College of Midwives of Alberta

IPAC Standards: Routine Practices, Single-Use and Reusable Medical Devices Standards

Standard of Practice 24

Current as of November 10, 2022

Contents

1. Definitions

The following definitions are the terms used in the *Standards*. They are highlighted in bold when they are used.

Additional precautions: measures used when Infection Prevention and Control routine practices alone may not prevent transmission of an infectious agent.t

Aseptic Technique: Practices based on the principle that infection may be introduced into the body from the outside. These practices prevent the introduction of microorganisms into the body and maximize and maintain sepsis (absence of pathogenic organisms).

Biological Indicator (**BI**): A test system containing viable bacterial spores providing a defined resistance to a specified **sterilization** process.

Chemical Indicator (**CI**): A test system that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to the process.

Cleaning: The removal of contamination from an item to render it visually free of soil and quantified as below specified levels of the substance to be measured.

Critical medical device: A **medical device** that enters sterile tissues, including the vascular system.

Decontamination / **decontaminated**: The process of **cleaning**, by use of physical and/or chemical means, to remove, inactivate, or destroy pathogenic micro-organisms, in order to render an object safe for handling.

Disinfectant: Chemical(s) used for **disinfection**, including high-level **disinfectant** (HLD), intermediate-level **disinfectant** (ILD), and low-level **disinfectant** (LLD).

Disinfection / **disinfect** / **disinfected**: The process to inactivate viable micro-organisms to a level previously specified as being appropriate for a defined purpose. (See definitions for high- level **disinfection**, intermediate-level **disinfection**, and low-level **disinfection**).

Drug identification number (**DIN**): A **drug identification number** (**DIN**) is an eight (8) digit numerical code assigned to each drug product marketed under the Food and Drugs Act and Regulations.

Hand hygiene: Hand washing, hand antisepsis or other actions taken to maintain healthy hands and fingernails.

Health care facility or setting: Any facility or setting in which a client receives health services. This includes, but is not limited to: hospitals, midwifery clinics and other community settings, and private

dwellings when health services are provided in the client's home.

High level disinfection: A process capable of killing vegetative bacteria, mycobacteria (including Mycobacterium tuberculosis), fungi, and lipid and nonlipid viruses, as well as some, but not necessarily high numbers of, bacterial spores.

Infection Prevention and Control (IPAC). In General, those practices that are implemented to minimize and eliminate the potential spread of infections in midwifery practice settings.

Intermediate level disinfection: A process capable of killing vegetative bacteria, mycobacteria (including
Mycobacterium tuberculosis), fungi, and lipid and nonlipid viruses. Reference:.

Installation qualification (**IQ**): The process of obtaining and documenting evidence that equipment has been provided and installed according to its specification.

Low level disinfection: A process capable of killing most vegetative bacteria and some fungi, as well as enveloped (lipid) viruses (e.g., influenza, hepatitis B and C, and HIV). **Low level disinfection** does not kill mycobacteria, non-enveloped viruses, or bacterial spores.

Manufacturer's instructions for use (**MIFU**): The validated, written directions provided by the manufacturer or distributor of a **medical device** or product, that contains the necessary information for the safe and effective use of the **medical device** or product.

Note: The term **MIFU** may also be used to refer to written instructions for use developed internally or by a commercial reprocessor, that have been validated by an approved laboratory.

Medical device: Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for a human being for any of the following purposes:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or handicap;
- investigation, replacement, or modification of the anatomy, or of a physiologic process; or
- control of conception,

and that does not achieve its principal intended purpose in or on the human body by pharmacological, immunological, or metabolic means, but that can be assisted in its function by such means.

Note: Under the Medical Devices Regulations, Health Canada licence high-level **disinfectants** and sterilants used in the **reprocessing** of **medical devices** as **medical devices**. However, in the context of these Standards, the term "**medical device**" does not include high-level **disinfectants** and sterilants

Medical device licence (**MDL**): A licence issued to a manufacturer by Health Canada, for a specific **medical device**.

Medical device reprocessing (**MDR**) area: Any area where the **reprocessing** of reusable **critical** and **semi-critical medical devices occurs**.

Non-critical medical device: A **medical device**, which either touches only intact skin but not mucous membranes, or does not touch the **client**.

One-way workflow: The practice of ensuring that **reprocessing** work flows in one direction from the dirtiest to the cleanest.

Operational qualification (**OQ**): The process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

Packaging: (verb) - A step in the **sterilization** process in which a **medical device** is enclosed in materials or a container designed to:

a) allow the penetration and removal of the sterilant during **sterilization**; and
b) protect the **medical device** from contamination and other damage following **sterilization** and until the time of use.

Performance qualification (**PQ**): The process of obtaining and documenting evidence that the equipment, as installed and operated according to operational procedures, consistently performs according to predetermined criteria and thereby yields product meeting its specification.

Personal protective equipment (**PPE**): Equipment or clothing worn by a person for protection from health or safety hazards associated with conditions at a work site.

Point of Care Risk Assessment (**PCRA**): an individual assessment of each client's potential risk of transmission of microorganisms. This must be performed by all health care providers and other staff who come into contact with them. Based on that risk assessment and a risk assessment of the task, one may determine appropriate intervention and interaction strategies (eg. hand hygiene, waste management, use of PPE to reduce the risk of transmission)

Process challenge device (**PCD**): An item providing a defined resistance to a **cleaning**, **disinfection**, or **sterilization** process and used to assess performance of the process.

Reprocessing / **reprocess** / **reprocessed**: The **cleaning**, **disinfection**, and/or **sterilization** of a potentially contaminated **medical device** so that it is safe and effective for use on a client.

Respiratory Hygiene: The recommended method for preventing transmission of respiratory illness. This includes: covering your cough/sneeze with a sleeve or a tissue; disposal of used tissue in the garbage; hand hygiene after coughing/sneezing; and masking if there are symptoms of respiratory illness.

Reusable medical device: A device that has been designed by the manufacturer, through the selection of materials and/or components, to be **reprocessed** and reused.

Routine Practices: The approach to infection control used to minimize or prevent exposure to microorganisms in health care facilities and settings, i.e., blood and body fluid, secretions, and excretions from all clients. Examples od routine practices include hand hygiene, point of care risk assessment, use of personal protective equipment , environmental cleaning, and waste and sharps handling.

Semi-critical medical device: A **medical device** that comes into contact with mucous membranes or non- intact skin, but does not penetrate them.

Single-use medical device: **Critical** and **semi-critical medical devices** labelled by their manufacturers to be used only once. The manufacturer may use terms, including but not limited to the following, to designate a device for single-use only:

- disposable;
- consumable;
- not for re-use or do not re-use;
- discard after single-use;
- do not use twice; or
- a symbol such as: ②

Sterilization / **sterilize** / **sterilized**: The validated process used to render a product free from viable microorganisms.

Validation / **validated**: A confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

2. 24A: Routine Practices

Registered Midwives are expected to ensure and promote effective **Infection Prevention and Control** (**IPAC**). Interventions and activities are implemented to minimize and eliminate the potential spread of infection in midwifery practice settings. New and evolving infectious diseases, new research leading to best practices, and advancing technology are constantly changing the practice of **IPAC**.

Standard 24A sets out the specific CMA requirements all midwifery registrants must adhere to in order to prevent the potential spread of infection between themselves, clients and staff in all practice settings.

1. A midwife must apply appropriate **IPAC** practices when providing care in accordance with applicable CMA *standards*, best practices, and facility requirements and the Public Health Agency of Canada document: *https://www.canada.ca/en/public-health/services/infectious-*

diseases/nosocomial-occupational-infections/routine-practices-additional-precautions-preventing-transmission-infection-healthcare-settings.html when providing care to all clients at all times (to prevent cross-contamination), which includes but are not limited to:

a. Perform **Point of Care Risk Assessment** (**PCRA**) for each client encounter
b. Perform **hand hygiene** correctly:
    i. before contact with a client
    ii. before performing an aseptic technique
    iii. after contact with a client
    iv. after contact with objects in the immediate vicinity of the client
    v. after removing gloves
    vi. after contact with blood, body fluids or a moving from a contaminated body site to a clean body site during client care

c. Use **personal protective equipment** (**PPE**)

d. Practice and engage in proper respiratory hygiene

e. Environmental **cleaning** of client care spaces

f. Use aseptic technique when performing invasive procedures or handling injectable products

g. Assess and implement additional precautions as necessary

h. Follow guidelines for management and **decontamination** of blood borne fluid exposures and needle stick injuries

3. Single-Use and **Reusable Medical Device**s Standards

The College of Midwives of Alberta (CMA) sets out *Standards* for the use of single-use **medical devices** and the **reprocessing** of **reusable medical devices**, for all midwifery care areas, including community birth settings.
These *standards* apply to all midwives when using **single use** and **reusable medical devices**.

These requirements are in addition to the Alberta Health 2019 Reusable and Single Use Medical Devices (RSUMD) Standards adhered to by all AHS contracted settings. This includes all midwifery practices in Alberta.

The Spaulding Classification System

Spaulding, E.H. 1971. The role of chemical **disinfection** in the prevention of nosocomial infections in Proceedings of the International Conference on Nosocomial Infections, 1970. Eds. Brachman, P.S. and Eickoff, T.C. Chicago: American Hospital Association: 254–274.

The Spaulding classification system is used to inform the designation of level of risk of infection from a used instrument and the appropriate level of **reprocessing** required. It divides **medical devices** into three categories based on the potential risk of infection: **critical medical devices**, **semi-critical medical devices**, and **non-critical medical devices**. The Spaulding classification system establishes the minimum level of **reprocessing** needed to ensure **medical devices** are safe for use between clients.

STERILIZATION		**INTERMEDIATE OR LOW LEVEL DISINFECTION**
*Devices below must be cleaned, and then **sterilized***		
Critical medical devices	**Semi-critical medical devices**	**Non-critical medical devices and equipment**
i.e, devices that entire sterile tissues, including the vascular system. Examples of **critical medical devices** include but are not limited to: • surgical **medical devices** • biopsy forceps and brushes	i.e., devices that make contact with intact mucous membrane or non-intact skin. Examples of **semi-critical medical devices** include but are not limited to: • respiratory equipment • vaginal specula • ultrasound transducer probes that come into contact with mucous membrane (e.g., vaginal probes, transesophageal echocardiogram probes) • pessary and diaphragm fitting rings	i.e., devices and equipment that make contact with intact skin or do not make direct contact. Examples of **non-critical medical devices** include but are not limited to: • stethoscopes • blood pressure cuffs

4. 24B: Single Use Medical Devices

1. **Single-use medical devices** shall only be used on a single client for a single procedure and then must be discarded.

2. A **single-use medical device** shall not be used beyond the expiry date specified by the manufacturer.

3. A sterile **single-use medical device** shall be maintained as sterile until point of use.

4. Opened but unused **medical devices** must be discarded.

5. Prior to using a **single-use medical device** that was purchased in an unsterile state, that single-use **medical device** shall be inspected and processed according to the validated **Manufacturer's Instructions for use** (**MIFU**).

6. A **single use medical device** shall be disposed of according to **MIFU** recommendations.

5. 24C: Reusable Medical Devices

Reprocessing of **Reusable Medical Devices**

Environment and Structural Requirements for a **Medical Device Reprocessing** (**MDR**) Area

1. The **MDR** area shall be a designated area, separate from client care areas, and activity in the area shall be restricted when **reprocessing reusable medical devices**.

2. All **MDR** areas shall:
   a. At minimum have spatial separation of clean and dirty areas and a one-way workflow pattern established to prevent cross-contamination. Ideally clean and dirty areas will be physically separated

   b. At minimum have a dedicated sink for **cleaning** equipment and a dedicated basin. A dedicated basin must be large enough to fully submerge the equipment being rinsed

   c. Have **hand hygiene** stations (either **hand hygiene** sinks or alcohol-based hand rub (ABHR) dispensers that have a Health Canada **Drug Information Number** (**DIN**) or a Natural Product Number (NPN) and contain 60% to 90% alcohol) at all entrances to, and

exits from the **MDR** area and readily available within the **MDR** area:

i. Designated **hand hygiene** sinks shall have properly functioning soap dispenser and paper towel dispensers
ii. Designated **hand hygiene** sinks shall be used for **hand hygiene** only.

e. Have work surfaces that can be cleaned:

i. All work surfaces and surrounding areas shall be intact, cut resistant and seamless and be composed on non-porous, non-shedding material capable of withstanding frequent **cleaning**.

f. Restrict access to the **MDR** area during **reprocessing** activities and until the area has been appropriately cleaned

g. Use **one way work flow**

h. Have adequate lighting for the tasks being performed in all work areas; and

i. Use a water source which meets the equipment manufacturers' specifications for water and steam quality

Storage

j. Areas where clean, **disinfected** and sterile **medical devices** are stored shall:

i. Be dedicated to the storage of clean, **disinfected**, or sterile items

ii. Be designed to have adequate space to prevent crushing or damage to **packaging**

iii. Have sufficient lighting to allow easy reading of labels and to determine the condition of **packaging**; and

iv. Be cleaned following an established schedule.

Procurement of **Reusable Medical Devices** and **Reprocessing** Equipment and Supplies

1. The decision to trial or purchase **reusable medical devices**, **reprocessing** equipment and supplies or reusable surgical textiles may include consultation with appropriate MDR and IPAC personnel.

2. Prior to trialing or purchasing a medical device including **medical device reprocessing** equipment, the midwife shall confirm that the device has a valid **medical device licence** (**MDL**) issued under the Government of Canada's *Medical Devices Regulations*.

   Note: The **Medical Devices** Active Licencing Listing (MDALL) contains product-specific information on all **medical devices** that are currently licenced for sale in Canada, or have been licenced in the past. This system has been designed to help health care workers who are contemplating the purchase of a Class II, III, or IV **medical device** to verify that the manufacture has an active **medical device licence**. Since **medical device licence's** can be suspended by Health Canada, cancelled during the annual renewal of licence's by Health Canada, or discontinued by the manufacturer, it is important to conduct this verification each time the purchase of a **medical device** is considered. MDALL can be accessed on Health Canada's website at *https://health-products.canada.ca/mdall-limh/*

   a. The midwife shall not trial or purchase a **reusable medical device** if the device does not have a valid **medical device** licence.

3. **Non-critical medical devices** intended for use between clients shall be purchased with validated **MIFU** for **reprocessing** when available, and when not available, a standard operating procedure for **disinfection** shall be developed in consultation with **IPAC** and **MDR** consultants as needed.

4. Prior to trialing or purchasing a reusable **critical** or **semi-critical medical device**, the midwife shall confirm that there is written confirmation that the **MIFU** for **reprocessing** have been validated according to Health Canada's requirements.
   a. The midwife will not purchase or trial a reusable critical or semi-critical medical device if there I no written confirmation that the MIFU for reprocessing has been validated.

   Note: Additional information about **MIFU** and the requirements Health Canada expects manufacturers to meet with respect to **validation** of **MIFU** can be found in Health Canada's "Guidance Document: Information to Be Provided by Manufacturers for the **Reprocessing** and **Sterilization** of **Reusable Medical Devices**." The document is available on the Health Canada website at *https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-information-manufacturers-sterilization-reusable-medical-devices.html*

5. Prior to trialing or purchasing a reusable **critical** or **semi-critical medical device**, personnel accountable for **MDR** shall review the written, validated **MIFU** to determine:

   a. That the recommended **reprocessing** procedures are specific to the **medical device** and the instructions are clear, complete, adequate, and in accordance with the level of **reprocessing** required for the **medical device**'s intended use

b. That there are instructions for disassembly, **cleaning**, type of **sterilization** or level of **disinfection** required, cycle parameters and maintenance

c. If there is a limit to the number of times the **medical device** can be **reprocessed** or if **reprocessing** will contribute to degradation of the **medical device**; and

d. That the recommended **reprocessing** procedures can be achieved, given the midwifery practice's **reprocessing** resources.

6. In the event that the **MIFU** does not contain the information required the midwife shall contact the manufacturer for clarification or additional information.

   Note: Health care settings that are not able to obtain the relevant information should report this to Health Canada at:
   a. 1-800-267-9675;
   b. mdpr@hc-sc.gc.ca; or
   c. https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/pubs/medeff/guide/2011-devices-materiaux/2011-devices-materiaux-eng.pdf

7. Before purchasing **reprocessing** equipment the midwife shall:

   a. Obtain technical and safety data, specifications and other information specific to the equipment for required utilities and connection (e.g. electrical, steam, water, plumbing, air supply and ventilation; and

   b. Ensure the minimum service space requirements set out by the manufacturer can be met.

General **Reprocessing** Requirements

1. **Reusable medical devices** that have been used shall be reprocessed.

   a. Contaminated **reusable medical devices** that have not undergone **reprocessing** shall be clearly identified.

2. **Reusable medical devices** that come from an opened or compromised package shall be reprocessed prior to use.

3. Newly purchased reusable **critical** and **semi-critical medical devices** shall be reprocessed

before initial use unless they are packaged and sterilized by the manufacturer.

4. **Cleaning** accessories shall be inspected before use to ensure they are not damaged. Damaged **cleaning** accessories shall not be used.

5. Reusable **cleaning** accessories shall be reprocessed after use in accordance with the **MIFU**, inspected for damage, and stored in a clean, dry place.

6. Single-use **cleaning** accessories shall be discarded following use.

Pre-**cleaning** and Transportation of Contaminated **Reusable Medical Devices**

1. Personnel shall pre-clean used **reusable medical devices** immediately after use and prior to transportation to the **reprocessing** area.

    a. At the point of use, single-use sharps shall be removed from **reusable medical devices** and disposed of in a puncture-resistant sharps container

    b. Organic matter shall not be allowed to dry on **reusable medical devices**. **Reusable medical devices** shall be cleaned with an enzymatic cleaner, thoroughly rinsed and dried before transport.

2. Contaminated items shall be transported in fully-enclosed, leak-proof containers that protect **reusable medical devices** from damage, and allow for effective **decontamination** or appropriate disposal after use.

    a. Sterile or clean **reusable medical devices** and soiled **reusable medical devices** shall be kept separated and transported in a manner that prevents cross-contamination

    b. All containers containing contaminated **medical devices** shall be so identified.

3. Contaminated **reusable medical devices** shall be transported to the **MDR** area in such a way so as not to contaminate the surrounding environment.

    a. Contaminated **reusable medical devices** shall follow transportation routes that minimize exposure to high-traffic and client-care areas and avoid areas designated for the storage of clean or sterile **medical devices** and supplies.

Preparation and **Cleaning** of **Reusable Medical Devices**

1. **Cleaning**

    a. Each **medical device** shall be thoroughly cleaned prior to **disinfection** or **sterilization**

    b. **Cleaning** methods shall be consistent with the **medical device**'s **MIFU** and appropriate for the type of **medical device** and the amount of soil to be removed

    c. When manual **cleaning**, the **medical device**'s **MIFU** for **reprocessing** shall be followed, including any specifications for detergent type, water type, or water temperature and **cleaning** methods

    d. Immersible **medical devices** shall be completely submerged during **cleaning** to prevent the generation of aerosols.

2. **Rinsing and Drying**

    a. Chemical residues and loosened soil shall be completely rinsed from the **medical device** prior to **disinfection** or **sterilization**

    b. **Reusable medical devices** shall be dried prior to **disinfection** or **sterilization** with a clean, lint-free, or low-lint soft-absorbent towel

    c. **Medical devices** shall be visually inspected for cleanliness, damage, integrity, and functionality prior to **disinfection**, **sterilization**, or subsequent use

        i. Cleaned **medical devices** that are visibly soiled shall be cleaned again

        ii. **Medical devices** that are damaged or in poor working condition shall be removed from service, labelled, and segregated from usable **medical devices**. Such **medical devices** shall either be repaired or disposed of in accordance with the practice policies.

Disinfection of **Reusable Medical Devices**

1. **Disinfection** of **reusable medical devices** shall follow the **MIFU** for the **disinfection** process, equipment, and products.

2. Only chemical **disinfectants** that have a Health Canada **DIN** or a **MDL** issued by Health Canada,

shall be used in health care settings for the **disinfection** of **reusable medical devices**.

3. A liquid chemical **disinfectant** shall not be used beyond its:

    a. Expiry date; and

    b. In-use life.

4. Reusable liquid chemical **disinfectant** solutions shall be:

    a. Clearly identified and include the expiry date

    b. Stored in containers that are cleaned, **disinfected**, and dried prior to changing the solution; and

    c. Kept covered with a tight-fitting lid, except when introducing or removing a **medical device** to or from the solution.

Non-Critical Medical Devices

Note: In most cases, **non-critical reusable medical devices** can be **disinfected** at the point of use.

1. **Non-critical reusable medical devices** shall be disinfected between client use using an **intermediate-level disinfectant** (**ILD**) or **low-level disinfectant** (**LLD**)

    a. **ILD** or **LLD** wipes shall be moist enough to thoroughly wet the surface for the indicated contact time and a new wipe shall be used if the area to be **disinfected** cannot be completely wetted with a single wipe.

Semi-Critical Medical Devices

1. If a **reusable semi-critical medical device** cannot be **sterilized**, then it shall not be reused and must be disposed of as a single use medical device

Sterilization of **Reusable Medical Devices**

1. A **reusable critical medical device** shall be **sterilized** between client use.

2. **Sterilization** of **reusable medical devices** shall take place in accordance with:

    a. The **MIFU** of the device; and

    b. The **MIFU** for the **sterilization** process, equipment, and products.

Qualification and Requalification

1. **Installation qualification** of **sterilization** equipment (including large chamber and table top steam sterilizers) shall be performed and documented according to the manufacturer's specifications.

2. **Operational qualification** of **sterilization** equipment (including large chamber and table top steam sterilizers) shall be performed at installation.

3. **Operational requalification** shall take place at least annually and following a major sterilizer repair, sterilizer relocation, an unexplained sterility failure, and, for steam sterilizers, following any disruption to steam supply or change to steam pressures.

4. **Operational qualification** and requalification testing shall include a verification of each cycle used by the health care setting, according to the **MIFU** for testing.

5. **Operational qualification** and requalification testing shall be conducted by:

    a. Running three consecutive cycles using a process challenge device (PCD) with biological indicators. For table-top steam sterilizers, testing will take place in a fully loaded chamber.
    b. Additionally, in dynamic air removal sterilizers that use pre-vacuum cycles, ensuring that the sterilizer:
        i. meets the requirements of an air removal test and leak-rate test; and
        ii. is tested with three consecutive air removal tests (e.g., Bowie-Dick) in an otherwise empty sterilizer

6. **Performance qualification** shall be performed to ensure setting-specific packages and loads can be sterilized with the equipment and processes used in the health care setting.

    a. **Performance qualification** shall use products (e.g., instrument sets) and sterilizer loads used by the health care setting. The products and loads shall:

        i. Be assembled according to the sterilizer **MIFU**; and

        ii. Adhere to any limitations of validated **medical devices**, materials, weights.

b. **Performance qualification** shall be performed when there are new materials, processes, or conditions that could affect **sterilization**.

Packages and Labels

1. **Packaging** of **reusable medical devices** for **sterilization** shall take place in accordance with the **MIFU** of the device, the **sterilization** equipment, and the **sterilization packaging** manufacturer, using a validated sterile barrier system (e.g., pouches or wrappers).

2. Packages shall be labelled with sterilizer load identification information, including the load number and the **sterilization** date.

    a. For pouches, a label shall be placed on the transparent portion of the **packaging**

    b. For wrapped packages, writing shall be on the closure tape, not directly on the wrappers

    c. Labelling shall be done with a water resistant, heat resistant, soft-tipped, non-toxic marker which does not bleed through the tape onto the wrapper.

Loading and Unloading

1. Packages shall be placed in the sterilizer chamber in a manner that facilitates air removal, sterilizing agent penetration, sterilant evacuation, and, in the case of steam **sterilization**, drying.

    a. Wrapped items shall not contact the interior walls of the sterilizer chamber, as contact can damage the wrapper

    b. Pouches and wrapped packages shall not be stacked or compressed

    c. Between packages there shall be adequate space to ensure effective sterilizing agent penetration, evacuation, and drying.

2. Sterile packages shall be cooled to room temperature and dry before handling.

3. Before removal from the **MDR** area, packages shall be inspected for:

    a. Package integrity

    b. Dryness

c. Presence of a label

d. The correct change in an external **chemical indicator**

e. An intact seal, if used; and

f. Evidence of potential contamination.

4. If a package does not meet the inspection criteria, the contents shall not be used.

Sterility Assurance

1. **Sterilization** indicators shall be used only for the sterilizer type and **sterilization** cycle for which they were designed and validated and shall be used according to the sterilizer and indicator **MIFUs.**

   a. **Sterilization** indicators shall not be used beyond their expiry date and shall be stored according to the **MIFU.**

2. Routine monitoring shall include assessment of:
   a. physical parameters of each sterilizer cycle (e.g., sterilization time, temperature, pressure,) which shall be verified before the load is released by: checking the sterilizer's displays, and manually recording in a log specifically for that purpose, at intervals during each cycle; or examination of the sterilizer printout or electronic record on completion of each cycle

   b. chemical indicator ;
   Note: If the sterilizer is not equipped with a printer, then a Type 5 chemical indicator must be in each package.

   c. the results of a biological indicator, if present.

3. Documentation of sterility assurance shall include a log as set out in 2a or a printout or electronic cycle parameter record if available, a load contents record, and associated chemical or biological indicator test results for each cycle, if present.

4. In the event of a failed indicator test or any other issue noted upon inspection, the service shall have processes in place to recall and reprocess the affected medical devices.

Chemical Indicators

1. Both internal and external **chemical indicators** shall be included with each package prepared

for **sterilization**.

a. The internal **chemical indicator** shall be placed in the area of the package that is least susceptible to **sterilizing** agent penetration

b. Notwithstanding a, if an internal **chemical indicator** is clearly visible from the outside of a package (e.g., through a plastic wrapper), an external **chemical indicator** is not required.

c. Use a Type 5 chemical indicator in each package.

Air Removal Test (i.e., Bowie-Dick/Dart)

1. For dynamic air removal-type sterilizers (pre-vacuum cycles), an air removal test shall be performed every day the sterilizer is used.

Biological Indicators

1. A **biological indicator** contained within a **process challenge device** (**PCD**) shall be used to test the sterilizer for each type of cycle used and at the shortest exposure time, within a full load. This test shall be done at least daily when the sterilizer is in use.

   Note: A **PCD** should present a challenge to the process that is equal to or greater than the challenge posed by the most difficult item that is routinely sterilized. A biological test pack is an example of a **PCD**. A **PCD** can be commercially manufactured or prepared in-house.

2. If a steam sterilizer will be used for multiple types of cycles, each type of cycle used shall be tested daily when being used.

3. At the conclusion of a **sterilization** cycle and before the load is removed, the operator shall confirm that the required parameters and all phases of the **sterilization** cycle including aeration (if required) have been met.

Storage

1. Reprocessed critical and **semi-critical medical devices** shall be protected from contamination by:

   a. Rotating stock via first-in, first-out

   b. Keeping items clean, dry, and protected

   c. Keeping items well-separated from soiled items and soiled areas via barriers and/or

distance.

d. Transport items in a manner that maintains their cleanliness/sterility

e. Ensuring they are not stored on the floor or a window sill, under sinks or near water sources, in open corridors or client rooms, or in the same area as hazardous materials.

Education and Training

1. The practice lead or person responsible for **MDR** in the midwifery practice shall ensure all personnel involved in the **reprocessing** of **critical** and **semi-critical medical devices** are appropriately educated and trained for the **reprocessing** duties/tasks that they perform.

    a. Persons who reprocess critical and **semi-critical medical devices** may be **medical device reprocessing** technicians from CMA approved programs or persons who have received training in **medical device reprocessing** at a level approved by the College of Midwives of Alberta (CMA)

    b. Personnel who reprocess critical and **semi-critical medical devices**, but are not **medical device reprocessing** technicians from approved courses, shall receive training in a formal **medical device reprocessing** training program recognized by the CMA, or comprehensive in-house training, and shall successfully complete competency testing.

        i. Comprehensive in-house training shall, at a minimum, set out principles that align with these *Standards*

        ii. Personnel who have not been fully trained and/or competency tested shall not reprocess critical and s**emi- critical medical devices** unless under the **direct supervision** of fully trained and/or competency tested personnel.

    c. The practice lead or person responsible for **MDR** within the midwifery practice shall maintain records of education, training, orientation, and competency assessment for new and existing personnel, as appropriate for the **MDR** duties/tasks performed according to requirements set out by the CMA.

Quality Management Systems

1. The midwifery practice shall have clear accountability and lines of responsibility for:

    a. All routine practices

    b. All aspects of **MDR, including how third 3rd party contractors process their devices**;

and

c. The appropriate use of **single-use medical devices**.

2. The midwifery practice shall have written policies and these Standards of Practice on-site and available to personnel for all aspects of **MDR**.

    a. The midwifery practice's **medical device reprocessing** policies shall include but not be limited to:

        i. All steps in the **reprocessing** of reusable **medical devices**, based on **MIFU**

        ii. The installation, operational, and **performance qualification** and requalification requirements of **reprocessing** equipment and products, based on **MIFU**

        iii. Regular inspection and preventative maintenance requirements for **reusable medical devices** and equipment, based on **MIFU**

        iv. Actions to be taken following a failed sterility indicator or unexplained parameter change, based on **MIFU**

        v. Recall procedures.

3. The midwifery practice shall have a written policy regarding **single-use medical devices** that is consistent with these *standards* available to all users.

4. The midwifery practice shall have policies in place that include but are not limited to:

    a. Required occupational health and safety activities with use of appropriate **PPE** when performing **MDR,** and when using single use medical devices

    b. **IPAC** routine practices

    c. Transportation and distribution of single use and reusable devices and products

    d. Regular monitoring and review of **MDR** logs and processes by a designated person other than the person performing the **MDR**

    e. Storage of items, including environmental conditions and requirements related to identification and labeling, to maintain sterility of packages and sterile medical devices over time and until point of use, based on MIFU

    f. The practices and procedures required to maintain sterility.

5. The midwifery practice shall conduct a regularly scheduled review of all written policies and revise when necessary.

6. The midwifery practice shall have a process for assessing risk when a breach or lack of compliance with these *standards* occurs and shall report as appropriate.

Documentation

1. The midwifery practice shall retain records of **reprocessing** for a period of 5 years. These records shall include, but not be limited to, the following:

    a. Preventative maintenance of **medical devices reprocessing** equipment

    b. Results of installation, operational, **performance qualification** and requalification, and routine testing of **reprocessing** equipment and products.

2. The **MIFU** for **medical devices**, equipment, and supplies shall be received and maintained in printed form (e.g., in binders, manuals, or monographs) or in electronic format and be readily accessible to those needing access and shall be updated as required.