

BIOMEDICAL ENGINEERING DOCUMENT APPROVAL

1. Purpose

All documents that have been sanctioned for use in the LMBME program must have a unique document identifier. Once a document is assigned a document number it remains with the document indefinitely.

All documents have an approval pathway to define who is responsible for approval and sign-off for successive iterations, and control over what documents become “Draft”, “Under Review”, “Archived” or “Released” on the Shared Health Organizations Portal (SHOP).

To identify the system used for cataloguing documents and maintain a standard nomenclature that links with the core businesses for the LMBME program. There is a requirement to standardize information including metadata, naming conventions, numbering, dates, keyword identification, topic identification and document ownership.

2. Definitions

Acronym or Word	Definition
Controlled Source Document	Documents governed by the LMBME program are known as “Controlled Documents” (e.g. Standard Operating Procedures, etc.)
Uncontrolled Source Document	External documents not governed by the LMBME program. (e.g. ANSI Standards)
Document System Administrator	The person that controls information posted to the SHOP site.
Document Author	The person that has created the document.
Document Approver	The person responsible for approving the document.
LMBME	Lower Mainland Biomedical Engineering
Draft	Documents that are in a work in progress or completed prior to an initial review.
Under Review	Documents that may require input (before or after they are released) from key stakeholders
Released	Documents that have been approved by the document approver and remain the most current revision.
Archived	Documents that have been retired or have been superseded by another document.
SHOP	Shared Health Organizations Portal

3. Scope

All documents pertaining to the LMBME in the Shared Health Organizations Portal (SHOP) system.

3.1 Included:

3.1.1 Controlled Source Documents

- Controlled Source Documents will have only one of the of the following statuses for each revision: Draft, Under Review, Released, Archived
- Document status will be logged in each document under the policy heading “Revision History”.
- Released documents will be posted on the SHOP site listed under Biomed-Engineering.
- Archived documents will be removed from SHOP and stored on the BME Employee Resources SharePoint site.

3.2 Excluded:

3.2.1 Uncontrolled Source Documents

- Uncontrolled Source Document status will be either: Current, or Obsolete
- Current uncontrolled source documents will be posted on the designated LMBME intranet site.
- Obsolete documents will be removed from the intranet site.

4. Procedure

4.1 How to Standardize a Document Title, Assign an Identifier and Tag Keywords

- ##### 4.1.1
- For information on document titles, assigning an Identifier and tagging documents with keywords, refer to the SHOP Style Guide available on the SHOP site.

4.2 Formatting

Standard formatting across all documents allows information to be presented in a clear and concise manner. Please find an appropriate document template from the BME Employee Resource SharePoint site or contact the BME Quality Improvement Leader. The templates have been created using the SHOP style guide formatting requirements and identifiers.

4.3 Document Creation and Review Process

4.3.1 Document Author

- a) The Document Author is the original drafter of the document or the newly appointed LMBME staff assigned to the reviewing or archiving of a document.

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b) The Document Author is responsible for seeing the document through each status change:

Status	Description
Draft	The document is being drafted
Under Review	The document has been sent out for review or is being revised
Released	The document has been approved for use
Archived	The document is no longer relevant and has been removed

- Each successive status change must be recorded in the Revision History section of the document.
- Each change should be incremented and recorded in the Revision No. by a tenth of a decimal.
- Content changes require formal approval before being released, grammatical or formatting corrections can be done as needed. The Document Author should use their discretion or consult with the Document Approver if unsure.

c) The document author must obtain approval from the approver.

- Only approved documents will be sent to the Documentation System Administrator to be posted on SHOP.
- Documents that are edited must be signed off by the Document Approver, regardless of the scope of change.

d) The document author is responsible for and must gather feedback from the end users of the document.

- Each document may have a different end user/audience:
 - Example: Working instructions for alerts on devices would require feedback and a review from Technologists
 - Example: Capital Planning instructions would require feedback and a review from staff involved in planning and purchasing

4.3.2 Document Approver

- The Document Approver is generally responsible for the LMBME Business Area referenced in the document. If in doubt the Document Approver will be the Executive Director.
- Is responsible for ensuring the end user(s)/audience for the document has been consulted in the development or review.
- Is responsible for reviewing the scope of the end user(s)/audience and consulting with other Lower Mainland Health Authorities as needed.
- Is responsible for reviewing and signing off on the content of the controlled document.
- The Document Approver cannot be the Document Author.
- No document shall be "Released" without having sign-off by the Document Approver.

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- g) Final approval of documents is required from the Directors with a formal communications plan on the release and implementation of the new or revised policy, SOP, guideline, etc.

4.3.3 Documentation System Administrator

- Ensure that the Document Number is created appropriately
- Ensure that the document has been approved for posting on SHOP. Only “Released” documents are posted on the site.
- Remove any “Archived” documents from SHOP and upload into BME Employee Resources SharePoint (Management Tab) for reference.
- Ensure the original final Word version of the document is uploaded into BME Employee Resources SharePoint (Management Tab) for reference and editing for future revisions.
- Ensure that all Documents in SHOP have had the individual’s names removed, the metadata table information is uploaded into SHOP and the metadata table is removed from the published version and the document is published as a PDF to increase document security.

5. Supporting Documents

- [SHOP Style Sheet](#)

Effective Date:	13-FEB-2020			
First Released:	13-NOV-2013			
Last Revised:	13-FEB-2020			
Last Reviewed:	13-FEB-2020			
Approved By:	LMBME -			
Owners:	LMBME – Quality Improvement, Project and Change Management Leader			
Revision History:	Version	Date	Description/ Key Changes	Revised By
	1.0	03-MAY-2013	Draft	Engineer
	1.1	13-NOV-2013	Review, Active	Executive Director
	1.2	10-JUL- 2019	Revised template & SHOP procedures	Quality Improvement
	1.3	13-FEB-2020	Removed SHOP Style Guide instructions and added link to file	Quality Improvement