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### WHAT CONSTITUTES A CLINICAL ENGINEERING ASSET?

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### **INTRODUCTION**

The Computerized Maintenance Management System (CMMS) database is the centre of all clinical engineering operations and acts as a repository for documentation including: service records, preventive maintenance schedules, warranty periods, and alerts & hazards.

To work towards a high degree of consistency and reliability of new data entered into the system, and to ensure accurate reporting, a formal process should be in place to determine what should be tracked in the CMMS (and what should not).

Most Clinical Engineering (CE) departments also have challenges determining assets they are responsible for and assets that fall to other service departments such as Physical Plant or Information Services.

#### **BACKGROUND**

The Lower Mainland Biomedical Engineering (LMBME) program in Vancouver British Columbia is a consolidated program of 4 regional Health Authorities with approximately 180 staff supporting 90,000+ medical devices across 27 major hospitals. Combining three legacy databases into one prompted the need to define a guideline to determine What Constitutes a Clinical Engineering Asset. This guideline was achieved by defining the criteria and process to decide what assets are entered into the CMMS, to assist all staff to determine objectively what constitutes an asset for LMBME

program. The authors believe this is a novel concept and are the first to introduce this topic for clinical engineering assets. Not only does this help CE departments better manage and maintain data integrity of their assets, but it helps define what CE departments do and don't do, and can initiate dialogues with overlapping service departments effectively clarifying roles and responsibilities for our customers.

The LMBME department formed a CMMS team responsible for overseeing the integrity of the data. This allowed decisions to be made by a limited number people applying uniform discretion to new assets which minimizes variability in naming convention. The team drafted this guideline to help determine which assets are approved for entry into the CMMS.

All new assets entered into the CMMS follow a strict naming convention. The CMMS team determines a manufacturer and model number pairing for each asset. This pairing creates a unique combination that is tied to other information such as the medical device license number, ECRI device type and code. Any new asset proposed for entry to the CMMS will be considered as either an *Included Asset* or an *Excluded Asset* of the CMMS.

## **Included Asset**

An included asset is defined as the following:

 Precedent: Although the responsibility for the support of an asset may be challenged the need to continue supporting assets exists until resolution. Therefore, if a model number of an asset already exists in the



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CMMS then a new asset with the same model may be entered using all of the available tools to ensure data integrity.

- 2. **Responsibility:** CE is responsible for maintaining the records of the incoming inspection, corrective repairs, and incidents throughout the lifecycle of the asset. Regardless, if the work is performed by inhouse, the manufacturer or a 3<sup>rd</sup> party, but is managed by CE.
- 3. **Alerts, Hazards & Recalls:** CE department is responsible for ensuring all are monitored, responded to and documented.
- 4. **Scheduled Maintenance:** CE department is responsible for ensuring all schedule maintenance is categorized for risk and priority. Then completed according to schedule and documented.

#### **Excluded Asset**

An Excluded Asset is defined as the following:

1. An asset that has been determined by the CMMS team to not meet the Included Asset criteria.

#### **DECISION PROCEDURE**

This decision procedure applies for all new model assets for consideration into the CMMS.

**Step 1**: Check to see if the model already exists in the CMMS. If it does it is automatically an *Included Asset*.

**Step 2**: Check the Excluded Assets List in Table 1. If the device is on the list, it is an *Excluded* 

Asset and will not be entered in the CMMS. If the device is not on the list then proceed to Step 3.

**Step 3**: Use the Decision Process Criteria below to guide decision to a final ruling.

**Step 4**: If disagreement occurs on the final ruling of the decision, an appeal can be made for an exception. There must be a compelling reason to overturn a decision.

# Decision Procedure Criteria

In general, there are two types of criteria considered: A) What probably will be an *Included Asset* and, B) What probably will be an *Excluded Asset* 

- A) If a device meets the test of more than one of the following criteria it will probably become an *Included Asset*:
- 1. It is a device that is used in the direct treatment, or diagnosis of a patient.
- 2. It has a medical device license from Health Canada.
- 3. It is a device that the LMBME is responsible for managing.
- 4. It is a device whose maintenance needs to be tracked as per the requirements of a recognized Accrediting or Regulatory Agency AND it is a device for which the LMBME is responsible.
- 5. Energy delivery devices (other than batteries) connected to medical devices while those devices are being used to treat or diagnose a patient. Examples would

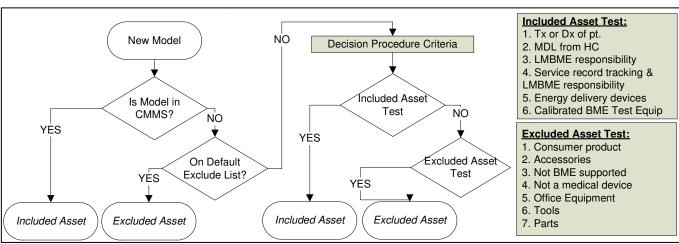


Figure 1: Flowchart of Decision Process Criteria Process



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include Uninterrupted Power Supplies and battery chargers.

- 6. Biomedical Test Equipment that requires regular calibration to a standard on a periodic basis.
- B) If a device meets the test of one of following criteria it will probably become an *Excluded Asset*.
- 1. **C**onsumer Products not used to directly treat or diagnose a patient almost without exception (e.g. LCD monitors, printers, webcams, etc.)
- Accessories some exceptions for high cost and/or high risk accessories (e.g. excluded Pulse Oximeter Probes, included TEE probes)
- 3. Not Supported by BME no exceptions
- 4. **N**ot a Medical Device almost without exception
- 5. **O**ffice Equipment no exceptions (e.g. fax machines, scanners, etc.)
- 6. Tools no exceptions.
- 7. **P**arts no exceptions. Batteries are treated as parts, except rechargeable batteries on critical devices.

### **Default Excluded Assets**

The list of devices in the Table 1 has been determined by the CMMS team to be *Excluded Assets*. This list was iterated based on assets that have failed to meet the Included Assets test and are put on this list to make adding new assets easier for successive attempts. These devices will not be entered into the CMMS under any circumstances.

Table 1: List of Excluded Assets

List of Excluded Assets
Amplifier, UHF
Backup Drive
Backup Tapes
CD player
CD/DVD Rom
Drill Motor, non surgical
Drills, non-surgical
DVD player
Engraver
External Hard Drive
Fan

Floppy Drive
Glue Gun
Hard Drive
Heat Gun
Keyboards
Knife, Electric
KVM Switch
Laser Pointer
Lathe
Lens, Camera
Motor
Mouse
Network
AP/Switch/Router/Hub (Managed by IT)
Pan, Electric Frying
Power Bars (exceptions)
Power Cords
Power Tools
Pulse Oximeter Probes
Roller Stand
Router
Saw, Table
Screwdrivers
Shuttle
Soldering/De-soldering station
Stereo
USB Hub
Video Projector
Video Switch
Washer/Dryer (Not scope washer)
Webcam

## **EXCEPTIONS**

The process outlined herein is not to be enforced without reason. This process means to apply a common standard to all decisions that must be made about *What Constitutes an Clinical Engineering Asset*. One of the most notable exceptions that do not fit the guidelines outlined is standalone power bars used in critical care areas. These are the responsibility of LMBME and are tagged and on a preventive maintenance schedule.

### **CONCLUSIONS**

The LMBME program has developed a procedure to define *What Constitutes a Clinical Engineering Asset* to be entered into the CE programs CMMS database. It has provided an objective and transparent method to define the responsibility and work that we do, and what we are required to track in the CMMS database.