









Decommissioning of Medical Devices: Biomedical Engineering

SOP # ABCD-14-16-40003

DECOMMISSIONING OF MEDICAL DEVICES

1. Purpose

To outline the steps for the decommissioning of medical devices across the four Lower Mainland 1.1.1 Health Authorities. A hierarchy of decommissioning steps is developed to ensure that all equipment is efficiently but responsibly transferred or disposed of. This policy also aims to provide a standardized, consistent and organized decommissioning procedure that can be followed across all LMBME.

2. Definitions

Acronym or Word	Definition		
Capital Asset	Equipment with an estimated cost that exceeds of \$5 000 and a useful life expectancy of more than one year Minor capital: >\$5,000 Major Capital: >\$100,000		
CMMS	Computerized Maintenance Management System – database for the management of medical assets within LMC		
Decommission	Withdraw medical equipment or applications from service. The equipment is then transferred or disposed of.		
Disposal	Trade-in, sale, donation or retirement (storage, dismantling for parts, make inoperable or discarding) of equipment		
Minor Equipment	Equipment with an estimated cost of less than \$5,000		
P3 (PPP)	Public-private partnership — a contractual agreement between a public sector entity and a private sector entity that outlines the provision of assets and the delivery of services		
Transfer	Permanent move of equipment to another department, site or health authority		

3. Scope

3.1 Included:

This policy covers the decommissioning of medical devices by Biomedical Engineering. Only medical devices that have already been clinically approved for decommissioning are considered.

3.2 Excluded:

- Any medical equipment not included in the CMMS (refer to BCBME SOP # P-14-16-40003 CMMS - What Constitutes an Asset?)
- Land and buildings
- Office furniture

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- Corporate Information Technology equipment (e.g. computers, monitors, printers, etc.)
- P3 facilities and equipment

4. Procedure

4.1 Confidential Information

- ***Prior to decommissioning, it must be ensured that any confidential information that may be contained within the equipment, whether physical or electronic, is destroyed***
- Electronic storage devices must be re-formatted or rendered unreadable using an appropriate mechanical, physical or electronic process (refer to LMC's Records Management Processes and Standards for Community Health Policy (page 43)). Improper or incomplete removal of stored confidential information may lead to information breaches and disclosure of sensitive patient information. Also review policy: ABCD-14-11-40001 - Medical Devices and Personal Information Security Policy

4.2 **Approval Process**

Based on the method of decommission, different levels of approval are required. (Refer to Figure 1: Approval Process Flow). Note: At this present time this document is only for (FHA, VCH, and PHSA). PHC is working with the clinical and executive leads to develop their internal process (TBD). If you are within PHC, please discuss with your supervisor, manager or director to determine which parts of this document you need to follow.

If an asset is sold, donated or transferred to another health authority, a Release and Waiver of Liability Form must be completed as well. See Reference links below.

4.2.1 Departmental

- Equipment transfers within the local health authority need only be approved by the head of the transferring department.
- Equipment disposals or transfers to other health authorities within LMC require the approval of the head of the transferring department, as well as the signature of the respective Director of Biomedical Engineering.

4.2.2 Capital Accounting

The retiring book value of the equipment being transferred or disposed of determines whether Capital Accounting needs to be notified.

a) Minor Equipment (<\$5,000)

Capital Accounting does not need to be notified for minor equipment.

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b) Capital Equipment (≥\$5,000)

When transferring or disposing of a capital asset, notify Capital Accounting by completing and sending an Asset Transfer/Disposal Request Form.

4.2.3 **Original Donor**

If the asset was originally funded by a donor, such as a Foundation, Auxiliary, Regional Hospital District or private individual, the donor's approval may be required (e.g. if the asset has not yet reached the end of its useful life). Refer to your facility's policy on the disposal of equipment funded by donors.

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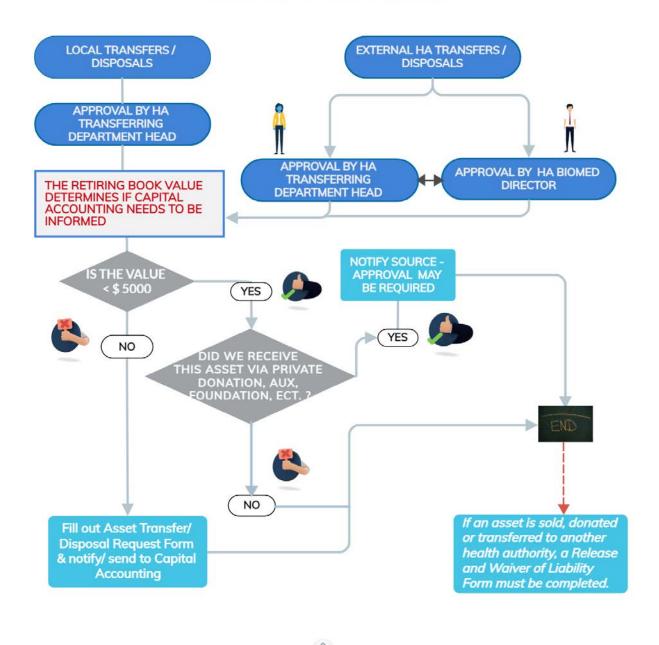
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Figure 1: Approval Process Flow

Approval Process

Based on the method of decommission



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4.3 **CMMS Asset Retirement**

If the intention for the equipment will be to transfer or dispose, the CMMS asset database must first be updated, by creating a 'Retire Asset' Work Order. (Follow the documentation on retiring assets within TMS CMMS.)

The reason for decommissioning as well as the method of decommissioning should be clearly stated. It is also important that the Asset Status of the equipment be changed from 'Active' to 'Retired'. Any documentation relevant to the decommissioning of the equipment can also be uploaded to the database for future reference.

Biomedical Engineering may send out a memo to inform all relevant users that the equipment has been officially transferred or disposed of.

4.4 **Decommissioning Hierarchy**

With the Focus to be what provides the most cost effective and/ or benefit to the local site, health organizations, health ministry or community. Please use the following as a guideline for decommissioning equipment within LMBME:

Value back to the health organization:

- Trade-in: Some vendors will buy back older models to encourage HA's to upgrade their devices. 0 This will help with offsetting some of the cost of the replacement purchase, if there is a good trade-in value this should be considered.
- Sell: to a third party, if there is a fair market value 0

Need/required at the local sites/HA's:

- Transfer to another department within the same site, if there is a need for the equipment 0
- Transfer to another site within the local health authority, if there is a need for the equipment 0
- Use for spare parts to support or update existing systems 0
- Transfer to another health authority within LMC, if there is a need for the equipment 0
- Transfer to another health authority within BC, if there is a need for the equipment 0

Community Benefit:

- Donation: first consider local and broaden out from there to outside the countries in need. It is 0 also important to review and follow the CMBES Guideline to Donating Medical equipment from Canadian HealthCare facilities.
- Recycle and discard: Recycling is good for our environment. 0

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4.0 Decommission Process Options

Note the order below is not linear or fixed. It is based on the type of equipment that is being decommissioned and on the reason for decommissioning.

For example:

- Equipment that exceeds \$5,000 is usually requested by Capital Accounting to be traded-in or sold.
- Equipment in high demand or surplus equipment would be transferred before attempting other disposal methods.
- Equipment which has been decommissioned for safety reasons would normally not be sold or donated, but rather dismantled for parts or discarded.

Prior to decommissioning, all equipment must be properly decontaminated to remove any potentially harmful fluids and is safe to handle (e.g. no hazardous radiation).

Trade-in

As part of the negotiation for a new acquisition, the old equipment can be traded-in to the vendor to offset some of the cost of the replacement purchase. This is usually the first option considered as trading-in old equipment is financially profitable, less time consuming and releases the hospital of all potential liabilities resulting from equipment defects or malfunctions. In cases where the vendor will dispose of the trade-in, it may be possible to remove some desired parts from the equipment before trading it in to the vendor.

Sale

There is a responsibility to ensure that any equipment being sold is in good enough condition and that putting it back onto the market will not present any major risk whatsoever.

Important considerations:

- Equipment must be sold <u>only to licensed and recognized third-party resellers</u> who refurbish equipment to the required standards before selling them to clinical or veterinary facilities.**
- If a device belonging to the Health Classes II, III or IV is being sold for medical use, it is important
 to make sure that the device has a current medical licence (<u>Health Canada Medical Devices</u>
 <u>Regulations</u>).
- If a device is being sold for non-clinical use, it should be clearly labeled as such.

Prior to selling any equipment, the <u>Release and Waiver of Liability form</u> for your HA, must be signed by the purchaser to release the hospital of all potential liabilities resulting from equipment defects or malfunctions.

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** The hospital only sells equipment through resellers instead of in person, due to the time involved in negotiating and analyzing bids, Health Canada restrictions on medical equipment resale and liability concerns should the equipment eventually fail after its sale.

Spare Parts and Back-up Equipment

In certain cases, it might be more advantages to use the equipment for spare parts to support or update existing systems. Also, it may be critical to keep some older devices as parts, or complete units. In some cases, the manufacturer does not always make their medical devices backward compatible. So older parts and devices may be the only way to keep the system running until the vendor comes up with a solution. If the spare parts are to be kept in storage for future use, careful consideration should be given as to whether it is worth keeping as storage space is limited.

The equipment can also be stored as back-ups in case of emergency situations such as epidemics or mass casualties. In this case the device can be made 'In-Active' in TMS if Risk class 2 or 3, and 1 can be stored as loaner.

Donation

Equipment can be donated to

- Clinical research groups associated with Biomedical Engineering
- Educational institutions (e.g. BCIT, UBC, SFU, etc.)
- Veterinary clinics
- Developing countries through charitable non-profit organizations

Note that this list is not in order of priority. The most appropriate recipient should be chosen in terms of the type of equipment being donated. The need for the equipment and the potential liability to the hospital resulting from the intended use for the equipment by the recipient.

Important considerations:

- Only equipment which is operational, fully accessorized with consumables and manuals should be considered for donation.
- It is also important to review and follow the CMBES Guideline to Donating Medical equipment from Canadian HealthCare facilities.
- If a device belonging to the Health Classes II, III or IV is being donated for medical use, it is important to make sure that the device has a current medical licence.
- Donations to developing countries should only be made through licensed and recognized charitable organizations who can handle the donation and who can ensure that the receiving agency will be able to test, accessorize and convert the supply voltage of the equipment if required. The equipment should also be appropriate for the technology level of the country.

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Prior to donating any equipment, the Release and Waiver of Liability form for your HA, must be signed to release the hospital of all potential liabilities resulting from equipment defects or malfunctions.

Refer to CMBES Guideline to Donating Medical equipment for more details within Canada.

Refer to WHO's Guidelines for Health Care Equipment Donations for more details around the world.

Recycling and Discarding

If no other use is found for a device, it should be discarded. Before it can be safely discarded, the following steps should be followed:

- Strip any recyclable plastic and metal parts, electronics.
- Batteries should be sent to the appropriate recycling facility. Different battery types have different recycling procedures (refer to your facility's battery disposal policy).
- Remove all inline fuses.
- Remove all means to power up the device (e.g. cut off mains cable on hard wired equipment). The power cords may be recycled separately.
- Remove all hoses able to pressurize a device (if driven by gases).
- Render the equipment inoperable to ensure it cannot be put backin service.

Note: Electronic medical equipment (except for devices that have been implanted or exposed to infectious bodily fluids) can be recycled and discarded at no cost through EPRA. If not too big, the equipment needs to be put in e-bags (gaylords) and placed on pallets. If the equipment is too big, it can be placed directly on pallets. For the full list of recyclable equipment, refer to EPRA's website.

Reference Documents

- BCBME SOP #P-14-16-40003 CMMS What Constitutes an Asset?
- Records Management Processes and Standards for Community Health Policy (page 43)
- ABCD-14-11-40001 Medical Devices and Personal Information Security Policy
- Information Security (IMITS)
- WHO's Guidelines for Health Care Equipment Donations
- CMBES Guideline to Donating Medical equipment
- LMBME SOP #ABCD-14-16-40010 Battery Safety and Recycling
- Recycle My Electronics website EPRA
- FHA
 - FH Disposal or Movement of Capital Equipment
 - Disposal & Removal Form 0
 - **FH Information Security Policy**

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- **VCH**
 - Asset Disposal/Transfer Request Form and Release and Waiver of Liability (Medical Equipment)
 - Reference 2: Asset Transfer Disposal Request Form Procedure
- PHC
 - B-00-11-10138 PHC Capital Equipment: Transfer and Disposal of
 - **Disposal Form** 0
 - Waiver Transfer of Medical Equipment Form О
- **PHSA**
 - PHSA Capital Assets Policy (includes section on Disposal)
 - Capital Asset Disposal Guidelines
 - Notice of Surplus Equipment Form
 - Assumption of Risks, Release, Waiver and Indemnity Agreement

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	1.1	29-JUN-2016	Review	Engineer		
	1.2	15-JUL-2016	Review	Engineer		
	1.3	04-OCT-2016	Incorporation of comments from Executive Director	Executive Director		
	2.0	16-NOV-2023	Revisions to include differences in HAs and move to new template	FH Manager		

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