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Non-Sterile Compounding Risk Assessment Template: Companion Guide

*This resource is intended to support registrants' understanding and completion of the **Non-Sterile Compounding Risk Assessment Template**. The sections and question numbers below correspond to those in the template.*

Introduction

The non-sterile compounding risk assessment template is primarily a **documentation tool** to help registrants ensure they are considering *risk to preparation* and *risk to person* for each preparation compounded at their pharmacy. It supports compliance with ***NAPRA's Model Standards for Pharmacy Compounding of Non-Sterile Preparations*** and aligns with **OCP's Non-Sterile Preparations Assessment Criteria**.

The purpose of a risk assessment is to determine the appropriate level of requirements necessary to have in place at your pharmacy to minimize contamination of each non-sterile preparation and to provide adequate protection for personnel.

KEY REMINDERS:

- One risk assessment must be completed for each compounded preparation, including for different strengths of the same preparation (e.g., hydrocortisone 1% powder in clotrimazole 1% cream, hydrocortisone 2% powder in clotrimazole 1% cream).
- Risk assessments must be reviewed every 12 months or more frequently if there is a change in practice or standards.
- Ongoing assessment of cumulative risk is needed to ensure the level of requirements in place is still sufficient to mitigate risks.
- All existing compounded preparations must have a risk assessment completed.
- Risk assessments may also be completed for preparations the pharmacy intends to compound in the future (e.g., to determine the level of requirements needed for a new pharmacy opening or if renovating to add compounding services).

1: Preparation name

Be sure to use clear, consistent, and descriptive nomenclature for easy identification, filing, and retrieval of the risk assessment. You can also leave room to add a pseudo-identification number (PIN) or a copy of the label to illustrate how the preparation name will appear on the container of the final compounded preparation.

As an example, here is one approach:

[API #1 + strength] [API#2 + strength] [dosage form]
Salicylic acid 5% Coal tar 10% topical solution

TIP

If full ingredient names and concentrations do not fit on the original label, consider adding an additional label to the patient's container. Avoiding abbreviations can help to prevent errors and alleviate ambiguity. For instance, abbreviations of ingredient names (e.g., "HCP" for "hydrocortisone powder") may not always be readily understood by patients or caregivers.

A. Identify the risk(s)

2: Description of and references for the ingredients

Drug Identification Number (DIN): DIN is a computer-generated eight-digit number assigned by Health Canada to a drug product before it is marketed in Canada.

Chemical Abstract Services Registry Number **(CAS# or CAS RN):** Active pharmaceutical ingredients (APIs) or bulk chemicals used in compounding do not have DINs. Therefore, a CAS number is assigned to each specific chemical substance as a standardized way to identify these products to reduce the risk of error.

Physical characteristics: Specifying the physical characteristics of the ingredients used in the preparation (e.g., liquid, volatile liquid, solid, solid powder, cream/ointment) is important for determining the potential risks (e.g., routes of exposure, microbial contamination, cross contamination).

References: Citing the resources that were consulted (e.g., safety data sheets [SDSs], product monographs) gives credibility to your risk assessment.

If you need more space to list the ingredients in your preparation, be sure to attach any extra pages to your risk assessment.

TIP

Suppliers update SDSs every three years. Documenting the dates of the available SDS helps ensure the pharmacy is using the latest version for their risk assessment.

3: NIOSH list

The *National Institute for Occupational Health and Safety (NIOSH) List of Hazardous Drugs in Healthcare, 2024* is one reference to assist registrants with identifying and handling hazardous drugs. While the NIOSH list is intended to assist in identifying which drugs routinely handled by healthcare workers are considered by NIOSH to be hazardous drugs, it is not specifically for pharmacies or compounding (e.g., you won't find information on quantities, concentrations, types of ventilation); rather, the information needs to be applied in context. **A drug can still be hazardous even if it's not on the NIOSH List**.

The list organizes drugs into Table 1, hazardous drugs with carcinogenic properties, and Table 2, other hazardous drugs.

The NIOSH 2024 list of hazardous drugs includes the following statement:

CAUTION: Drugs purchased and used by a facility may have entered the marketplace after the list below was assembled. This list is not all inclusive.

Drugs reviewed for this update were new drug approvals or received safety-related new warnings from FDA during the period from January 2014 through December 2015.

TIP

There is no single, universally accepted list of hazardous drugs, and the NIOSH list is not exhaustive. Drugs or active pharmaceutical ingredients (APIs) not included on the NIOSH list may not have met NIOSH's specific criteria at the time of review, but this does not necessarily indicate that a drug is not hazardous. Drugs and APIs not listed may still exhibit characteristics such as carcinogenicity, teratogenicity, reproductive toxicity, genotoxicity, or organ toxicity, which would warrant protective measures.

Because new drugs and formulations are continuously being brought to market between NIOSH's periodic updates, you should establish your own process to regularly identify and evaluate new drugs as they enter your facility. This includes whether drugs categorized as hazardous require re-categorization as new toxicity data becomes available.

4: WHMIS information on health hazards

The Workplace Hazardous Materials Information System (WHMIS) is Canada's hazard communication standard to support the safe use of hazardous materials in the workplace. It includes products used in various workplaces, not just pharmacies. These are categorized as either a physical hazard or a health hazard (as per **Schedule 2** of the *Hazardous Products Act*). **Safety data sheets** (SDSs) are required as part of an organization's WHMIS program.

TIP

Health hazard classes can be identified by **pictograms**, which appear on the API's label.

Health hazard(s) for an API are further identified on its SDS, under Section 2 – **Hazards Identification**.

5: Risk to person (compounding personnel)

Identify the potential risks of the ingredients your compounding personnel are handling. This will help you determine what risk mitigation measures are needed (later in the risk assessment).

If you check "No/ not applicable" to any of 5a, 5b, or 5c, be sure to outline in the rationale for the risk assessment how this was verified against your available references.

TIP

Consider the physical characteristics identified in question 2, including how the ingredients are manipulated (e.g., crushing a tablet, opening a capsule), and the risks these may present to persons via different routes of exposure (e.g., skin, eyes, inhalation, oral).

In addition to NIOSH, WHMIS information that can help you determine potential risks the ingredients might present to the compounder can be found in the SDS (e.g., section 8, "Exposure controls / personal protection," and section 11, "Toxicological information.").

Product monographs (if applicable) can also provide useful information before handling a drug (e.g., warnings, precautions).

6: Risk to preparation

Assess where there might be potential contamination risks to the preparation (and, therefore, potential risks to the patient). The purpose of this question is to recognize that the answer may be "yes" and to describe what these are to indicate that you have worked through the different ways the preparation could become contaminated. If there are risks, you will need to figure out how to mitigate them and describe these measures in section C of the template.

TIP

Based on the information gathered so far, here are some things to consider:

- Liquids, creams and ointments may be particularly susceptible to microbial and other contamination
- Cross-contamination can occur:
  - a) Due to a lack of dedicated equipment if compounding hazardous and non-hazardous non-sterile preparations
  - b) From other ingredients, preparations or materials due to limited space for compounding
- Workflow interruptions can occur due to poor workspace layout as well as distractions from other staff, patients, or activities

B. Assess the risk(s)

7–9: Occasional small quantity

The NAPRA non-sterile compounding standards do not assign a specific numerical value to define occasional small quantity. What is considered an "occasional small quantity" for a preparation can depend on several factors.

Questions 7 to 9 ask you to document the factors that should be considered when determining whether an occasional small quantity of a compound is being prepared so that you can provide an appropriate rationale for your decision.

Things to consider (whether you check "Yes" or "No" to "occasional small quantity"):

- Concentration/quantity/amount of the APIs used (e.g., the intensity of exposure)
- Average quantity prepared (e.g., weight, volume, individual units or batches)
- Frequency of compounding (e.g., daily, weekly, monthly, or less)
- Cumulative risk: the combined risk of all the individual compounded preparations and their frequencies (even if you consider them each to be an "occasional small quantity")

TIP

Evaluate your practice continually and ensure that you are prepared to address the following:

- Do you have a process to assess cumulative risk (e.g., generating a summary report for all drugs or APIs accessed within a set time frame to determine intensity and duration of exposure within your pharmacy)?
- At what quantity and frequency will you defer to a higher level of requirement (i.e., when this is no longer an "occasional small quantity" or when you have reached your upper limit of compounding)?

10–12: Complexity of the compounded preparation

If a compound requires specialized knowledge, competencies, equipment, or facilities, it is likely to be more complex. This section asks you to consider the degree to which these are required – in addition to all the other factors that need to be weighed (see the table below) – in order to arrive at an appropriate conclusion.

Definitions of simple, moderate, and complex non-sterile preparations are outlined in the **NAPRA guidance document**, pages 40 and 41.

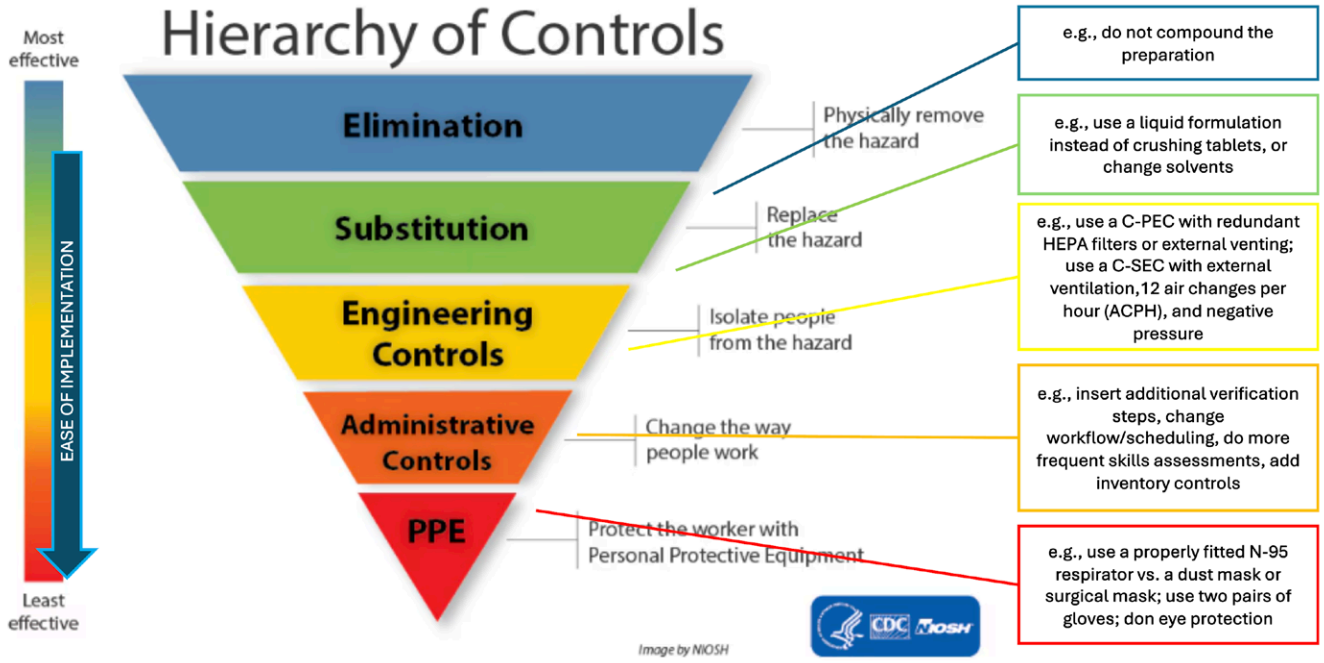
Simple
• Has a United States Pharmacopeia (USP) compounding monograph or appears in a peer-reviewed journal article *and* • Contains specific quantities of all components, compounding procedure and equipment *and* • Provides stability data for that formulation with appropriate beyond-use date (BUDs)
Moderate
• Requires special calculations or procedures (such as 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 procedures to ensure appropriate therapeutic outcomes (e.g., transdermal delivery system, modified-release dosage forms, some inserts and suppositories for systemic effects)

Note: The definitions of simple, moderate, and complex, as referenced in NAPRA, were sourced from the United States Pharmacopeia (USP) General Chapter <795>. Since the time of publication of the NAPRA guidance document, revisions have been made to this section of the USP and these definitions are no longer included. However, because the College has adopted the NAPRA standards and accompanying guidance in their entirety, these definitions continue to apply.

C. Mitigate the risk(s)

13–16: Mitigating risk to person (e.g., exposure) and to preparation (e.g., contamination)

Non-sterile compounding supervisors should familiarize themselves with NIOSH's "hierarchy of controls" – five levels for reducing or removing hazards from most to least effective. This can help you establish a preferred order of action based on the effectiveness of that control.



Examples of PPE types and some possible descriptors are in red:

PPE	Required	Type (please be specific)
Eye protection	☐ Yes ☐ No	*Goggles*
Mask / respirator	☐ Yes ☐ No	*Fit-tested N95 or N100 (NIOSH-approved)* **TIP:** Surgical masks do not provide respiratory protection against drug exposure and therefore should not be used when respiratory protection against hazardous drug exposure is required (USP <800>, section 7.5).
Face protection	☐ Yes ☐ No	*Face shield, full-face respiratory mask*
Gloves	☐ Yes ☐ No	*Types: Latex, nitrile, vinyl* *Descriptors: Regular, chemotherapy gloves meeting ATSM standards, double gloves*
Gown / lab coat	☐ Yes ☐ No	*Designated lab coat, disposable gown, hazardous gown*
Other PPE, please specify:	☐ Yes ☐ No	*Head, hair, shoe, or sleeve covers*

TIP

Consider the precautions described in section 8 of the products' safety data sheets (SDSs), the products' monographs, and any other measures identified in your assessment of risk (e.g., PPE, eye wash station).

While PPE is important, it remains the least effective due to the many ways it can fail (if it is not available, if personnel are not properly trained, non-compliance with procedures, etc.).

D. Risk assessment – rationale

17: Assigned level of risk

Assigning a level of risk to an individual non-sterile preparation can help you determine whether your pharmacy has the appropriate level of requirements (A, B, or C) to compound it (e.g., a "level A compound" in a "level A pharmacy").

If you do not have the appropriate level of requirements but have identified risk mitigation measures you can implement to allow you to compound the preparation safely and accurately, be sure to include this in the rationale for your risk assessment.

18: Determining appropriate level of requirements

After reflecting on and document responses to the questions above, you should be able to determine whether your pharmacy has the appropriate level of requirements to compound the preparation, including the necessary risk mitigation measures.

Use this final portion of the risk assessment to summarize the relevant information gathered to support your rationale and decisions.

TIP

To ensure your rationale addresses whether your level of requirements is appropriate and the precautions in place will manage risk to preparation and risk to person, ask yourself:

Are any of the following required for compounding the preparation?

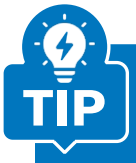
- Specialized equipment or facilities
- Special education or competencies for your compounding personnel
- An uninterrupted workflow
- Additional risk mitigation measures (e.g., extra verification steps, PPE)

If you answer "yes" to any of the above, your rationale should identify whether a higher level of requirements than what you have assigned for your pharmacy is required. If it is not possible to defer to a higher level, your rationale should outline what additional risk mitigation measures you need and the evidence to show that these will be effective.

E. Sign-off

The non-sterile compounding supervisor must ensure that a risk assessment is performed to determine appropriate level of requirements for each compounded preparation.

The risk assessment for each compounded preparation must be reviewed at least every 12 months to ensure that it is still valid, or more frequently if there is a change in practice or standards, as per OCP's Non-Sterile Compounding Assessment Criteria (section 4).



To demonstrate the validity and currency of the risk assessments, the non-sterile compounding supervisor should document their review by dating and signing each risk assessment.

Additional resources

- Non-Sterile Compounding Supervisor Training Course, Module 3: Assessing Risk Levels in Non-Sterile Compounding
- Non-Sterile Compounding Supervisor Training Course: Practice Risk Assessment Scenarios
- Compounding - Non-Sterile Practice Topic

External resources

- Canadian Centre for Occupational Health and Safety Fact Sheets:
  - WHMIS - Hazard Classes and Categories
  - Respirators - Respirators Versus Surgical Masks Versus Non-Medical Masks
  - Emergency Showers and Eyewash Stations
  - Chemical Protective Clothing - Glove Selection