Inspection and Identification of Damaged/Defective Devices

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OBJECTIVES

Ensure that medical devices are safe for patient use

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 and Operating Rooms.

Note: Site specific procedures shall be developed and followed based on the specific equipment that is used.

ELEMENTS

1. Inspection identification & disposal of damaged/defective devices
   - 1.1 All devices should be complete, carefully function tested, and inspected for wear and damage according to manufacturer's instructions for use (MIFU).
   - 1.2 Damaged devices or devices in poor working condition shall be removed from service, labelled, and segregated from usable devices.
     - a) Use a unique identifier to ensure the item does not return to service before it has been repaired or refurbished.
     - b) The label shall indicate the device is out of service; state the problem; and the action to be taken.
     - c) Specific areas of wear or damage should be identified and the fault location indicated.
   - 1.3 Contaminated medical devices that are to be transported for repair shall be carefully prepared for transportation according to the MIFU, the healthcare facilities' protocols, and provincial and federal guidelines for the transport of dangerous goods as applicable.
     - a) Procedures shall take into account the manufacturer's and/or repair service's recommendations for the conditions of transport, including temperature and humidity conditions, handling requirements, and restrictions (e.g., agitation, bumps, and other movement).
     - b) Documentation supplied with each device to be transported for repair shall clearly state if it has been cleaned prior to transportation.

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1.4 Documentation of the repair service performed must be obtained and record maintained as per AHS policy.

1.5 Following repair the device should be visually inspected and function tested according to the MIFU and reprocessed prior to being placed back into service.

1.6 Non-repairable devices should be disposed of according to MIFU and site-based practice.

DEFINITIONS

None

REFERENCES

- Non-Alberta Health Services documents
  - Canadian Standards Association. (2018). *Canadian medical device reprocessing* (CAN/CSA Z314-18).

VERSION HISTORY

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