process design, operator behavior, workspace configuration, material characteristics, and validated operating procedures.

The case study results give this a principle concrete, quantitative form. The same booth, evaluated under nominally the same OEB 3 acceptance criteria, produced a compliant personal exposure result for none of the three operators tested, while producing compliant or near-compliant area results at almost every static location for all three. If containment performance were solely an equipment attribute, this pattern would be difficult to explain: the airflow design, filtration, and enclosure geometry were identical across all three test runs. What varied was everything the equipment does not control: which operator was performing the task, how closely their working position adhered to the safe working zone, whether an unplanned bag-shaking step was introduced, and how the operator's own body interacted aerodynamically with the downflow field at the moment particulate was generated.

This is the practical meaning of "engineering capability" versus "operational capability" introduced in Section 5.5. The booth's engineering capability, as evidenced by the area sampling data, was consistent with OEB 3 containment. The operational capability actually realized during the test, shaped by workspace crowding, an off-

procedure handling step, and the specific interaction between three different operators and the downflow field, was not. A validation program that reports only the equipment's guaranteed containment specification, without characterizing the operating envelope within which that specification holds, provides an incomplete and potentially misleading picture of the exposure risk a facility should expect during routine production.

The magnitude of the personal exposure exceedances observed here is also instructive. A modest exceedance might reasonably be attributed to measurement variability or a marginal deviation from ideal technique. An exceedance of this magnitude, occurring against a background of compliant area data, is much more consistent with a discrete, localized event, such as a bag-shaking burst captured directly in an operator's thermal plume and wake, than with a general degradation of the booth's downflow performance. This distinction matters operationally: it points toward corrective actions focused on process step control, workstation layout, and operator technique, rather than toward re-engineering the booth's airflow system, which the area sampling data suggests is not the primary deficiency.

It is also worth noting the apparent influence of operator-specific factors on the severity of exceedance. Operator 1, the most experienced of the three at powder weighing, produced the smallest personal exposure exceedance (with still roughly double the OEB 3 limit). Operator 3, with no prior experience handling API-type powders, produced a substantially larger exceedance (roughly 93 times the limit). While a sample size of three operators cannot support a statistically rigorous claim, this pattern is directionally consistent with the human factors and ergonomics literature discussed in Section 5.7, and it reinforces that operator training and technique are not a secondary consideration layered on top of a fixed containment specification, but an active determinant of the exposure outcome actually achieved.

## 10. Engineering Lessons Learned

Several engineering-focused conclusions follow directly from the case study and the mechanisms discussed in Section 5.

- Safe working zone boundaries must be treated as hard constraints during workstation layout, not as nominal guidance. Ancillary equipment sizing and placement should be planned around the validated zone before, not after, the booth is installed.
- Perforated work surfaces should be the default specification for weighing tables and racks positioned near the exhaust grille in a downflow booth, particularly for OEB 3 and higher applications, to reduce local aerodynamic obstruction of the downflow path.
- Container and drum geometry should be assessed as part of process design, not left implicit. Tall, narrow-mouth drums pose a greater internal turbulence and headspace risk than wide, shallow containers, particularly as the batch nears completion.
- Any handling step capable of generating a transient, high-intensity aerosol release, such as bag shaking, tapping, or vigorous scooping, should be explicitly identified during process design and either engineered around (for example, through a dedicated bag-emptying fixture) or excluded from the validated SOP rather than introduced impromptu during operations.
- Booth sizing decisions should account for the full ergonomic footprint of the intended operator population and ancillary equipment, not only the footprint of the powder-handling equipment itself. A compact booth that is dimensionally adequate for the equipment alone may still be operationally inadequate once realistic working clearances are added.

These lessons reinforce a broader point: many of the highest-value improvements available after an out-of-specification SMEPAC result are not increases in exhaust airflow or filtration capacity, but changes to layout, process sequencing, and fixture design that keep the operator, the container, and the task within the envelope the engineering control was designed to handle.

## 11. Practical Recommendations for End Users

### 11.1 Applying the hierarchy of controls

The NIOSH hierarchy of controls provides a structured way to prioritize corrective actions arising from a SMEPAC study, ranking interventions from most to least effective: elimination, substitution, engineering controls, administrative controls, and personal protective equipment (PPE) [9,10]. Applied to the findings of this case study, elimination or substitution would mean reconsidering whether the bag-shaking step is necessary at all, for example through improved liner or drum design that reduces residual powder retention. Engineering controls, which sit above administrative controls and PPE in effectiveness, would include the perforated worktop and drum/container

geometry changes discussed in Section 10, along with any workstation reconfiguration that restores adequate clearance within the safe working zone. Administrative controls would formalize the SOP to explicitly prohibit off-procedure handling steps such as unplanned bag shaking, and would define permitted operator positioning relative to the safe working zone boundary. PPE, including respiratory protection appropriate to OEB 3 handling, remains an essential last line of defense but should not be relied upon to compensate for avoidable deficiencies higher in the hierarchy.

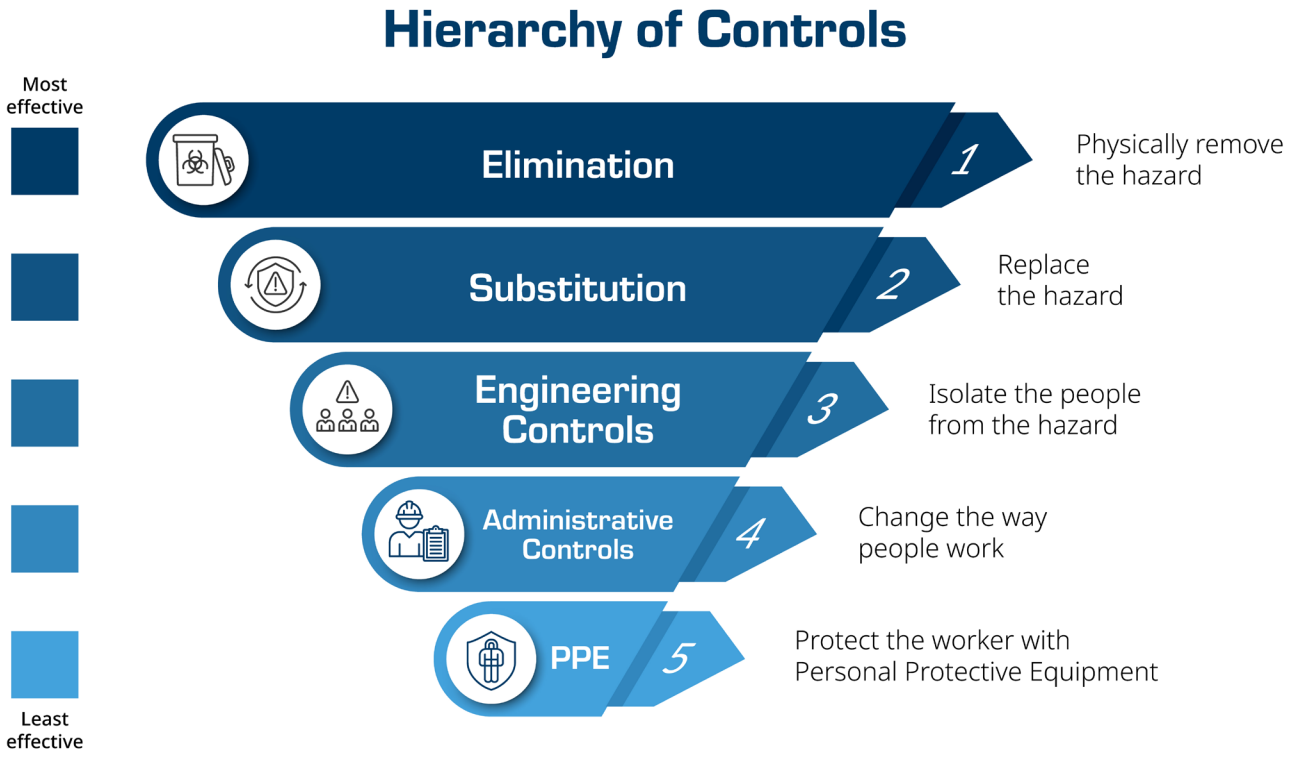



*Figure 6. Hierarchy of Controls*

### 11.2 Engineering recommendations for booth layout optimization

Booth layout should be optimized with the safe working zone as the primary design constraint, not as a boundary to be respected after equipment placement has already been decided. Practical recommendations arising from this case study include sizing and positioning ancillary equipment, such as receiving drums and tooling, outside the safe working zone wherever the process allows, reserving the zone itself for the operator's hands and the immediate point of powder transfer; specifying perforated work surfaces for any table or rack positioned within or adjacent to the safe working zone; and validating drum and container dimensions against the booth's working envelope during process design, rather than during equipment commissioning, so that container geometry effects on downflow capture (Section 5.3) are known quantities before routine production begins.

### 11.3 Human factors engineering

Human factors engineering, applying knowledge of human capabilities and limitations to the design of tasks, equipment, and workspaces, are directly applicable to containment booth design and should be treated as a core design discipline rather than an afterthought, consistent with the general ergonomic design principles set out in ISO 6385 [11]. Working height and reach distance should be evaluated against the anthropometric range of the intended operator population, not a single average stature, since Section 5.7 and the case study results both illustrate that operators at the smaller end of the population may be pushed toward or past the safe working zone boundary by a fixed working height designed around a larger assumption. Equipment orientation should account for both left- and right-hand dominant operators where the process allows, and training programs should explicitly address the aerodynamic reasoning behind the safe working zone and the prohibition on off-procedure handling steps, rather than presenting these as arbitrary rules, since operators who understand the underlying mechanism are better equipped to recognize when an improvised deviation, such as reaching further into a drum or shaking a bag, is likely to compromise containment.

### 11.4 Process and procedural recommendations

The SOP governing any OEB 3 or higher dispensing operation should explicitly enumerate every handling step expected to occur, including edge cases such as recovering residual powder from a liner bag, and should require that any activity not covered by the validated SOP be evaluated through a documented risk assessment before being incorporated into routine operations, consistent with the risk-based interpretation of SMEPAC data discussed in Section 4.2 and the AIHA framework for assessing and managing occupational exposures [12]. Thorough wet wiping decontamination between operations, covering booth walls and all contacted surfaces rather than only primary working equipment should be a mandatory, explicitly defined step. Finally, SMEPAC results, including out-of-specification results, should be formally captured in the facility's Contamination Control Strategy and further risk assessment with the specific root cause and corrective action linked to the affected critical control point, so that the assessment retains its value as an input to ongoing risk management rather than being closed out as a one-time compliance record.

## 12. Conclusion

This case study demonstrates that containment performance is not an inherent property of equipment alone; rather, it is an outcome created by the interaction between engineering design, operating conditions, workspace configuration, and human behavior. The downflow booth evaluated in this study demonstrated control of airborne contamination within the defined working zone, with area concentrations remaining consistent with the intended OEB 3 containment objective. However, elevated personal breathing-zone exposure was observed when operational conditions extended beyond the validated containment zone through a combination of workspace limitations, handling practices, and operator-specific interactions with the airflow field.

The findings highlight a fundamental principle in containment engineering: a containment system is only as effective as the conditions under which it is designed and operated. Airflow patterns, workstation layout, material handling practices, and operator movement are not independent variables; they form an integrated system that determines the final exposure outcome. Factors such as operator-induced wake effects, thermal plumes, source location relative to the exhaust capture zone, container geometry, and unnecessary powder disturbance are not merely secondary considerations, they are critical contributors to real-world containment performance.

For containment engineers, this reinforces that a containment specification cannot exist in isolation from its operational boundaries. The safe working zone, equipment arrangement, ergonomic considerations, and process workflow must receive the same engineering attention as airflow velocity, filtration efficiency, and enclosure design. For end users and occupational hygienists, SMEPAC should be interpreted not simply as a pass-or-fail qualification exercise, but as a powerful diagnostic tool that reveals opportunities to strengthen the complete containment strategy.

Ultimately, the most valuable outcome of a containment verification study is not the confirmation of a perfect result, but the understanding gained when performance deviates from expectation. A challenging SMEPAC result does not represent a failure of containment engineering; it represents an opportunity to discover the hidden interactions between equipment, process, and people.

**Because true containment performance is not achieved by equipment alone, it is achieved when engineering design and human operation work together within a clearly defined safe working zone.**

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## Disclaimer

*This white paper is intended solely for educational and informational purposes. It presents a technical discussion of containment engineering principles, SMEPAC-based performance evaluation, and the interpretation of a representative case study involving downflow booth operations. The observations, analyses, and conclusions presented herein are based on the specific operating conditions, equipment configuration, and process parameters described in the case study, and should not be interpreted as universally applicable to all containment systems or manufacturing environments.*

*This publication does not constitute regulatory guidance, engineering design advice, validation guidance, or a product performance specification. Containment performance should always be evaluated within the context of the intended process, facility layout, material characteristics, occupational exposure limits, applicable regulatory requirements, and validated operating procedures.*


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