Implementation of the Non-Sterile Compounding Standards in Ontario

Webinar held November 4, 2020

Ontario College of Pharmacists
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Webinar: Part Two

Slides in Part 2 of the webinar cover:

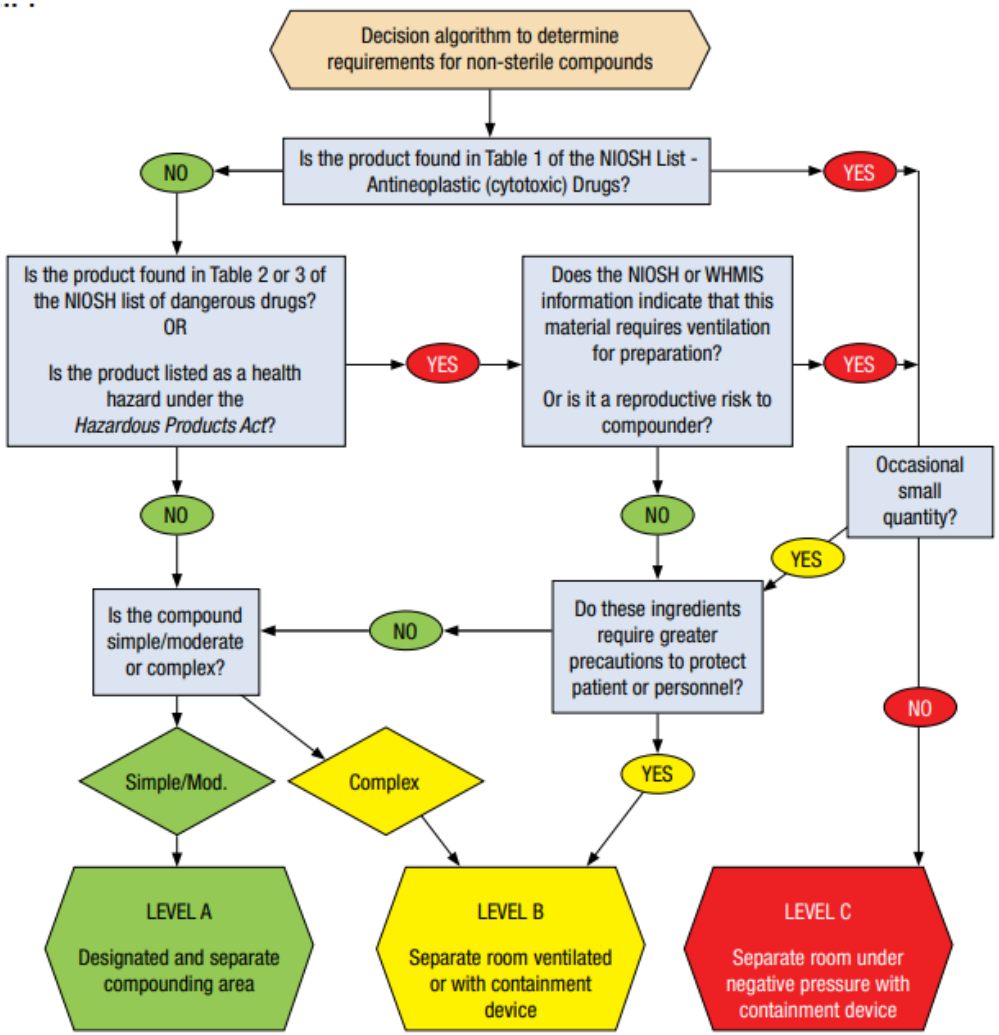
- Risk Assessments
- Requirements for All Levels
- Level B&C Requirements
- Compounding Hazardous Preparations

Questions Received from Registrants

RISK ASSESSMENT

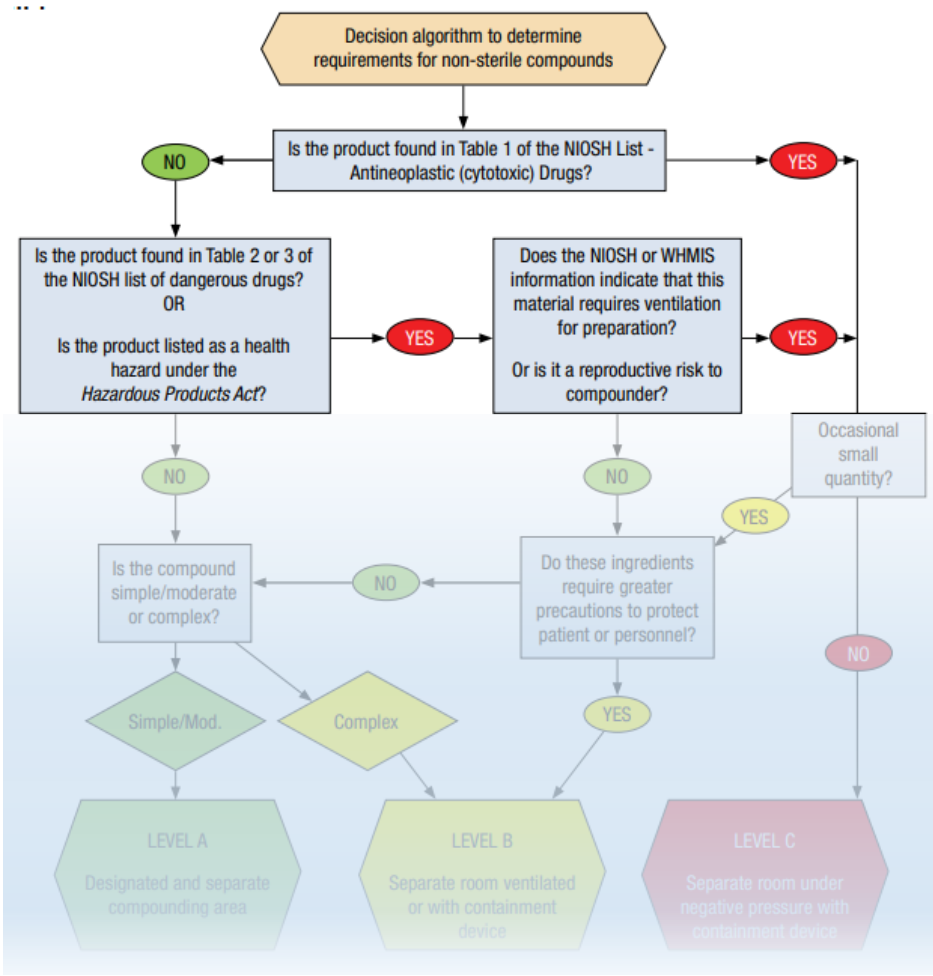
- How do we make safety assessment on which compounds we are allowed to make?
- Do we refer to MSDS [material safety data sheets] and and/or product monograph?
  - Following MSDS seems confusing and symbols vary depending on where you download from
- What if those resources aren't readily available?
- How do we classify as B or C based on quantity?
- How do I decide if compound falls under A, B or C if it is not listed on NIOSH list?

Risk Assessment: Decision Algorithm



- If there is uncertainty as to the level of risk, defer to the higher standard
- Undertaken for each compounded product
- Documentation to justify the level of requirements
- Must also consider cumulative risk associated with all preparations compounded in the pharmacy

Risk Assessment: Decision Algorithm



IDENTIFY THE RISK(S)

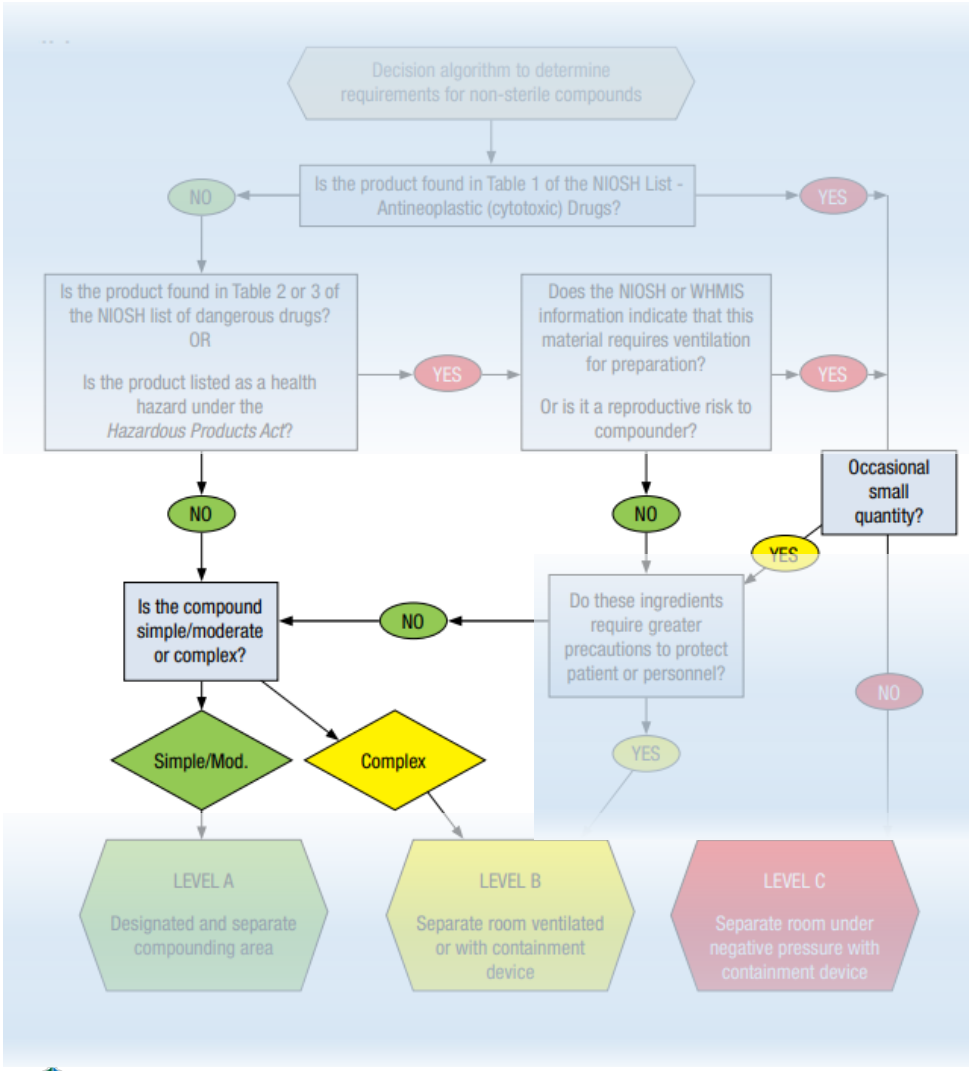
Hazardous ingredients?

- NIOSH Group 1
  - Antineoplastic/cytotoxic
- NIOSH Group 2
  - Meet ≥ 1 criteria
- NIOSH Group 3
  - Reproductive risk
- WHMIS (Safety Data Sheets)
  - Health hazards (e.g., skin, eye, respiratory, etc.)

Frequently Asked Questions

Sections 4, 8

Risk Assessment: Decision Algorithm



ASSESS THE RISK(S)

Occasional small quantity?

- Amount being handled
- Concentration
- Time of exposure
- Frequency
- No defined quantity per preparation or time period

Complexity?

- Simple/Moderate
- Complex

Frequently Asked Questions

Sections 4, 8, 9

Risk Assessment: Decision Algorithm

SIMPLE

- Has USP Compounded Preparation Monographs or appears in peer reviewed journal article, and;
- Contains specific quantities of all components, procedure and equipment, and;
- Provides stability data for that formulation with appropriate BUD

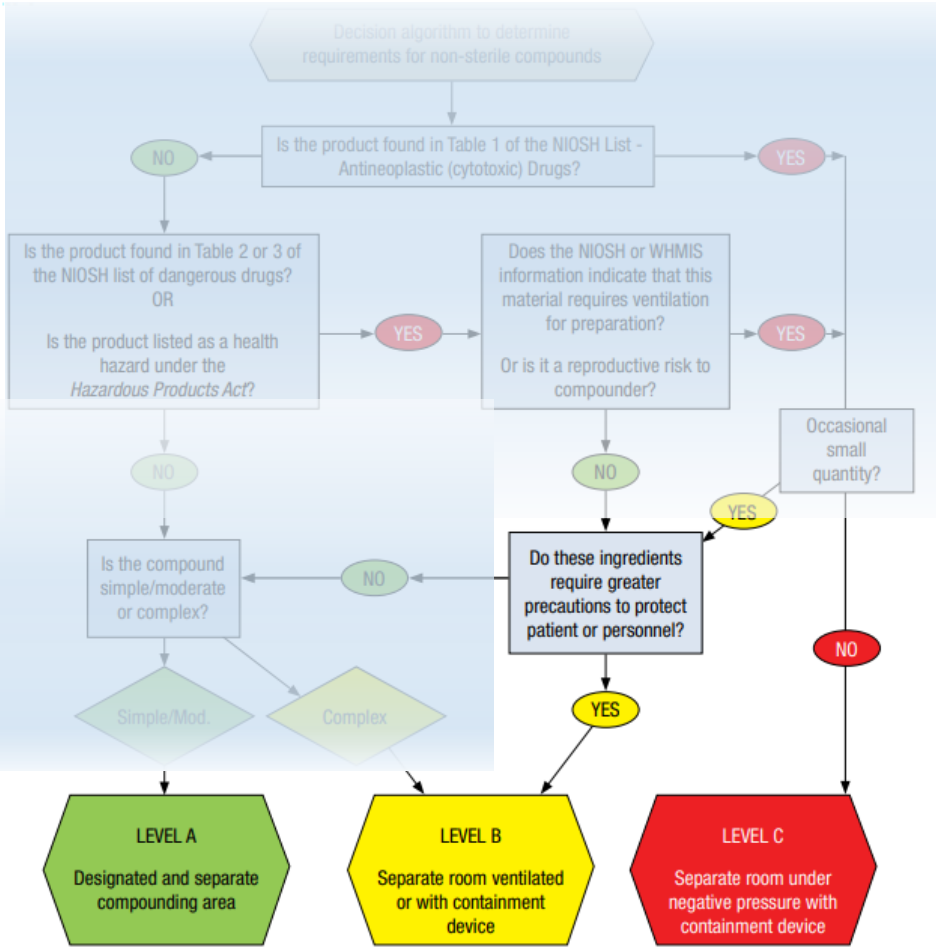
MODERATE

- Requires special calculations or procedures (e.g., calibration of dosage unit mold cavities) to determine quantities of components, or;
- Stability data for that specific formulation are not available

COMPLEX

- Requires special training, environment, facilities, equipment, and procedure to ensure appropriate therapeutic outcomes
- Possible examples include transdermal delivery system and modified-release dosage forms, and some inserts and suppositories for systemic effects.

Risk Assessment: Decision Algorithm



MITIGATE THE RISK(S)

Precautions required to…

Protect patients?

- Liquids, creams and ointments may be particularly susceptible to microbial contamination
- Cross-contamination with other products (e.g., allergens)

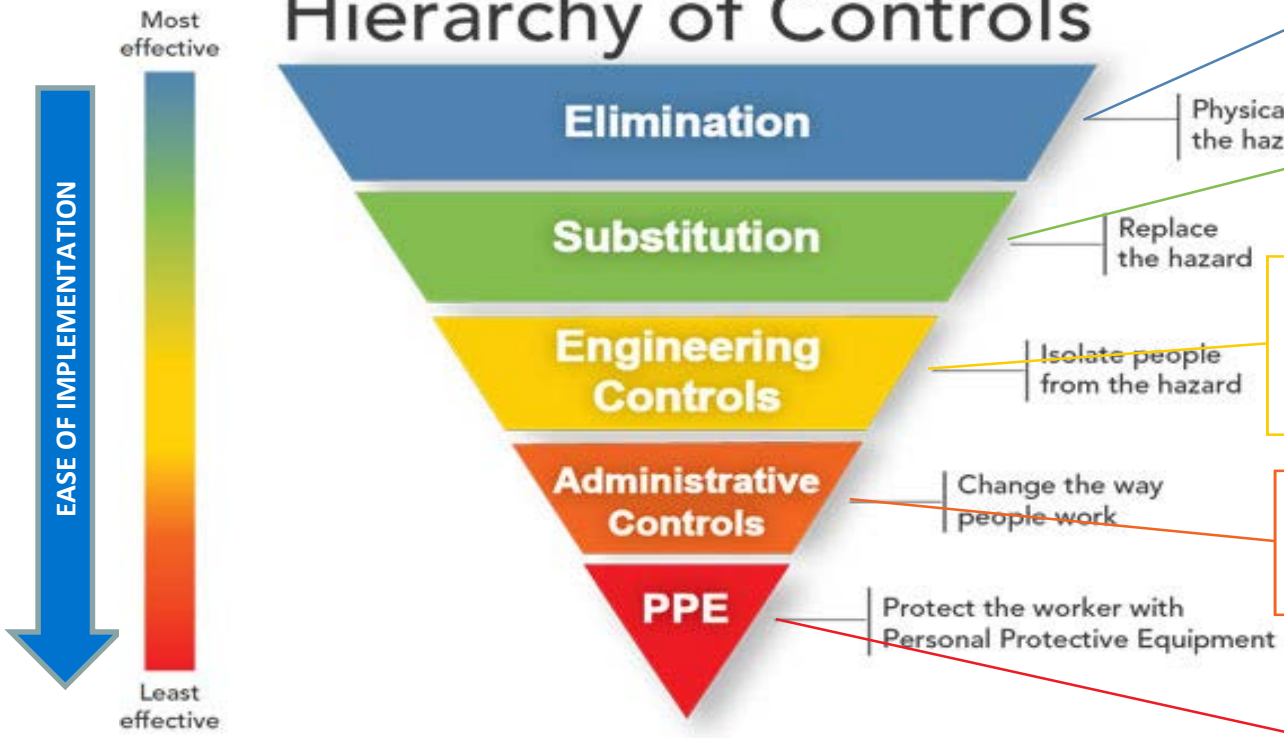
Protect personnel?

- Exposure through the skin, by ingestion, injection (needle-stick injury) or inhalation
- "Hierarchy of Controls"

Frequently Asked Questions

Sections 4, 8, 9

Risk Assessment: Mitigation



E.g. Do not compound the preparation

E.g. Using a liquid formulation instead of crushing tablets ; changing solvents

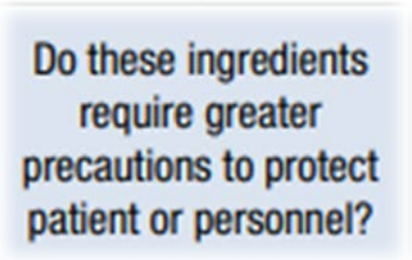
E.g. C-PEC (with redundant HEPA filters or external venting) ; C-SEC (externally ventilated, 12 ACPH, negative pressure)

E.g. additional verification steps; workflow/scheduling; more frequent skills assessments; inventory control

E.g. a properly fitted N-95 respirator vs. a dust mask or surgical mask, two pairs of gloves, eye protection

Article: Closer Look at PPE

Risk Assessment: Mitigation



If necessary to compound a preparation requiring a level of requirement not currently in place, document:

- Potential risks of compounding the product, and;
- Steps that must be taken to mitigate the risks, and;
- References confirming these steps actually will minimize risks

EXAMPLES FROM NAPRA GUIDANCE DOCUMENT:

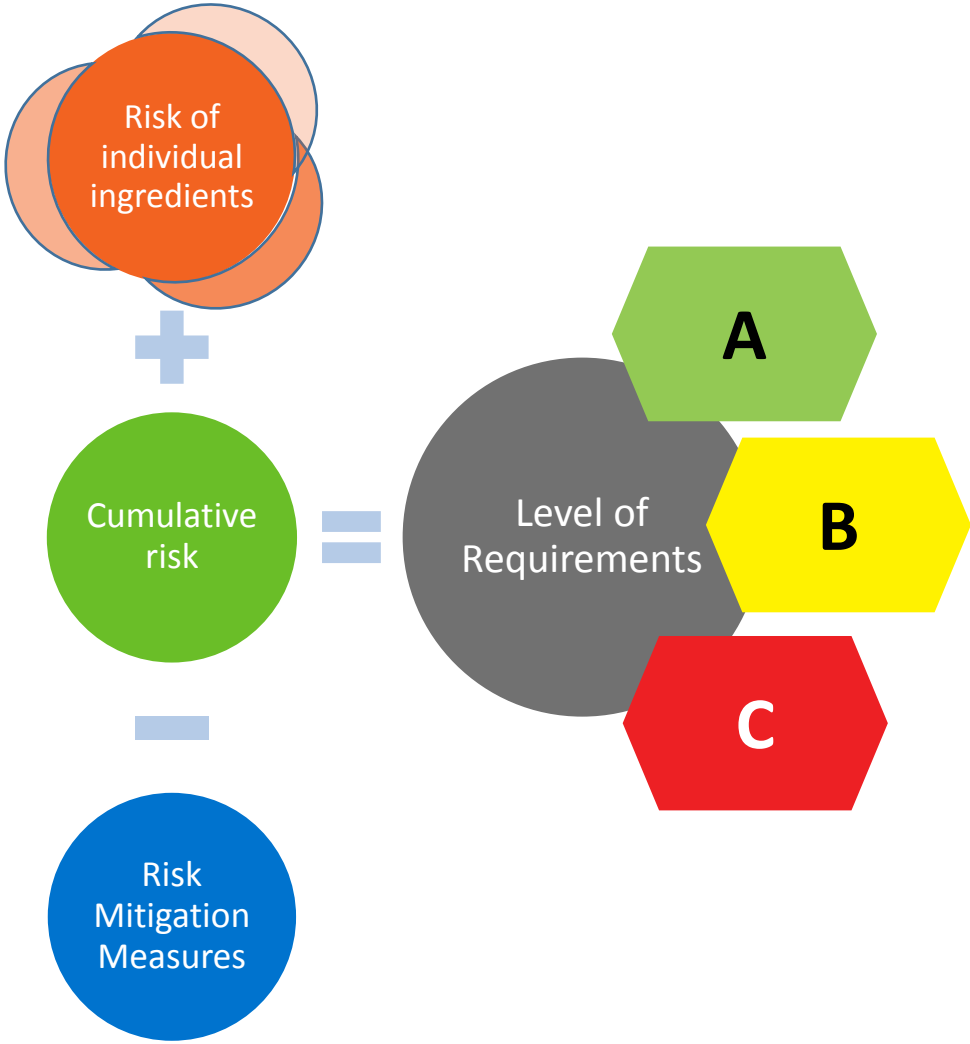
- For a complex compound:
  - Extra measures required (e.g., uninterrupted workflow, extra verification steps, additional equipment)
- For a small quantity of a hazardous product:
  - Alternative containment strategies, and/or work practices to minimize occupational exposure

Risk Assessment: Other Factors

- Physical characteristics
- Manipulations performed
- Potential for microbial and/or cross-contamination

- Volume of ingredient being handled (including receiving)
- Frequency of low- and high-risk preparations
- Accumulation of exposure over time to each person

- Competency of personnel
- Facilities & Equipment
- Administrative controls
- Evidence of effectiveness



Sections 4, 8, 9

Questions Received from Registrants

LEVEL OF REQUIREMENTS

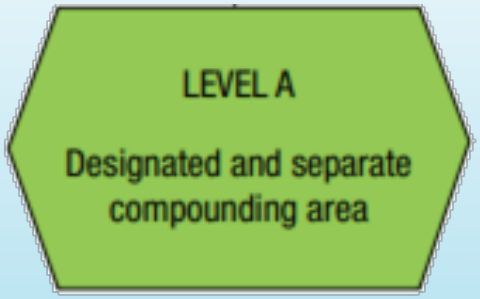
- Requirements for Level A
- What can be compounded at each Level?
- What type of mixtures can a regular/average pharmacy continue to compound?
  - What is required for non-complicated general compounding?
  - For 1-2 simple mixtures per month, what do I need to do?
  - What are the basic documents and physical changes needed for very basic compounding?
  - Can any pharmacy still compound simple preparations?
  - List of compounds are allowed on a routine basis

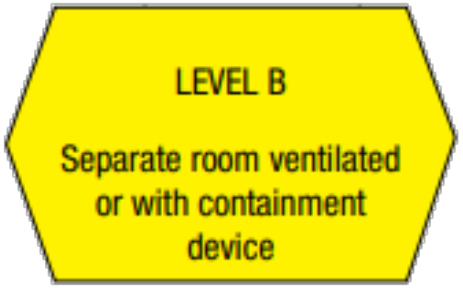
Questions Received from Registrants

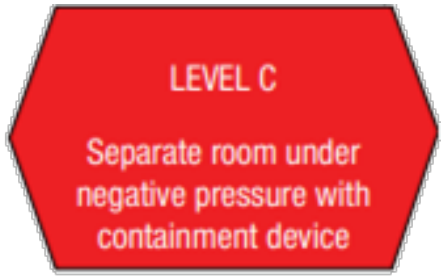
LEVEL OF REQUIREMENTS

- Are physical changes to dispensary required?
  - Do we need physical separation of compounding area?
- Details and specifics on compounding sheets
- Requirements, sources and reference material for master formulation records
  - What about simple compounding that has no references?
- Minimum training requirements
  - Personnel training (pharmacy, cleaners)
  - Need proof of training?
  - Useful training guides available?
  - Advice on companies for supervisor certification

Level of Requirements







- Requirements for all levels
- Simple and moderate compounded preparations

Frequently Asked Questions

Article: Are you doing it?

Sections 5, 8

Requirements for all levels

- **Compounding personnel**
  - Non-sterile compounding supervisor must be pharmacist or pharmacy technician
  - Policy – Supervision of Pharmacy Personnel
- **Training and skills assessment**
  - No specific training program or external course required
- **Policies and procedures**
  - For all compounding related activities including cleaning
  - Examples and template provided
  - Review every 3 years or sooner if needed

Requirements for all levels

- **Facilities & Equipment**
  - Designated, separate space for compounding
    - Non-sterile compounding areas must be separate and distinct from sterile compounding areas
  - Low traffic area big enough for orderly placement of all materials and for personnel to maneuver safely
  - Clean hot and cold water supply with sink (preferably stainless steel and touchless controls)
  - Maintenance, cleaning and calibration
    - Equipment, instruments and accessories must be thoroughly cleaned between uses in different preparations
    - Not sufficient to use only isopropyl alcohol (IPA) 70% as the cleaning agent; also rinse with purified water

Requirements for all levels

- Assigning **Beyond-use Dates (BUD)**
- **Master Formulation Record** (MFR)
- Selection, quality and storage of **ingredients**
- **Compounding Record**
- **Verification** of final compounded preparation
- **Labelling**, packaging and storage procedures
- Recall, incident and accident procedures
- **Risk assessment reviewed** at least every 12 months
  - Table 6 outlines review frequency of other documentation

Requirements for all levels

- **Personal Protective Equipment** (PPE)
  - Hand hygiene before and after
  - Powder-free non-latex gloves
  - Clean lab coat reserved for compounding or disposable gown
- **Personnel Conduct**
  - Report active respiratory, eye, skin (hand) infection
  - Tie back loose hair
  - No fake/long nails
  - Remove jewelry
  - No food/drink/gum

Article: Closer Look at PPE

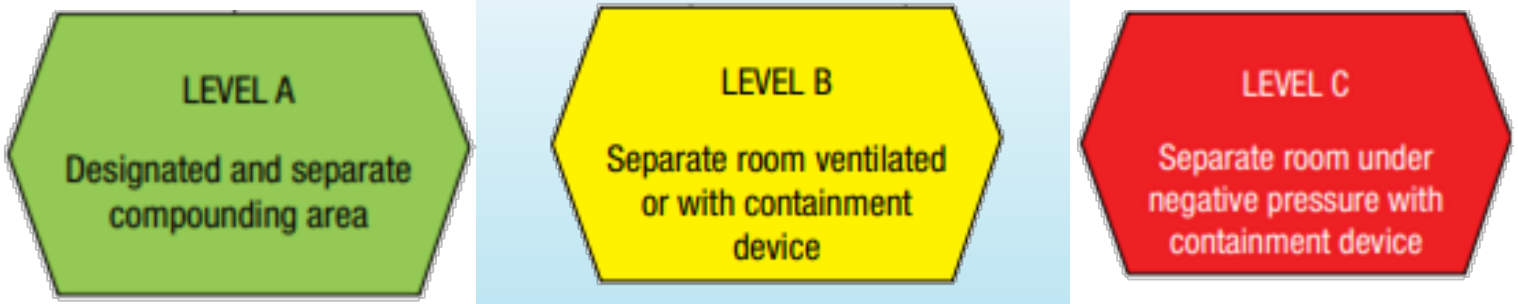
Section 6

Questions Received from Registrants

LEVEL B & C REQUIREMENTS

- Level B compound done in Level A requirements
- Level B without a separate room
- Is it necessary to have both a Level B and Level C room?
- Layout of the compounding room or checklist of what needs to be included
- When do we need to have negative pressure room?
- Does hazardous compounding need to be similar to a sterile compounding area (e.g., anteroom for donning/doffing?)

Level of Requirements

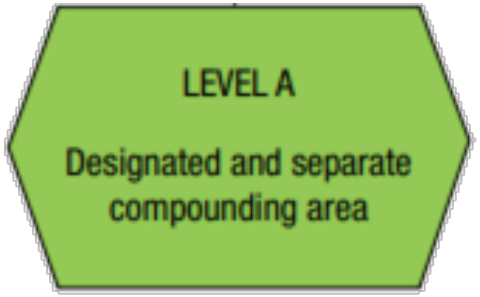


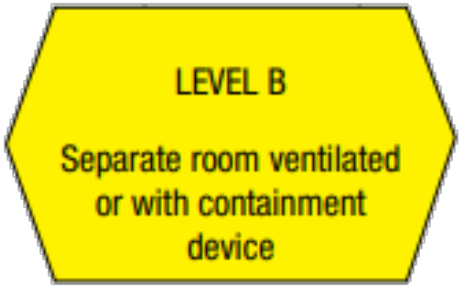
- Complex compounded preparations
- Occasional small quantities of products requiring ventilation

Requirements for Level B

- Dedicated, entirely closed off room with sink
  - Preparations that require more specialized equipment, instruments and an environment without interruptions
- Well-ventilated and/or ventilated containment device
  - Containment device (“hood”) = Engineering Control (C-PEC)
    - Containment Ventilated Enclosure (CVE)
    - Class I or II Biological Safety Cabinet (BSC)
    - Compounding Aseptic Containment Isolator (CACI)
  - May be required for certain powders, aromatic or allergenic products, NIOSH Group 2 or 3, etc.
  - C-PEC should either be externally vented (the preferred option) or have redundant HEPA filters in a series

Level of Requirements





- NIOSH Group 1
- NIOSH Group 2/3 used routinely
- Very irritating to respiratory tract, skin or mucous membranes

Requirements for Level C

- Separate controlled room (C-SEC) *and* C-PEC
  - Dedicated to hazardous preparations
  - Dedicated equipment and instruments
- Ventilation of C-SEC
  - HEPA-filtered air, exhausted to the outside
  - Minimum 12 Air Changes Per Hour
  - Negative pressure (–2.5 Pa) relative to surrounding areas
- C-SEC and C-PEC must be examined and certified at least every 6 months
- Sink, drains > 1 m from C-PEC

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Sections 8, 9

Requirements for Compounding Hazardous Preparations

- Reusable equipment and work surfaces must be adequately prepared between compounding of different preparations
- Deactivating, decontaminating and cleaning

Requirements for Compounding Hazardous Preparations

- PPE approved for hazardous use:
  - Gloves
  - Head, hair, shoe and sleeve covers
  - Respiratory protection
  - Eye and face protection
- Verification and maintenance of C-PEC
- Appropriate area for unpacking and storing product
- Hazardous waste management
- Spill/accident management

Article: Closer Look at PPE

Section 9

Requirements for Compounding Hazardous Preparations

- For hazardous products with greater health risks (e.g., NIOSH 1, WHMIS strong irritants):
  - Level C precautions required, specifically a separate room under negative pressure and externally vented
- For less hazardous products (e.g., NIOSH 2/3, some WHMIS)
  - Level B requirements and extra PPE as described in Section 9.2.3 may be sufficient
  - Small quantities of simple or moderate preparations may *sometimes* be compounded in Level A with certain additional precautions, depending on the risk