

## 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.
<input type="checkbox"/> Review the <b>NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations</b> and <b>Guidance Document for Pharmacy Compounding of Non-Sterile Preparations</b> .	
<input type="checkbox"/> Read the <i>Pharmacy Connection</i> article <b>Timelines Announced for Non-Sterile Compounding Standards</b> (Winter 2019)	
<input type="checkbox"/> Read the <i>Pharmacy Connection</i> article <b>Implementing the Non-Sterile Compounding Standards: The Community Pharmacy Experience</b> (Summer 2019)	
<input type="checkbox"/> Read the <i>Pharmacy Connection</i> article <b>Consider These Steps While Preparing for the First Phase of Non-Sterile Compounding Compliance: The Hamilton Health Sciences Experience</b> (Spring 2019)	
<input type="checkbox"/> <b>Designate a regulated pharmacy professional to be the non-sterile compounding (NSC) supervisor.</b> (Section 5.1)	
<input type="checkbox"/> Identify all personnel engaged in non-sterile compounding and associated cleaning	
<input type="checkbox"/> <b>Evaluate the pharmacy's current and/or anticipated compounding services and preparations to assess risks and determine the level of requirements to be implemented.</b> (Section 4)	
<input type="checkbox"/> Identify the non-sterile preparations being compounded and the compounding ingredients (e.g., Active Pharmaceutical Ingredients) required (Section 6.3)	
<input type="checkbox"/> 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)	
<input type="checkbox"/> Identify ingredients classified as hazardous by reviewing the <b>NIOSH List of Hazardous Drugs</b>	
<input type="checkbox"/> Identify ingredients that pose a potential health hazard according to WHMIS by reviewing the safety data sheets (SDS) provided by the supplier or manufacturer	
<input type="checkbox"/> Perform a risk assessment for each preparation compounded by the pharmacy using the <b>Decision Algorithm for Risk Assessment</b> as a guide (Section 4.2)	
<input type="checkbox"/> <b>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</b> (Section 8)	
<input type="checkbox"/> Read the <i>Pharmacy Connection</i> article <b>Implementing the Non-Sterile Compounding Standards: A Closer Look at Personal Protective Equipment</b> (Summer 2019).	

<input type="checkbox"/> Read the <i>Pharmacy Connection</i> article <a href="#">Non-Sterile Compounding FAQs (Summer 2019)</a>	
<input type="checkbox"/> <b>Perform a gap analysis to compare the pharmacy's current practices to the minimum standards.</b>	
<input type="checkbox"/> The <a href="#">Non-Sterile Compounding Assessment Criteria document</a> may be used for this activity	
<input type="checkbox"/> Identify any gaps in the knowledge and skills of compounding/cleaning personnel. (Section 5.2)	
<input type="checkbox"/> Develop a plan of action to address the identified gaps based on the Phase 2 and 3 implementation deadlines.	
<input type="checkbox"/> Read the <i>Pharmacy Connection</i> article <a href="#">Preparing for Phase 2 of the Non-Sterile Compounding Standards (Fall 2019)</a> .	
<b>PHASE 2 – DEADLINE JULY 1, 2021</b>	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.
<input type="checkbox"/> <b>Create Master Formulation Records for each preparation, which must include all necessary information to compound the preparation.</b> (Section 6)	
<input type="checkbox"/> Assign a beyond-use date for each preparation. (Section 6.1)	
<input type="checkbox"/> <b>Develop policies and procedures for all aspects of non-sterile compounding.</b> (Section 5.3) Begin with those related to personnel (e.g., conduct, hygiene, attire).	
<input type="checkbox"/> Hazardous preparations require additional policies and procedures. (Section 9.3, 9.4, 9.5)	
<input type="checkbox"/> <b>Complete a skills assessment for existing non-sterile compounding/cleaning personnel.</b> (Section 5.2)	
<input type="checkbox"/> <b>Develop a training program for non-sterile compounding personnel.</b> (Section 5.2)	
<input type="checkbox"/> Ensure there is training on policies and procedures as they are developed.	
<input type="checkbox"/> <b>Develop a quality assurance program for personnel to verify ongoing effectiveness of, and compliance with, policies and procedures.</b> (Section 7.3, 7.4)	
<input type="checkbox"/> <b>Begin developing other components of the pharmacy's quality assurance program.</b> (Section 7)	
<b>PHASE 3 – DEADLINE JANUARY 1, 2022</b>	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.
<input type="checkbox"/> <b>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.</b> (Section 5.4)	
<input type="checkbox"/> Document these activities in the general maintenance log. (Section 5.4)	
<input type="checkbox"/> Ensure facilities and equipment (including C-PEC) is certified and maintained as per standards. (Table 6)	
<input type="checkbox"/> Implement proper deactivation, decontamination, and cleaning procedures for hazardous preparations. (Section 9.2, 9.3)	
<input type="checkbox"/> Ensure that an environmental monitoring plan is in place for hazardous preparations. (Section 9.6)	
<input type="checkbox"/> <b>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.</b> (Section 9.1)	
<input type="checkbox"/> <b>Develop a quality assurance program for facilities, equipment, preparation processes (including those in Section 6), and documentation (Section 7)</b>	