Newfoundland Case Study: Pass-Through Placement in Canadian Sterile Compounding Pharmacies

Heather Ryan, BSc Pharm
Hazardous Compounding Supervisor
NLHS Eastern Urban Zone

Pass-throughs are designed to streamline the transfer of products in and out of the cleanroom. Their placement is crucial for optimizing workflow and minimizing traffic into classified areas. Positioning a pass-through between the cleanroom and an unclassified area helps reduce foot traffic and therefore the risk of contamination into the anteroom. This setup also allows the anteroom to be dedicated to garbing and hand hygiene activities.

In Canada a requirement for placing the pass-through in the anteroom comes from the National Association of Pharmacy Regulatory Authorities (NAPRA) Hazardous Sterile Compounding guidelines section 5.3.2.5 where it states, *"the anteroom must contain a pass-through for transferring products into the clean room and/or a cart reserved for use in the "clean" area of the anteroom and the clean room."*

This presents a challenge, as we want to minimize staff movement in and out of the anteroom to reduce the risk of contamination. Any contaminants introduced into the anteroom could potentially be transferred to the cleanroom. To better understand the rationale behind this guidance in the NAPRA Model Standards, we contacted the NAPRA committee via email. They directed us to the sections listed in the following table, which were referenced during the development of the NAPRA Model Standards.

Pass-through sections from the International Society of Oncology Pharmacy Practitioners (ISOPP) are included as they were referenced in the CSHP Compounding guidelines.

Reference	Discussion on Placement
USP Chapter <797> It is also critical to control materials (e.g., supplies and equipment) as they move from classified areas of lower quality to those of higher quality (e.g., ISO Class 8 anteroom to ISO Class 7 buffer room to ISP Class 5 PEC) to minimize the influx of contaminants. Airlocks and interlocking doors can be used to facilitate better control of air balance between areas of differing ISO classification (e.g., between the buffer room and anteroom), or between a classified area and an unclassified area (e.g., between the anteroom and an unclassified area such as a hallway). If a pass-through is used, both doors must never be opened at the same time, and doors should be interlocking.	Pass-through should be interlocking. No requirement for placement in the anteroom.

Préparation de produits stériles non dangereux en pharmacie- Norme 2014.01 Ordre des pharmaciens du Québec, 2014 6.3 Facilities and equipment for the compounding of non-hazardous sterile products -Pass-through A pass-through, with or without ventilation, sealed, made of stainless steel or a smooth, non-porous, antistatic material resistant to damage from cleaning products should be installed for transferring products in and out of the clean room. It is important to ensure the pass-through is airtight. It is also recommended that it be equipped with an interlocking system that prevents both doors from being open at once. Otherwise, a door opening procedure must be implemented. If there is no pass-through, the clean room cart may be used to transport the material from the "clean" area of the ante-area. The clean room must be isolated from the rest of the pharmacy or unclassified areas to reduce the risk of introducing viable and non-viable contaminants.[1] It is physically separated from contiguous areas by walls, doors and pass-throughs.	Suggest pass-through should be installed for material transfer, recommend interlocking but no requirement for placement in the anteroom.
CSHP Compounding Guidelines for Pharmacies (2014) Pass-through chambers (hatches) may be used to connect the cleanroom to the anteroom, the anteroom to an adjacent uncontrolled environment, and the cleanroom to an adjacent uncontrolled environment, providing a means to transfer supplies and preparations. More generally, any combination of rooms and pass-through chambers may be used to support safe and effective compounding workflow. However, connecting the cleanroom to an uncontrolled environment increases the risk of the cleanroom to contamination, necessitating additional care and design consideration. Pass-through chambers for hazardous drugs Pass through chambers in a cleanroom suitable for compounding with hazardous drugs may be	Allows for pass-through placement from cleanroom to uncontrolled space. Pass-throughs in hazardous environments should be HEPA filtered. The wording on having a hazardous cleanroom with a pass-through from cleanroom to uncontrolled space "should be discouraged" is only if the pass-through does not have interlocking doors. (Confirmed with CSHP by email)

located either between the cleanroom and the anteroom or between the cleanroom and the uncontrolled work area. Use of the latter options is discouraged. Pass-throughs directly connecting uncontrolled environments and cleanrooms used for hazardous drugs should have high-efficiency particulate air (HEPA) filtration. (Reference ISOPP)	
ISOPP 6.2.7 Pass-through hatches A pass-through hatch is essential to prevent direct access between the cytotoxic cleanroom and the external environment. There are two possibilities for the location of such hatches. These hatches may either be between the cleanroom and the anteroom or between the cleanroom and the external environment. If the latter option is selected, then interlocking doors must be used and the unit must be HEPA filtered. Hatch doors should preferably be fitted with an audible or visual alarm to prevent doors being opened simultaneously. In order to minimize cross contamination, separate hatches for entry and exit of products are preferable.	Supports Pass-throughs from Cleanroom to Unclassified space with the requirement of having interlocking doors and HEPA filters. Also suggests two pass-throughs: one entering and one leaving the cleanroom.

After reviewing all the references that were used when writing the sterile compounding standards none of the references required the pass-through to be in the anteroom.

Under the objectives, in the Sterile Compounding standards, there is a paragraph "*These Model Standards represent the minimum requirements to be applied in compounding sterile preparations; however, it is always possible to exceed these standards. The use of other technologies, techniques, materials, and procedures may be acceptable, so long as they are proven equivalent or superior to those described here.*"

Ultimately, each province's Pharmacy Regulatory Authority is responsible for enforcing the standards. Leveraging this flexibility, we presented to our regulatory body that the use of HEPA-filtered, interlocking pass-throughs represented exceptional technology that exceeded the minimum requirements. As a result, we received approval to construct our cleanrooms with the pass-throughs located outside the anteroom, with the condition that all particles and viable testing had to be successfully completed prior to opening.

In summary

- None of the references provided by NAPRA Model Standards require pass-through placement in the Anteroom.
- Using Interlocking, HEPA-filtered pass-throughs would exceed the minimum requirements in the sterile compounding standards.
- Pass-throughs can improve pharmacy efficiency and increase production by reducing unnecessary traffic within the space, and at the same time protect the sterile compounding area.
- We have overseen or consulted on three new builds/renovations (hazardous and non-hazardous) where we have put pass-throughs directly from the cleanroom to unclassified space (staging area/ hazardous storage room). All three of these facilities have passed certification to NAPRA requirements. Proof that pass-throughs can be placed outside of the anteroom.
- It has now been two years since our initial certification, and we have consistently maintained our ISO classification without any issues.
- This article was originally written in 2023. The updated USP<797> (May 2024) states, “It is also critical to control materials (e.g., supplies and equipment) as they move from classified areas of lower quality to those of higher quality (e.g., from an ISO Class 8 anteroom to an ISO Class 7 buffer room to an ISO Class 5 PEC) to minimize the influx of contaminants. Airlocks and interlocking doors may be used to facilitate better control of air balance between areas of differing ISO classification (e.g., between the buffer room and anteroom) or between a classified area and an unclassified area (e.g., between the anteroom and a hallway). If a pass-through chamber is used, both doors must never be opened at the same time, and doors should be interlocking.”