

## Considerations for the Evaluation of the Compounding Practice Environment

The following information is provided to pharmacy practitioners to consider when undertaking an evaluation of the compounding practice and environment. It is intended to provide a brief overview of some of the relevant factors and legislation. It is important to recognize that there is no one correct way to evaluate a practice environment. This document is provided only as reference and is not all encompassing. Depending upon the unique context of each practice site, additional factors, not captured here, may need be taken into consideration.

### Evaluation of Complexity

The evaluation should consider the compounding practice from two perspectives. One is an examination of the complexity of the compounded non-sterile preparations (CNSPs) being prepared. Currently, most pharmacies prepare relatively simple compounds that include few steps and require minimal equipment. These types of compounds can most often be easily prepared in a traditional pharmacy environment. As the practice of pharmacy has evolved, however, so has the practice of compounding, and now can include formulations that require multiple calculations and steps, and the use of specialized equipment. The complexity of this type of compounding may warrant that it takes place in a separate, designated room, so that those undertaking the activities associated with the preparation can do so in a manner and environment that affords them the opportunity to concentrate on the task without the inevitable interruptions that occur in the day-to-day operations of a community pharmacy. This will help to ensure that CNSPs are prepared safely and accurately.

The determination of whether the complexity of the compounding activities requires that they should be prepared in a separate environment is subjective. Some pharmacy practitioners will determine that a separate room is necessary, while others will determine that CNSPs can be prepared safely and accurately within the main dispensary and that a separate room is not necessary. The visual algorithm included with this document provides some questions that pharmacy practitioners may wish to consider when making this determination.

### Evaluation for the Safety of the Compounder

The second perspective that should be evaluated is the risk posed to the persons involved in the preparation of CNSPs. Exposure to substances and chemicals (including active pharmaceutical ingredients) in a pharmacy has the potential to impact the health and well-being of all pharmacy personnel. The degree of potential risk associated with exposure depends upon the level and type of exposure to and the toxicity of the substances. As the practice of pharmacy continues to evolve, so does the recognition that the potential harm associated with exposure must be evaluated and appropriate mitigation measures put in place.

Substances and chemicals considered hazardous are regulated federally by the [Hazardous Products Act](#) (HPA) and subject to the requirements for labelling and Safety Data Sheets (SDS) under the [Hazardous Products Regulations](#). Added to the federal requirements, each jurisdiction in Canada has [Workplace Hazardous Materials Information System](#) (WHMIS) regulations which require workplaces to have appropriately labelled hazardous products and SDS available, and includes a requirement for education in the workplace. In contrast, although a drug, based on its chemical and physical properties may be a hazardous product, drugs, including those used in compounding are regulated by the federal [Food and Drugs Act](#) and are not subject to the regulations under the

HPA. It is important to recognize, however, that although drugs are not classified as hazardous products under the HPA, this does not mean that inappropriate exposure to them carries no risk and the [Occupational Health and Safety](#) (OHS) Act and its various regulations (e.g., WHMIS regulations, First Aid Regulations, Workplace Health and Safety Regulations, Occupational Safety General Regulations) require that workers are educated about risks and protected from them.

Provincial Occupational Health and Safety laws place certain duties on employers and emphasize “proactive approaches to prevent accidents, injury and disease through an internal responsibility system based on the cooperation and involvement of the workplace parties in occupational health and safety matters”. This legislation requires that employers provide education to their employees regarding the safe use, storage, handling, and disposal of products used in the workplace and that measures are put in place to ensure workers are safe, including when employees undertake activities related to compounding in pharmacies. (personal protective equipment, appropriate lighting, and ventilation, etc.). Employers, pharmacy managers, and other pharmacy practitioners who are unfamiliar with the requirements under this legislation are encouraged to review it and/or seek outside input to determine whether they meet OHS requirements.

### **Hazards Associated with Drugs**

The [National Institute for Occupational Safety and Health](#) (NIOSH) in the United States maintains a list (the [NIOSH list](#)) of hazardous drugs in healthcare settings and the guidance document [Managing Hazardous Drug Exposures: Information for Healthcare Settings](#). Many healthcare institutions use the information contained in NIOSH as the basis for their policies for handling hazardous drugs. NIOSH categorizes drugs in tables according to the type of risk they present but also provides valuable information about the rationale for the categorization and some of the risk mitigation strategies that can be used when handling drugs that appear on the list. Pharmacy practitioners are encouraged to consult these documents in their entirety to help gain an understanding of both their content and intended use.

The exclusion of a drug from the tables within the NIOSH list does not mean that a drug lacks the potential to cause harm to those who are inappropriately exposed to it. Rather, it indicates that the drug in question does not meet the NIOSH criteria for being hazardous. All drugs have the potential to cause harm but the extent to which harm will occur in the context of preparing CNSPs can depend upon many factors, including:

- the toxicity of the drug (e.g., methadone is known to be toxic at low doses whereas amlodipine likely is not)
- the quantity of drug being compounded (e.g., 2mg vs 2g of the same drug)
- the risk of exposure (e.g., what kind of PPE or environmental controls are in place)
- the type of manipulation that is occurring (e.g., pouring liquid vs crushing tablets vs weighing powder)
- the specific characteristics of the person being exposed (e.g., the risk to a person actively trying to conceive vs one who is not)
- numerous other factors not listed here that may be important depending upon the context

Information about the specific risks associated with a drug can be gathered through several resources including:

- drug product monographs and special handling information provided by manufacturers
- SDS provided by suppliers of Active Pharmaceutical Ingredients (APIs)
- hazard communication labels on APIs
- SDS available on-line
- generally accepted knowledge about a drug, etc.

### Other Hazardous Products

The Workplace Hazardous Materials Information System (WHMIS) is the national communication standard for hazardous chemicals used in the workplace. This system uses the labels and SDS required by the Hazardous Products Regulations to provide health and safety information for the use, handling, and storage of hazardous products in the workplace. The WHMIS has been aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) to help ensure a more uniform worldwide system of hazardous product recognition and information. In Nova Scotia, information about the responsibilities of employers regarding occupational health and safety generally and WHMIS specifically can be found at Nova Scotia Occupational Health and Safety.

The Canadian Centre for Occupational Health and Safety also offers several free courses, including WHMIS training, available to Nova Scotia residents through Nova Scotia Occupational Health and Safety.

Below is a visual representation of the concepts described in this document. It is intended as an aid to understanding what criteria might be used to evaluate the complexity of compounding activities and to contextualize how Occupational Health and Safety requirements apply to the practice of pharmacy compounding.

# Evaluation of the Compounding Practice Environment (Questions to Consider)

