Failed Sterilizer Load Assessment and Management Process

Rationale:

Initiation of a recall may indicate a potential or real risk to patient safety, regadless of whether all items are recovered. Infection Control Professionals (ICP) can use this assessment tool as a guide to respond to a report of a sterilization load failure. Each event must be reviewed and assessed individually to determine the potential degree of risk to patients.

A sterilization load failure may be indentified in a number of ways, which may include:

1. Mechanical failure of the sterilizer such as inadequate temperature, exposure time, and steam pressure.
2. Chemical Indicator tape did not change color
3. Incubated BI is positive
4. Internal chemical indicator did not change, that is, showed inadequate processing
5. Packs found to be wet, after adequate drying time.
6. Instruments are damaged, stained, burnt, or still contaminated with debris
7. Equipment Failure

In the event of a failed sterilization load, it is necessary for MDRD to initiate a Recall Procedure as per internal protocol. All items in the failed load should be recalled and quarantined. If items have been used on patients , all patients should be identified, if possible. If the recall is the result of a positive BI, more than one load may be involved in the recall if only one BI is done each day.

Any area performing reprocessing activities must maintain and implement policies and procedures for each sterilization method and maintain documentation for each incident where one or more sterilization parameters are not met.

Definitions:

MDR: Any department or area that is responsible for decontaminating and sterilizing medical devices used for patient care activities.

Recall: The process of gathering medical devices sterilized in a load that had a failure of one or more sterilizing parameters. If devices were distributed to user area(s) a recall notice is distributed. The recall notice shall include information regarding the sterilizer method, sterilizer identification, date of sterilization, sterilization load number and contents, user area(s) that received devices and documentation of success of recovery.

User area: Any patient care or clinical area that receives medical devices from a sterilizer load.

Failed Sterilizer Load Recall Process Map

- **MDR department** initiates a recall as per internal protocol.
- **MDR department** completes the *Failed Sterilizer Load Recall Worksheet* and uses the *Recall Risk Assessment Matrix and Response* to assign the appropriate Recall Risk
- **MDR department** notifies IPC of the recall and provides a copy of the completed *Failed Sterilizer Load Recall Worksheet.*

- **MDR department** attempts to recover medical devices reprocessed in the recalled sterilizer load from the **user area**.

  Note: If the sterilization failure was a positive BI, **MDR department** will attempt to recover all medical devices processed in that sterilizer since the last negative BI.

- **IPC and MDR departments** follow the actions outlined in the *Sterilizer Load Recall: Risk Assessment Matrix and Response* for the level of risk identified

Failed Sterilizer Load Recall Worksheet

Sterilization Method:_____ **Sterilizer Identification:** _____

Date and Load Number of Each Failed Load: _____

1. Sterilization parameter not met (check all that apply):

A) ☐ Positive biological indicator _____ (specify daily or load specific)

B) ☐ Biological indicator read or processed improperly (e.g. read too soon, improper incubation)

C) ☐ Internal chemical indicator or integrator failed

D) ☐ External chemical indicator did not change

E) ☐ Mechanical parameters were not met (Check all that apply)

- ☐ Time — Time load was in sterilization phase: _____
  Required sterilization time: _____
- ☐ Temperature — Temperature recorded: _____
  Required temperature: _____
- ☐ Pressure — Actual Pressure_____
  Required Pressure_____
- ☐ Load processed in a sterilizer designated 'out of service'
- ☐ Other mechanical failure (specify): _____

2. Other indications of a failed sterilizer load:

A) ☐ Wet load after adequate drying time

B) ☐ Printout missing

C) ☐ Load records do not match sterilizer printout

D) ☐ Load contents distributed without exposure to sterilization

E) ☐ Biological indicator not included in load containing implant

F) ☐ item not decontaminated adequately, debris found _____

G) ☐ Other (specify): _____

Assigned Risk: (see *Sterilizer Load Recall Risk Assessment and Response)*

☐ Low Risk

☐ High Risk

Name of Individual completing form	**Signature**	**Date**

Distribution: IPC, MDR, User Area(s)

Failed Sterilizer Load Recall Risk Assessment Matrix and Response

Recall Risk Matrix

LOW Risk	**HIGH** Risk
▪ Only one of the following is checked: 1A, 1B, 1E***,** 2A, 2B, 2C, 2E, 2F* *(Confirm that all remaining parameters have been met)*	▪ One of the following is checked: 1C, 1D, 1E*****, 2D, 2F* ▪ Two or more 'Low Risk' items are checked

***Item 1E and 2F** must be assessed on a case by case basis to determine if they fall into the low or high risk category.
When assessing mechanical parameter failures, minor variations from time or temperature parameters may occur within 'safety limits' built into the sterilization process. Detailed information must be reviewed with MDR and IPC.

Risk Response

LOW Risk	**MDR:** • Follow internal policy for recall events. • If failure was due to human error or non-compliance: o Generate a Reporting and Learning System (RLS) Report o Perform a process review. IPC, Engineering and Maintenance or end user area may be asked to participate in review as appropriate. • Notify the Safety Alerts Clinical Engineering and Coordinator for Support Services if review indicates potential for repeat event due mechanical failure. • Notify the Surgical Quality Assurance Committee if review indicates a major system or process gap. **IPC Professional:** • Consult with IPC Clinical Practice Coordinator, Director or IPC Physician/MOH to determine if case requires any further action. • Keep a copy of relevant recall forms from reprocessing department for files • Keep a copy of the *Failed Sterilizer Load Recall Worksheet* for files

HIGH Risk	**MDR Department:** **Immediately notify IPC of a high risk recall** • Follow internal policy for recall events. • Generate an RLS Report • Perform a process review. IPC, Engineering and Maintenance or end user area may be asked to participate in review as appropriate. • Notify the Safety Alerts Clinical Engineering and Coordinator for Support Services if review indicates potential for repeat event due mechanical failure. • Notify the Surgical Quality Assurance Committee if review indicates a major system or process gap **IPC Professional:** • Notify zone IPC Director of failure • In collaboration with MDR, determine what medical devices were not recovered in the recall • In collaboration with MDR, notify user areas and attempt to identify patients exposed to medical devices involved in the recall • Consult zone IPC Director, Clinical Practice Coordinator and IPC Physician/MOH to determine follow-up actions • Conduct a process review with MDR. Engineering and Maintenance or end user area may be asked to participate in the review as appropriate. • Keep a copy of relevant recall forms from the reprocessing department for files • Keep a copy of *Failure of Sterilizer Load Recall Worksheet* for files **IPC Director:** • Notify additional groups as necessary. This may include: o Site administration o Manager(s) of area(s) involved • In collaboration with MDR management, determine whether "Urgent Notification to Emerging Issue" is required and if so, who will initiate **IPC Physician/MOH:** • Direct actions and follow-up of affected patients in consultation with attending physician(s). o This **must** include disclosure of the event to the patient or guardian as per current organizational disclosure policy. o This **may** also include: ▪ Prophylactic antimicrobial treatment ▪ Serology testing with short- or long-term follow-up ▪ Enhanced infection surveillance