Ontario College of Pharmacists
Putting patients first since 1871

SAVE PRINT CLEAR ALL

Checklist Overview Of Phases 1, 2 and 3

*The following checklist is intended to as a guide for pharmacy professionals and pharmacies as they work to implement the requirements of the **NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations** and **Guidance Document for Pharmacy Compounding of Non-Sterile Preparations**. It does not replace the standards or guidance document. It is the responsibility of the pharmacy to understand, and ensure compliance with, the standards.*

***For more information, please visit the Non-Sterile Compounding Key Initiative on the OCP website.** Sections in parentheses are from the Guidance Document.*

PHASE 1 – DEADLINE JANUARY 1, 2020	Verify that the following requirements have been completed and if necessary, develop a plan to address any outstanding requirements.

☐ **Review the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations and Guidance Document for Pharmacy Compounding of Non-Sterile Preparations**.
☐ Read the *Pharmacy Connection* article Timelines Announced for Non-Sterile Compounding Standards (Winter 2019)
☐ Read the *Pharmacy Connection* article Implementing the Non-Sterile Compounding Standards: The Community Pharmacy Experience (Summer 2019)
☐ Read the *Pharmacy Connection* article Consider These Steps While Preparing for the First Phase of Non-Sterile Compounding Compliance: The Hamilton Health Sciences Experience (Spring 2019)
☐ **Designate a regulated pharmacy professional to be the non-sterile compounding (NSC) supervisor.** (Section 5.1)
☐ Identify all personnel engaged in non-sterile compounding and associated cleaning
☐ **Evaluate the pharmacy's current and/or anticipated compounding services and preparations to assess risks and determine the level of requirements to be implemented.** (Section 4)
☐ Identify the non-sterile preparations being compounded and the compounding ingredients (e.g., Active Pharmaceutical Ingredients) required (Section 6.3)
☐ Determine if each preparation is still being made or if a comparable manufactured product is commercially available, therefore eliminating the need for compounding (Section 2.1 and 3)
☐ Identify ingredients classified as hazardous by reviewing the NIOSH List of Hazardous Drugs
☐ Identify ingredients that pose a potential health hazard according to WHMIS by reviewing the safety data sheets (SDS) provided by the supplier or manufacturer
☐ Perform a risk assessment for each preparation compounded by the pharmacy using the Decision Algorithm for Risk Assessment as a guide (Section 4.2)
☐ **Determine, using the results of the risk assessments and taking into account the frequency and quantity of compounding and risk mitigation measures, if your pharmacy compounding space currently meets the requirements needed to prepare Level A, B, or C compounds** (Section 8)
☐ Read the *Pharmacy Connection* article Implementing the Non-Sterile Compounding Standards: A Closer Look at Personal Protective Equipment (Summer 2019).

☐ Read the *Pharmacy Connection* article Non-Sterile Compounding FAQs (Summer 2019)
☐ **Perform a gap analysis to compare the pharmacy's current practices to the minimum standards.**
☐ The Non-Sterile Compounding Assessment Criteria document may be used for this activity
☐ Identify any gaps in the knowledge and skills of compounding/cleaning personnel. (Section 5.2)
☐ Develop a plan of action to address the identified gaps based on the Phase 2 and 3 implementation deadlines.
☐ Read the *Pharmacy Connection* article Preparing for Phase 2 of the Non-Sterile Compounding Standards (Fall 2019).

PHASE 2 – DEADLINE JULY 1, 2021	Policies and procedures to meet and maintain the standards, including personnel training, should be developed along with a quality assurance program. Planning for Phase 3 should happen in tandem with Phase 2, as the physical or space changes needed may require additional time and resources.

☐ **Create Master Formulation Records for each preparation, which must include all necessary information to compound the preparation**. (Section 6)
☐ Assign a beyond-use date for each preparation. (Section 6.1)
☐ **Develop policies and procedures for all aspects of non-sterile compounding**. (Section 5.3) Begin with those related to personnel (e.g., conduct, hygiene, attire).
☐ Hazardous preparations require additional policies and procedures. (Section 9.3, 9.4, 9.5)
☐ **Complete a skills assessment for existing non-sterile compounding/cleaning personnel.** (Section 5.2)
☐ **Develop a training program for non-sterile compounding personnel.** (Section 5.2)
☐ Ensure there is training on policies and procedures as they are developed.
☐ **Develop a quality assurance program for personnel to verify ongoing effectiveness of, and compliance with, policies and procedures.** (Section 7.3, 7.4)
☐ **Begin developing other components of the pharmacy's quality assurance program**. (Section 7)

PHASE 3 – DEADLINE JANUARY 1, 2022	The focus is on ensuring that the facility and equipment required for the preparation of all non-sterile compounds are in compliance with the standards.

☐ **Establish protocols and schedules for cleaning and maintenance of the compounding area facilities and equipment to maintain the quality and integrity of the final preparations.** (Section 5.4)
☐ Document these activities in the general maintenance log. (Section 5.4)
☐ Ensure facilities and equipment (including C-PEC) is certified and maintained as per standards. (Table 6)
☐ Implement proper deactivation, decontamination, and cleaning procedures for hazardous preparations. (Section 9.2, 9.3)
☐ Ensure that an environmental monitoring plan is in place for hazardous preparations. (Section 9.6)
☐ **Ensure that the proper facilities are in place for Level C requirements, including lighting, heating, ventilation and air conditioning systems, water supply, work surfaces, furniture, walls and flooring**. (Section 9.1)
☐ **Develop a quality assurance program for facilities, equipment, preparation processes (including those in Section 6), and documentation (Section 7)**