Understanding NAPRA Model Standards for Pharmacy Compounding of Sterile Preparations

Presenter Disclosure

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- **Relationships with financial sponsors:**
  - **Grants/Research Support:** None
  - **Speakers Bureau/Honoraria:** None
  - **Consulting Fees:** None
  - **Other:** None

Mitigating Potential Bias

- Not Applicable

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  - **Grants/Research Support:** None
  - **Speakers Bureau/Honoraria:** None
  - **Consulting Fees:** None
  - **Other:** None

Mitigating Potential Bias

- Not Applicable

Learning objectives

At the end of this session, participants will be able to:

1. Understand the purpose of the NAPRA Model standards and identify core components.

2. Identify changes in practice necessary at the CCPs and how the changes will be implemented.

3. Understand the 3 phases for implementation of the NAPRA Model Standards.

NAPRA Model Standards

NAPRA Model Standards for Pharmacy Compounding

- Hazardous Sterile Preparations
- Non-Hazardous Sterile Preparations

NAPRA standards are based on USP<797> and USP <800>

NAPRA Model Standards

- Released in February 2016
- The NAPRA Model Standards were developed in part as a response to increased awareness of the risks involved in compounding sterile preparations to both patients and compounding personnel.

NAPRA Model Standards

3 phases of implementation in Manitoba

- January 2019 – Phase 1
- June 2019 – Phase 2
- January 2021 – Phase 3

NAPRA Model Standards

Phase 1 – January 1, 2019

- 5.1 Develop and implement a training and assessment program for staff involved in hazardous and non-hazardous sterile compounding.
- 5.2 Develop and implement documented policies and procedures for hazardous and non-hazardous sterile compounding.
- 6.2, 6.3, and 6.4 Develop and implement protocols and preparation logs for compounded sterile preparations.

NAPRA Model Standards

- 6.7, 6.8, 6.9, 6.12 Develop and implement protocols for hazardous and non-hazardous medication packaging, storage, transport, waste management, and delivery procedures
- 6.10, 6.11 Develop recall procedures (traceability), and incident/accident management procedures.
- Develop and implement a quality assurance program for hazardous and non-hazardous sterile compounding.

NAPRA Model Standards

Phase 2 – June 2019

- 6.5, 6.6 Educate and validate all staff involved in hazardous and non-hazardous compounding (includes conduct of personnel in areas reserved for compounding, handwashing, garbing, aseptic compounding techniques, cleaning and disinfecting, verification, and labelling).

NAPRA Model Standards

Phase 3 – January 2021

- 6.1 Establish documented beyond-use dates and dating methods.
- 5.3 Facilities and Equipment

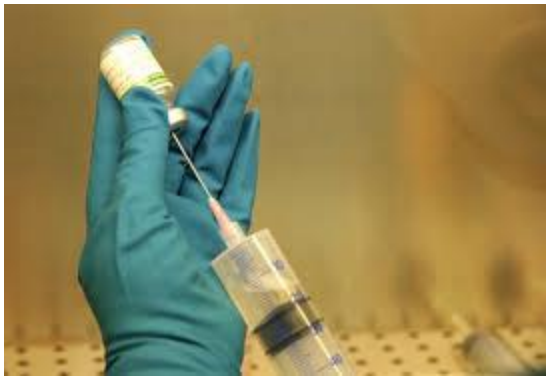
  Compliance with the NAPRA Model Standards for Hazardous Sterile Compounding Standards

Core components of the NAPRA Model standards

- Personnel
- Policies and Procedures
- Facilities and Equipment
- General Maintenance Log

Core components of the NAPRA Model Standards

- Personnel
  - Sterile Compounding supervisor
  - Training and assessment



Core components of the NAPRA Model Standards

- Policies and Procedures
  - Detailed
  - Current; updated

Core components of the NAPRA Model Standards

- Facilities and Equipment
  - Primary Engineering Controls
  - Secondary Engineering Controls
    - Anterooms
    - Clean rooms
  - Pass throughs, carts, refrigerators and freezers

Core components of the NAPRA Model Standards

- General Maintenance Log
  - Cleaning, disinfecting, certification and maintenance of the facility
  - Certification and maintenance of the Primary Engineering Control and other equipment

NAPRA Model Standards

- Product and Preparation Requirements
  - Beyond Use Dating
  - Conduct of Personnel
  - Storage of hazardous products
  - Transportation and delivery

NAPRA standards in Manitoba

Alignment of all sites across the province that compound hazardous and non-hazardous sterile products

- Policies and procedures
- Training
- Reference documents
- Support

NAPRA Standards

Guarantee overall *quality* & *safety* of compounded sterile preparations

- What environment are these preparations made in?
- What training do personnel have?
- What quality assurance procedures are in place to prevent complications and protect the public?

Sterile Compounding Supervisor

- Pharmacist/pharmacy technician designated to supervise activities related to the compounding of sterile preparations.
- May assign technical tasks related to sterile preparation compounding to a pharmacy assistant with the appropriate training
- Ensures requirements of the Standards are met.

Quality & Safety

Describe requirements for compounding areas to keep personnel safe and ensure quality of the preparations

- Clean room - Negative pressure (hazardous), positive pressure (non-hazardous)
- Air quality (room and PEC) – temperature, humidity, particle and microorganism content
- Cleaning and disinfecting

Compounding Areas

- Clean room and anteroom
  - Separate for hazardous and non-hazardous
  - Facility updates at CCP sites
  - Use and contents outlined in Standards
- Segregated compounding areas
  - BSC located in an environment not meeting ISO Class 7 air quality → must meet conditions, reduced BUD of final product (12 hours)

Cleaning (Hazardous)

Cleaning in controlled areas must be performed to ensure the cleanliness required for the quality and integrity of final compounded sterile preparations.

- Decontamination
- Deactivation
- Disinfection

Decontamination

- Transfer of a hazardous drug contaminant from a fixed surface to a disposable surface.
- The wipe is then contained and discarded as hazardous waste.
- Bactericidal/sporicidal wipes (e.g. Accel Intervention®), sterile water, sterile 70% isopropyl alcohol

Deactivation

- The treatment of a hazardous drug to create a less hazardous agent.
- Need to ensure product used will not corrode the surfaces it is used on.
- Peridox® RTU

Disinfection

- The process of destroying microorganisms

Germicidal disinfectant detergent

- Required to disinfect all surfaces in a clean room and anteroom. Many types are acceptable. Daily use of a germicidal disinfectant should be augmented with weekly (or monthly) use of a sporicidal agent.

Disinfectant

- sterile 70% isopropyl alcohol
- Peridox RTU (sporicidal)

Table 8

Minimum frequency of surface decontamination, deactivation and disinfection of the inside of a biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI)				
Surface	**Frequency**[129,130,131,132,133]	**Decontamination***	**Deactivation†**	**Disinfection‡**
Work surface in BSC or CACI	- Before start of compounding			✓
Work surface in BSC or CACI	- On each preparation change, upon removal from BSC or CACI - At the start or end of each shift - When surface contamination is suspected - If there has been non-compliance with aseptic techniques	✓		✓
All surfaces inside BSC or CACI	- At start of workday - At start of workday if BSC or CACI has not been used for one or more days - When there has been a spill - Before and after certification - After service interruption (ex power outage) - If the C-PEC is moved	✓		✓
All surfaces inside BSC or CACI and subfloor of BSC or CACI	- Weekly, at the end of a workday or as recommended by manufacturer	✓	✓	✓

*Surface decontamination = application of a decontaminating agent
†Deactivation = application of sodium hypochlorite followed by sodium thiosulphate or a decontaminating agent
‡Disinfection = application of sterile 70% isopropyl alcohol.

Table 9

Minimum frequency and areas of the laminar airflow workbench (LAFW) to be cleaned and disinfected by compounding personnel*		
Surface of LAFW	**Frequency**	**Cleaning and disinfecting products†**
All surfaces	- At the start of each workday - At the end of each workday	Germicidal disinfecting detergent, followed by sterile 70% isopropyl alcohol (minimum twice daily)
Work surface	- Before starting any sterile-product preparation - At each shift change - Whenever surface contamination is suspected - If there has been non-compliance with aseptic techniques	Sterile 70% isopropyl alcohol
Work surface and any surface that has been splashed	- When there is a spill	Sterile water for injection or irrigation (for cleaning), followed by sterile 70% isopropyl alcohol (for disinfecting)
All surfaces and subfloor	- Weekly (at the end of a workday)	Sterile water for injection or irrigation (for cleaning), followed by a sporicidal agent and then sterile 70% isopropyl alcohol (for disinfecting)
*Requirements are similar for cleaning and disinfecting a compounding aseptic isolator. †Other products may be acceptable for disinfecting, if approved by the infectious disease department of the health care facility.		

Cleaning

Equipment used for cleaning and disinfection

- Non-shedding
- Disposable
- Disinfected before each entry into a controlled area (mop handle, outside of bottles, etc.)

Personal Protective Equipment

- Hair net, beard cover, face mask
- Shoe covers (hazardous – 2 pairs)
- Gown
- Gloves (hazardous – 2 pairs, outer pair sterile)

- Verification duties in the clean room – must be garbed exactly the same way as compounding personnel

PPE highlights

Gloves

→Changes (30 minutes hazardous, 1 hour non-hazardous)

→Non-powdered, sterile, compliant with ASTM International D-6978-05 standard (hazardous),

PPE

Masks (Hazardous)

→**N95 or N100** (NIOSH-approved)

Compounding of hazardous sterile preps

→**Chemical cartridge respirator with a full face-piece or with face shield and goggles**

Splash risk, cleaning spill, cleaning underneath the work surface of PEC, unpacking suspected damaged drugs from supplier, BSC with front window open.

NAPRA Standards

- Facilities & equipment
- Beyond-use date and dating methods
- Preparation protocols and logs
- Packaging
- Receipt, storage, transport and delivery
- Recall procedures
- Incident and accident management
- Hazardous waste management

- Quality assurance
  - Outline QA program content
  - Certification of equipment and facilities, sampling plans, hazardous drug sampling, etc.
  - Personnel
  - Compounded sterile preparations
  - Documentation of quality control activities

Take Home Messages

- 3 Phases of implementation (January 2019, June 2019, June 2021) in Manitoba
- All areas of compounding of sterile preparations will be affected
- Each site will have different changes to make
- Provincial support

Questions?