

# **COMPOUNDING FAQ**

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**NEWFOUNDLAND & LABRADOR  
PHARMACY BOARD**

## GENERAL COMPOUNDING QUESTIONS

### **What is the relationship between the compounding supervisor and pharmacist-in-charge?**

The pharmacist-in-charge (PIC) is responsible for developing, organizing and supervising all activities related to pharmacy compounding. The PIC may share or assign these responsibilities to a pharmacist or pharmacy technician, who will be designated as a “compounding supervisor.” Otherwise, the PIC is the compounding supervisor by default.

A compounding supervisor is a pharmacist or pharmacy technician designated to supervise activities related to the compounding of specific preparations. This role may be carried out by the PIC or the PIC may delegate this role to another appropriate staff member. This person works with the PIC, pharmacy management and compounding personnel. A compounding supervisor develops, organizes and oversees all activities related to the given area of compounding.

If the PIC designates a pharmacist or pharmacy technician as the compounding supervisor and this person does not carry out their responsibilities for any reason, the PIC must assume the responsibilities of compounding supervisor. In addition, the PIC must ensure the compounding supervisor adequately fulfills their role as the PIC is ultimately responsible for the operation of the pharmacy. For these reasons, the PIC must be qualified to perform and oversee the different types of compounding activities of the pharmacy.

### **Can a pharmacist or pharmacy technician be a compounding supervisor at more than one site?**

The intention is that there is a person designated as compounding supervisor per site to develop, organize and supervise all activities related to pharmacy compounding of sterile products. This may be the pharmacist-in-charge, or a shared responsibility with an individual who has been delegated this role. This does not necessarily mean that “compounding supervisor” must be a person’s sole responsibility, or that a person cannot be compounding supervisor at more than one site. However, the acceptability of having an individual responsible for more than one site would depend on the scope of compounding services at the site and whether the compounding supervisor can fully meet the responsibilities outlined in section 5.1.1.2 of the standards at each site.

### **Can a pharmacy have more than one compounding supervisor (i.e. can multiple staff share this role)?**

If the scope of compounding activities requires more than one qualified individual to meet the responsibilities of a compounding supervisor, the pharmacist-in-charge may designate more than one individual to this role. However, the individuals must be specifically designated as compounding supervisors (i.e. it cannot be “pharmacist/ pharmacy technician on duty”) and there must be a clear delineation of compounding supervisor duties to ensure all responsibilities are fully met.

Each type of compounding practice (sterile hazardous/non-hazardous, non-sterile non-hazardous/hazardous) may have a different compounding supervisor as well.




## Does NLPB approve facility design?

Pharmacists-in-charge (PIC) are required to submit an [Application for Renovation of an Existing Pharmacy/Dispensary](#) to NLPB at least 15 days in advance of planned renovations, and receive approval of the application, before starting the renovation. It is recommended to submit renovation applications at the earliest opportunity, especially for complex facility designs, so that NLPB staff can review, ask questions and provide feedback.

With that said, NLPB does not approve the **design** of compounding facilities. The design and construction of compounding facilities requires specific engineering expertise to ensure the necessary ventilation, air flow and pressure differential, and certain equipment (such as containment primary engineers controls [C-PECs]) require maintenance and certification by qualified individuals. It is important that pharmacy personnel collaborate with engineers and contractors in the design of their compounding space. While the design of a space requires expertise beyond that of a pharmacist, input from pharmacy personnel is still important so that workflow and efficiency is taken into account.


PIC and compounding supervisors are responsible for ensuring that their compounding space is appropriately designed in accordance with the applicable standards and they must be able to demonstrate this is the case to NLPB assessors.

## NON-STERILE COMPOUNDING QUESTIONS



### What is the difference between the standards and the guidance document? Do I have to follow everything in the guidance document? ( *...it is a HUGE document* )

The standards are the minimum requirements for all registrants involved in non-sterile compounding. It is mandatory that pharmacies involved in non-sterile compounding be compliant with the standards. The guidance document was developed by NAPRA as a resource, if needed, to provide more detail and direction on implementing the standards. Registrants may choose to meet the required standard using another process than one suggested in the guidance document; this is acceptable as long as the process meets or exceeds the requirements in the standard. The pharmacy must have documentation to support the rationale for alternate approaches.



### If we find that our non-regulated pharmacy team members need more training, where can we access this?

Some pharmacists and pharmacy technicians have already participated in in-house training and have proactively performed reviews of the compounding techniques of non-regulated pharmacy staff members. Registrants are cautioned to only use this method of remediation if they are current in their knowledge and experience base. Some companies supplying compounding ingredients offer training opportunities for pharmacists and pharmacy technicians who are new to compounding, or to those seeking to improve their skills. Pharmacists-in-charge and compounding supervisors are encouraged to research those options and, if appropriate, have at least one staff member take the training, and train and assess others at the practice site.



## How do I decide what I should and should not be compounding?

Consider the following questions:

- ***Are the active ingredients already available in a manufactured product?***
- ***Is there a manufactured product that would have a similar therapeutic benefit?***
- ***Do you have a referenced formulation, with stability data and a beyond-use-date? If not, do you have the general knowledge to: assess compatibility of ingredients, determine how to compound the product, assign a beyond-use-date, etc.?***
- ***Do you have an appropriate space to compound the given preparation?***
- ***Do you have the necessary equipment and ingredients to make the compounded preparation?***
- ***Have you completed a risk assessment of the preparation?***
- ***Can you mitigate any identified potential health hazards to compounding personnel?***
- ***Would the patient be better served at another pharmacy that has appropriate facilities, equipment and expertise?***

Risk assessment is an important part of this decision. Refer to section 4 of the standards and guidance document for the expectations and guidance on risk assessments. The guidance document provides an algorithm to assist with the risk assessment process as well as a list of factors to consider that help with putting information into context.


The decision to not compound should not be taken lightly. It is also important to consider the NLPB Code of Ethics. Pharmacy professionals are expected to hold the health and well-being of their patients as their primary consideration and do what they can to meet patients' health needs. The default should be to aim to provide services to the extent that is possible, and when it is not possible to compound a specific product, refer the patient to a colleague who can. Pharmacy professionals need to be able to explain to patients why they can or cannot provide a compounded preparation.



## Can you provide examples or a list of Level A, B, and C Compounding?

As a self-regulated health professional, you are expected to use your knowledge, skills and judgment to perform a risk assessment of each preparation compounded in your pharmacy. Consider all the factors outlined in the standards and guidelines, utilize all necessary resources and references, then assign the risk level and document your decision with rationale in the master formulation record.

Examples of how a risk assessment may be conducted have been provided by other regulatory bodies in Canada (available on [Pharmacy Practice Resources](#) page of nlpb.ca); however, the individual factors in your practice setting may result in a different risk assessment for the same formulation than these examples or another practice site. If there is uncertainty regarding the risk level to assign, the compounding supervisor, in collaboration with the manager, may choose to adhere to the standard for the higher risk level in the interest of safety.



**The decision algorithm for risk assessment (Diagram 1 in the guidance document) references both the “NIOSH list of dangerous drugs” and “health hazard(s) under the Hazardous Products Act.” What is the difference between the two?**


In Canada, legislation (the Hazardous Products Act and related Regulations) requires that hazardous products used in the workplace are labelled to identify the associated hazards. [Schedule 2 under the Hazardous Products Act](#) provides a listing of health hazard classes.

The Government of Canada, Canadian Centre for Occupational Health and Safety defines the WHMIS (Workplace Hazardous Materials Information System) as a “comprehensive plan for providing information on the safe use of hazardous materials used in Canadian workplaces. Information is provided by means of product labels, material safety data sheets (MSDS) and worker education programs.” Pharmacy professionals can assess whether an active pharmaceutical ingredient (API) is a health hazard under the Hazardous Products Act by referring to the API label and the SDS sheet for the API.

The NIOSH list is an American reference from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH), and includes ingredients more specific to health care materials: [NIOSH List of Antineoplastic and Other Hazardous Drugs in Health care Settings 2016](#)

Both the NIOSH list and WHMIS should be considered as part of a risk assessment, as each provides information regarding potential health hazards associated with compounding ingredients.

It is important to note a SDS may indicate that an API represents a health hazard even if the drug is not included on the NIOSH list of hazardous drugs.



**How do I determine if a product is listed as a health hazard under the Hazardous Products Act? How do I use the product safety data sheet (SDS) to determine the hazards identified with that product?**

Pharmacy professionals are expected to refer to Safety Data Sheets (SDSs) for active pharmaceutical ingredients (APIs) to determine any associated health hazard classes. SDS sheets should be accessible from the manufacturer of the API - therefore, a pharmacy professional should be able to access an SDS directly from the manufacturer or from the distributor the API was purchased from. On each SDS, refer to Section 2 for the Hazards Identification. In addition, refer to Section 8 of an SDS for information regarding the recommended exposure limits, engineering controls, and personnel protective equipment.

This fact sheet on [Safety Data Sheets](#) may be helpful.

Compounding supervisors must ensure that SDS sheets for APIs are used to conduct risk assessments of compounds, and that risk assessments for compounded preparations are available to all staff involved in compounding to make sure that they are aware of all possible risks.



### What should I do if I am uncertain about the risk level of a compound?

If after conducting a risk assessment to the best of your ability you are still uncertain as to the level of risk, then registrants should always defer to the higher standard.




### What is a small quantity?

A “small quantity” depends on the risk assessment for each API which should include an assessment of the frequency of compounding with these ingredients. As per section 4.1 of the guidance document, some factors to consider in the risk assessment include the:

- complexity of compounding the preparation;
- need for verification and uninterrupted workflow;
- frequency of compounding high-risk or low-risk preparations;
- risk of cross-contamination with other products (e.g., allergens);
- concentration of ingredients in the product;
- quantity of ingredients being handled;
- physical characteristics of ingredients (e.g., liquid vs. solid vs. powders, or water-soluble vs. lipid soluble);
- education and competency of compounding personnel;
- availability of appropriate facilities and equipment;
- classification of ingredients if identified by WHMIS as presenting a health hazard, or a drug classified by NIOSH as hazardous (see reference to NIOSH in section 4.3 of the guidance document);
- type of hazardous drug (e.g., anti-neoplastic, non-antineoplastic, reproductive risk only);
- exposure to compounding personnel for each preparation and accumulation of exposure over time; and,
- risk of microbial contamination (liquids, creams, and ointments may be particularly susceptible to microbial and other contamination).

The risk assessment must be reviewed on a continuum to identify and mitigate risk thereby providing quality assurance. A decision algorithm to assist in determining requirements for non-sterile compounding can be found in section 4.2 of the guidance document.

**Note:** Occasional small quantities of materials must not be considered in isolation. If several different high-risk or low-risk preparations are being compounded, the cumulative risk must be considered even if they are compounded on different days. This must be documented in the risk assessment.



**Can I continue to compound preparations that are assessed to be a higher level than my facility (for example, a Level B or C compound in a Level A space) until the final implementation deadline?**

That depends - can you safely make a high quality compound? The high-level principle is that once you know better, the expectation is that you do better. If through the risk assessment process you determine that an ingredient in a compound poses a health risk to pharmacy staff, then you need to be able to mitigate that risk in order to continue compounding. Similarly, if you determine that you do not have the necessary information, equipment, or supplies to properly compound a given preparation, then the expectation is that you refer the patient to a pharmacy that has the capability to make a high quality product. It is never okay to knowingly put patients or pharmacy personnel at risk.

**Section 4 of the guidance document also addresses this question as follows:**

*If it is necessary to compound a preparation requiring procedures or processes that are not currently in place within the pharmacy, the documentation should specify the potential risks of compounding the product, the extra steps that must be taken to mitigate the risks and references confirming that these steps actually will minimize risks to the quality of the product and safety of personnel.*

*The following examples illustrate these concepts:*

- *For a complex compound, the documentation should specify extra measures required, such as measures to ensure uninterrupted workflow, extra verification steps, extra equipment and supporting references.*
- *If a small quantity of a hazardous product is used in compounding, there must be documentation of alternative containment strategies and/or work practices being employed for specific dosage forms to minimize occupational exposure.*



**Do you need separate areas for compounding hazardous and non-hazardous non-sterile preparations?**

It is preferable to have separate areas for performing hazardous and non-hazardous non-sterile compounding. If the same area is being used for hazardous and non-hazardous non-sterile compounding, compounding personnel must ensure proper deactivation and decontamination process are in place to prevent cross-contamination. This includes having dedicated equipment to perform compounding activities in a separate room. Disposable or clean equipment for compounding (such as mortars and pestles, spatulas) must be dedicated for use with hazardous drugs. Additionally, if hazardous materials are used in the same space during compounding as non-hazardous materials, then non-hazardous compounded preparations must be packaged to identify that they may have been exposed to hazardous materials.



**My pharmacy will be making Level A compounds only; do I need to renovate my pharmacy?**

There are specific physical requirements that must be met in order to perform any level of compounding; therefore, depending on the current state of the pharmacy, renovations or modifications may be necessary. These include:

- A designated compounding area that has enough space to store equipment and supplies and for compounding personnel to work comfortably and safely. This area should be located in an space of reduced traffic to prevent contamination of the product and where there is minimal distraction to employees.
- A source of hot and cold running water must be contained within or close to the compounding area.
- The compounding area must have sufficient lighting.
- The compounding area must be designed to facilitate repeated cleaning.
  - Work surfaces, furniture, walls and flooring should be made of smooth, impenetrable and non-porous material.
  - Consider the need to change the surface you compound on, replacement of a section of flooring or appropriate flooring cover, etc.

The scope of compounding activities that pharmacies need to carry out to support their patients will vary from pharmacy to pharmacy. As such, pharmacy professionals need to apply the principles in the standard to their own practice site.



**For Level A compounding, does a “designated compounding area” mean a separate room?**

No, a separate room is not required.

While “separate” and “designated for the preparation of compounds” ideally means the space is only used for that purpose, NLPB recognizes the challenges that would create for some pharmacies. If the compounding area needs to be used for other functions, it must be maintained such that it can be cleaned quickly and made appropriate for safe compounding when needed. However, other activities cannot be performed in this area while compounding is occurring.



**What is the minimum size for a designated Level A compounding area?**

There is no minimum size requirement.

The compounding area must be large enough for compounding personnel to work comfortably and safely, with room to store equipment and products in an orderly manner in clean and secure surroundings. Also, the area should be designed and arranged to prevent cross-contamination between products, and it should be located away from parts of the pharmacy where there is a considerable amount of traffic (e.g., aisles, entrance, exits).





## What is Level B compounding?

Level B compounding includes:

- Complex, non-hazardous compounding; AND/OR,
- Occasional compounding with potentially hazardous or irritating ingredients

As per the USP 795 definition that is included in the guidance document, complex compounding means making a preparation that requires special training, environment, facilities, equipment and procedure to ensure appropriate therapeutic outcomes. Examples of possible complex preparation types include transdermal [delivery system] dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.



## What are the physical requirements for Level B compounding?

Section 8.2 of the Non-Sterile Compounding Standards states that, in addition to the Level A requirements, Level B compounding requires:

- A separate well-ventilated room (always); and,
- A ventilated containment device, if compounding with certain powders, aromatic products or hazardous products that pose risk to the compounder.

Examples of the latter include allergenic products or products that could have unintended effects, such as hormones, but that may not require the extensive precautions of Level C requirements if prepared in **small quantities and risk can be mitigated** (see section 4.2 of the guidance document for risk assessment). If a ventilated containment device is used, the pharmacy should follow the same requirements as outlined in section 9.2.3 of the Non-Sterile Compounding Standards.



## My colleague told me that pharmacies that meet Level A requirements cannot compound with any powders or ingredients that are designated as health hazards - is that correct?

Not necessarily. As per the guidance document, many non-sterile preparations can be compounded within a Level A space. These preparations could include simple and moderate compounds that contain hazardous drugs in NIOSH Group 2 or 3, or materials designated as health hazards by the Hazardous Products Act but are deemed to pose little or no risk for compounding personnel when compounded in occasional small quantities (i.e. quantities determined to represent low risk to compounders in a particular instance at the pharmacy if appropriate precautions are taken).

It is important to remember that not all Level A spaces are the same. The scope of activities that may be performed in a specific pharmacy depends on the unique characteristics of that site. The pharmacist-in-charge and compounding supervisor of each pharmacy must carry out a site-specific assessment of what compounding activities are appropriate and these may differ from other Level A pharmacies.



## What are the differences between the Level B and C facility requirements?

The facility requirements for Level A, B, and C build upon each other in accordance with risk to both patients and compounders.

Level C requirements include:

- A separate, well-ventilated room with:
  - Appropriate air exchange (at least 12 air changes per hour [ACPH]);
  - Negative pressure (-2.5 Pa relative to surrounding areas);
  - A ventilated containment device (i.e. containment primary engineering control [CPEC]); and,
  - PPE appropriate for handling hazardous products.

Section 9 of the Non-Sterile Compounding Standards and guidance document provides additional specific details on facility requirements for hazardous preparations. The notable differences from Level B are the specific air exchange and pressure requirements, the requirement for a C-PEC, and external ventilation. A Level B room is not required to be under negative pressure, and it may or may not have a C-PEC based on the risk of the APIs used for compounding and the amount/frequency they are used.

Level C facility requirements must be met when compounding any amount and any dosage form of hazardous drugs that are classified by NIOSH as Group 1 or hazardous materials that are classified by WHMIS to present health hazards such as very irritating to the respiratory tract, skin or mucous membranes. Level C facility requirements also apply to NIOSH Group 2 and 3 drugs involving routine use of large quantities of APIs, according to the risk assessment.



## How do I determine whether external ventilation is needed for non-sterile compounding?

Pharmacists-in-charge and compounding supervisors must determine whether external ventilation is required for both the compounding room, as well as for the containment primary engineering control (C-PEC) through their risk assessment. All risk assessments must be made available to staff involved in compounding.

External ventilation is not required for a Level A designated and separate compounding area.

External ventilation is not required for a Level B separate compounding room; however, this room must be "well-ventilated."

External ventilation through high-efficiency particulate air (HEPA) filtration is required for a room used for compounding hazardous preparations needing Level C requirements. When in doubt, defer to the higher standard (Level C).

Examples of C-PECs used in a Level B or C compounding room include containment ventilated enclosures, Class I or Class II Biological Safety Cabinets, compounding aseptic containment isolators (CACIs), etc. If the C-PEC is being used to handle hazardous products, it should be externally vented (preferred option) or have redundant HEPA filters in a series.