WORKING WITH CONTAMINATED OR SUSPECTED CONTAMINATED MEDICAL DEVICES – BIOMEDICAL ENGINEERING

1. Introduction

1.1 Purpose

Employees of the Lower Mainland Biomedical Engineering Department may need to work on known contaminated medical devices as well as devices that they suspect are contaminated. It is the expectation that all devices arriving in a Biomedical Engineering Department have been properly cleaned and disinfected beforehand but in some instances this may not be the case. There may have been a lapse in best practices for disinfecting equipment by clinical/nonclinical staff or the device may have been involved in a critical incident and it can't be cleaned and disinfected before an investigation is completed. This policy outlines the best practices to be used when handling a medical device that is known to be contaminated as well as one that a Biomedical Engineering Technologist suspects is contaminated.

1.2 Scope

This is a joint policy between the Fraser Health Authority (FHA), Providence Health Care (PHC), Provincial Health Services Authority (PHSA) and Vancouver Coastal Health (VCH). This policy covers:

- All employees of the Lower Mainland Biomedical Engineering Department as well as all students, vendors or anyone else working under the direction of a Biomedical Engineering Department employee.
- Any device sent by hospital staff to a Biomedical Engineering Department.
- Any medical devices that Biomedical Engineering Technologists remove from a clinical area during a repair/inspection/installation.
- Principles for working with contaminated or suspected contaminated devices which fall under all three (3) Spaulding classifications: critical, semi-critical and non-critical.

1.3 Exceptions

This policy is in effect at all times at all sites. If there are any questions about what should be done when dealing with a contaminated device or a device that a Biomedical Engineering Technologist suspects is contaminated, seek direction from the site's Infection Prevention And Control Department. Medical device/equipment reprocessing is not covered by this policy.

2. Policy

2.1 Principles

Working with Contaminated Or Suspected Contaminated Medical Devices Policy # ABCD-14-11-40004

The Lower Mainland Biomedical Engineering Department will adhere to the following principles when working with known contaminated devices and devices a Biomedical Engineering Technologist suspects are contaminated.

- All Biomedical Engineering Technologists must be provided with training for hand hygiene and appropriate Personal Protective Equipment (PPE) usage.
- Hands must be cleaned before and after working with medical devices.
- Appropriate Personal Protective Equipment (PPE) must be worn when cleaning and disinfecting devices.
- Appropriate cleaning and disinfecting products must be used.
- If a site's Infection Prevention And Control Department has determined that a patient has a rare or emerging high consequences pathogen, i.e. Ebola, the following protocol must be followed:
    - "Recommendations for Cleaning and Decontaminating Medical Equipment used with Persons under Investigation or Confirmed of Having a Rare or Emerging High Consequences Pathogen" – Available within the Learning Hub course
- If a medical device has been involved in a spill incident, the site's Code Brown procedure must be followed.
    - If an employee has been exposed to a hazardous substance, they must seek immediate medical attention.
- All contaminated devices must be cleaned and disinfected before they are moved from one location to another.

  If a Biomedical Engineering Technologist is removing a medical device from a clinical area, they are responsible for ensuring that the device is cleaned/disinfected before it leaves the area. The Technologist can choose to clean/disinfect the medical device themselves or they can ask the clinical area staff to clean/disinfect the device.
- If a device must be moved while it is contaminated, efforts to reduce the cross-contamination risk must be taken by following the guidance from the site's Infection Prevention and Control Department.
- It is an expectation that all devices arrive clean/disinfected in a Biomedical Engineering Department. A Biomedical Engineering Technologist may choose to do an additional cleaning/disinfecting before working on a device.
- If a medical device arrives that is visibly contaminated or the Biomedical Engineering Technologist suspects the device is contaminated, they can send the device back to the clinical area for cleaning/disinfecting or they can choose to do it themselves while following the instructions stated in Section 4.4 of the Contaminated Device Standard Operating Procedure.
- Each Biomedical Engineering Department should have a designated area or room in which to work on contaminated equipment. If they do not, they must follow the appropriate procedures for establishing a "dirty area" as stated in section 4.4 of the Contaminated Device Standard Operating Procedure.

- All sharps and disposable items must be removed from the contaminated devices and disposed of in the correct container/bin.
- All devices must be cleaned and disinfected before being shipped to a vendor.
    - If a device must be returned to the vendor in a contaminated state (e.g. endoscope with leak) the vendor's and the site's contaminated device return procedures must be followed.
- The Biomedical Engineering Technologist will follow their site's protocols when returning medical devices to a clinical area or to the Medical Device Reprocessing Department (MDRD).

3. Procedure

For the Procedure and Steps follow SOP #ABCD-14-16-40007.

4. Compliance

All staff members are responsible for adhering to this policy and monitoring their activities in accordance with the policy. All staff members are responsible for reporting unsafe situations to their Supervisor or Manager.

5. Supporting Documents

5.1 Guidelines/Procedures/Forms

- SOP# ABCD-14-16-40007: Working with Contaminated or Suspected Contaminated Medical Devices – Biomedical Engineering

6. Definitions

Acronym or Word	Definition
Spaulding's Classification of Medical Devices	The Spaulding classification, originally proposed in 1957, is a widely used system for matching the disinfection and sterilization of surfaces, particularly those of re-usable medical/surgical devices, with available processes.
Critical device	Device that enters sterile tissues, including the vascular system – i.e. MIS scope
Semi-critical device	Device that comes in contact with non-intact skin or mucous membranes but does not penetrate them – i.e. endoscope
Non-critical device	Device that touches only intact skin and not mucous membranes or does not directly touch the patient – i.e. ECG monitor

7. References

- Lower Mainland Health Authority guidance documents for cleaning/disinfecting devices:
  - FHA: Cleaning and Disinfecting Medical Equipment Resources
  - PHSA: BCCW Master Equipment Cleaning Guide
  - PHC & VCH: VCH Master Equipment Cleaning & Disinfecting Manual

- Lower Mainland Health Authority Infection Prevention And Control (IPAC) websites:
  - FHA IPAC
  - PHC IPAC
  - PHSA BC Children's & Women's IPAC
  - VCH IPAC
- "Recommendations for Cleaning and Decontaminating Medical Equipment used with Persons under Investigation or Confirmed of Having a Rare or Emerging High Consequences Pathogen" – Available within the Learning Hub course

- LMBME SOP# ABCD-14-16-40007

- LMBME SOP #012 Decommissioning of Medical Devices SOP

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