



Frequently Asked Questions: NAPRA Model Standards for Pharmacy Compounding of Non-sterile Preparations¹

? Can you explain what is required of me and my team during Phase 1 of the implementation timeline for the *Model Standards for Pharmacy Compounding of Non-sterile Preparations*?

During “Phase 1”, the New Brunswick College of Pharmacists (the College) expects pharmacies involved in non-sterile compounding to evaluate their current practices and determine what areas require work to be compliant with the Standards. Once this gap analysis is achieved, the pharmacy should have a documented plan such as a timeline as to when they expect to be compliant.

Since Phases 2 and 3 of the implementation plan contain a greater workload than Phase 1, all pharmacies involved in non-sterile compounding are encouraged to commence work on those sections of the implementation timeline ahead of the required deadlines.

<https://pharmacyconnection.ca/non-sterile-compounding-winter-2019/>

? How do I prepare a Gap Analysis? Is there a form or checklist I can use?

An example of a gap analysis document is provided here for consideration (<https://cphm.ca/uploaded/web/Pharmacy%20Compounding%20Standards/CPhM%20Quality%20Assurance%20Self-Assessment%20NON-STERILE%20Compounding.pdf>). The College does not require a particular form to be used for this purpose, however. *(By including it, the College is not endorsing this particular resource.)*

? What is the difference between the Standards document and the Guidelines? Do I have to follow everything in the Guidelines; that is a HUGE document!

The Standards are now the minimum requirements for all members of the College involved in non-sterile compounding. It is mandatory that pharmacies involved in non-sterile compounding be compliant with the Standards.

The Guidelines were developed by NAPRA as a resource, if needed, and provide more detail and direction on implementing the Standards. Members may choose to meet the required Standard using another process than one suggested in the Guideline document; this is acceptable as long as the process meets or exceeds the requirements in the Standard.

? As part of our Risk Assessment, what is more important, the WHMIS list, or the NIOSH list? I don't understand the difference between the two.

While both resources may be used as part of a risk assessment process in the pharmacy, each provides a different perspective to ingredient classification.

- WHMIS refers to products used in various workplaces, as outlined in Health Canada's Workplace Hazardous Materials Information System. WHMIS encompasses a far wider group of chemicals used in workplaces.
- NIOSH refers to a list of ingredients identified by the American National Institute for Occupational Safety and Health; <https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf?id=10.26616/NIOSH PUB2016161> and is more specific to health care materials.

Practitioners may be familiar with WHMIS's Material Safety Data Sheets with regard to products used in the pharmacy for such things as cleaning supplies. The NIOSH list may be more useful for medications used during compounding.

Ultimately, the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations references both documents, and as such, both may be used while performing risk assessments of various ingredients used in making compounds.

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

Some pharmacists and pharmacy technicians (licensed members) have already participated in in-house training and have proactively performed reviews of the compounding techniques of non-regulated pharmacy staff members. Members 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. Members are encouraged to research those options, and if appropriate, have at least one licensed member take the training, and then, train and assess others at the practice site.

There are tools which can be used to assess pharmacy team members on an ongoing basis. Here is an example of one <https://education.lp3network.com/>. (By including, the College is not endorsing this particular resource.)

? What do I need to include in a Master Formulation Record?

The Standards document provides the following list on page 9 under the heading *Product and Preparation Requirements*:

Master Formulation Record (see section GD-6.2 for requirements and template)

- Must be developed for each non-sterile compound by regulated pharmacy personnel with adequate experience and broad scientific knowledge
- Must include all necessary information to compound the non-sterile preparation
- Must contain supporting rationale and references
- Must be kept in a format that is readily accessible to compounding personnel

The Guidance document also provides a template which would meet the requirements for a Master Formulation Record (pages 25 to 27, under 6.2.1).

? **What does “mitigating risk” mean exactly, in relation to Level B risk compounds?**

The table on page 5 of the Standards document contains an outline regarding what to look for when seeking to mitigate risk, particularly to compounding personnel. Key points to consider in your decision making are:

- the level of risk the ingredient(s) may present
- the volume/frequency of that ingredient’s use
- the **combined** exposure to all higher risk ingredients

If there is uncertainty as to the level of risk, then personnel **shall defer to the higher standard.**

? **What if my pharmacy only makes very simple compounds, like 50:50 creams, or Magic Mouthwash—do I still have to go through this process?**

The Standards are now the minimum requirements for all members of the College involved in non-sterile compounding. It is mandatory that pharmacies involved in non-sterile compounding be compliant with the Standards.

While there will be less work for your pharmacy, particularly when it comes to preparation of Master Formulation Records, the Standards must still be met whenever a compound is prepared.

? **Can we utilize our current workspace with minor modifications to complete level A compounding? I think our community pharmacy has two possibilities for designating a “separate area” and I’ve included photos to demonstrate what we thought may be appropriate: either next to our sink by moving our computer, or in the dispensing area. Can our compounding area then also be used for other pharmacy activities?**



The [NAPRA Model Standards for Pharmacy Compounding of Non-sterile Preparations](#) (the Standards), as well as the accompanying [Guidance document](#) set out the minimum standards for non-sterile compounding of medications.

Section 5.4.1 of the Standards states “Compounding must be performed in a separate, specifically designated space.” The Standards then provides more specifics about size, lighting, cleaning, ventilation, and storage of equipment. The standards also state the area utilized for compounding have sufficient storage for compounding supplies. Further detail is provided on pages 20-21 of the Guidance document.

When assessing your practice, such as the facilities in the photos provided, asking yourself the following questions will help reveal if the Standards can be met in the space you have.

- Is your compounding space **separate** and **designated for the preparation of compounds**?
- Is the space removed from traffic, designed to prevent cross-contamination, located to decrease potential for distraction for personnel?
- Is the space easily maintained and able to be kept sufficiently clean for compounding activities?
- Is lighting and temperature appropriate for staff to safely meet compounding standards?
- Is a source of hot and cold running water in close proximity?

The spaces shown in the photos provided would likely not be appropriate, however, giving an answer based on those two photos alone is challenging. It is important to consider the “designated” area itself, and the bigger picture with relation to workflow and other activities happening within the dispensary. Working through the questions, above, and referencing the Guidance document, particularly

Section 5.4.1, will help in making a well-informed decision on the appropriateness of those spaces for non-sterile compounding.

Pharmacists and pharmacy technicians are encouraged to view the following video, referenced in the Guidance document (<https://www.youtube.com/watch?v=TTtguuj83f8>). This video displays an excellent facility that meets the requirements outlined in the Standard and is one that all pharmacies should aspire to.

Not all areas appropriate for compounding will look the same, and as such, pharmacy team members need to apply the principles in the Standard to their own practice site. Staff at the College can be of assistance if you hit a roadblock in that process.

The expectation during [Phase 1 of the Implementation Timeline \[LINK\]](#) is pharmacy team members carry out a gap analysis, identify deficiencies in current practice and create a plan for improvement. Practitioners must assess their facilities, recognize the deficiencies and work with pharmacy managers to create a plan for improvement. The facilities required for Level A compounding must be in place by the end of Phase 2 (June 30, 2020).

Thinking Practically

While “separate” and “designated for the preparation of compounds” ideally means the space is **only** used for that purpose, the College recognizes the challenges that would create for some practice sites.

If the separate space is used for other functions, it **must** be maintained such that it can be cleaned quickly and made appropriate for safe compounding, when needed.

Suggested Resources

Alberta College of Pharmacists

[Getting Started - Three priorities to prepare for non-sterile compounding](#)

[Compounding Essentials](#)

[Templates](#)

NAPRA

[Decision Algorithm to determine requirements for non-sterile compounds](#)

Ontario College of Pharmacists

[Compounding: Are you doing it?](#)