PLANNED MAINTENANCE (PM) PROCEDURES

1. Purpose

Based off the PM Program BCBME SOP005, this SOP will define:

1.1 The process for initiating, reviewing, and approving PM Procedures

1.2 The principles and details that determines what is included in the PM Procedures

1.3 The level of detail and documentation required for recording PM work orders

1.4 When general, generic device type and model specific procedures are applied

2. Definitions

Acronym or Word	Definition
AEM Procedure (aka Modification)	Alternate Equipment Maintenance (AEM) Procedure is the modification of an OEM Procedure by adding, deleting, or changing steps to either, remove unnecessary/redundant steps, or improve the reliability or safety of medical equipment using risk based assessments (probability/Impact) by a qualified clinical engineer.
BCBME	British Columbia Biomedical Engineering
CMMS	Computerized Maintenance Management System, which is the database that houses all medical device records, including repairs, inspections, purchase information, warranties, parts, etc.
CMMS PM Writer	Staff that have been trained to upload procedures into the CMMS procedure module. CMMS PM Writers do not need to be subject matter experts (SMEs)
General Procedure	Basic procedure used in absence of generic device type or model specific.
Generic Device Type Procedure	A procedure developed for multiple makes and models for a category of device.
Manufacturer Procedure	Procedure developed by the manufacturer usually included in the Service Manual or provided during factory training.
Model Specific Procedure	Procedure developed for a specific make and model of a device.
PM	Planned Maintenance: One or more scheduled inspections and/or maintenance procedures used to verify the function, minimize the probability of failure, and improve the reliability & safety of a particular device. Often includes periodic tasks such as the replacement of parts, calibration, cleaning/lubrication, performance verification, safety inspections, software updates/patches, and/or required

	accreditation/regulatory testing. Aliases: Preventive Maintenance, Scheduled Maintenance, Performance Assurance
Provincial PM Program Committee	PM Program Committee is made up of Provincial Representation and is responsible for oversite of the PM Program including PM Change requests for new/update PM Procedures.
PM Developer	The Subject Matter Expert (SME) that develops the procedure that will be used in the CMMS.
PM Procedure	The step-by-step instructions that are to be completed during a PM.
PM Instructions	This is "what you do" and include the steps to be followed when performing the PM.
PM Recording	This is "what you record" when performing the PM Procedure, and consists of yes/no checkboxes, data recordings, and comments
PM Manager	PM Manager will be responsible for overseeing the PM Program including PM Risk and PM Procedures
Revision Number	The revision number is used to track changes to the PM Procedure
Service Manual	Manual provided by the manufacturer as part of the device purchase or during factory level training
SME	Subject Matter Expert - A Biomedical Engineering Staff member with 5 or more years and/or factory trained in a particular device type/subcategory or model. SME may be either a Clinical Engineer or Biomedical Engineering Technologist.
Version Number	The version number is used to track the difference between manufacturer releases of models, manuals and software

3. Scope

This SOP applies to all BCBME PM Procedures.

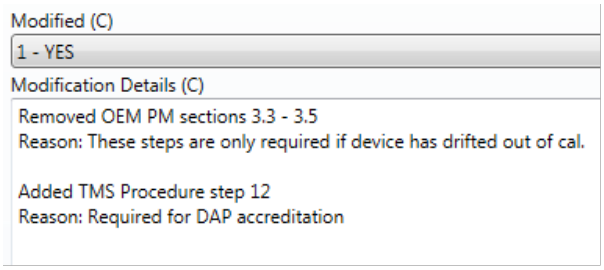
PM Procedures are part of the PM Program. They include the PM Instructions to be followed when performing a PM and also include the PM Recordings that are to be completed when performing PM. During development of PM Procedures consideration is given to:

- The safety of the patients and staff
- The acceptable performance of the device
- The criticality of the device (i.e. the CMMS Risk #)
- The probability & impact of device failure or malfunction
- The availability and efficient use Biomedical Engineering resources

4. Principles

4.1 Approved Guidelines and Principles

- PM Procedures will be standardized for the whole of the BCBME
  - Allows for consistent data to be collected across the Province
  - Ensures steps that are added due to incidents, alerts and recalls, as a safety requirement, are visible and followed by all of BCBME
- PM Procedures will be based on the manufacture's recommended procedures; any significant deviation from the manufacturer procedure will be considered an Alternate Equipment Maintenance procedure.
- PM Procedures should be developed to streamline the PM procedure whenever possible by:
  - Re-ordering steps
  - Consolidating steps
  - This would not be considered an AEM procedure requiring review
- Alternate Equipment Maintenance (AEM) Procedure is the modification of an OEM Procedure by adding, deleting, or changing steps to either streamline the PM procedure, remove unnecessary/redundant steps, or improve the reliability or safety of medical equipment using risk based assessments by a qualified clinical engineer. An AEM procedure may be created in the following circumstances:
  - There is no manufacturer procedure or the procedure is inadequate
  - An Alternate Equipment Maintenance (AEM) review determines that changes to the manufacturer's procedures can safely be made
  - Step(s) within a manufacturer's procedure is not really necessary or provides little or no value
  - Recommended modifications from Incident Investigation or Device Reliability Studies
- All modifications to the OEM PM procedure (creating an AEM procedure) will be documented in the CMMS. (A request can be made to the HA CMMS administrator to see the modification).



Example of PM Modification

- In cases where a device type procedure (sub category) is being considered instead of a model specific procedure, the SME will review all model specific procedures and develop a device type procedure that employs the minimum steps required to ensure that all models of that device type will be safe and perform according to manufacturer specifications when the Procedure is followed.
- There will be version control for PM Procedures. Each PM procedure will have a unique revision number and approval date.
- Those using a PM Procedure will have the opportunity to review and request changes through the Provincial PM Change Request Process.
    - Reviews/Requests will be prioritized by the Provincial PM Program Committee
- All PM Procedure instructions will be documented in the CMMS and all PM Procedure results will be recorded in the CMMS
- All modifications and updates to PM Procedures will be tracked via the PM Change Request process using PM Change Tickets.
- The Procedures will be developed by SMEs and entered into the CMMS by CMMS PM Writers.
- The CMMS system will use the following hierarchy for selecting the correct procedure for a PM:

    1. Model specific procedure (OEM or AEM Procedure)
    2. Generic device type procedure (Sub-category)*
    3. General procedure*

    *The technologist may augment generic device type or general procedures with the manufacturer procedure (if it exists), until such time that the model specific procedure is developed and applied to the CMMS

- A model can have multiple schedules

4.2 PM Procedure Approvals

There will be an approval process for all PM Procedures:

- PM Procedures that are equivalent to the OEM procedure may be approved directly by a member of the PM Program Committee.
- PM Procedures, which have been modified from the OEM procedure (AEM Procedure) or developed by BCBME, must be reviewed and approved by the PM Program Manager or designated Clinical Engineer(s).
- All PM Procedure Data Recordings must be approved by the PM Committee.

4.3 PM Data Recording

The data recorded on the PM Forms can be used for multiple purposes, including:

- Review of Effectiveness of the PM procedure
- What steps pass or fail
- How can we improve the PM by adding, grouping or removing steps

General Data Recording Requirements:

1. The directors or engineers have specifically asked/called for a data reading to be tracked for trending purposes
2. It is an exceptional circumstance where the measurement is required for future PM completion. The SME has provided background on the relevance and value of tracking the data.
3. Incident Investigation Requirements
4. Equipment Reliability Studies
5. An Accreditation or Legislated Requirement
6. It is a device usage readings e.g. # of hours on device
7. Tracking of Software Versions, Network Configurations, or Patches related to cybersecurity

5. Procedure

5.1 Initiating a PM Procedure

The development of a PM procedure can be initiated in two ways:

1. A device model (including variations/revisions of the same model) meets the threshold below of requiring a CMMS model specific PM Procedure and is flagged on the report that is reviewed regularly by the Provincial PM Program Committee. The Committee will then assign a SME to develop the PM Procedure.

    a. The federation of directors in conjunction with the PM Program Manager will define the Risk 1 and 2 Device Thresholds:

        i. Risk 1 device models with 5 or more assets in the province

        ii. Risk 2 device models with 20 or more assets in the province

    b. The list of devices meeting the threshold for a procedure requirement will be reviewed bi-monthly by the PM Program Committee and PM Change requests will be created as needed

2. By submitting a request through the Online Change Request Form. The PM Procedure request should include the following:

    - Model
    - Manufacturer
    - Manufacturer's PM Procedure and Checklist
    - Details of your request

    Note: Sometimes requests are submitted to develop procedures for models that don't meet the threshold and may be declined. It will be important to communicate in the request why a unique procedure should be developed (e.g., stemming from an alert mitigation).

5.2 CMMS PM Procedure Processes:

- A Procedure will be auto-loaded into the WO when the WO is created.
- If the procedure in the WO is NOT the model specific procedure (i.e. the Generic procedure), the technologist should follow the manufacturer's procedure, but MUST complete the Comments and Pass/Fail in TMS and attach the manufacturer's check list.
- If a model has multiple schedules, then:
    - Multiple Procedures will be created e.g. 6 month and 12 month procedure or DAP requirements
    - Technologists will need to use the 'Swiss Flag'  to open a PM WO and select the correct procedure they will be completing

5.3 Completing a PM Procedure

- All PM Procedures will be performed as per the Procedure in the CMMS
- Staff will be required to complete the PM Procedure in full, including the acknowledgement section that includes the following sub-procedures:
    - **Notes/Comments** – this includes all the instructions/steps that the technologist must complete, plus a Comments box to enter notes/comments
    - One of the following options must be selected in order to save the WO:
        - **PM/II PASSED** – All steps were completed within the specifications of the PM procedure, including PM parts as per procedure
        - **PM/II PASSED with Corrective Action** – The device required repairs or calibrations which may or may not have required parts that are not part of the PM Procedure. Any calibrations that were completed prematurely due to noticed drifting to prevent a future failure would also be considered corrective action.
        - **DEVICE RETIRED** – Device failed PM and will be retired. A RA WO will need to be created after closing the PM WO

- If a device is put back into service when it does not meet Manufacturer's specifications, then the reason and the details will be recorded in the Comments of the Procedure in the CMMS.
    - Documented Approval from a supervisor or manager is required.
- Complex/Lengthy Procedures (Diagnostic Imaging) procedures:
    - Reference an attached procedure
    - Have a Choice List that allows the section completed to be indicated for situations where parts are installed at different times
        - Choice List to be created for specific/Safety Checks/incidents
    - Manufacturer's Procedure & Checklist to be attached to the PM Procedure

5.4 Modification Decision Process (Creating an AEM procedure)

- The SME will review the manufacturer's procedure and determine if any modifications are appropriate
- If they are considering a modification, they will consult with other factory trained or SME on that device.
- The modification will apply to all Health Authorities, so should only be employed where there is consensus that this modification is or should be practiced across all Health Authorities

6. Reference Documents

- BCBME SOP005 – Planned Maintenance Program
- BCBME SOP007 – Work Order Recording
- Guideline # P-14-07-40002 – Developing PM Procedures

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	1.1	Oct 10, 2015	Final Draft for Province	LM Director, PM Risk & Quality Manager
	1.2	Feb 01, 2016	Revised to allow for new "Developing PM Procedures" SOP	LM Director
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	1.5	May 24, 2016	'PM Engineer' term modified by Fed Dirs.	PM Risk & Quality Manager
	1.6	Oct 12, 2016	Added 1 e) to Appendix A	LM Engineer
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