



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

Implementation Framework

UPDATED MARCH 24, 2020

Priority 1: Assessing Risk and Gaps Compliance by January 31, 2021

Determine what nonsterile compounded preparations and services you are providing. “What compounds are you making or planning to make?” Are changes to your infrastructure necessary?

- Review Standards (S) and Guidance (G) to complete a gap analysis of all areas (to assist with planning/prioritizing overall implementation)
- Identify the compounding supervisor who will develop, organize and oversee all activities. (G4.1.2.)
- Identify all personnel who will require skills and training assessment (G4.1.3-4.2.2)
- Identify the levels of requirements for the compounds you are preparing (G Diagram 1).(G3.1-3.3)
 - Complete the risk assessment for each nonsterile compound that you are preparing.
 - Ensure master formulations are comprehensive and evidence-based with safety data sheets for each chemical used. (G5.2)
 - Refer to the NIOSH list, MSDS and WHMIS to determine level of risk to the compounding personnel (G3.3)
 - Identify the need for (and sources for) personal protective equipment (PPE) and safety equipment (G8.4, 8.2.3)
 - Pharmacist to review/approve BUDs for all compounds as a part of the risk assessment (G5.1.1) Determine the gaps for which additional training (including for cleaning personnel) is needed.
- Determine the gaps for which facility improvements are required given the time and planning needed to make structural changes.
- Identify the cleaning supplies required and identify suppliers



- Identify the need for policies and procedures regarding staff compliance with hygiene requirements (e.g. no makeup, no jewelry, suitable work clothing etc.)
- Develop and implement an action plan to address identified gaps
 - Plan for risk mitigation where possible in interim (G9)

Priority 2: Compounding and Cleaning Personnel Training and Quality Assurance Compliance by July 31, 2021

What kind of training, evidence of and assessment of training, policies and procedures do you have in place to support you in meeting the standards?

- Review policies and procedures and identify gaps based on findings from priority 1.
- Refer to checklist regarding responsibilities for pharmacy personnel (regulated and non-regulated) and delineate these responsibilities. Note the responsibilities for nonhazardous and hazardous nonsterile compounding. (G4.2.1 and 4.2.1.1)
- Assess the skills required for cleaning personnel (G4.2.2)
- Complete the skills assessment checklist and determine and document skills training program required to address gaps and maintain quality practice.
- Revise or develop policies and procedures including a quality assurance program (G6.6).
 - Ensure that your quality assurance program addresses the following: verification and maintenance of equipment, environmental control of facilities and primary engineering control, environmental monitoring of chemical contamination for hazardous products, and quality assurance of compounded nonsterile preparations (protocol, compliance with prescription, documentation).
- Ensure your policies and procedures address proper hygiene for personnel (GD Template 1;GD 5.5)



- Master formulation records should include all necessary information to compound a non-sterile preparation (GD template 2).
- Ensure that near misses, drug incident, and accident reporting, investigation and follow up are addressed. (G8.4, GD Template 3)
- For hazardous, ensure that procedures for receiving, unpacking and storing hazardous products as well as a waste management program are established and documented. (S9.5; GD 8.1.4-8.1.5.)

Priority 3: Facilities and Equipment Compliance by January 31, 2022

Are your facilities and equipment are in compliance with respect to the preparation of hazardous and nonhazardous nonsterile compounds that may require specific handling requirements?

- Ensure hoods are certified every 6 months, no hazardous material is left lying around, and cleaning and decontamination equipment and supplies are in place for hazardous compounding. (S9.2, G8.3, 8.6.1) NB: Containers should not be reused.
- Ensure that your facilities and equipment meet the requirements for lighting, heating, ventilation and air conditioning systems, water supply, work surfaces, furniture, walls and flooring. (S9.1)
- Establish protocols and schedules for cleaning facilities and equipment to maintain quality and integrity of the final preparations. (G4.4.1.6)
- Ensure routine maintenance of all facilities and equipment including the cleaning of specialized equipment and documentation in a general maintenance log. (G4.4.2.1)
- Finalize your quality assurance program and ensure that it addresses the following: facilities, equipment, personnel metrics, final compounded non-sterile preparations, and documentation. (G6)
- For facilities that compound hazardous preparations, ensure that proper deactivation, decontamination and cleaning procedures are addressed. (G8.3)
- Environmental monitoring (G8.6.3)



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