Open Letter to Colleges of Pharmacy and Inspectors
From Mary Nazzal PharmD, Melanie Dorey R.Ph.T from Critical Compounding Resources, and David Phillips from Con-Test and current (2025) president of CETA

Re: Key Considerations Before Taking Enforcement Action on Pass-Through Locations Between Unclassified Rooms and ISO-Classified Cleanrooms

The National Association of Pharmacy Regulatory Authorities (NAPRA) Model Standards require that an anteroom contain either:

- a pass-through chamber for transferring products into the cleanroom, and/or
- a cart reserved for use in the "clean" zones of both the anteroom and cleanroom.

Although well-intentioned, these requirements impose a restrictive condition—that the pass-through must be located within the anteroom—which, in practice, is suboptimal for many pharmacy workflows. This arrangement frequently compels staff to enter the anteroom solely to access the pass-through, thereby increasing the presence of un-garbed personnel, gowning activities, crossings of the line of demarcation, and overall traffic within classified areas. Consequently, this elevates the bioburden within controlled spaces and poses a greater risk to the cleanroom environment compared to using a pass-through located elsewhere. Paradoxically, this configuration may increase the risk of contamination and regulatory non-compliance rather than mitigate it. Over time, this language in the Model Standards has produced unintended downstream consequences. To comply, many facilities have resorted to costly redesigns, building additional ISO-classified rooms around cleanroom suites simply to position a pass-through "within" an anteroom. These buildouts require substantial investment in HVAC capacity, increased energy consumption, HEPA filtration, certification, and ongoing maintenance — costs that, in many scenarios, are unnecessary and yield no measurable improvement in sterility assurance.

Critical Compounding Resources (CCR) and David R Phillips from Con-Test, submit this letter to provide a clear, evidence-based rationale for permitting pass-through installations directly between a non-ISO-classified space (e.g., a general workroom or standard pharmacy area) and an ISO-classified space (e.g., cleanroom). This is a well-established configuration in sterile compounding environments that, when properly designed, monitored, and maintained, aligns with the intent of NAPRA's standards, fully supports compliance with *USP <797> (2023)*, reduces contamination risk, and protects both personnel and product integrity.

We respectfully urge NAPRA Model Standards committee to consider revising its Model Standards to explicitly allow such pass-through designs, following the clear precedent set by *USP <797>*. Adopting this alignment would provide facilities with practical, safe, and cost-effective solutions that maintain — and even enhance — patient and product safety.

Regulatory Support and Risk Management Considerations

USP <797> (2023) places no prohibition on installing a pass-through between a non-classified space and an ISO-classified space. The chapter advises the use of interlocking doors and requires that both doors remain closed except when transferring materials — but it does not mandate HEPA filtration, nor does it

require that both connected spaces be ISO-classified.

Design and Engineering Controls in Place

In the United States, USP <797> outlines specific measures for pass-through system design to ensure safety, minimize contamination risk, and maintain compliance. These safeguards include:

1. Sealed, Interlocked Doors

Pass-through units are equipped with sealed — ideally mechanically interlocked — doors, preventing simultaneous opening and uncontrolled air exchange between spaces. At no time may both doors be open concurrently.

2. Material Transfer Protocols

All materials entering a classified space must be thoroughly wiped with a sporicidal or EPA-registered disinfectant, applied using low-lint wipers by gloved personnel. Contact times must be respected to ensure complete disinfection before the item is transferred.

3. Cleaning and Disinfecting

On all days when compounding occurs, the pass-through chamber is cleaned and disinfected and Sporicidal agents are applied on a routine basis.

4. Environmental Monitoring and Certification

Pass-through chambers attached to classified areas undergo microbial surface sampling on a risk-based schedule. Depending on the design air sampling may be performed as well.

Additional particle counting and airflow visualization studies — including testing while the door is open — can verify that environmental conditions remain in a state of control. The CETA Application Guide CAG-014 – Airflow Visualization Study, has specific testing procedures to visualize and validate pass-through operation from unclassified to classified spaces.

The CETA CAG-014 procedure verifies that pass-throughs and airlocks maintain cleanroom protection when connecting classified areas to spaces of lower air quality. Testing is performed both *as-built* and under *dynamic operating conditions* with typical materials and transfers in progress. The pass-through or airlock is filled with smoke from the lesser-quality side, and the inner door to the classified space is opened only after the manufacturer's recommended purge time. The test confirms that no smoke enters critical zones—such as sterile staging, preparation, or storage areas. Any smoke intrusion into these areas is deemed unacceptable and triggers an investigation to determine whether HVAC rebalancing or other mechanical corrections are required.

The CETA Application Guide: CAG-015 describes the testing of pass-throughs, which certifiers may use for further direction on testing these units.

Air Change Mitigation

The compact internal volume of a wall-mounted pass-through imposes an extremely low air-quality

burden. In addition, the high air-change rate (ACPH) of the classified buffer space rapidly dilutes and removes any transient influx of non-classified air, restoring optimal environmental conditions within moments.

Placement of secondary engineering controls such as exhaust or return vents underneath or near the pass-through opening in the classified space can further help mitigate any contamination concerns.

Industry Acknowledgement and Expert Endorsements

According to **Controlled Environment Consulting (CEC)** in their Jan 2024 publication "*Pass-Through Options for Sterile Compounding Facilities*", wall-mounted, non-HEPA-filtered pass-throughs can be installed between non-classified and ISO-classified areas **when interlocked and sealed**."

Furthermore, **Critical Compounding Resources (CCR)** supports this configuration when all risk controls are implemented. In their July 2024 design guidance, CCR states:

"CCR believes that a small wall pass-through does not need to be HEPA-filtered. These devices allow only a small amount of air into the classified room which will be diluted and quickly mitigated given the ACPH required inside the buffer room."

Recommendation for Inspectors

When assessing a pharmacy's pass-through systems, please keep the following key principles front of mind to ensure best-practice contamination control:

1. Sealed, Interlocked Doors
    - Does the pass-through feature sealed, mechanically interlocked doors?
    - If interlocks are absent, is there a clearly defined, enforced policy to prevent both doors from being opened simultaneously?
2. Material Wipe-Down Protocols
    - Are personnel consistently following proper wipe down procedures for all items before transfer, using approved disinfectants and observing required contact times?
3. Cleaning & Disinfection Practices
    - Is the pass-through cleaned and disinfected on a routine, documented schedule in accordance with facility SOPs and applicable standards?
4. Environmental Monitoring & Results
    - Is environmental monitoring performed within and around the pass-through on a risk-based schedule?
    - Are results consistently within established action limits, and is appropriate follow-up conducted when deviations occur?

In conclusion, we respectfully urge Colleges of Pharmacies, inspectors, and regulatory authorities across Canada to reconsider the current restrictive requirement that pass-throughs must be located within anterooms. This outdated interpretation leads to workflow inefficiencies, increased contamination risks, and costly facility redesigns. Evidence-based practices, supported by USP <797> (2023) and expert guidance, demonstrate that properly designed, sealed, and interlocked pass-throughs between non-classified and ISO-classified spaces provide safe, effective, and compliant solutions that protect patient safety and product integrity. We encourage NAPRA to revise its Model Standards to explicitly permit these configurations, aligning regulatory expectations with contemporary best practices and engineering controls. Such revisions will enable pharmacies to maintain the highest standards of safety and compliance while optimizing facility design and operational workflows.

Sincerely,

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David Phillips President of CETA, Con-Test

References

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