Standard Operating Procedure

Customer Concerns

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OBJECTIVES

- Outline steps required for addressing customer concerns regarding medical device reprocessing.
- Provide a feedback to the customer to ensure concern is addressed.
- Identify roles and responsibilities of MDR staff when addressing customer concerns.

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, Operating Rooms and Clinical Areas.

ELEMENTS

1. To address customer concerns there shall be processes to allow end users and/or patients to obtain resolution of the concern regarding reprocessed critical and semi-critical medical devices.
   - 1.1 Internal processes for end users shall be established as per site protocols using:
     - a) An internal written communication tool or form that identifies the concern, date, contact person, person with concern, action and report back to end user.
     - b) The Reporting and Learning System (RLS) for consistent reporting practices by end users, to allow for system tracking and identification of ongoing issues and subsequent resolution. RLS can be accessed through Alberta Health Services Insite page.
   - 1.2 Investigation and follow-up of customer concerns
     - a) MDR management will respond to customer concerns and give direction accordingly.
     - b) Concerns will be investigated with appropriate action taken to resolve all issues.
     - c) Customer concerns shall be monitored and documented as per site procedure.

DEFINITIONS

Customer: the intended user/recipient of a reprocessed critical and semi-critical medical device. The customer can be a clinical end user (e.g. internal to the organization - Operating Room staff, Endo unit staff, sterile processing staff, nursing unit). The customer can be a patient/resident/client (external to the organization) on whom the reprocessed critical and semi-critical medical device has been used for a procedure.

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Alberta Health Services
Infection Prevention & Control

REFERENCES

- Non-Alberta Health Services documents
  - *Canadian Medical Device Reprocessing*. (Canadian Standards Association) (CAN/CSA-Z314-18)
  - *Reprocessing of Reusable Medical Devices*. 2019. Accreditation Canada (AC), Qmentum Program
  - The ORNAC Standards, Guidelines, and Position Statements for Perioperative Registered Nurses. 2017. Clause 4.20.5

VERSION HISTORY

Date	Action taken
November 2018	Initial approval
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