Checklist Overview of Phases 1, 2, and 3

Model Standards for Pharmacy Compounding of Non-Sterile Preparations

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 pharmacy team members involved in non-sterile compounding to understand, and ensure compliance with, the standards.

For more information, please visit the Compounding (Non-sterile Preparations) section of the Practice Requirements webpage at the NBCP website **[LINK]**. Applicable sections of the Guidance Document are noted for each goal.

Phase 1 - Implementation Timeline Link	
HIGH LEVEL GOALS	**DETAILED GOALS**
☐ **Standards and Guidance document reviewed** ☐ **Gap analysis completed** ☐ **Action plan created**	☐ Review the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations and Guidance Document for Pharmacy Compounding of Non-Sterile Preparations.
	☐ Evaluate the pharmacy's current and/or anticipated compounding services and preparations to assess risks and determine the level of requirements to be implemented. **GD – Section 4**
	☐ Determine, using the results of the risk assessments and considering 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. **GD – Section 8**
	☐ Perform a gap analysis to compare the pharmacy's current practices to the minimum standards.
	☐ Develop a plan of action to address the identified gaps based on the Phase 2 and 3 implementation deadlines.

	☐ Look ahead to Phase 2 requirements; considered early implementation.

Phase 2 Implementation Timeline Link	
Policies and procedures to meet and maintain the standards, including personnel training, should be developed, along with a quality assurance program.	
HIGH LEVEL GOALS	**DETAILED GOALS**
☐ **All Level A compounding requirements met** ☐ **Personnel training and skills assessment complete** ☐ **Risk assessment complete** ☐ **Policies and procedures documented**	☐ Designate a regulated pharmacy professional to be the non-sterile compounding (NSC) supervisor. **GD – Section 5.1**
	☐ Identify all personnel engaged in non-sterile compounding and associated cleaning.
	☐ Identify the non-sterile preparations being compounded and the compounding ingredients (e.g., Active Pharmaceutical Ingredients) required. **GD – 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. **GD – Sections 2.1 & 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. **GD – Section 4.2**
	☐ Identify any gaps in the knowledge and skills of compounding/cleaning personnel. **GD – Section 5.2**
	☐ Create Master Formulation Records (MFR) for each preparation, which must include all necessary information to

	compound the preparation. **GD – Section 6** **May be <u>completed</u> in Phase 3.*
	☐ Assign a beyond-use date for each preparation. **GD – Section 6 .1** **May be completed in Phase 3.*
	☐ Develop policies and procedures for all aspects of non-sterile compounding. **GD – Section 5.3 ****Suggestion: begin with those related to personnel (e.g., conduct, hygiene, attire).*
	☐ Develop a training program for non-sterile compounding personnel. **GD – Section 5.2**
	☐ Ensure there is training on all policies and procedures, as they are developed.
	☐ Complete a skills assessment for existing non-sterile compounding/cleaning personnel. **GD – Section 5.2**
	☐ Note: Hazardous preparations require additional policies and procedures. **GD – Sections 9.3, 9.4, 9.5** **May be <u>completed</u> in Phase 3.*
	☐ Begin development of a quality assurance program for personnel to verify ongoing effectiveness of, and compliance with, policies and procedures. **GD – Sections 7.3 & 7.4** **May be <u>completed</u> in Phase 3.*
	☐ Begin developing other components of the pharmacy's quality assurance program. **GD – Section 7** **May be <u>completed</u> in Phase 3*.
	☐ Look ahead to additional Phase 3 requirements; consider early implementation.

Phase 3 Implementation Timeline Link	
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.	
HIGH LEVEL GOALS	**DETAILED GOALS**
☐ **All Level B requirements met** (if applicable to the pharmacy) ☐ **Labelling and packaging** ☐ **Beyond use dating** (carry over from Phase 2) ☐ **Master formulation records created** (carry over from Phase 2) ☐ **Facilities & equipment; cleaning and maintenance** ☐ **Quality and storage of ingredients** ☐ **Compounding record** ☐ **Storage, transport & delivery** ☐ **Product recalls** ☐ **Incident reporting** ☐ **Quality assurance** (carry over from Phase 2)	☐ Complete a quality assurance program for facilities, equipment, preparation processes (including those in Section 6), and documentation. **GD – Section 7** ☐ Establish protocols and schedules for the cleaning and maintenance of the compounding area facilities and equipment to maintain the quality and integrity of the final preparations. **GD – Section 5.4** ☐ Ensure documentation of cleaning and maintenance activities is being completed and retained. **GD – Section 5.4** ☐ Ensure facilities and equipment (including C-PEC, if applicable) is certified and maintained as per standards (Table 6). ☐ Implement proper deactivation, decontamination, and cleaning procedures for any hazardous preparations (Level B or C). **GD – Sections 9.2 & 9.3** ☐ Ensure that an environmental monitoring plan is in place for hazardous preparations (Level B or C). **GD – Section 9.6**

Full Compliance Implementation Timeline Link
☐ **All requirements from Phases 1, 2, and 3** ☐ **All Level C requirements met (if applicable to the pharmacy)** ☐ **Hazardous preparations (if applicable to the pharmacy)** ☐ **If applicable, 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. GD – Section 9.1**