Standard Operating Procedure

Contingency Plans for Large Scale Inventory Loss (i.e. Excessive Humidity in Sterile Storage Room)

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OBJECTIVES

- Identify a strategy for managing inventory problems as a result of climate-control failure (temperature & humidity) or water leaks in storage or work areas.
- Identify a strategy to minimize impact to MDR customers including the OR, internal and external units, and departments.
- Identify key contacts and staff responsibilities in the context of restoring and maintaining daily operations.
- Identify a back-up plan to cover temporary inventory shortages.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staff, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary) working within Medical Device Reprocessing.

ELEMENTS

1. Temperature and humidity Issues
   1.1 If temperature or humidity levels fall outside CSA recommended parameters, the MDR Manager or designate will take action to prevent contamination of inventory (adapted from Z314.3-09)

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Alberta Health Services
Infection Prevention & Control

A. Sterile Storage Temperature should be maintained between 18° C and 23 °C. Relative humidity shall be maintained between 30% and 60%.	
Action 1: At 60% humidity and/or 23°C temperature immediately initiate corrective action	• Notify Facilities Maintenance and Engineering (FM&E) of excess humidity and/or temperature reading in affected areas and request corrective action; and • Notify status of event to next level management [Operating Room (OR) Manager, Site Administrator, Infection Prevention & Control (IP&C) and Director] and determine if transfer of packages to an alternative site with controlled humidity and/or temperature is feasible. Keep as little inventory as possible in affected storage areas.
Action 2: At a range of 61% to 69% relative humidity and/or temperature higher than 23°C	• Check packages for moisture or damage (e.g., labels peeling due to moisture or visible moisture on package), the packaged items will not be used. The contents need to be repackaged and sterilized or discarded if single-use medical devices.
Action 3: If greater than 70% relative humidity and/or higher than 23°C is detected	• Check packages for moisture. If not visibly wet or damaged, the packages can be used; and • If the next humidity reading 24 hours later is still greater than 70%, the site needs to perform a risk assessment to determine which items can be used, reprocessed or discarded. Consideration should be given to the following: o Storage environment – to reduce the risk to accidental contamination, it is critical that packaged items be sorted in a limited access area, where storage shelves are clean and environment is maintained as specified by CSA standards. A proper storage environment requires personnel to wear appropriate attire and to practice frequent hand hygiene. When relative humidity levels exceed 70% having a controlled storage environment helps reduce the risk of contamination. o Packaging – Some packaging materials are better able to withstand the effects of high humidity than others. Generally, packages that have plastic covers or are sealed in aluminum foil pouches are relatively impermeable to moisture, whereas the plastic-paper pouches and uncoated textile wraps are permeable to moisture. o Duration of exposure to high humidity – Longer exposure of the package to excess humidity usually leads to a higher risk of contamination. Routine/continuous monitoring is important for evaluating the duration of exposure to high humidity.

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B. Decontamination Temperature should be maintained between 18°C and 20°C for soiled areas and 18° C and 23°C for clean areas. Relative humidity shall be maintained between 30% and 60% and preferable in the range of 40% to 50%. *Note: Sterile items should never be stored in Decontamination.*	
Action 1: At 50% relative humidity and/or a temperature at 20°C	• Immediately initiate corrective action by notifying FM&E of excess humidity and/or temperature reading in affected areas and request corrective action.
Action 2: If greater than 60%relative humidity and/or a temperature greater than 20°C	• Consult with staff to determine comfort levels and ensure safe work conditions.
Action 3: If next humidity reading 24 hours later is still higher than 60% relative humidity and/or a temperature higher than 23°C	• Perform a risk assessment to determine safe work conditions for staff.

1.2 Provide updates of the event to the next level of management (OR Manager, Site Administrator, IP&C and Director) affected units and departments and MDR staff as required.

1.3 Provide direction and assistance to MDR staff.

1.4 Communicate with all affected units and departments to determine potential impact to booked and emergency cases.

1.5 Coordinate the reprocessing of all suspect or visually contaminated supplies, packages, sets & trays.

1.6 Determine the need for additional staff and supplies and follow-up as required:

a) Contact Contracting, Procurement & Supply Management (CPSM) and vendors to facilitate assistance with required supplies;

b) Evaluate staffing needs and schedule additional staff as required;

c) Consult with other sites to assist with production support and loaner instruments as required.

1.7 Complete all required documentation:

a) Reporting and Leaning System (RLS) online report

(i) Date and time of disruption (from time of notification to resolution)

(ii) Steps taken to resolve the issue(s).

(iii) Cause of disruption, for example, system error, user error

(iv) Impact to affected units and departments

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b) Provide a post-action report to next level management and appropriate stakeholders including an incident summary and a response assessment.

2. Water leaks

2.1 When concerns of water leakage are recognized, the MDR Manager or designate will:

a) Contact FM&E to report any concerns with water leakage which has or may potentially contaminate MDR inventory and supplies.

b) Provide updates of the event to the next level of management (Operating Room Manager, Site Administrator, IP&C and Director) affected units and departments and MDR staff as required.

c) Provide direction and assistance to MDR staff.

d) Communicate with all affected units and departments to determine potential impact to booked and emergency cases.

e) Coordinate the reprocessing of all suspect or visually contaminated supplies, packages, sets & trays.

f) Determine the need for additional staff and supplies and follow-up as required:

(i) Contact CPSM and vendors to facilitate assistance with required supplies.
(ii) Evaluate staffing needs and schedule additional staff as required.
(iii) Consult with other sites to assist with production support and loaner instruments as required.
(iv) Complete all required documentation in the Reporting and Leaning System (RLS) online report
- Date and time of disruption (from time of notification to resolution)
- Steps taken to resolve the issue(s)Cause of disruption, for example, system error, user error
- Impact to affected units and departments.

(v) Provide a post-action report to next level management and appropriate stakeholders including an incident summary and a response assessment.

DEFINITIONS

None

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REFERENCES

- Alberta Health Services governance documents
  - *Critical and Semi-Critical Single-Use Medical Devices* AHS Policy (#PS-07-2012)

- Non-Alberta Health Services documents
  - *Canadian Medical Device Reprocessing. (Canadian Standards Association)* (CAN/CSA Z314-18)

VERSION HISTORY

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