Timelines Announced for Non-Sterile Compounding Standards

Pharmacy Connection | March 21, 2019

Please note that on March 23, 2020, Council approved an extension to the deadlines for implementation of the non-sterile compounding standards. This change is in recognition of the evolving COVID-19 pandemic situation and the need for pharmacy professional to focus on continuity of care and minimizing public risk. The

- *Phase 2: July 1, 2021 - Personnel Training and Quality Assurance*
- *Phase 3; January 1, 2022 - Facilities and Equipment*

In December 2018, Council approved a three-phase approach for implementation of the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations. The priorities and timelines for completion of each phase are:

Phase 1: January 1, 2020 - Assessing Risks and Gaps

Phase 2: July 1, 2020 - Personnel Training and Quality Assurance

Phase 3: January 1, 2021 - Facilities and Equipment

ABOUT THE STANDARDS

The College expects that all pharmacists and pharmacy technicians engaged in non-sterile compounding have thoroughly reviewed the Standards and the accompanying Guidance Document. For ease of use, the numbered sections in the Guidance Document correspond to the sections of the Standards.

Adherence to these standards is an important way of protecting patients and staff and ultimately enhancing the quality and safety of pharmacy care in the province. This article focuses on preparing for the first of the three-phase roll out.

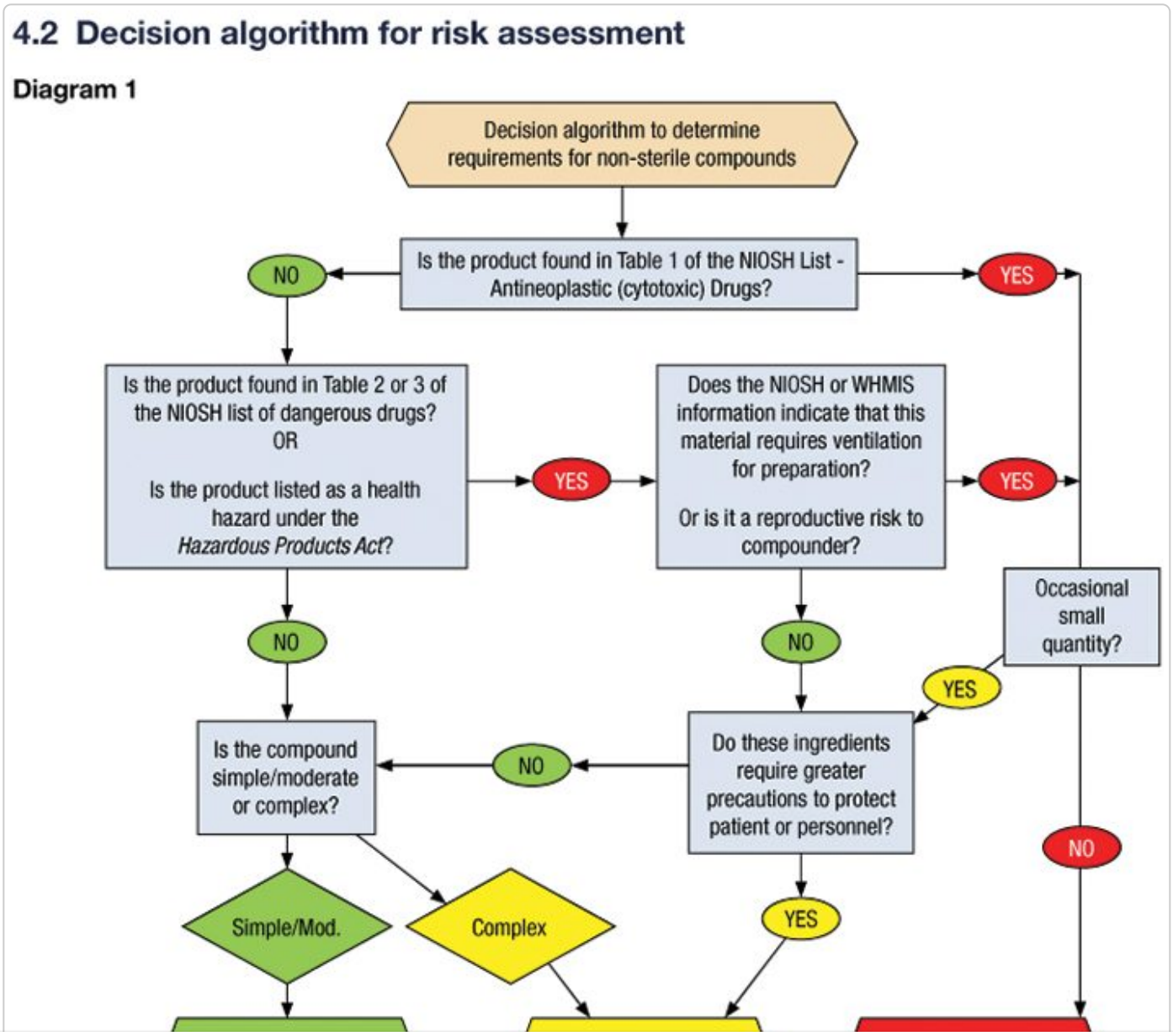
PHASE 1 – ASSESSING RISKS AND GAPS

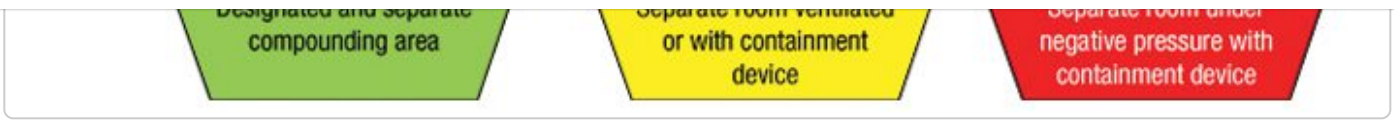
RISK ASSESSMENT

To provide non-sterile compounding services that meet or exceed the minimum standards, a risk assessment must be completed for each preparation compounded by the pharmacy. The Designated

Three levels of requirements are defined in Section 8 of the Standards (A, B and C) which correlate to the risks associated with the preparation and its complexity. Both *risk of contamination* to the preparation, which is essential for patient safety, and *risk to personnel*, which must be mitigated by adequate protection measures, are considered.

The steps for conducting a risk assessment are described in Section 4 of the Standards. The complexity of the compounds are categorized as simple, moderate or complex. The *level of requirements* the pharmacy needs to have in place is dependent on the category of the products compounded. The Decision Algorithm (Section 4.2 of the Guidance) can be used in conjunction with workplace guidelines provided in Section 4.3 to determine if a preparation needs Level A, B or C compliance requirements.





WORKPLACE GUIDELINES

Workplace guidelines that play a role in pharmacy compounding include the Workplace Hazardous Materials Information System and the National Institute for Organizational Health and Safety.

The Workplace Hazardous Materials Information System (WHMIS) 2015 *Safety Data Sheets* (SDS)

- Essential to occupational health and safety, the SDS provides a summary of a product's hazards
- Must be provided by the manufacturer or supplier per federal Hazardous Products Regulations
- Identify measures for risk mitigation, such as Personal Protective Equipment (PPE)
- For more information, the Canadian Centre for Occupational Health and Safety (CCOHS) offers several WHMIS 2015 Fact Sheets, including one outlining the content of the SDS
- Additional external resources include Health Canada and the province-specific information from WHMIS.org and the Ontario Ministry of Labour

The National Institute for Occupational Safety and Health (NIOSH) *List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016*

- Drugs listed in Group 1 (Table 1) are antineoplastic and pose an occupational hazard due to their cytotoxicity and/or reproductive risks
- Preparations containing Group 1 drugs warrant Level C requirements and must be handled using the recommended engineering controls (e.g., specialized equipment and facility design)
- The PPE requirements at Level C are significantly more extensive than those encountered in Level A. These, along with other provisions specific to Level C, are explained in Section 9

GAP ANALYSIS

evaluating the pharmacy's current practices in comparison to the minimum standards in each area.

The knowledge and skills of compounding personnel must be assessed for gaps. The potential need for training is not limited to the compounding processes or technique; personnel must also be educated on policies and procedures related to attire, personal protective equipment, cleaning, maintenance, conduct and behaviour.

The nature and extent of the gaps identified will be a good indicator of the magnitude of changes the pharmacy needs to make in order to fully achieve and maintain the standards. A significant factor to the success and sustainability of any program is collaboration between the people involved.

Where change is needed, it is important to be cognizant that pharmacy personnel will require sufficient time and training to modify their usual routines and adapt to the Standards. The Designated Manager and/or compounding supervisor should develop a plan of action to address gaps with this in mind.

TEAM RESPONSIBLITIES

To proactively prepare for Phase 2 (Personnel Training and Quality Assurance) compliance by July 1, 2020, the College suggests compounding pharmacies consider holding a team meeting to determine how staff will divide the workload in Phase 1. Use the list below and corresponding guidance document references as resources to assist you.

- Identify the compounding supervisor who will develop, organize and oversee all activities. (5.1.2.)
- Confirm all personnel who will require skills and training assessment. (5.1.3-5.2.2)
- Complete the risk assessment for each non-sterile compound that you are preparing.
  - Refer to the NIOSH list, SDS and WHMIS to determine level of risk to the compounding personnel (4.3)
- Identify the levels of requirements for the compounds you are preparing. Refer to algorithm in the NAPRA guidance document. (4.1-4.3)
- Ensure master formulations are comprehensive and evidence-based with safety data sheets for each chemical used. (6.2)

and Templates There are Printable and Fillable Forms available on the NAPRA website of some of these resources to facilitate their use.

The tools and resources provided above will help pharmacy professionals prepare to meet the deadlines approved by Council for non-sterile compounding compliance. Future articles will focus on Phases 2 and 3.

If you have any questions about these standards or the implementation dates, please contact pharmacypractice@ocpinfo.com.

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