Standards 101

Breaking Down Phase One of the Compounding Standards Implementation Plans

Overview

- During this webinar, we will:
  - Discuss the role of the compounding supervisor
  - Discuss the self-assessment document (gap analysis tools) for non-sterile compounding
  - Define Level A, B, and C non-sterile compounding
  - Work through examples of how to conduct a risk assessment for non-sterile compounds
  - Provide answers to frequently asked questions about non-sterile compounding standards and guidelines
  - Address any additional questions from registrants about Phase One of the compounding standards implementation plans

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Phase 1- Summary of Action Items

- All relevant staff including management read the standards and guidelines
- Assign the compounding supervisor role
- Complete the Non-sterile Compounding Self-assessment (gaps analysis)- NOW AVAILABLE!
- Identify all personnel who will require skills and training assessment (including cleaning personnel)
- Identify policies and procedures that need to be developed, who will be responsible for development, and start development
- Complete risk assessments of non- sterile compounds prepared by the pharmacy and determine what facility and equipment upgrades are required
- Begin creating/reviewing/revising master formulation records and assign appropriate, evidence-based BUDs
- Create a list of required PPE, begin sourcing, and implement

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Remember…

- Phase One activities must be completed by **December 31, 2019**
- Registrants must aim to meet the standards at the earliest opportunity
  - Prioritize people and processes
    - Product preparation and conduct of personnel requirements are expected to be met ASAP
  - Quality and safety of compounded products and safety of compounding personnel must remain the priority

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Compounding Supervisor

- Role should be assigned ASAP
- Responsible for development, organization and oversight of all activities related to the compounding of non-sterile preparations at the pharmacy
- May be the PIC or delegate pharmacist or pharmacy technician
- Must be a specific individual

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Non-sterile Compounding Self-Assessment

- “Gaps analysis”
- PIC and Compounding Supervisor to complete in collaboration with compounding personnel
- Available on the Standard, Guidelines, Policies, and Position page of the NLPB website
- This **DOES NOT** need to be submitted to NLPB, but must be available for audit
- The completed self-assessment is intended to inform the implementation action plan and should be a working document

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Level A Compounding

- What is included?
  - Simple and moderate compounds as defined in USP 795
  - Definitions provided in section 8 of guidance document
  - Many non-sterile preparations can be considered
  - May also include NIOSH Group 2 or 3, or materials designated as health hazards by Hazardous Products Act if they pose little or no risk when compounded in occasional small quantities
    - Must be able to minimize contamination of compounding area and risk to personnel- the risk assessment will guide this

MUST CONSIDER CUMULATIVE RISK

when in doubt → refer to the highest risk level

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Level A Compounding

- Physical Requirements
  - Designated compounding area (does not need to be a separate room)
  - No set size specifications
    - Personnel must be able to work comfortably and safely
    - Sufficient space for equipment and supplies
  - Located in an area of minimal distraction
  - Appropriate temperature and humidity control
  - Sufficient lighting
  - A sink must be contained within or close to area
  - Conducive to regular cleaning
    - Work surfaces, furniture, walls and flooring- **smooth, impervious and non-porous**
    - **Stainless steel** preferable for work surface

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Level B Compounding

- What is included?
  - Complex compounds as defined by USP 795
    - Special training, environment, facilities, equipment, procedures; e.g. transdermal dosage forms, modified-release preparations, some inserts or suppositories
  - Small quantities of products that require ventilation and are compounded occasionally (NIOSH Group 2 or 3) - if risk can be mitigated
    - Aromatic products, allergenic products, hormone-containing products

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Level B Compounding

- Physical requirements (in addition to Level A requirements)
  - Separate, well ventilated room
  - Larger workspace and appropriate equipment
  - Environment conducive to limited interruptions
  - Greater protection for cross contamination
  - May require a ventilated containment device if certain powders, aromatic or hazardous products are utilized
    - Remember cumulative risk must be considered based on quantity and frequency

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Level C Compounding

- What is included?
  - Any compounds that include any amount and any dosage form of hazardous drugs that are classified by NIOSH as Group 1 or hazardous materials classified by WHIMIS as being very irritating to respiratory tract, skin or mucous membranes
  - May apply to products containing NIOSH Group 2 or 3 drugs or lower hazard APIs if compounded frequently or in large quantities

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Level C Compounding

- Physical Requirements (in addition to Level A & B)
  - Separate negative pressure room (differential of -2.5 Pa to surrounding areas)
  - Physical separation from other preparation rooms
  - Appropriate air exchange (at least 12 ACPH)
  - External venting through HEPA filtration
  - Consider back-up power source
  - C-PEC (water sources must be at least 1 metre away)
  - No windows or doors opening to exterior
  - Temperature control <20 degrees Celsius
  - Eye wash station

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Level C Compounding

- Pharmacy must have an appropriate area for unpacking hazardous products and a C-PEC available to unpack hazardous products that appear to be damaged
- Hazardous products must be stored in a dedicated room that is:
  - Negative pressure (-2.5 Pa differential)
  - Exhausted to the exterior, with 12 ACPH
  - Appropriately ventilated
  - Has shelving with lips to prevent spills due to breakage
- Storage and preparation areas containing hazardous drug must be identified with signage

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Risk Assessment

Getting started…

- Review NIOSH list of hazardous drugs
- Create a list of all hazardous drugs on site
- Organize by where there are on NIOSH table
  - Group 1, 2, 3
- Gather Safety Data Sheets for all APIs on site
- Review SDS sheets
  - Section 2- Hazards identification
  - Section 8- Exposure controls

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Other factors to consider during risk assessment

- Complexity of compounding the preparation
- Need for verification and uninterrupted workflow
- Frequency of compounding high-risk or low-risk preparations
- Risk of cross-contamination with other products (e.g., allergens)
- Concentration of ingredients in the product
- Quantity of ingredients being handled
- Physical characteristics of ingredients, such as liquid vs. solid vs. powders, or water-soluble vs. lipid-soluble
- Education and competency of compounding personnel

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Risk Assessment

- Begin reviewing and updating all master formulation records
  - Assess risk for each compound using NIOSH tables and Section 2 of SDS
    - Assign A, B, or C
- Guidance document includes an algorithm to guide risk assessment process
  - Section 4, Diagram 1
- BUDs should be assigned based on stability studies
  - If no data available, apply maximum BUDs in Table 4

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Examples of Risk Assessments

- https://abpharmacy.ca/standards-pharmacy-compounding-non-sterile-preparations
  - Diclofenac
  - Hydrocortisone 1% / Ketoconazole 2% (1:1)
- https://www.saskpharm.ca/site/profprac/compounding?nav=sidebar
  - Risk assessment overview: Methadone

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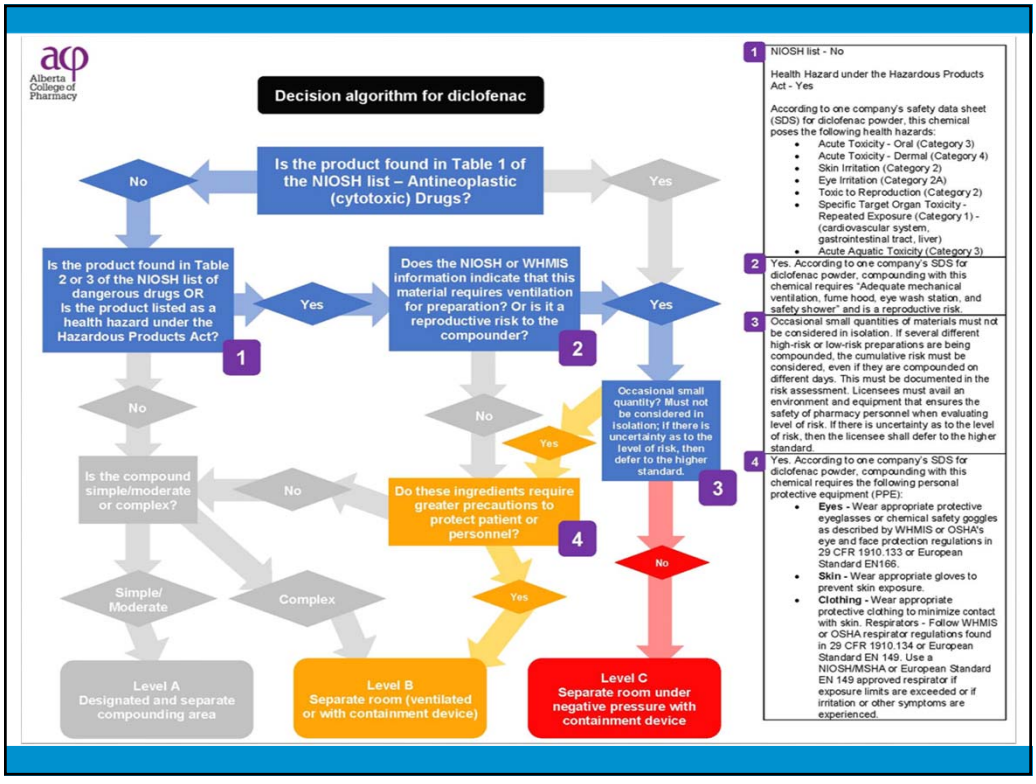

Hydrocortisone/ketoconazole cream example

- No SDS sheets were available for the creams so those for powders were considered in combination with product monographs for the creams (contraindications, warnings, precautions)
- Rationale provided for risk assessment of Level A:
  - Health hazards mitigated by cream formulation
  - Low volume, low frequency, low ingredient concentration
  - Risk mitigation
    - PPE- Regular gloves, designated compounding jacket, eye protection

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Risk assessment outcomes

Does the pharmacy have the necessary facilities, PPE, and/or specific engineering controls for the risk level of compounds?

- If no, options include:
  - Plan for renovation of facility (Don't forget to apply!) and risk mitigate in interim- **ALL pharmacies should aim to operate at Level A**
  - Transfer prescription to a compounding pharmacy that meets requirements
  - Seek central fill agreement with a pharmacy that meets compounding and central fill requirements (see NLPB Central Fill Policy)
  - Collaborate with prescriber to determine alternate product, if appropriate

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Risk Mitigation

- If it is necessary to compound a preparation that requirements procedures or processes or physical requirements that are not yet in place:
  - Document potential risks and extra steps that must be taken to mitigate risks (include references to support)
  - Examples:
    - Complex compounds- document extra measures required such as uninterrupted workflow, extra verification steps, extra equipment
    - Hazardous products- if small quantity, document alternative containment strategies and/or work practices that limit exposure

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Frequently Asked Questions

Q. What is the difference between the Standards & Guidelines? Do I have to follow everything in the guidelines?

A. Standards are the minimum requirements that must be met. The Guidelines are a resource to assist pharmacy professionals with meeting the Standards and should generally be adhered to. Guidelines are not recommendations. They establish the professionally accepted means by which registrants can achieve compliance with the Standards. That said, registrants may choose to meet the Standards through an alternate means as long as they can produce evidence that all requirements are sufficiently met.

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Frequently Asked Questions

Q. My pharmacy only makes simple compounds like hyderm/nystatin and other 50:50 creams- do these standards impact my practice and pharmacy?

A. Yes! While there will be less work associated with meeting the standards in a less complex compounding practice (particularly when it comes to staff training, P&P development, and master formulation records) **ALL** pharmacies performing any level of non-sterile compounding must meet the minimum requirements of the Standards.

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Frequently Asked Questions

Q. Will the Board be providing a list of compounds that fall in each risk category?

A. No. Risk assessments can vary from pharmacy to pharmacy based on staff composition, level of training, equipment, infrastructure, etc.; therefore, an individual assessment will need to be performed. However, we have provided examples for how to complete a risk assessment to help registrants understand the process.

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Frequently Asked Questions

Q. What should I do if I am unsure of the risk level of a compound?

A. If there is uncertainty in level of risk, registrants should defer to the higher standard. Apply the concept- "You don't know what you don't know"!

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Frequently Asked Questions

Q. How do I determine if a product is listed as a health hazard under the *Hazardous Products Act*? How do I use product safety data sheets to determine risk?

A. See Schedule 2 under the *Hazardous Products Act* for a listing of health hazard classes. Manufacturer supplied SDS for the active API will provide information on any associated health hazard classes and required PPE/risk mitigation measures (section 2 and section 8, respectively).

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Frequently Asked Questions

Q. Do you need separate areas for compounding hazardous (Level C) and non-hazardous non-sterile preparations?

A. The guidance document states that this is preferable. If this is not possible and the same area is being used for both, the compounder must ensure proper deactivation and decontamination. This includes dedicated equipment for hazardous preparations. In addition, if the compounding area is the same, non-hazardous materials need to include a label that indicates they may have been exposed to hazardous materials. Logistically, this will likely be challenging.

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Frequently Asked Questions

Q. What are the requirements for compounding diclofenac gel?

A. While the Board will not be providing specific lists for compounding risk levels, diclofenac gel will need to be compounded in a pharmacy that meets level B or C facility requirements, based on the risk assessment performed. If occasional, small quantities are being compounded, level B may be sufficient.

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Frequently Asked Questions

Q. Can computer-generated compounding worksheets be used to satisfy master formulation record requirements and ongoing compounding records?

A. Yes - however, refer to section 6.2 of the guidance document for content requirements. Keep in mind that master formulation records must be current, include supporting rationale and references, and compounding personnel must have ready access and be informed of any changes.

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And now it's your turn!

- Please type your questions in the chat field
- If you have questions following the webinar, please contact npatten@nlpb.ca
- Thank you for your participation! We are committed to working with you throughout this process

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