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

? 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/NIOSHPUB2016161 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.

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?