Ontario College of Pharmacists
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# Non-Sterile Compounding Standards and Implementation: Frequently Asked Questions

Commonly asked questions regarding the implementation of the NAPRA Standards for Pharmacy Compounding of Non-Sterile Preparations. For more information, please visit the Non-Sterile Compounding Key Initiative.

*Note: OCP would like to thank the Alberta College of Pharmacists and the New Brunswick College of Pharmacists for allowing us to adapt their Frequently Asked Questions (FAQs).*

## STANDARDS, TIMELINES AND RESOURCES

### Can a pharmacy decide not to prepare compounded medications?

Compounding is within the scope of practice and authorized acts for pharmacy professionals defined in the *Pharmacy Act*, and compounding non-sterile preparations according to recognized guidelines and standards is an entry-to-practice competency for both pharmacists and pharmacy technicians. It is reasonable that the public and other health practitioners expect any pharmacy to provide some compounding services. The requirements for "all levels of compounding" (Section 5 in the NAPRA standards), corresponding to Level A, should be attainable for all pharmacies already engaged in compounding. Moreover, the Code of Ethics expects that "registrants make every reasonable effort to provide quality cost-effective pharmacy care and services to patients and society."

As explained in the standards, "given that pharmacists and pharmacy technicians are expected to maintain competency in basic compounding skills, they are also expected to provide compounded preparations within their level of expertise and within the limitations of available and appropriate facilities and equipment." The Designated Manager/department head must ensure, with the best interest of the patient in mind, that the pharmacy has the resources necessary to compound a preparation in a safe and appropriate manner. When this is not possible, they have an ethical obligation to "assume responsibility for making reasonable efforts to ensure continuity of patient care when they are unable to provide requested pharmacy services." Patient care should not be jeopardized by abrupt cessation of compounding services due to the transition to the new standards.

### How long do I have to meet the new standards at my pharmacy?

Board (Council) approved a three-phased approach for implementation. In recognition of the evolving COVID-19 pandemic situation and the need for pharmacy professionals to focus on continuity of care and minimizing public risk, on March 23, 2020, Board (Council) approved an extension of the deadlines for pharmacies to meet the standards. The updated timelines for completion of each phase are:

- **Phase 1**: January 1, 2020 – Assessing Risks and Gaps
- **Phase 2**: July 1, 2021 – Personnel Training and Quality Assurance
- **Phase 3**: January 1, 2022 – Facilities and Equipment
  Learn more about each phase on the Non-Sterile Compounding Standards and Implementation page of the OCP website.

## What is the difference between the standards and guidance documents?

The standards are now the **minimum requirements** for all registrants involved in non-sterile compounding. Standards establish requirements, using the language of "must." It is mandatory that the people and places involved in non-sterile compounding be compliant with the standards.

The Guidance Document for Pharmacy Compounding of Non-Sterile Preparations was developed by NAPRA as a supplemental resource and provides direction on and assistance with implementing the new standards. The guidance uses the language of "should" and establishes the professionally-accepted means by which pharmacies can achieve compliance with the standards. Pharmacies and pharmacy professionals may choose to meet the required standard using another process than one suggested in the guidance document; this is acceptable as long as the process meets or exceeds the requirements in the standard.

## Can you explain what is required of me and my team during each phase of implementation?

The College has prepared a checklist to provide guidance to pharmacy professionals and pharmacies as they work to implement the requirements but it is not intended to replace the standards. It is the responsibility of the pharmacy professional/pharmacy to review and ensure compliance with the standards.

## How do I prepare a gap analysis/self-assessment? Is there a form or checklist I can use?

The College has produced a Non Sterile Preparations Assessment Criteria document. This document is intended to be used by pharmacy professionals to assess the gaps between current processes/practices at the pharmacy and the requirements of the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations.

The document lays out each standard and the accompanying section in the NAPRA Guidance Document for Pharmacy Compounding of Non-Sterile Preparations to illustrate specific insights or activities required to ensure adherence to the standard. Pharmacy professionals can "check off" each standard as it is met and track their progress at meeting the standards. However, this document is not meant to replace the standards. Pharmacies should not send this document to the College.

## What are the minimum dimensions of a designated compounding area?

There is no minimum size requirement. The compounding area must be large enough for compounding personnel to work comfortably and safely, with room to store equipment and products in an orderly manner in clean and secure surroundings. Also, the area should be designed and arranged to prevent cross-contamination between products, and it should be located away from parts of the pharmacy where there is a considerable amount of traffic (e.g., aisles, entrance and exit).

## Phase 2 of the NAPRA Non-Sterile Compounding Standards implementation involves personnel training and skills assessment. What courses does the College recommend? What if we cannot get all the compounding staff trained by July 1, 2021?

*Refer to Section 5.2, Table 1, Table 2, Checklist 1 and Table 8.4 of the NAPRA Guidance Document for Pharmacy*

*Refer to Section 5.2, Table 1, Table 2, Checklist 1 and Table 8.4 of the NAPRA Guidance Document for Pharmacy Compounding of Non-sterile Preparations.*

In Phase 1, the knowledge and skills of non-sterile compounding personnel should have been assessed for gaps to identify training needs and help plan for the work needed in Phase 2 and, ultimately, to fully achieve the standards by January 1, 2022. Depending on the extent of these gaps, it may be appropriate to put into place an intermediary risk mitigation strategy that addresses safety, while providing continuity of care for patients.

There is no requirement in the NAPRA Model Standards for Pharmacy Compounding of Non-sterile Preparations for personnel to complete a formal, accredited or third-party training program. The pharmacy manager/department head (or designated non-sterile compounding supervisor) may choose to develop their own training tools and program to suit their specific needs. The intended outcome is that the expertise of personnel responsible for compounding must be commensurate with their assigned duties. The potential need for training is not limited to the compounding processes or technique; personnel must also be educated on policies and procedures, such as those related to attire, personal protective equipment, cleaning, and conduct, which must also be developed during Phase 2.

Refer to Table 8.4 of the Guidance Document for an overview of training topics for each Level (A, B or C), as well as the specific sections relevant to the type of personnel or preparation. Fillable and printable forms for Phase 2 activities can be found on the NAPRA website:

- Checklist 1: Skills assessment checklist for compounding process
- Table 1: Elements to cover in training of compounding personnel
- Table 2: Elements to cover in training of cleaning personnel
- Table 3: Examples of policies and procedures

For registrants interested in exploring external courses, OCP provides a listing of CE resources however the listings are not exhaustive, and inclusion of a course is not to be construed as an endorsement.

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## We are planning to renovate our pharmacy space to meet Level B requirements. Do we need to move the sink so it is inside the compounding room?

*Refer to Sections 5.4.1.4, 9.1.1 and 9.2.1 of the NAPRA Guidance Document for Pharmacy Compounding of Non-sterile Preparations.*

It is a standard of accreditation for all pharmacies to have two sinks or one double sink in the dispensary. These standards must be maintained at all times. Accredited pharmacies engaged in non-sterile compounding must also implement the Model Standards for Pharmacy Compounding of Non-Sterile Preparations and the sink requirements outlined in the accompanying guidance document (GD).

A Level B compounding room requires a sink within the room that meets the requirements of Section 5.4.1.4. If there is a C-PEC in the room for compounding hazardous drugs, Section 9.1.1, consideration should also be given to the placement of water sources and drains so that the operation of the C-PEC is not compromised. These are summarized in the Table below.

Any material changes to the existing accredited area require a Notice of Renovation to be submitted to the College, and an Operations Advisor will be assigned to review the floor plan.

| LEVEL | SINK LOCATION | GD SECTION | COMMENTS |
|---|---|---|---|
| A | • In or close to the compounding area | 5.4.1.4 | • If the designated compounding area is in the dispensary, the minimum sink requirement for accreditation may serve to meet both sets of standards.<br>• Consider accessibility (for example, compounding volume and number of personnel compared to the available time and space), ease of use, potential for splashing nearby areas, etc. |

| | | | |
|---|---|---|---|
| B | • In the compounding room | 5.4.1.4 | • If there is a C-PEC, consider Section 9.1.1 and consult supplier regarding proper installation and certification |
| C | • In the compounding room<br>• Water sources and drains should be located at least 1 meter away from the C-PEC. | 5.4.1.4<br>9.11 | • To avoid interfering with required ISO classifications in a Level C room (see footnote 56 for reference to <USP 800>) |
| All levels | • Clean, potable, hot and cold running water for washing hands and equipment<br>• Preferably made of stainless steel and having touchless control | 5.4.1.4 | • Plumbing system should be free of defects that could contribute to contamination |

## How do I determine whether external ventilation is needed for non-sterile compounding?

*Refer to Sections 5.4.1.3, 8.2, 8.3, 9.1, 9.1.1, 9.1.2, 9.1.3 and 9.1.5 of the NAPRA Guidance Document for Pharmacy Compounding of Non-sterile Preparations.*

Ventilation (the "V" in HVAC) is an engineering control intended to remove or control contaminants released in indoor work environments by bringing in fresh air. Fans, while they circulate the air, are not suitable for ventilation as they would blow the contaminant around the work area without effectively controlling it. Opening a window or door might allow outdoor air in, however it is not controllable and risks bringing in other contaminants and disrupting the compounding environment.

The Canadian Centre for Occupational Health and Safety (CCOHS) Fact Sheet on Industrial Ventilation may be helpful for background information on this subject. Compounding personnel should know how the secondary ventilation (HVAC) system operates.

The external ventilation requirements differ between Levels A, B and C (see table below).

| LEVEL | EXTERNAL VENTILATION | GD SECTION |
|---|---|---|
| A | • External ventilation is not required for the designated compounding area<br>• Refer to the requirements for all levels of compounding | • 5.4.1.3 |
| B | • External ventilation is not required for the compounding room; however, this room must be well-ventilated or have a ventilated containment device (C-PEC) | • 8.2<br>• 9.2.1 |
| C | • External ventilation through high-efficiency particulate air (HEPA) filtration is required for compounding and storage of hazardous products, particularly antineoplastic drugs<br>• If this is not possible, the Designated Manager/department head should determine if having redundant HEPA filters in a series would result in adequate protection for personnel | • 9.1.2<br>• 9.2.1 |
| All levels | • The Standards of Operation require pharmacies to be designed, constructed and maintained to ensure the integrity and the safe and appropriate storage of all drugs and medications; including, the proper conditions of sanitation, temperature, light, humidity, ventilation, segregation and security | |

For storage of other hazardous products (e.g., non-antineoplastics, products that carry a reproductive risk, and final dosage forms) external ventilation is recommended but this may not always be possible.

### Do we need two separate designated compounding areas for hazardous and non-hazardous non-sterile preparations?

*Refer to Sections 9.1, 9.1.1, 9.2.1, 9.2.2 and 9.3 of the NAPRA Guidance Document for Pharmacy Compounding of Non-sterile Preparations.*

It is preferable to have separate areas for compounding hazardous and non-hazardous non-sterile preparations, however, if this is impossible and the same area is used, compounding and/or cleaning personnel must, at minimum, be assured that the area and any reusable equipment has been meticulously deactivated, decontaminated and cleaned to prevent any risk of cross-contamination from the hazardous materials before other preparations are compounded.

Because of the difficulty of removing hazardous product contamination, the surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in the non-sterile compounding area should be smooth, impermeable, free from cracks and crevices, and made of non-shedding material. It is strongly recommended that equipment be dedicated for compounding each of hazardous and non-hazardous drugs. Alternatively, disposable equipment should be used, if possible, to reduce the chances of cross-contamination.

The Designated Manager/department head and/or non-sterile compounding supervisor must have policies and procedure in place for the deactivation, decontamination and cleaning required after compounding hazardous non-sterile preparations. As part of the pharmacy's quality assurance program, personnel must be trained and their work routinely assessed to ensure compliance with procedures.

## RISK ASSESSMENT AND MITIGATION

### Can you provide examples of level A, B and C compounds?

As a self-regulated health professional, you are expected to use your knowledge, skills and judgment to perform a risk assessment of each preparation compounded in your pharmacy. Consider all the factors outlined in the standards, utilizing all necessary resources and references, then assign the risk level and document your decision with rationale in the master formulation record. Examples of how a risk assessment may be conducted have been provided by other regulatory bodies in Canada, however, the individual factors in your practice setting may result in a different risk assessment for the same formulation than another practice site. If there is uncertainty regarding the risk level to assign, the compounding supervisor, in collaboration with the manager, may choose to adhere to the higher standard in the interest of safety.

### As part of our risk assessment, should we follow the WHMIS list or the NIOSH list? I don't understand the difference between the two.

*Refer to Sections 4.3 and 8.3 of the NAPRA Guidance Document for Pharmacy Compounding of Non-sterile Preparations.*

The National Institute for Occupational Safety and Health (NIOSH) is an occupational health and safety agency, part of the Centers for Disease Control and Prevention in the U.S. The NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings places hazardous drugs into one of 3 groups based on specific criteria. The actual risk to personnel depends on how the drug is handled and what risk mitigation measures are in place.

In Canada, Workplace Hazardous Materials Information System (WHMIS) is implemented through federal and provincial occupational health and safety legislation. Health Canada administers the *Hazardous Products Act* (HPA) and regulations which establish hazard classifications, cautionary labelling requirements, and the provision of Safety Data Sheets (SDS). WHMIS includes products used in various workplaces — a far wider group of chemicals than NIOSH — that are

WHMIS includes products used in various workplaces — a far wider group of chemicals than NIOSH — that are categorized as either physical or health hazards (See Schedule 2 of the HPA).

The Model Standards for Pharmacy Compounding of Non-sterile Preparations require both references to be consulted in the risk assessment process, such as described in Section 4 of the Guidance Document and illustrated in the Decision Algorithm. Risk assessments for compounded preparations should be available to all compounding personnel.

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## How do I determine if a product is listed as a health hazard under the Hazardous Products Act? How do I use the product safety data sheet (SDS) to determine the hazards identified with that product?

*Refer to Section 4.3, 6.4.3, 8.3 and Glossary of the NAPRA Guidance Document for Pharmacy Compounding of Non-sterile Preparations.*

To determine if an active pharmaceutical ingredient (API) is a health hazard under the *Hazardous Products Act* (HPA), check Section 2 – Hazards Identification of the Safety Data Sheets (SDS): health hazard classes can be identified by a pictogram (see below) which also appear on the API's label.

Section 8 of an SDS includes information on engineering controls and personnel protective equipment that may be helpful in determining appropriate risk mitigation measures when applied in the context of the pharmacy's compounding practice and cumulative risk assessment.

When manufactured drugs (i.e., those with a DIN, approved by Health Canada) are used to compound a preparation, active and inactive ingredients must be considered. In addition to consulting the SDS of the ingredients, the drug's Product Monograph includes information on Storage, Stability and Disposal and Special Handling Instructions to consider. SDS should be available to all compounding personnel.

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## What is a small quantity?

Small quantity depends on the risk assessment for each API which should include an assessment of frequency of compounding with these ingredients. As per the guidance document Section 4.1, some factors to consider in the risk assessment include the:

- 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 preparation;
- quantity of ingredients being handled;
- physical characteristics of ingredients (e.g., liquid vs. solid vs. powders, or water-soluble vs. lipid-soluble);
- education and competency of compounding personnel;
- availability of appropriate facilities and equipment;
- classification of ingredients if identified by WHMIS as presenting a health hazard, or a drug classified by NIOSH as hazardous (see reference to NIOSH in section 4.3);
- type of hazardous drug (e.g., anti-neoplastic, non-antineoplastic, reproductive risk only);
- exposure to compounding personnel for each preparation and accumulation of exposure over time; and

- exposure to compounding personnel for each preparation and accumulation of exposure over time, and
- risk of microbial contamination (liquids, creams, and ointments may be particularly susceptible to microbial and other contamination).

The risk assessment must be reviewed on a continuum to identify and mitigate risk, thereby providing quality assurance.

A decision algorithm to assist in determining requirements for non-sterile compounding can be found in section 4.2.

*Note:* Occasional small quantities of materials must not be considered in isolation. If several different high-risk or low-risk preparations are being compounded, the cumulative risk must be considered even if they are compounded on different days. This must be documented in the risk assessment. Registrants must make available an environment and equipment that ensures the safety of pharmacy personnel when evaluating level of risk. If there is uncertainty as to the level of risk, then the registrant shall defer to the higher standard.

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## What does “mitigating risk” mean exactly, in relation to level B risk compounds?

The table on page 5 of the standards document contains an outline regarding what to look for when seeking to mitigate risk, particularly to compounding personnel. Key points to consider in your decision making are:

- the level of risk the ingredient(s) may present;
- the volume/frequency of that ingredient’s use; and
- the **combined** exposure to all higher risk ingredients.

If there is uncertainty as to the level of risk, then personnel **shall defer to the higher standard.**

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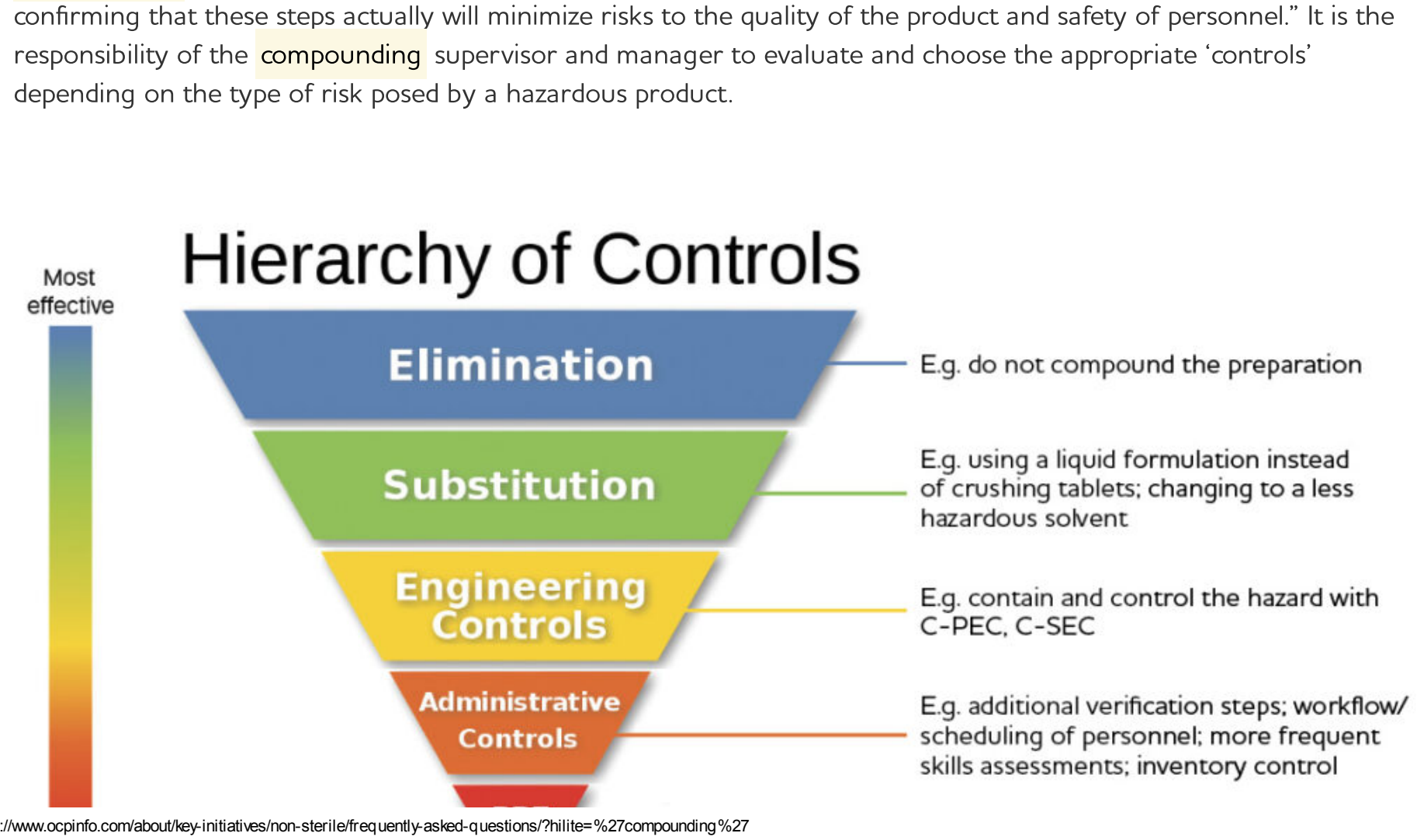
## Section 9 in the NAPRA Guidance Document states that “the compounding of hazardous nonsterile preparations requires safety measures to protect personnel and the environment” and refers to the NIOSH “hierarchy of controls” diagram depicting various levels of controls that can be implemented. Can you explain what this means?

The NIOSH website explains that a hierarchy of controls is “a means of determining how to implement feasible and effective control solutions” to minimize the risk of exposure to occupational hazards. Compounding supervisors should review the descriptions of each level of control. The diagram below (from the November 4th OCP webinar) provides examples of what the various controls might be in the context of pharmacy compounding.

The Guidance Document states that if there are “extra steps that must be taken to mitigate the risks” associated with compounding a particular preparation, these must be documented on the risk assessment along with “references confirming that these steps actually will minimize risks to the quality of the product and safety of personnel.” It is the responsibility of the compounding supervisor and manager to evaluate and choose the appropriate ‘controls’ depending on the type of risk posed by a hazardous product.




Adapted from: https://www.cdc.gov/niosh/topics/hierarchy/default.html

## Helpful Links

NON-STERILE COMPOUNDING STANDARDS AND IMPLEMENTATION

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