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National Association of Pharmacy Regulatory Authorities ®
Association nationale des organismes de réglementation de la pharmacie

Model Compounding Competencies for Pharmacists and Pharmacy Technicians in Canada

SASKATCHEWAN COLLEGE OF PHARMACY PROFESSIONALS

Adopted by the Saskatchewan College of Pharmacy Professionals

Model Compounding Competencies for Pharmacists and Pharmacy Technicians in Canada

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I. Acronyms Used Within This Document

BUD	Beyond-use date
CSP	Compounded sterile preparation
CSP Log	Compounded sterile preparation log
CStPP	Compounded sterile preparation protocol
CS	Compounding supervisor
MFR	Master formulation record
MSPC	Model standards and guidance document for pharmacy compounding
P&P	Policies and procedures
PM	Pharmacy manager
PPE	Personal protective equipment
QA	Quality assurance
SCS	Sterile compounding supervisor

II. Definitions

The following provides definitions for key terms that are not found in, or are modified from, NAPRA's model standards and guidance document for pharmacy compounding (1-4), *Professional Competencies for Canadian Pharmacists at Entry to Practice* (5), *Professional Competencies for Canadian Pharmacy Technicians at Entry to Practice* (6) (hereafter jointly referred to as the NAPRA entry-to-practice competencies) and *Model Standards of Practice for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals* (7). Readers are referred to these documents for definitions of standard terms used within the *Model Compounding Competencies*.

Pharmacy professionals	persons authorized to practise as a pharmacist or pharmacy technician by the pharmacy regulatory authority in one of the provinces or territories of Canada
Compounding pharmacy professionals	pharmacists or pharmacy technicians who are involved in ensuring the safe compounding of quality non-sterile, sterile, and/or hazardous preparations
Preparation	preparations are compounded by compounding pharmacy professionals or, where authorized by jurisdictions, by non-regulated pharmacy personnel under the supervision of compounding pharmacy professionals
Product[i]	products are available commercially from a manufacturer[ii]
Components	includes all active pharmaceutical ingredients, vehicles, bases, diluents, excipients, containers, etc., required to compound a preparation
Quality	the suitability of a component, product, or preparation for its intended use, including integrity and stability as defined below (modified from reference 8)
Integrity	attributes of compounded preparations such as the identity, strength, and purity of components, and sterility and lack of contamination (drawn from references 9 and 10)
Stability	the extent to which a preparation retains physical and chemical properties and characteristics within specified limits until its BUD (11)

i This definition differs from that in NAPRA's *Professional competencies for Canadian pharmacy technicians at entry to practice* (6) in that it differentiates drug products from drug preparations.

ii This definition does not apply to the term "hazardous product" which maintains the definition from NAPRA's model standards and guidance document for pharmacy compounding (1-4).

II. Definitions

Master formulation record (MFR)	contains all information necessary to compound a **non-sterile** preparation, including components, packaging, labelling, storing, transport, QA, required equipment, BUD, etc. The full list of required information can be found in section 6.2 of NAPRA's *Guidance Document for Pharmacy Compounding of Non-sterile Preparations* (2).
Compounded sterile preparation protocol (CStPP)	contains all information necessary to compound a **sterile** preparation, including components, packaging, labelling, storing, transport, QA, required equipment, BUD, etc. The full list of required information can be found in section 6.2 of NAPRA's *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations and Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations* (3,4).
Independent verification	checking by an authorized compounding pharmacy professional who did not perform the original compounding act. The *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations and Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations* (3,4) refer to independent verification as second verification. This document uses independent verification to also mean second verification.

III. Short Forms Used Within This Document

To facilitate reading of this document, the following short forms are used. These short forms are not formal definitions adopted by NAPRA.

Pharmacy managers of compounding pharmacies	includes both pharmacy managers in community pharmacies providing compounding services and pharmacy managers and/or heads of departments of pharmacy in hospitals or other settings providing compounding services
Staff pharmacy professionals	includes compounding pharmacy professionals, including pharmacists and pharmacy technicians, who are **not** functioning as either compounding supervisors or pharmacy managers of compounding pharmacies

IV. Background

This document defines the *Model Compounding Competencies* required of compounding pharmacy professionals in Canada to ensure safe, quality compounding. Competencies are defined for compounding of the three categories of non-sterile, sterile, and hazardous preparations. The intent is that all pharmacy professionals who are involved in a given category of compounding, including pharmacy professionals with supervisory or management responsibilities for compounding, must be able to demonstrate the defined competencies.

NAPRA developed these *Model Compounding Competencies* for the following objectives:

- to provide competencies against which compounding educational programs can be mapped to ensure that individuals taking the educational programs will be able to meet the NAPRA compounding standards; and
- to provide competencies for compounding that pharmacy regulatory authorities can map assessment initiatives against.

NAPRA recognizes that a number of the *Model Compounding Competencies* across the three categories of compounding may not be fully addressed in all entry-to-practice educational programs for pharmacy professionals and may require additional experience, training, or education. It is intended that subsequent work by NAPRA will clarify which of the compounding competencies defined in this document are required of all pharmacy professionals at entry to practice.

The *Model Compounding Competencies* are supplemental to NAPRA's entry-to-practice competencies and are, therefore, presented in the same format and use the same terminology. Pharmacy professionals are expected to meet their relevant entry-to-practice competencies while performing compounding-related responsibilities. For clarity, this includes responsibilities for pharmacists ensuring the therapeutic appropriateness of prescriptions for compounded preparations, and for pharmacy professionals' managing and reporting of adverse events and medication incidents.

IV. Background

NAPRA's entry-to-practice competencies for pharmacists and pharmacy technicians remain, by definition, high level. Complex competencies are not broken down into lists of detailed expectations. Key competencies define **what** is to be achieved or performed, with associated enabling competencies defining **what** a pharmacy professional is expected to do to meet the key competencies (12, 13). The more granular and detailed description of **how** these competencies are to be performed, and the level of performance expected, are found within NAPRA's *Model Standards of Practice for Pharmacists and Pharmacy Technicians in Canada* (14). This approach to defining professional competencies ensures that descriptions of practice expectations are not overwhelming. However, the lack of detail can prove challenging for professional practice areas under development or review such as compounding. In these situations, the development of more comprehensive descriptions of the complex competencies is necessary.

The *Model Compounding Competencies* provide this greater level of detail, overlapping and expanding upon enabling competencies currently included in NAPRA's entry-to-practice competencies. Specifically, the first *Model Compounding Competency* describes the competencies required of pharmacy professionals when compounding preparations while the second identifies competencies required for assuring the quality of preparations prior to distribution. These expand on the competencies listed in the Product Distribution section of NAPRA's entry-to-practice competencies. The third *Model Compounding Competency* describes management-related compounding competencies and expands on the competencies listed in the Practice Setting section and the Quality and Safety section of NAPRA's entry-to-practice competencies.

In the *Model Compounding Competencies*, competencies required only for specific types of compounding are identified in two manners: in the text of the competency and the formatting. Competencies required for non-sterile compounding only are placed in boxes shaded in grey, while boxes shaded in blue are used to indicate competencies required for sterile compounding and boxes shaded in red are used to indicate competencies required for hazardous compounding, as illustrated below. All competencies not placed in shaded boxes are required for all types of compounding, including non-sterile, sterile, and hazardous compounding.

X.X.X Competency required for all compounding (sterile, non-sterile, and hazardous)
X.X.X Competency required for compounding of all non-sterile preparations
X.X.X Competency required for compounding of all sterile preparations
X.X.X Competency required for compounding of all hazardous preparations

IV. Background

Although the third compounding competency is titled Compounding Pharmacy Management, this section includes a number of supervisory and management-related compounding competencies that are required of all compounding pharmacy professionals, including staff compounding pharmacists and staff compounding pharmacy technicians.

The three *Model Compounding Competencies* identify the differing compounding responsibilities required of staff compounding pharmacy technicians, staff compounding pharmacists, compounding supervisors, and pharmacy managers of compounding pharmacies. These are identified in different columns as follows:

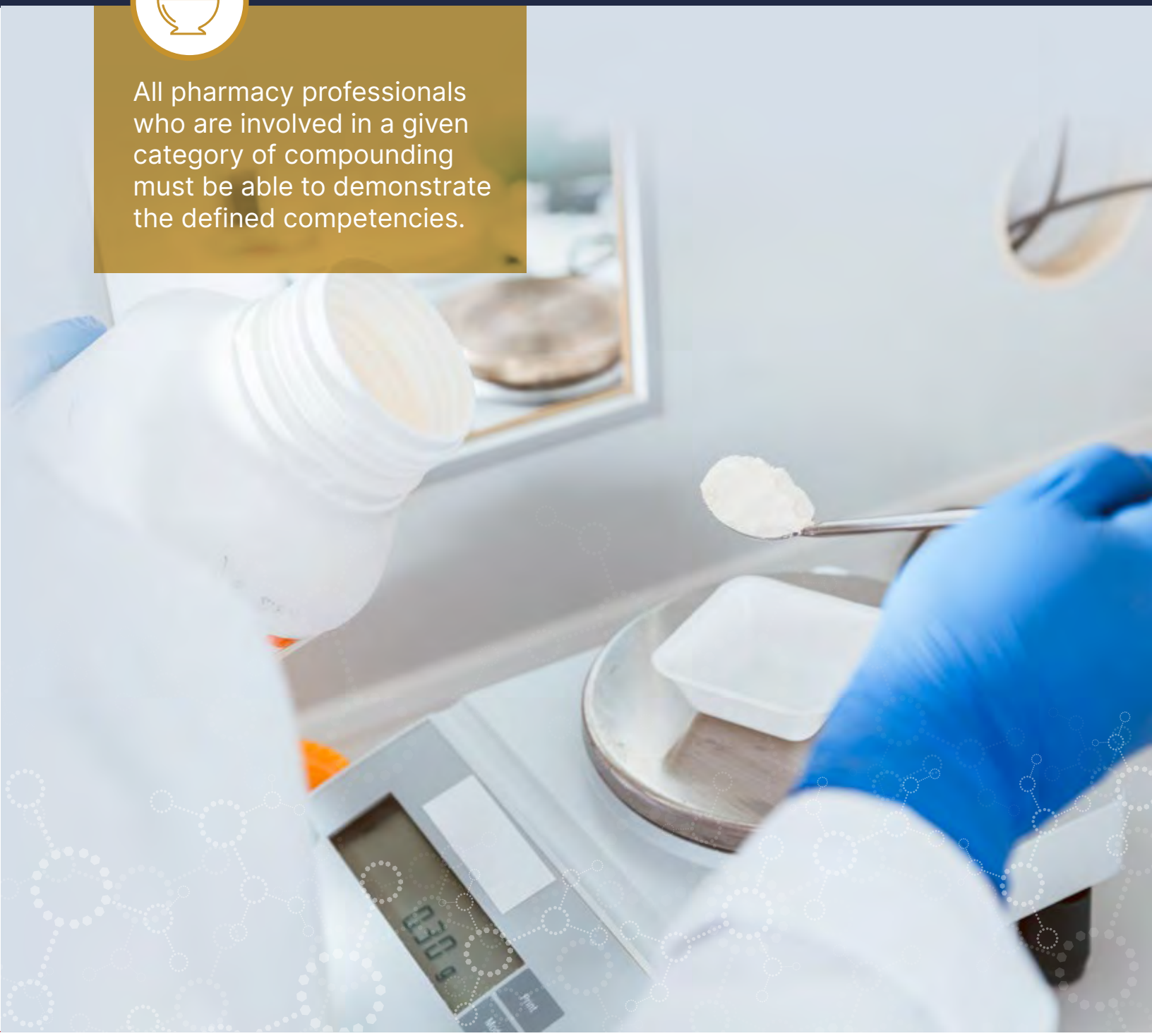
- Columns A and B identify the key and enabling compounding competencies.
- Columns C and D identify when staff compounding pharmacy technicians and/or staff compounding pharmacists are authorized within NAPRA's model standards and guidance document for pharmacy compounding (1-4) to perform specific compounding tasks and, therefore, are expected to fulfill the identified compounding competencies.
  - For a limited number of these compounding competencies, one or more jurisdictions have authorizations for staff pharmacy technicians or staff pharmacists that differ from the model standards and guidance document for pharmacy compounding (1-4). These are identified in text in columns C and D of the *Model Compounding Competencies*.
- Column E identifies compounding competencies expected of compounding supervisors. Although NAPRA's model standards and guidance document for pharmacy compounding (1-4) authorize pharmacy technicians to function as compounding supervisors, some jurisdictions restrict the responsibilities of pharmacy technicians who are functioning as compounding supervisors. Such situations are identified and stated in text in Column E of the *Model Compounding Competencies*.
- Column F identifies compounding competencies expected of pharmacy managers of compounding pharmacies. In community pharmacies, only pharmacists are authorized to fulfill this role while pharmacy technicians in some provinces may be authorized to function as a pharmacy manager or pharmacy head of department in a hospital setting. For most jurisdictions, therefore, and in community pharmacy settings, the compounding competencies identified for pharmacy managers of compounding pharmacies may be fulfilled only by pharmacists.
- Columns E and F also indicate that compounding supervisors and pharmacy managers of compounding pharmacies must be able to fulfill the compounding competencies expected of staff compounding pharmacy professionals.

Given the variability of authorizations across jurisdictions, compounding pharmacy professionals are responsible for knowing and adhering to the regulations of their province or territory of practice.

To act as a third-party evaluator as addressed in NAPRA's model standards and guidance document for pharmacy compounding (1-4), pharmacy professionals must have the qualifications and authorizations to meet all competencies required of *sterile compounding supervisors*. They must also be at arm's length from the pharmacy and staff under evaluation.

V. Compounding Competencies

All pharmacy professionals who are involved in a given category of compounding must be able to demonstrate the defined competencies.



V. Compounding Competencies

1. Compounding: Pharmacy professionals safely compound quality preparations by adhering to legislation, standards, policies, and procedures.

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
1.1 perform the required preparatory steps prior to compounding preparations	1.1.1 determine whether pharmacy compounding should occur or whether the activity would be considered a form of manufacturing according to the federal legislative framework[iii]	✓	✓	✓	✓
	1.1.2 for non-sterile compounding:[iv] complete a formal assessment of risk to the preparation and risk to persons using decision algorithms and evidence-based references	✓	✓	✓	✓
	1.1.3 determine whether any required components are hazardous products	✓	✓	✓	✓
	1.1.4 confirm that the pharmacy has the required environment, facilities, and equipment for compounding and storing a preparation	✓	✓	✓	✓
	1.1.5 facilitate patient access to preparations that cannot be compounded at their pharmacy by outsourcing compounding[v] or referring patients to another compounding pharmacy	✓	✓	✓	✓
	1.1.6 adhere to a current, previously verified MFR/ CStPP	✓	✓	✓	✓

iii The competency of ensuring the therapeutic appropriateness of the prescribed compounded preparation lies with the pharmacist as per NAPRA's *Professional competencies for Canadian pharmacists at entry to practice* (5).

iv This competency is specific to non-sterile compounding as only the *Model standards for pharmacy compounding of non-sterile preparations* (1) require completion of this risk assessment.

v Jurisdictions vary in authorization to outsource compounding of a preparation to another pharmacy.

1. Compounding: Pharmacy professionals safely compound quality preparations by adhering to legislation, standards, policies, and procedures. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
1.1 perform the required preparatory steps prior to compounding preparations *(continued)*	1.1.7 modify existing or develop new MFR/CStPP using an evidence-based approach	✓ NAPRA MSPC permit for staff pharmacy technicians, but jurisdictions vary in authorization.	✓	✓ NAPRA MSPC permit for CS and SCS pharmacists and pharmacy technicians, but jurisdictions vary in authorization for pharmacy technicians.	✓
	1.1.7a for sterile compounding: **ensure** approval of modified or newly developed CStPP by the sterile compounding supervisor or delegate	✓	✓	✓	✓
	1.1.8 for non-sterile compounding: establish BUD by assessing the components and applying evidence-based compounding references on stability and compatibility	✓ NAPRA MSPC permit for staff pharmacy technicians, but jurisdictions vary in authorization.	✓	✓ NAPRA MSPC permit for CS pharmacists and pharmacy technicians, but jurisdictions vary in authorization for pharmacy technicians.	✓
	1.1.8a for sterile compounding: establish BUD by applying evidence-based compounding references, assessing risk level for contamination and/or completing sterility testing	✗	✓ NAPRA MSPC permit for staff pharmacists, but jurisdictions vary in authorization.	✓ NAPRA MSPC permit for SCS pharmacists and pharmacy technicians, but jurisdictions vary in authorization for pharmacy technicians.[vi]	✓

vi Since sterile compounding supervisors are authorized to establish BUD (item 5.1.1.2 on page 9 of reference 3), then for jurisdictions that authorize pharmacy technicians to act as sterile compounding supervisors (SCS), pharmacy technicians who are SCS would also be authorized to establish BUD for sterile preparations. The appendices in the *Model standards for pharmacy compounding of hazardous sterile preparations* (page 84 of reference 4) and the *Model standards for pharmacy compounding of non-hazardous sterile preparations* (item 1.19 on page 73 of reference 3) require updating to indicate that pharmacy technicians are authorized to fulfill this competency, with a note that only if functioning as SCS.

1. Compounding: Pharmacy professionals safely compound quality preparations by adhering to legislation, standards, policies, and procedures. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
1.1 perform the required preparatory steps prior to compounding preparations *(continued)*	1.1.8b for sterile compounding: adhere to BUD requirements for single-dose, open ampoules and multi-dose component containers	✓	✓	✓	✓
	1.1.9 perform calculations to determine the quantities of components needed	✓	✓	✓	✓
	1.1.10 confirm that the components are of required quality, appropriately sourced and stored, and available in the required amounts	✓	✓	✓	✓
	1.1.11 follow requirements for personnel conduct, hygiene, and hand-washing and garbing procedures, including use of PPE, and identify when health or other conditions prohibit compounding	✓	✓	✓	✓
	1.1.12 prepare the compounding components, equipment, and area, including cleaning and calibration	✓	✓	✓	✓
	1.1.13 ask for additional information or guidance to address any issue of concern, uncertainty, or competence before proceeding to compound the preparation[vii]	✓	✓	✓	✓

vii Modified from the *National competency standards framework for pharmacists in Australia* (15).

1. Compounding: Pharmacy professionals safely compound quality preparations by adhering to legislation, standards, policies, and procedures. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
1.2 compound preparations according to the MFR/ CStPP and the prescription	1.2.1 measure required components using the appropriate equipment	✓	✓	✓	✓
	1.2.2 ensure verification of calculations, component identity, and measurements prior to compounding	✓	✓	✓	✓
	1.2.2a for non-sterile compounding: only **when independent verification is not possible**, complete a verification of their own calculations, component identity, and measurements prior to compounding	NAPRA MSPC do not specify whether staff pharmacy technicians are permitted, and jurisdictions vary in authorization.[viii]	✓[ix]	✓ NAPRA MSPC permit for CS pharmacists but do not specify whether CS pharmacy technicians are permitted, and jurisdictions vary in authorization for pharmacy technicians.	✓
	1.2.2b for sterile compounding: ensure **independent** verification of calculations, component identity, and measurements prior to compounding	✓	✓	✓[x]	✓
	1.2.3 combine components using evidence-based, systematic techniques that are consistent with the MFR/CStPP and prescription[xi]	✓	✓	✓	✓

viii The model standards require updating to indicate that it is not required for a pharmacist to validate all calculations prior to compounding (e.g., page 17, point B8 of the *Guidance document for pharmacy compounding of non-sterile preparations* [2], Appendix 1, point B8 of the *Model standards for pharmacy compounding of hazardous sterile preparations* [4], and Appendix 1, point B8 of the *Model standards for pharmacy compounding of non-hazardous sterile preparations* [3]).

ix Section 5.1, page 11 of the *Guidance document for pharmacy compounding of non-sterile preparations* (2) states that "If the pharmacy is small, one pharmacist may be responsible for fulfilling all roles and tasks; however, it is best practice to have another person verify calculations and measurements."

x Section 6.6.6.1 of the *Model standards for pharmacy compounding of non-hazardous sterile preparations* (3) and the *Model standards for pharmacy compounding of hazardous sterile preparations* (4) means that the SCS is expected to develop policies and procedures for their workplace that ensure the appropriate verification steps outlined in section 6.6.6.1, but not necessarily that the SCS performs the verification themselves.

xi Modified from the *National competency standards framework for pharmacists in Australia* (15).

1. Compounding: Pharmacy professionals safely compound quality preparations by adhering to legislation, standards, policies, and procedures. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
1.2 compound preparations according to the MFR/ CStPP and the prescription *(continued)*	1.2.3a for sterile compounding: follow aseptic techniques throughout the compounding process	✓	✓	✓	✓
	1.2.3b for sterile compounding: perform required sterilization and sterility testing of high-risk compounded preparations	✓	✓	✓	✓
	1.2.3c for hazardous compounding: follow safe handling and containment strategies required for hazardous components throughout the compounding process	✓	✓	✓	✓
	1.2.4 use compounding equipment in accordance with manufacturer specifications and standards	✓	✓	✓	✓
	1.2.5 for hazardous compounding: follow emergency measures for managing accidental exposures and spills	✓	✓	✓	✓
1.3 finish preparations according to the MFR/ CStPP and the prescription	1.3.1 package preparations in containers that maintain preparation quality	✓	✓	✓	✓
	1.3.2 label preparation containers in a manner that ensures correct storage and use, including supplementary and auxiliary labels	✓	✓	✓	✓
	1.3.3 store the preparation as required to ensure quality	✓	✓	✓	✓

1. Compounding: Pharmacy professionals safely compound quality preparations by adhering to legislation, standards, policies, and procedures. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
1.3 finish preparations according to the MFR/ CStPP and the prescription *(continued)*	1.3.3a for hazardous compounding: package, label, and store hazardous preparations in the manner required to minimize safety risks	✓	✓	✓	✓
1.4 assure the quality of the preparations they have compounded	1.4.1 complete a visual inspection of the physical appearance of compounded preparations and containers, and ensure accuracy of labelling	✓	✓	✓	✓
	1.4.1a for sterile compounding: verify the sterility of high-risk preparations by conducting sterility and bacterial endotoxin tests	✓ NAPRA MSPC permit for staff pharmacy technicians, but jurisdictions vary in authorization.[xii]	✓	✓	✓
	1.4.2 ensure verification of the quality and accuracy of final compounded preparations, and packaging, labelling, and documentation	✓	✓	✓	✓

xii Page 73, item 2.4 of the NAPRA *Model standards for pharmacy compounding of non-hazardous sterile preparations* (3) and page 85, item 3.4 of the NAPRA *Model standards for pharmacy compounding of hazardous sterile preparations* (4) state that only pharmacists can perform the bacterial endotoxin test; however, provinces and territories vary in authorization.

1. Compounding: Pharmacy professionals safely compound quality preparations by adhering to legislation, standards, policies, and procedures. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
1.4 assure the quality of the preparations they have compounded *(continued)*	1.4.2a for non-sterile compounding: only **when an independent verification is not possible**, complete a verification of the quality and accuracy of final preparations they compounded, and their packaging, labelling, and documentation	NAPRA MSPC do not specify whether staff pharmacy technicians are permitted, and jurisdictions vary in authorization.	✓ [xiii]	✓ NAPRA MSPC permit for CS pharmacists, but do not specify whether pharmacy technician CS are permitted, and jurisdictions vary in authorization for pharmacy technicians.	✓
	1.4.2b for sterile compounding: **ensure** independent verification of the quality and accuracy of final CSP and packaging, labelling, and documentation.	✓	✓	✓	✓
1.5 clean and organize after compounding	1.5.1 clean the equipment and compounding area, using designated equipment and processes	✓	✓	✓	✓
	1.5.1a for hazardous compounding: deactivate, decontaminate, clean, and disinfect premises and equipment	✓	✓	✓	✓
	1.5.2 for hazardous compounding: destroy and/or dispose of hazardous waste in a manner that minimizes risks	✓	✓	✓	✓

xiii Section 5.1, page 11 of the *Guidance document for pharmacy compounding of non-sterile preparations* (2) states that "If the pharmacy is small, one pharmacist may be responsible for fulfilling all roles and tasks; however, it is best practice to have another person verify calculations and measurements." The authorization for one pharmacist to fulfill all roles and tasks enables pharmacists to complete the final verification if an independent verification is not possible.

1. Compounding: Pharmacy professionals safely compound quality preparations by adhering to legislation, standards, policies, and procedures. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
1.5 clean and organize after compounding *(continued)*	1.5.3 store compounding equipment and components safely and following manufacturer's instructions, to ensure quality and to minimize risk of contamination	✓	✓	✓	✓
1.6 complete documentation for compounding of each preparation[xiv]	1.6.1 for non-sterile compounding: document risk assessment rationale, references, and mitigation requirements on the MFR	✓	✓	✓	✓
	1.6.2 document development of and modifications to MFR/CStPP	✓ NAPRA MSPC permit for staff pharmacy technicians, but jurisdictions vary in authorization.	✓	✓	✓
	1.6.3 complete compounding records[xv] or CSP logs[xvi] for both individual and batch compounding including any deviations from the MFR/CStPP	✓	✓	✓	✓

xiv For clarity, all documentation required when compounding a preparation has been clustered in one key competency. This does not mean that documentation occurs at the end of the compounding process. Instead, documentation occurs throughout the compounding process.

xv The full list of information required within the compounding record can be found in section 6.4 of NAPRA's *Guidance document for pharmacy compounding of non-sterile preparations* (2).

xvi The full list of information required within the CSP log can be found in section 6.3 of NAPRA's *Model standards for pharmacy compounding of non-hazardous sterile preparations* (3).

2. Quality control of compounded preparations: Pharmacy professionals ensure the quality and safety of compounded preparations prior to dispensing or release.

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
2.1 perform independent verification of the quality of preparations compounded by other pharmacy professionals or non-regulated pharmacy personnel[xvii]	2.1.1 for non-sterile compounding: provide independent verification of new MFR and modifications to existing MFR	NAPRA MSPC do not specify whether staff pharmacy technicians are permitted, and jurisdictions vary in authorization.	✓	✓ NAPRA MSPC permit for CS pharmacists but do not specify whether pharmacy technician CS are permitted, and jurisdictions vary in authorization for pharmacy technicians.	✓
	2.1.1a for sterile compounding: provide independent verification of new CStPP and modifications to existing CStPP	✓ NAPRA MSPC permit staff pharmacy technicians only if functioning as SCS delegate, but jurisdictions vary in authorization.[xviii]	✓ NAPRA MSPC permit staff pharmacists only if functioning as SCS delegate, but jurisdictions vary in authorization.[xix]	✓ NAPRA MSPC permit for SCS pharmacists and pharmacy technicians, but jurisdictions vary in authorization for pharmacy technicians.	✓
	2.1.2 prior to compounding by other pharmacy professionals or non-regulated pharmacy personnel,[xx] verify calculations, component identity, and measurements	✓[xxi]	✓	✓[xxii]	✓

xvii NAPRA's model standards and guidance document for pharmacy compounding (1-4) permit delegation of compounding tasks to non-regulated pharmacy personnel, but jurisdictions vary in their authorization of non-regulated pharmacy personnel to perform compounding tasks.

xviii All modified or new CStPP must be approved by the sterile compounding supervisor or delegated according to section 6.2 of the *Model standards for pharmacy compounding of non-hazardous sterile preparations* (3). The list of requirements for CStPP and template for drafting CStPP require updating to remove the requirement for a pharmacist's signature and indication that only pharmacists can approve.

xix Same as above.

xx NAPRA's model standards and guidance document for pharmacy compounding (1-4) permit delegation of compounding tasks to non-regulated pharmacy personnel, but jurisdictions vary in their authorization of non-regulated pharmacy personnel to perform compounding tasks.

xxi NAPRA's model standards and guidance document for pharmacy compounding (1-4) require updating to indicate that it is **not** only a pharmacist who can verify calculations prior to compounding of non-sterile and sterile preparations.

xxii Section 6.6.6.1 of the *Model standards for pharmacy compounding of non-hazardous sterile preparations* (3) and the *Model standards for pharmacy compounding of hazardous sterile preparations* (4) means that the SCS is expected to develop policies and procedures for their workplace that ensure the appropriate verification steps outlined in section 6.6.6.1, but not necessarily that the SCS performs the verification themselves.

2. Quality control of compounded preparations: Pharmacy professionals ensure the quality and safety of compounded preparations prior to dispensing or release. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
2.1 perform independent verification of the quality of preparations compounded by other pharmacy professionals or non-regulated pharmacy personnel *(continued)*	2.1.3 verify the quality of final compounded preparations, including components, adherence to MFR/ CStPP, appearance, and accuracy and completeness of labelling and documentation of preparations compounded by other pharmacy professionals or non-regulated pharmacy personnel	✓ NAPRA MSPC permit for staff pharmacy technicians, but jurisdictions vary in authorization.	✓	✓ NAPRA MSPC permit for CS and SCS pharmacists and pharmacy technicians, but jurisdictions vary in authorization for pharmacy technicians.	✓
2.2 maintain the quality and safety of compounded preparations prior to dispensing or release	2.2.1 ensure transportation and delivery of preparations as required to ensure their quality and safety	✓	✓	✓	✓
	2.2.1a for hazardous compounding: ensure transportation and delivery of hazardous preparations as required to minimize risks	✓	✓	✓	✓
	2.2.2 for preparations compounded on behalf of other pharmacies, package and transport preparations appropriately, and communicate required information to the pharmacy where the preparations will be dispensed[xxiii]	✓	✓	✓	✓
	2.2.3 for preparations compounded by other pharmacies, receive, verify, store, and label preparations appropriately[xxiv]	✓	✓	✓	✓

xxiii Jurisdictions vary in authorization to outsource compounding of a preparation to another pharmacy.

xxiv Same as above.

3. Compounding pharmacy management: Pharmacy professionals participate in the management of the pharmacy to ensure the quality and safety of compounding.

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
3.1 develop, review, and update compounding P&P that operationalize the compounding standards of practice	3.1.1 develop and maintain P&P specifying the obligations and required conduct of compounding and cleaning personnel	✗	✗	✓	✓
	3.1.2 develop and maintain P&P specifying the training and skills assessment programs required for compounding and cleaning personnel, including required documentation	✗	✗	✓	✓
	3.1.3 develop and maintain P&P assigning the performance of compounding activities to other pharmacy professionals or non-regulated pharmacy personnel	✗	✗	✓	✓
	3.1.3a for sterile compounding: develop and maintain P&P for assigning competency training to other pharmacy professionals, and training and assessment of personnel and environmental verification testing to third-party evaluators	✗	✗	✓	✓
	3.1.4 develop and maintain P&P for assigning the performance of compounding management to another pharmacy professional and designating them as the compounding supervisor	✗	✗	✗	✓

3. Compounding pharmacy management: Pharmacy professionals participate in the management of the pharmacy to ensure the quality and safety of compounding. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
3.1 develop, review, and update compounding P&P that operationalize the compounding standards of practice *(continued)*	3.1.5 for non-sterile compounding: develop and maintain P&P for determining the cumulative risk of compounding and incorporating into risk assessments	✗	✗	✓	✓
	3.1.6 develop and maintain P&P specifying required compounding facilities, equipment, references, scheduled cleaning, maintenance, certification, and documentation	✗	✗	✓	✓
	3.1.6a for hazardous compounding: develop and maintain P&P specifying deactivation and decontamination requirements	✗	✗	✓	✓
	3.1.7 develop and maintain P&P requiring evidence-based development and review of MFR/CStPP, including for determining and extending BUD	✗	✗	✓	✓
	3.1.8 develop and maintain P&P specifying sourcing, supply, storage, traceability, disposal, safety data information, and documentation requirements of components	✗	✗	✓	✓
	3.1.8a for hazardous compounding: develop and maintain P&P specifying receipt / unpacking, and hazardous waste management requirements	✗	✗	✓	✓

3. Compounding pharmacy management: Pharmacy professionals participate in the management of the pharmacy to ensure the quality and safety of compounding. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
3.1 develop, review, and update compounding P&P that operationalize the compounding standards of practice *(continued)*	3.1.9 develop and maintain P&P specifying compounding procedure requirements, including required processes, techniques, use of PPE, verifications, and compounding records	✗	✗	✓	✓
	3.1.9a for hazardous compounding: develop and maintain P&P specifying prevention, management, equipment, documentation, and reporting requirements for spills and accidental exposure to hazardous products	✗	✗	✓	✓
	3.1.10 develop and maintain P&P specifying the labelling, packaging, storage, and transportation requirements for compounded preparations	✗	✗	✓	✓
	3.1.10a for hazardous compounding: develop and maintain P&P specifying requirements for transport and management of spills and accidental exposure to hazardous preparations during transportation	✗	✗	✓	✓
	3.1.11 develop and maintain P&P managing returned and/or expired components and preparations	✗	✗	✓	✓
	3.1.12 develop and maintain P&P ensuring traceability, managing recalled compounded components and preparations, and for post-recall analysis	✗	✗	✓	✓

3. Compounding pharmacy management: Pharmacy professionals participate in the management of the pharmacy to ensure the quality and safety of compounding. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
3.1 develop, review, and update compounding P&P that operationalize the compounding standards of practice *(continued)*	3.1.13 develop and maintain P&P for acquisition of prescribed preparations for patients from other compounding pharmacies[xxv]	✗	✗	✓	✓
	3.1.14 develop and maintain P&P for compounding of prescribed preparations on behalf of other pharmacies[xxvi]	✗	✗	✓	✓
3.2 implement QA programs that ensure compliance with a pharmacy's compounding P&P	3.2.1 develop, review, update, and document a QA program, specifying the verifications of the facilities, equipment, personnel conduct/ skills, and compounding procedures to be completed to evaluate compliance with compounding P&P, the frequency of these verifications, corrective actions to be taken, and required documentation	✗	✗	✓	✓
	3.2.2 ensure the compounding supervisor develops, maintains, documents, and makes available the required compounding P&P	✗	✗	✗	✓
	3.2.3 ensure the compounding supervisor develops, implements, and evaluates compliance with the required QA program, including investigating and acting upon deviations, and documenting results	✗	✗	✗	✓

xxv Jurisdictions vary in authorization to outsource compounding of a preparation to another pharmacy.

xxvi Same as above.

3. Compounding pharmacy management: Pharmacy professionals participate in the management of the pharmacy to ensure the quality and safety of compounding. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
3.2 implement QA programs that ensure compliance with a pharmacy's compounding P&P *(continued)*	3.2.4 complete required QA verifications and determine the level of compliance to the pharmacy's compounding P&P as specified in the pharmacy's QA program	✓ NAPRA MSPC permit for staff pharmacy technicians, but jurisdictions vary in authorization.	✓	✓	✓
	3.2.4a for sterile compounding: perform required personnel and facility/environmental QA testing (e.g., gloved fingertip and media fill tests, surface and air sampling)	✓ NAPRA MSPC permit for staff pharmacy technicians, but jurisdictions vary in authorization.	✓	✓	✓
	3.2.4b for hazardous compounding: perform required facility/ environmental QA testing for chemical contamination	✓ NAPRA MSPC permit for staff pharmacy technicians, but jurisdictions vary in authorization.	✓	✓	✓
	3.2.5 take immediate action to minimize risks when potential non-compliance with the QA program is detected, including notifying the compounding supervisor	✓	✓	✓	✓
	3.2.6 analyze the results of the QA program verifications, take required corrective/ preventive actions and complete/retain documentation to ensure adherence to compounding P&P	✗	✗	✓	✓

3. Compounding pharmacy management: Pharmacy professionals participate in the management of the pharmacy to ensure the quality and safety of compounding. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
3.2 implement QA programs that ensure compliance with a pharmacy's compounding P&P *(continued)*	3.2.6a for sterile compounding: analyze environmental sterility sampling results, responding as required to ensure sterility and completing required documentation	✗	✗	✓	✓
	3.2.6b for sterile compounding: analyze aseptic technique QA results, responding as required to ensure sterility and completing required documentation	✗	✗	✓	✓
	3.2.6c for hazardous compounding: analyze environment testing for chemical contamination, responding as required to minimize or mitigate safety risks and completing required documentation	✗	✗	✓	✓
	3.2.7 for non-sterile compounding: determine the cumulative risk of compounding for incorporation into risk assessments for non-sterile compounding	✗	✗	✓	✓

3. Compounding pharmacy management: Pharmacy professionals participate in the management of the pharmacy to ensure the quality and safety of compounding. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
3.3 supervise other members of the compounding team	3.3.1 provide and document results of training and skills assessments to pharmacy personnel for compounding of preparations	✓ NAPRA MSPC permit for staff pharmacy technicians, but jurisdictions vary in authorization.	✓	✓	✓
	3.3.1a for hazardous compounding: provide and document results of training to compounding and cleaning personnel regarding containment strategies for hazardous products, including prevention and management of spills and accidental exposure, and waste management	✓ NAPRA MSPC permit for staff pharmacy technicians, but jurisdictions vary in authorization.	✓	✓	✓
	3.3.1b for sterile compounding: perform and document results of initial and ongoing assessments of personnel's sterile compounding competency[xxvii]	✗	✗	✓[xxviii]	✓
	3.3.2 supervise non-regulated pharmacy personnel when they are performing assigned compounding tasks[xxix]	✓	✓	✓	✓

xxvii As per NAPRA's *Model standards for pharmacy compounding of non-hazardous sterile preparations* (3), the compounding supervisor may assign the training to a pharmacist or pharmacy technician on their team, while continuing to perform the assessment portion, or may assign both the training and assessment of personnel to a third-party evaluator. For clarity, model compounding competency 3.3.1b addresses assessment of overall sterile compounding competency, which goes beyond the QA testing included in the model compounding competency 3.2.4a.

xxviii Same as above.

xxix NAPRA's model standards and guidance document for pharmacy compounding (1-4) permit delegation of compounding tasks to non-regulated pharmacy personnel, but jurisdictions vary in their authorization of non-regulated pharmacy personnel to perform compounding tasks.

3. Compounding pharmacy management: Pharmacy professionals participate in the management of the pharmacy to ensure the quality and safety of compounding. *(Cont'd)*

A. Key Competencies	B. Enabling Competencies	C. Staff Compounding Pharmacy Technicians	D. Staff Compounding Pharmacists	E. Compounding Supervisors	F. Pharmacy Managers of Compounding Pharmacies
Compounding pharmacy professionals are able to:					
3.4 contribute to pharmacy compounding operations	3.4.1 complete required cleaning and maintenance of equipment and facilities, and document in general maintenance logs	✓	✓	✓	✓
	3.4.2 document results of quality assurance verifications, including logs, reports, and follow-up	✓	✓	✓	✓
	3.4.2a for hazardous compounding: complete required documentation, logs, reports, and analyses of spills and accidental exposures	✓	✓	✓	✓
3.5 contribute to pharmacy inventory management	3.5.1 source required compounding components, materials, equipment, and supplies	✓	✓	✓	✓
	3.5.2 for hazardous compounding: follow procedures and PPE-use required for receipt, unpacking, and storing of hazardous products	✓	✓	✓	✓
	3.5.3 manage recalled, returned, and expired components and compounded preparations	✓	✓	✓	✓

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