Policy and Procedures (PnPs): Not just for Pharmacists!

Presented by Melanie Dorey R.Ph.T
Co-owner of Critical Compounding Resources

Disclosure slide

- Presenter's Name: Melanie Dorey
- I have the following relationships with commercial interests:
  - Current/past Employee of
    - Co-owner of Critical Compounding Resources
    - Childrens Hospital of Eastern Ontario
    - La Cite Collegiale (Pharmacy Technician Program)
- Speaking Fees for current program:
  - I have received no speaker's fee for this learning activity

Learning Objectives

At the end of this presentation, you will be able to:

1. Define policy and procedures per NAPRA Model Standards
2. List the required policy and procedures per the NAPRA Model Standards.
3. Describe the key strategies to developing comprehensive policies and procedures.
4. Identify the reasons why a pharmacy technician may be better suited for the development and review of the facility's policies and procedures.

Define PnP per NAPRA Model Standards

Policy

- All the general principles adopted by a private or public organization for conducting its activities. By extension, the term “policy” also refers to the text or document presenting these principles.

Procedure

- All steps to be taken, the means to be used and the methods to be followed in performing a task.

Policies and Procedures (PnP)

- Policies and Procedures (PnPs) also referred to as SOPs
- Develop and maintain the entire sterile compounding set of PnPs
  - See Appendix 1
  - May require additional PnPs to capture all procedures performed in your compounding facility.
  - Include competency forms, logs (cleaning, calibration, etc.).

Appendix 1 NAPRA Model Standards

APPENDIX 1 POLICIES AND PROCEDURES FOR THE COMPOUNDING OF NON-HAZARDOUS STERILE PREPARATIONS

NON-HAZARDOUS STERILE PREPARATIONS			
Policy #		Topic	✓
A		**PERSONNEL AND FACILITIES**	
	1.	**Obligations of personnel**	
	1.1	Attire and dress code (e.g., personal clothing, jewelry, makeup, hairstyles)	
	1.2	Health conditions (reasons for temporary withdrawal from compounding activities)	
	1.3	Expected behaviour in controlled areas (e.g., no drinking, eating or other activities not related to compounding; expectation that procedures will be followed; avoidance of unnecessary conversations)	
	2.	**Training and assessment of personnel**	
	2.1	Initial training and assessment program	
	2.2	Program to assess maintenance of competency	
	2.3	Training and assessment of cleaning and disinfecting personnel	
	3.	**Delegation of activities**	
	3.1	Delegation of technical activities to persons other than pharmacists or pharmacy technicians	
	4.	**Facilities and equipment**	
	4.1	Access to controlled areas	
	4.2	Necessary facilities and equipment	
	4.3	Maintenance of facilities and equipment (e.g., certification of rooms and devices, calibration, maintenance of pre-filters and high-efficiency particulate air filters, verification of pressure)	

Appendix 1 NAPRA Model Standards

	4.4	Cleaning and disinfecting activities for facilities and equipment	
B		**COMPOUNDED STERILE PREPARATIONS**	
	1.	Bringing equipment and products into the clean room and primary engineering control	
	2.	Determining beyond-use dates of products used in a preparation	
	3.	Determining beyond-use dates of final preparations	
	4.	Hand and forearm hygiene	
	5.	Garbing in compounding areas and for compounding	
	6.	Cleaning and disinfecting the primary engineering control	
	7.	Aseptic techniques (with details for each of the techniques used)	
	8.	Verification of the compounding process (including validation of calculations by a pharmacist) and of final preparations	
	9.	Labelling of final preparations	
	10.	Packaging of final preparations	
	11.	Preparation of injectable products outside regular operating hours of the compounding department of a health care facility	
	12.	Storage of products used and final preparations	
	13.	Transport and delivery of final preparations (to the patient, to patient care units or to the dispensing pharmacist)	
	14.	Recording of preparations in the patient file	

Appendix 1 NAPRA Model Standards

	15.	Biomedical waste management (e.g., at the pharmacy, returns from patients or patient care units, instructions to patients)	
	16.	Recall of sterile products or compounded sterile preparations	
C		**QUALITY ASSURANCE PROGRAM**	
	1.	Verification and maintenance of equipment	
	2.	Environmental control of facilities and primary engineering control (e.g., pressure verification, air and surface sampling plan)	
	3.	Quality assurance of aseptic process for personnel (e.g., gloved fingertip sampling, media fill tests)	
	4.	Quality assurance of compounded sterile preparations (e.g., existence of a protocol, compliance with prescription, documentation in logs)	

PnP NAPRA Model Standard Requirements

- Sterile compounding supervisor must:
  - establish the content of PnPs
  - ensure application of and compliance
  - ensure that all established PnPs are promptly updated whenever there is a change in practice or standards
  - PnPs must be reviewed at least every 3 years.

<u>Best Practice Recommendation</u>

Review PnPs annually.

Policies and Procedures (PnP)

- Include compounding staff in the development and review of PnPs. Staff know what is going on in the sterile compounding environment.
- Do not just copy and paste from the Model Standards into your PnPs!
- PnPs must represent what is actually happening and are *much more detailed* than the Model Standards!

Who is best to develop and review the PnPs?

- Create a working group including compounding supervisor, pharmacy technicians who often compound and understand the operations of the compounding facility.
- Assign the most competent compounder to the PnP which they are most proficient at the procedures.
- Determine a development and review process with reasonable timelines.
- Respect the workload of these assigned pharmacy technicians and assign days to complete this work.

NAPRA Model Compounding Competencies for Pharmacists and Pharmacy Technicians in Canada

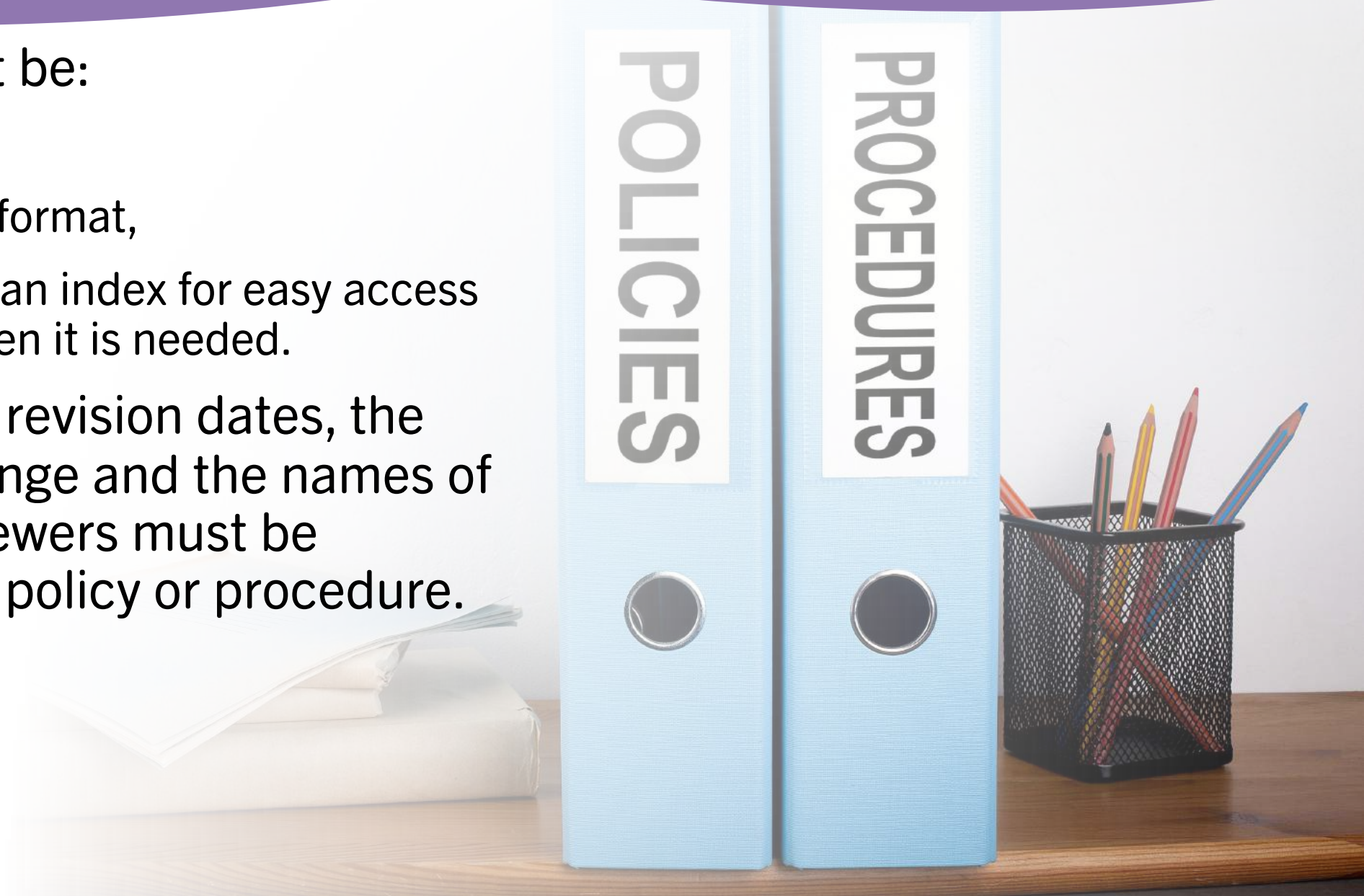
V. Compounding Competencies

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	✓	✓	✓	✓

NAPRA Model Standard Requirements

- Procedures must be:
  - clear,
  - follow a standard format,
  - and must include an index for easy access to information when it is needed.
- The drafting and revision dates, the date of each change and the names of authors and reviewers must be included in each policy or procedure.



PnP NAPRA Model Standard Requirements

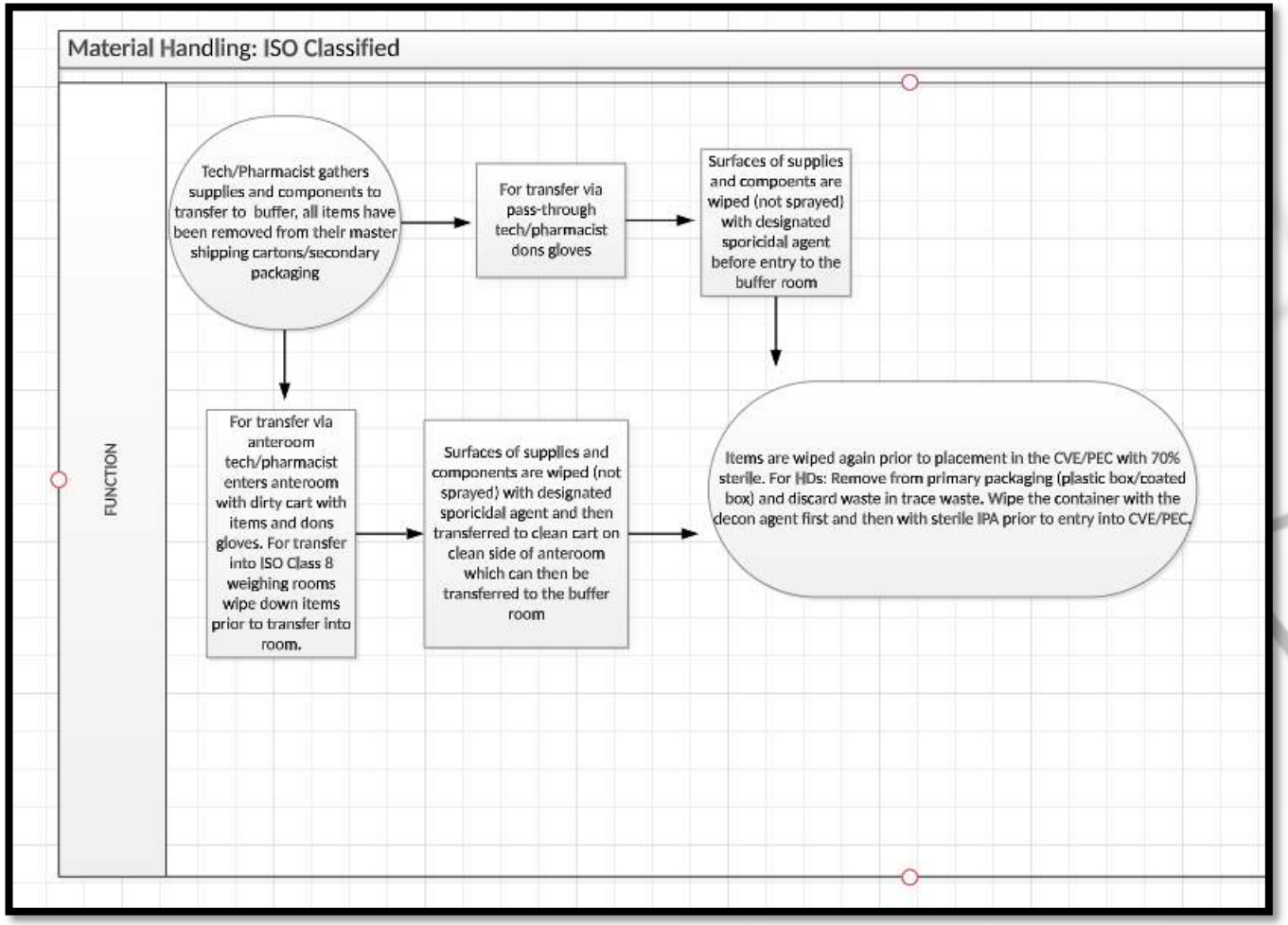
- Where compounding is undertaken by another pharmacy, as permitted by provincial/territorial legislation, the pharmacist or pharmacy technician at the dispensing facility should include in its general procedures manual information about policies and procedures for acquiring compounded sterile preparations for patients (originating pharmacy, entry in the file, delivery, etc.).
  - Importance of communicating required information with receiving pharmacy

Developing a Good PnP

- Recommend the following when writing compounding PnPs:
  - Staff involved in writing the PnPs
  - Develop or purchase a template of PnPs that best represents your compounding operations.
  - They need to be thorough but not too complex, consider job aids for detailed work
  - Use and reference reputable resources
  - Ensure easily accessible
  - Ensure easy to read and navigate
  - Include table of contents

Job-Aids

- A guide that provides simple instruction on how to complete a task



NAPRA Model Standards – Appendix 4

APPENDIX 4 PROCEDURE TEMPLATE

Pharmacy name: **Or** Hospital XYZ pharmacy department:	**Procedure #** _____ **Revised:** ☐ **Yes** ☐ **No** **Approved by**_____ **Date** ____*(dd/mm/yyyy)*____ **Effective date:** _____ *(dd/mm/yyyy)*
Procedure title:	

Aim and objective:

- Describe the objective of the procedure.

Target personnel: Use this section to describe the expected responsibilities for each group that will be affected by this procedure.

- ☐ Sterile compounding supervisor
- ☐ Pharmacist
- ☐ Pharmacy technician
- ☐ Pharmacy assistant
- ☐ Cleaning and disinfecting personnel
- ☐ Other: _____

Example

SOP Part:	Five: Compounding, Labelling, Final Verification, BUD Assignment, Documentation and Quality Assurance
SOP Title:	Master Formulation Record and Compounding Records
SOP and Version Number:	NS-SOP-502
Last Revision Approved by:	XXX XXX
Last Revision Date:	XX-XX-XXXX

Purpose

This SOP aims to ensure that the pharmacy implements and maintains the use of Master Formulation Records (MFRs) and Compounding Records (CRs) to provide safe, consistent compounding procedures and a record of compounding history.

Policy(ies)

- Pharmacy reviews applicable pharmacy regulatory authority requirements and adds any additional requirements to this SOP.
- Pharmacists and pharmacy technicians are trained in developing master formulation records (written or electronic).
- Appropriate procedures for safe compounding are researched and documented on the Master Formulation Record for each compound.
- The Master Formulation Record for a non-sterile preparation includes all necessary information to compound the preparation with supporting rationale and references.

Example (continued)

Scope (Responsibilities)

- The non-sterile compounding supervisor ensures that Master Formulation Records are developed, reviewed, and updated.
- The compounding pharmacist or pharmacy technician ensures a compounding record is completed for each compounded preparation, including any deviations from the Master Formulation Record and follows the compounding process defined in the Master Formulation Record.

Procedures

1. Master Formulation Records Development
    1.1. Determine whether a valid formula exists. If not, proceed to Step 2.
    1.2. Develop a Master Formulation Record utilizing NS-F-502A MFR/CR Template in consultation with experts and reliable resources.
        1.2.1. The MFR includes:
            1.2.1.1. official or assigned name, strength, and dosage form of the preparation
            1.2.1.2. expected yield
            1.2.1.3. calculations needed to determine and verify quantities of ingredients and doses of APIs for the quantity produced

Related Internal Resources

- NS-F-502A MFR/CR Template
- NS-F-502B Batching Record

Don’t Forget to Create a Quality Assurance PnP

- Have a quality assurance/quality management system PnP and include:
  - Roles and responsibilities
  - Training of personnel responsible for the individual aspects of the QA program

Document Control

Best Practice Recommendation

In your QA PnP, define the process for developing and revising documentation and ensure the process is followed!

Will the process be:

- Written or electronic
- Password protected
- Who is authorised to make changes
- Who performs final verification … depends on the jurisdiction
- What process is followed during changes
- Can personnel from affected departments read and comment pre-release

Documentation

Remember, if it's not documented it didn’t happen…

And if there is no PnP, how can staff know how to perform the tasks.

PnP Templates from a Vendor vs In-house PnPs

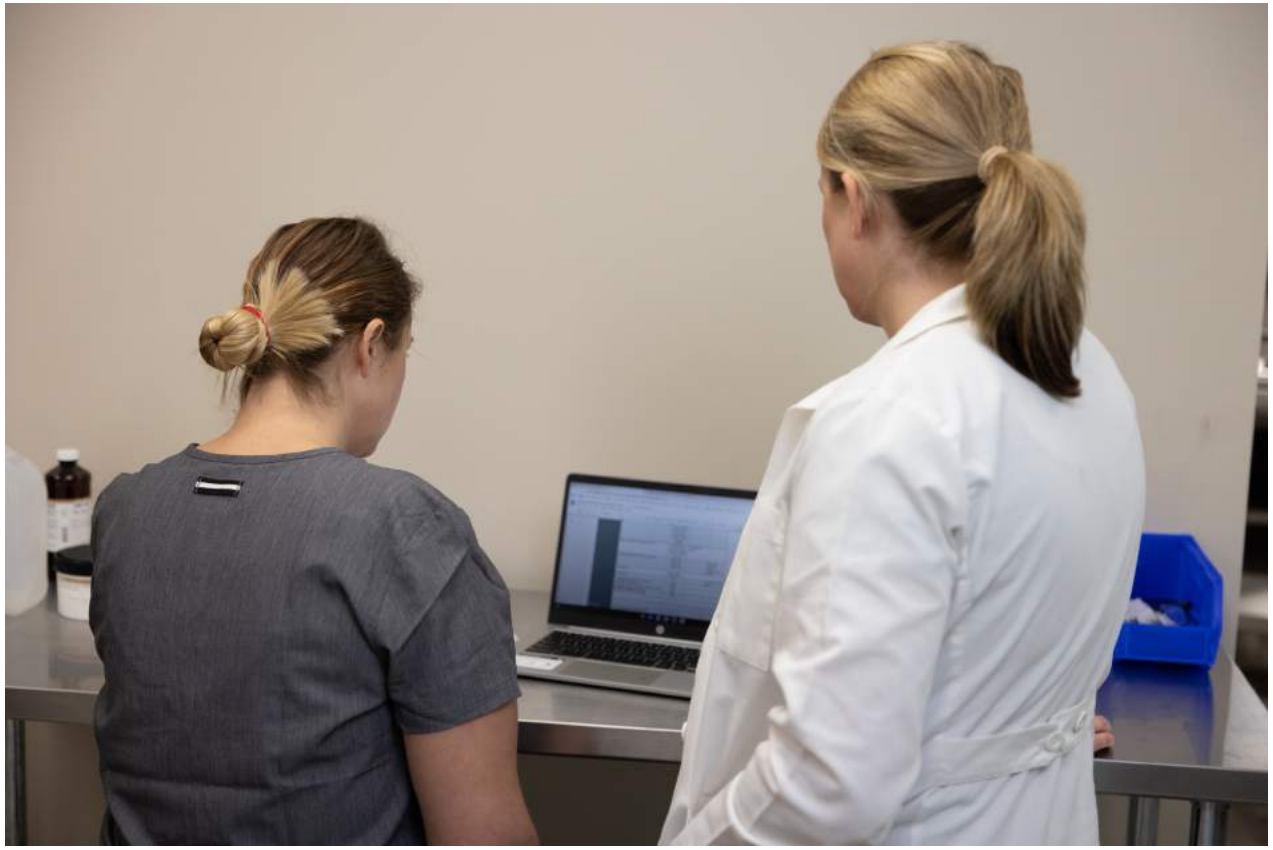
- Many vendors in Canada sell PnP templates or they are included with quality management systems or other softwares.
  - These PnPs must still be reviewed and customized to the facility specific procedures.
  - Are the vendors doing annual updates or will you do them?
  - Always ask for a sample pre-purchase
  - Can be a time saver if the PnP templates are high quality
- In-house PnPs usually better represent the tasks performed in the compounding facility

PnPs for the Entire Pharmacy Operations

- General operations PnP
- Non-sterile compounding PnPs
- New staff orientation and training
- Automation/Pharmacy software PnPs
- Medication dispensing, inventory, storage, waste, etc.
- Narcotics
- And the list goes on and on…

Pharmacy Technicians can HELP with PnPs!

- Even for the entire operation pharmacy technicians can help in the development and review process of PnPs.
- Especially in the daily tasks taking place in the pharmacy.
- Create a working group sourced with staff who are experts in each of the areas.
- Develop a process



Ensure Compliance with PnPs

- It's important to ensure staff are following PnPs while performing tasks
  - Audits can be an important tool in ensuring procedures are being followed.

Audits

Perform internal audits

- Audit compounding documentation, logs, etc.
- Visual audits for compliance
- Audits are vital to an effective QA program

Ensure documents completed correctly and confirmation took place

- When audit shows excellent practice, tell staff
- If missing information, follow up with individual staff and investigate why

Perform audits regularly

- At a minimum, monthly audits recommended

How to Receive Feedback about PnPs

- Staff also need a way to bring forward comments or concerns about a procedure.
  - Email compounding supervisor
  - Reporting system
  - Daily huddles
  - Etc.

Closing Points

- Policies and Procedures (PnPs) must be developed and regularly reviewed for pharmacy operations.
- Pharmacy Technicians play a vital role in all elements of the pharmacy's operation which makes them better suited to develop and review policy and procedures.
- Follow the NAPRA Model Standards and your health authority's requirements for PnP development and review.
- We are all responsible for the pharmacy's operations and therefore we want accurate PnPs that represent what is actually happening in our pharmacies and also meet regulatory compliance.

References

- NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations, National Association of Pharmacy Regulatory Authorities, November 2016.
- NAPRA Model Compounding Competencies for Pharmacists and Pharmacy Technicians in Canada. July 2022.