Lower Mainland Biomedical Engineering Professional Practice Management Plan

PPMP Review Record

This PPMP must be reviewed annually and updated as required to document evolving business practices of Lower Mainland Biomedical Engineering. See section "PPMP Review" for further information.

Annual PPMP Review Record			
Date	Reason	RO	Comments
yyyy.mm.dd	Annual Review		

Table of Contents

1. Introduction

This PPMP has been developed to meet the requirements set out in section 7.7.3 of the Bylaws of Engineers and Geoscientists BC.

As the Bylaw mandates, this PPMP includes the following sections or elements:

- Firm organizational structure.
- Name of the Responsible Officer.
- Name(s) of the Responsible Registrant(s) and the division, department or practice area for which they are responsible.
- Practice areas or scope of engineering and/or geoscience in which the firm operates.
- Code of Conduct and policies regarding ethical behaviour with specific references to how these documents align and reinforce behaviours in keeping with:
    - Engineers and Geoscientists BC Code of Ethics.
    - Engineers and Geoscientists BC guidelines on human rights, equity, diversity and inclusion.
    - Ethical business practices addressing corruption, conflict of interest, and contractual matters.
- Continuing education and professional development policies and procedures including how they align with the Engineers and Geoscientists BC Continuing Education Program and help employees particularly professionals remain competent in their roles and practice areas.
- Quality Management policies and procedures covering the following required areas:
    - Professional Practice Guidelines
    - Retaining Project Documentation
    - Checking Engineering and Geoscience Work
    - Independent Review of High-Risk Activities or Work
    - Authenticating Documents
    - Direct Supervision
- Not applicable areas:
    - Independent Review of Structural Design
    - Field Review During Construction or Implementation

All revisions made to this PPMP must be reviewed and approved in writing by the Responsible Officer and Responsible Registrant(s). Refer to the Issue/Revision Record at the front of this PPMP for the status.

Sections in this PPMP have been prepared as follows:

- Introduction and Purpose are Engineers and Geoscientists BC explanations and use Engineers and Geoscientists BC terminology. They are provided to help educate those using this PPMP.
- Policy, Guidelines for Detailed Procedures and Standard Operating Procedures are LMBME's and use LMBME's terminology. They are provided for use by all employees.

2. Lower Mainland Biomedical Engineering

Lower Mainland Biomedical Engineering (LMBME) focuses on healthcare technology management by providing a wide range of technical and engineering expertise. LMBME manages medical devices throughout their entire life cycle; starting from the planning for purchase and development of specifications stage, through the purchasing, implementation, maintenance, and finally end of life and disposition stage. LMBME also plays a key role in technology related patient safety. It conducts medical equipment incident investigations, monitors medical equipment recalls and alerts, and identifies potential hazards with medical technology.

LMBME provides their services to four BC Health Organizations (Fraser Health Authority, Providence Healthcare, Provincial Health Services Authority, and Vancouver Coastal Health) under the Lower Mainland consolidation structure. Providence Healthcare has overall accountability for LMBME; however, LMBME provides equal service to all of it's supported health organizations. The department incorporated on March 31, 2000.

LMBME has 175 Technologists who have site-specific responsibilities, supporting more than 100,000 medical devices spread across 27 major hospitals and a few more minor sites.

LMBME's Regional Engineering Team provides engineering services for all Lower Mainland Health Organizations. The team is composed of four staff Clinical Engineers, an internal consultant Clinical Engineer, and one Clinical Engineer Manager who collaborate within a multidisciplinary environment to solve complex healthcare technology problems.

LMBME also employs Engineers who work in operations management roles (i.e. Operations Manager, Director, Executive Director).

Responsible Officer: Carol Park, P.Eng. Executive Director, LMBME

Responsible Registrant: Brendan Gribbons, P.Eng., Director, PHC/VCH and Engineering, LMBME

Industry: Government – Healthcare

Area of Practice: Biomedical – Equipment

Organizational Structure

3. Regulated Engineering Practice Areas

LMBME Engineers may conduct the following duties which involve regulated engineering practice:

- Incident investigation process development and leadership
- Incident investigation tasks
- Safety alert/recall management process development and leadership
- Safety alert/recall management tasks
- Assessment of medical devices involved with research studies
- Technical risk assessments
- Medical device modifications
- Preventive maintenance program process development, implementation, and management
- Regulatory compliance
- Development of custom medical devices

4. PPMP Review

4.1 Policy

This PPMP will undergo an annual review and revision, as needed, to incorporate input from root cause analyses of non-conformances, internal audit findings, client feedback, user suggestions and management reviews.

LMBME Engineers are required to review their responsibilities outlined in this PPMP on an annual basis.

- Annually, the Responsible Officer will initiate the Responsible Registrant to conduct review and revision of the PPMP, including review of LMBME's compliance with the PPMP requirements.
    - Review and revision will be documented in the Issue/Revision Record at the front of this PPMP

- Annually, the Responsible Officer will initiate all LMBME Engineers to review their responsibilities outlined in the PPMP.
    - Engineers will confirm completion of their review, and this will be documented in their continuing education tracking document in Sharepoint.

5. Code of Conduct

5.1 Introduction and Purpose

LMBME's Code of Conduct

Providence Healthcare's Code of Conduct and LMBME's Code of Conduct sets out the behaviour and actions required of individuals employed by or under contract with LMBME. The codes of conduct apply to all employees and contractors working for LMBME.

5.2 Engineers and Geoscientists BC Code of Ethics

The Engineers and Geoscientists BC Code of Ethics has been established to support and inform professional registrants in fulfilling their duty to the public, clients, the professions, and their fellow professional registrants. The Code of Ethics is not intended to, nor does it define conduct for all situations that a professional registrant may encounter. Instead, it provides guidance to inform the behaviour, decisions, and professional judgment of professional registrants that Engineers and Geoscientists BC regulates. A professional registrant should incorporate ethics into their daily decision-making.

The Engineers and Geoscientists BC Code of Ethics serves several purposes. It designates the standard of conduct expected of professional registrants in easily understandable terms. It distinguishes appropriate professional conduct from that which fails to meet a required standard. The Code of Ethics also provides a basis on which allegations of unprofessional conduct are adjudicated by the Discipline Committee or other groups charged with responsibilities related to the conduct of professional registrants.

The Code of Ethics, Schedule A of the Bylaws of Engineers and Geoscientists BC, applies to all registrants.

Refer to the Engineers and Geoscientists BC Code of Ethics for more details about the Principles on which it is based.

5.3 Policy

All employees and contractors working for LMBME must understand and comply with PHC's and LMBME's Code of Conduct.

All professionals registered to practice by, or in training to be registered with, Engineers and Geoscientists BC, or other employees working on engineering projects for LMBME must comply with the Engineers and Geoscientists BC Code of Ethics.

All employees and contractors must comply with LMBME's policies and Code of Conduct with respect to human rights, equity, diversity, or inclusivity.

LMBME's policies and Code of Conduct will be periodically reviewed to confirm that they comply with the Engineers and Geoscientists BC requirements and any related professional practice guidelines that have been published by Engineers and Geoscientists BC.

5.4 Reference Documents

- Providence Healthcare Code of Conduct
- Lower Mainland Biomedical Engineering Code of Conduct
- Engineers and Geoscientists BC's Code of Ethics
- Engineers and Geoscientists BC's Human Rights and Diversity Professional Practice Guidelines

6. Continuing Education Program

6.1 Introduction and Purpose

6.1.1 Introduction

Registrant firms play an important role in supporting professionals they employ in the maintenance of their competency and meeting their requirements under the Engineers and Geoscientists BC's Continuing Education Program. Employers can set standards that empower professionals to undertake appropriate and adequate continuing education activities.

Under the *Professional Governance Act* and the Continuing Education Program by Registrant Firms requirements as set out in section 7.6.16 of the Bylaws of Engineers and Geoscientists BC, all registrant firms must develop, maintain, and follow documented procedures to support professionals they employ in meeting their Continuing Education Program requirements and maintaining their competency with respect to their role and practice areas. The continuing education requirements are further explained in the Guide to the Continuing Education Program.

These internal procedures will vary among registrant firms but should outline a vision and goals for supporting continuing competency and education and policies supporting learning activities.

Registrant firms that have more than one professional in their employ must also provide support in meeting individual Continuing Education Program requirements by conducting an annual documented review with each professional. This review should be focused on the maintenance of the professional's competence with respect to their role and area of practice at the firm. The review should identify potential gaps in the professional's competency as well as identifying means and methods of addressing any identified gaps and maintaining their competency.

6.1.2 Purpose

Professionals are required under the Engineers and Geoscientists BC Code of Ethics to "maintain competence in relevant specializations, including advances in the regulated practice and relevant science". To support this important principle of professional practice, professionals are required under the *Professional Governance Act* and the Bylaws of Engineers and Geoscientists BC to create continuing education plans and meet mandated levels of continuing education.

This section describes LMBME's documented procedure to be followed by its professionals to meet the required standard for continuing education and competence.

6.2 Policy

Maintaining our collective competence:

- Helps to protect public safety and the environment.
- Fosters excellence.
- Maintains and advances our knowledge and expertise.
- Enhances and expands our domains of practice.
- Enhances our image.
- Improves the quality and value of services we provide.

Managers must conduct and document performance reviews with all their direct reports that will include:

- Accountable compensation discussion (competency-based assessment):
    - Five competencies are evaluated that focus on the skills, motivators, knowledge and behaviours staff demonstrate in performing their job: communication, serving others, partnerships, innovation/initiative, and quality.
    - In addition, staff reflect on their key accomplishments in the last year, the impact their accomplishments made, and which PHC Values they brought to life and how. Lastly, staff identify skills/areas to develop in the following year.
    - The review is conducted annually and documented in PHC's HR system, HR Connect.
- Clinical Engineer continuing education plan assessment:
    - All registered staff members (P.Eng or EIT) are required to complete the EGBC continuing education plan template (see Appendix) on an annual basis.
    - The plan is reviewed with the staff member's manager. If the staff member's manager is not a Professional Engineer, the staff member will review their plan with a different LMBME staff member who is a Professional Engineer.
    - The staff member's progress towards completing their education goals is reviewed with their manager after six months.
    - Staff's education plans and review conversation are documented in Sharepoint.

For professionals registered with Engineers and Geoscientists BC, performance reviews and learning plans will align with the Engineers and Geoscientists BC Continuing Education Program.

Learning plans will be supported through:

- Paid time off for professional development.
- Tuition or participation fees approved for programs, courses, or training.
- Registrations fees for approved conferences.
- In-house webinars, seminars, training, and workshops.

- Self-directed learning
- Mentoring.
- Career coaching.

6.3 Detailed Procedure and Reference Documents

- PHC Accountable Compensation Process
- EGBC Continuing Education Plan Template

7. Professional Practice Guidelines and Practice Advisories

7.1 Introduction and Purpose

7.1.1 Introduction

A professional practice guideline sets the minimum standards of competence, conduct and practice expected from a professional engaged in the activities it addresses. Professionals must have regard for applicable standards, policies, plans, and practices established by the government or by Engineers and Geoscientists BC, including Engineers and Geoscientists BC professional practice guidelines.

Professionals must establish, maintain, and follow documented procedures to:

- Stay informed of, knowledgeable about, and meet the intent of all applicable standards, policies, plans, and practices established by the government or by Engineers and Geoscientists BC, including professional practice guidelines relevant to their practice.
- Document in writing the reason(s) for a departure from any relevant portion of a professional practice guideline.

Engineers and Geoscientists BC publishes professional practice guidelines on specific professional services or activities where additional guidance is deemed necessary. Professional practice guidelines are written by subject matter experts and reviewed by stakeholders before publication. Engineers and Geoscientists BC's preparation of professional practice guidelines is informed by a risk-based analysis of the professional activity or service that falls under regulated practice.

The use of professional practice guidelines is mandated by section 7.3.1 of the Bylaws of Engineers and Geoscientists BC and is supported by the Engineers and Geoscientists *BC's Guide to the Standard for the Use of Professional Practice Guidelines*.

During compliance audits, auditors will be confirming professionals are knowledgeable of, competent in, and meet the intent of professional practice guidelines relevant to their work.

7.1.2 Purpose

Each professional practice guideline establishes the standards of competence, conduct and practice that all professionals are expected to meet when engaged in the relevant professional engineering work. Professional practice guidelines may also assist in interpreting the standards of professional and ethical conduct established by the Bylaws of Engineers and Geoscientists BC.

Engineers and Geoscientists BC chooses professional practice guideline topics with a risk-based analysis, prioritizing professional practice guidelines that address practice activities involving increased risk to the

safety, health and welfare of the public, including the protection of the environment and the promotion of health and safety in the workplace.

This section describes LMBME's documented procedure to be followed by its professionals to meet the standard for the use of Engineers and Geoscientists BC professional practice guidelines.

7.2 Policy

Projects undertaken must meet all regulatory and statutory requirements, and applicable professional practice guidelines and standards including meeting the intent of relevant Engineers and Geoscientists BC professional practice guidelines and practice advisories.

Professionals must stay informed of, knowledgeable about, and meet the intent of all applicable standards, codes, policies, plans, and practices established by the government or by Engineers and Geoscientists BC, including professional practice guidelines relevant to their practice.

Professionals will document in writing the reason(s) for a departure from any relevant portion of a professional practice guideline.

7.3 Guiding Principles for Detailed Practice Area Procedures

This high-level procedure applies across LMBME and will inform any detailed procedures, if required, for use of professional practice guidelines in each division, department or practice areas.

LMBME and all professionals employed or under contract with LMBME must have regard for applicable standards, policies, plans, and practices established by the government or by Engineers and Geoscientists BC, including professional practice guidelines by:

- Establishing, maintaining, and following documented procedures that describe how they will stay informed of, knowledgeable about, and meet the intent of all applicable standards, policies, plans, and practices established by the government or by Engineers and Geoscientists BC including:
    - Monitoring communications about changes to regulations, guidelines and standards including those from Engineers and Geoscientists BC.
    - Reviewing related websites including the Engineers and Geoscientists BC website to retrieve the current versions and to find out about updates to regulations, guidelines and standards.
    - Determining what impact these changes will have on LMBME's related practices and work.
    - Supporting related professional development to reinforce the use of professional practice guidelines.

- Before starting work on any project involving regulated engineering practice, professionals of record will identify, confirm and document regulatory and statutory requirements or advice including those found in:
    - B.C. Reg. 100/2004: Electrical Safety Regulation
    - CAN/CSA C22.2 NO. 60601-1:14 (R2018): Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition, 2005-12, including amendment 1:2012, with Canadian deviations)
    - CSA C22.1:21: Canadian Electrical Code, Part I (25th Edition), Safety Standard for Electrical Installations
    - Food and Drugs Act (R.S.C., 1985, c. F-27)
        - Medical Devices Regulations (SOR/98-282)
    - CSA Z32:15 (R2020): Electrical safety and essential electrical systems in health care facilities
    - CSA Z8000-2018: Canadian Health Care Facilities
    - CSA SPE-3000:19: Model code for the field evaluation of medical electrical equipment (MEE) and medical electrical systems (MES)
    - Health Canada List of Recognized Standards for Medical Devices
    - Canadian Medical and Biological Engineering Society Clinical Engineering Standards of Practice
    - Accreditation Canada standards
- During the work, professionals of record will:
    - Have the work designed or developed to meet all regulatory and statutory requirements including those found in professional practice guidelines and practice advisories.
    - Carry out or have carried out reviews to confirm that all requirements have been met.
    - Document in writing the reasons for any departure from any relevant portion of a professional practice guideline or practice advisory.

8. Document and Records Management

8.1 Introduction and Purpose

8.1.1 Introduction

Retaining project documentation means retaining any document that is evidence of regulated practice activities, events or transactions, or is evidence that professionals have met their professional and contractual obligations, or that has been prepared and delivered for the project or work, regardless of the media used to create or store the records.

A professional must establish, maintain, and follow documented procedures for the retention and preservation of complete project documentation related to the regulated practice engaged in by the professional. Retaining complete project documentation is mandated by section 7.3.2 of the Bylaws of Engineers and Geoscientists BC and described in the *Guide to the Standard for Retention of Project Documentation.*

During compliance audits, auditors will be confirming registrants are complying with LMBME's records management policies and procedures to ensure retention and preservation of complete project documentation for at least 10 years after the completion of the project or 10 years after the documentation is no longer used.

8.1.2 Purpose

Retaining complete and easily retrievable documentation is critical to professional practice and helps professionals demonstrate that they are holding public safety paramount and serving the public interest as required by the *Professional Governance Act* and Code of Ethics.

Documentation or records, such as correspondence, email, minutes of meeting, reports, drawings, specifications, test reports, input data, and other records, may also:

- Provide accurate records of the basis for engineering work and decision-making.
- Allow another qualified professional engineer, professional licensee engineering, unfamiliar with the work or service, to review the file and effectively carry on with the work.
- Facilitate well-run projects or work that meet objectives and professional standards.
- Allow a firm to demonstrate that it, and its professionals, have met required professional standards.
- Be useful in resolving issues and defending claims.
- Meet legal and regulatory requirements.

This section describes how project documents and records will be retained by LMBME's engineers.

8.2 Policy

All LMBME's records will be classified and retained according to the procedures outlined in Table 1.

Records will be preserved and retained for the longer of 10 years after the end of a project or 10 years after the records is no longer in use.

Documents and records must be filed and stored when the project or work is active to allow for easy filing, retrieval and shared access by those involved.

8.3 Guiding Principles for Detailed Practice Area Procedure

Specific documentation procedures are detailed in Table 1.

Table 1: Documentation Procedures for Biomedical Engineering Regulated Practice Areas

[1]Documentation being updated. Refer to LMBME Documentation Improvement & Development Plan

Regulated Practice Area	Documentation of Process (Including Record Retention Process)	Documentation/Record Retention Location
Incident investigation process development and leadership	LMBME SOP 004: RSM – LMBME Patient Safety & Learning System (PSLS) Quality Assurance Program[1] LMBME SOP 005: Incident Investigations[1]	SHOP: SOP documentation
Incident investigation tasks		TMS: Task records BC Patient Safety and Learning System: Task records
Safety alert/recall management process development and leadership	LMBME Policy# ABCD-14-11-40003: Hazard Reports and Safety Alerts[1] LMBME SOP # ABCD-14-16-40002: Hazard Reports and Safety Alerts[1]	SHOP: Policy, SOP documentation
Safety alert/recall management tasks		TMS: Task records
Assessment of medical devices involved with research studies	LMBME SOP # ABCD-14-16-400: Investigational Medical Device SOP[1]	SHOP: SOP documentation TMS: Assessment records
Technical risk assessments	BCBME SOP in development[2]	SHOP: SOP documentation Sharepoint
Medical device modifications	BCBME SOP in development[2]	SHOP: SOP documentation Sharepoint TMS: Assessment records
Preventive maintenance program process	BCBME SOP 005: Preventive Maintenance Program[1]	SHOP: SOP documentation BCBME Change Request Log: TMS: Device risk classification, PM schedule & procedures, PM exceptions
Regulatory compliance	BCBME SOP 012: Incoming Inspections	TMS: Incoming inspection records
Development of custom medical devices	BCBME SOP in development[2]	Sharepoint: SOP documentation

[2]Documentation being developed. Refer to LMBME's Documentation Improvement & Development Plan

a) Shared Health Organization Portal (SHOP)

- All documentation stored on the Shared Health Organization Portal (SHOP) will follow the document control and approval process outlined in SOP # ABCD-14-16-40001: Document Approval – Biomedical Engineering
- LMBME's PPMP is stored in SHOP

b) BCPSLS, TMS, BCBME Change Request Log

- Procedures for records management in BCPSLS, TMS and the BCBME Change Request Log are described in the applicable regulated practice area SOP.

c) Sharepoint

Setting up Project Filing

- Set up a project folder on Sharepoint
  - Create folder in the applicable master folder:
    - Development of custom devices
    - Medical device modifications
    - Technical risk assessments
  - Folder nomenclature: *YYYY_MM_DD - Project Name*

Preparing Documents

- Use LMBME's document standards for consistent, professional appearance.
- Use standard templates and forms, where available.
  - Technical risk assessment template
- Use validated and approved software and media for creating and maintaining documents.
- Use standard file naming conventions to save document files.
- Include document identifiers (project name, project number, filename, file directory) in the document, as appropriate.
- Include project name and topic in the subject line of project or work-related e-mail containing information that must be retained.
- Review, spellcheck and check documents to confirm they are correct, complete and ready to issue.

Filing & Issuing Documents

- File documents in their appropriate folder on Sharepoint.
- File all project or work e-mail messages that must be retained in the appropriate folder of their related project or work file structure. Email may be filed in any of several ways so that email records are with the retained project records by the time of closeout:
    - Saved to the project filing when sent or received.
    - Stored in a project-labelled Personal Folder or similar throughout the project and moved at closeout.
    - Periodically, converted and saved to a portfolio PDF and saved to the project filing.
    - Printed and save to physical document project files.
    - Other means to assure that project records retained at closeout include email records.
- File issued electronic documents exactly as issued
    - Store communications (e.g. email) to record who receives which document revisions and when
- Use Sharepoint's check-in/check-out system wherever multiple users have access to working documents.

Revising Documents

- Include a revision record indicating revision number, what was revised and by whom, on documents where version control is required (technical assessments, reports, etc.).
- Clearly identify what was revised for documents subject to version control.
- Create and/or use a standard checking process for all revisions.

Receiving Documents

- Determine whether the document is a record to be retained or a document that is kept for convenience until no longer needed.
- Store documents in the project file to record when documents are received.

Archiving Records

- Records will be preserved and retained for the longer of 10 years after the end of a project or 10 years after the records is no longer in use.

8.4 Reference Documents

Put any documents here that are referenced or overlap.

- LMBME Documentation Improvement Plan

9. Checking Engineering Work

9.1 Introduction and Purpose

9.1.1 Introduction

Checking is a documented quality control processes to confirm that the engineering work is complete, correct, meets all input requirements, and is suited for its intended use or purpose. Checks, as defined by Engineers and Geoscientists BC, encompass all the various checks that occur or ought to occur throughout the development, presentation, production and performance of any professional engineering in any sector.

Prior to checking, a risk assessment must be completed to determine the extent of checking required and whether an independent review is required; refer to section titled **Independent Review of High-Risk Professional Activities or Work,** of this PPMP.

Depending on the risk, checking may be carried out by a qualified individual independent of, or associated with, the work being checked, or by the professional, who prepared the work. Checking engineering work is mandated by section 7.3.4 of the Bylaws of Engineers and Geoscientists BC and described in the *Engineers and Geoscientists BC Guide to the Standard for Documented Checks of Engineering and Geoscience Work*.

During compliance audits, auditors will be confirming professionals are carrying out documented checks of engineering work using a documented process appropriate to the risk associated with the work, and retaining records of those checks according to the procedures below.

9.1.2 Purpose

Professionals are required to have documented checks of their engineering work conducted, using a written quality control process that is appropriate to the level of risk associated with the work. Checks are used by professionals to confirm that work they have prepared meets all input requirements and is suitable for its intended purpose.

This section describes how checks of professional engineering work will be carried out and documented in LMBME.

9.2 Policy

Checks must be carried out to confirm that the work is complete, correct, meets all input requirements and is suitable for its intended purpose.

The responsibility for carrying out, or arranging to have carried out, required checks of professional engineering work rests with the professional of record.

Those preparing professional engineering work are required to check their work before providing it to others for documented checking and not rely solely on the checker(s) to find errors and omissions.

9.3 Guiding Principles for Detailed Practice Area Procedures

This high-level procedure applies across the firm and will inform the detailed procedures for checking professional engineering work.

Before proceeding with the work:

- Assess the competencies required to confirm that qualified professionals are available to perform the work. Only proceed with work, where qualified professionals are available.
- Assess the risk using BCBME's risk assessment template, and use it to determine the extent and levels of checking required and document and retain a record of the risk assessment.
  - Low residual risk: self-checking acceptable
  - Moderate residual risk: checking by internal P.Eng required
  - High/extreme residual risk: checking by internal/external P.Eng required (refer to section for Independent Review of High-Risk Professional Activities or Work)
- Identify qualified checkers to carry out the project checks.
- Include adequate time for all checks in the project plan and budget.
- Identify, confirm and document all input requirements to reference and use for the work and required checks.
- Identify, collect and conduct documented checks of all input data to confirm it is complete, correct, current and suitable prior to relying on it.
- Validate spreadsheets and software before using them in analysis or calculations.
- Check spreadsheet and software output using hand calculations, site measures, seasoned reviews of the output or other means suitable to the work being undertaken.
- Plan when, how, by whom and to what extent checks will occur during the work.
- Plan for independent review of activities or work assessed as high.
- Check all work, including calculations, as planned.
- Always self-check work before handing work off for others to check.
- Arrange for or review all final design or development work to confirm that it is complete, meets all input requirements and is suitable for its intended purpose.
- When checking one discipline or practice area in a document that includes other disciplines or practice areas, qualify the check to indicate what the check covers.

- Have all deliverables and professional documents, such as specifications and reports checked to confirm that they are correct, complete and consistent.
- Review, authenticate and have the permit to practice number applied to all professional documents before they are delivered to others who will rely on them.
- Keep a record of all checks legibly indicating the purpose, date of check or review, professional of record, checker's name, issues of significance found and how the issues were addressed or the rationale for not addressing them.

LMBME requires checks to be documented using the following process/procedure:

- Describe how work was checked in the BCBME risk assessment template.

9.4 Reference Documents

- BCBME RA template

10. Independent Review of High-Risk Professional Activities or Work

10.1 Introduction and Purpose

10.1.1 Introduction

Independent review of high-risk professional activities or work is a documented evaluation of the design concept, details, and documentation, based on a qualitative examination of the substantially complete documents for high-risk professional activity or work that occurs before those documents are issued to those who will rely on them, such as for construction or implementation.

Independent review of high-risk professional activity or work must be carried out by a professional engineer or professional licensee engineering with appropriate experience in the type and scale of the professional activity or work subject to the documented independent review. The level of experience required for a specific high-risk professional activity or work will depend on the risk and complexity of the work. The independent reviewer's experience must be sufficient to critique concepts and identify deficiencies in professional activities or work with complexity equal to or greater than the high-risk professional activity or work being reviewed.

Independent reviews may be one of two types:

Type 1 Independent Review, an independent review carried out by an appropriately qualified and experienced professional who has not been previously involved in the high-risk professional activities or work and is employed at the same firm as the professional of record.

Type 2 Independent Review, an independent review carried out by an appropriately qualified and experienced Professional who has not been previously involved in the high-risk professional activities or work and is not employed at the same firm as the professional of record.

Before starting professional activities or work, professionals must conduct a risk assessment to determine whether the activities or work are high-risk and, if so, whether a Type 1 independent review or Type 2 independent review is required.

Independent reviews of high-risk professional activities or work are mandated by section 7.3.6 of the Bylaws of Engineers and Geoscientists BC and described in the Engineers and Geoscientists BC's *Guide to the Standard for Documented Independent Review of High-Risk Professional Activities or Work*.

During compliance audits, auditors will be confirming that professionals who are carrying out high-risk activities or work are arranging to have documented independent reviews carried out for the high-risk activities or work they prepare or directly supervise, and that appropriate records documenting the reviews are being retained.

10.1.2 Purpose

Professionals have an obligation to assess the risk of work they carry out and complete their work in a manner that appropriately mitigates the risk to the public and the environment. Independent reviews are required when the professional activity or work they have assessed is deemed to be high risk because it involves the potential for severe consequences that could harm the public or damage the environment.

Professional practice guidelines may specify professional activities or work that must undergo an independent review despite not being assessed as high-risk by the professional. A professional may choose to conduct an independent review even though their work is not deemed to be high-risk.

This section describes how independent review of high-risk professional activities or work will be carried out and documented in LMBME.

10.2 Policy

When essential to the task, documented risk assessments will be completed. Table 2 contains guidance for circumstances requiring documented risk assessments.

Where work is deemed to be high-risk or where mandated by regulation, an independent review will be carried out.

Where LMBME does not have experience with the type and scale of the professional activities or work, or the work is innovative and complex, involves emerging technology or does not have well-defined solutions, a qualified independent reviewer will be sourced externally. Otherwise, the reviewer will be a qualified engineering professional, employed by LMBME, who has not been involved in the process.

Table 2: Documented Risk Assessment Guidance for Regulated Practice Areas

Regulated Practice Area	Documented Risk Assessment
Incident investigation process development and leadership	N/A
Incident investigation tasks	Not generally required
Safety alert/recall management process development and leadership	N/A
Safety alert/recall management tasks	Not generally required
Assessment of medical devices involved with research studies	Not generally required
Technical risk assessments	Documented risk assessment required in all circumstances
Medical device modifications	Documented risk assessment required in all circumstances
Preventive maintenance (PM) program process	A specialized risk assessment tool is used for the PM program process which is based upon WHO (World Health Organization) guidelines
Regulatory compliance	N/A
Development of custom medical devices	Documented risk assessment required in all circumstances

10.3 Guiding Principles for Detailed Practice Area Procedures

This high-level procedure applies across the firm and will inform any more detailed procedures for assessing project risk and carrying out independent reviews of high-risk professional activities or work in LMBME.

Professionals of records must:

- Conduct a risk assessment that considers:
  - Hazards associated with the work.
  - Severity and likelihood of consequences.
  - Complexity of the work.
  - Effect of errors or omissions on hazards during construction or implementation.
  - Nature of the assumptions made during the work.
  - Innovation or departure from previous practice.
  - Regulations or authorities requiring independent review of the work.

- For work deemed high-risk due to the severity of consequences resulting from errors or omissions, plan the work to allow for an independent review.
- Where LMBME does not have experience with the type and scale of the work, or the work is innovative and complex, involves emerging technology or does not have well-defined solutions, identify and engage a qualified external resource to carry out the independent review.
- To avoid surprises and significant rework, confirm the various stages, from concept to construction or implementation documents, when the work will be independently reviewed.
- Arrange to have the work checked to confirm that the work and documents meet all requirements and are suitable for their intended purpose.

For Work Involving Design

The independent reviewer must:

- Determine the extent of independent review required and record the rationale for this determination.
- Review the design criteria, sources of risk identified in the risk assessment (including risks imposed by components designed by other disciplines and risks from external sources), and performance requirements.
- Review statutory and regulatory requirements.
- Review geographical and/or environmental requirements.
- Review material properties.
- Review appropriateness and implementation of mitigation measures.
- Review the concept and integrity of the design.
- Where applicable, review the integration of third-party components and artifacts into the work.
- Examine representative samples of the assumptions in the work, components, and detailing.
- Review supporting documents to determine whether they are sufficient to identify the essential components of the work and provide sufficient information to guide the construction or implementation.
- Evaluate documents related to the work to ensure they are complete, consistent, coordinated and in general compliance with the appropriate codes, standards, and other requirements.
- Perform calculations on a representative sample of components to determine whether the analysis, design and detailing generally comply with the appropriate codes, standards, and other requirements.
- Document additional steps taken as well as steps which were deemed not applicable to the work and discuss with the professional of record.

- Discuss any concerns with the professional of record. The professional of record must adequately resolve concerns noted in the independent review.
- Provide a formal record of the independent review to the professional of record highlighting any concerns (see **Appendix A: Checklist and Signoff for an Independent Review of High-Risk Professional Activities or Work**). If significant concerns are noted, the professional of record must revise the work and resubmit the revised work for an independent review.
- If requested, provide the record of the independent review to any authority charged with approving the work.
- Retain and preserve the record of the independent review for a minimum of 10 years.

For Work Involving Assessments, Investigations, Reviews, or Reports

The independent reviewer must:

- Determine the extent of review required and record the rationale for this determination.
- Review hazards identified in the risk assessment (including risks imposed by the work of other professionals and risks from external sources).
- Review the context or situation, available data, and performance criteria for the work.
- Where applicable, review geographical and/or environmental requirements and conditions.
- Where applicable, review test/experimental procedures and results.
- Where applicable, review the integration of third-party components and artifacts into the work.
- Review appropriateness and implementation of mitigation measures.
- Review the assumptions made by the professional of record for the work.
- Review the concept and integrity of the result of the work.
- Review supporting documents to determine whether they are sufficient to identify the result of the work, and, where applicable, provide sufficient information to guide the construction or implementation.
- Review statutory and regulatory requirements.
- Evaluate documents related to the work to ensure they are complete, consistent, coordinated and in general compliance with the appropriate codes, standards, and other requirements.
- Document additional steps taken as well as steps which were deemed not applicable to the work and discuss with the professional of record.
- Discuss any concerns with the professional of record. The professional of record must adequately resolve concerns noted in the independent review.
- Provide a formal record of the independent review to the professional of record highlighting any concerns (see **Appendix A: Checklist and Signoff for an Independent Review of High-Risk**

Professional Activities or Work). If significant concerns are noted, the professional of record must revise the work and resubmit it for an independent review.

- The independent reviewer must provide the review record to any authority charged with approving the work upon request.
- Retain and preserve the record of the independent review for a minimum of 10 years.

10.4 Reference Documents

- BCBME RA template
- Appendix: Checklist and Signoff for an Independent Review of High-Risk Professional Activities or Work

12. Authenticating Documents

12.1 Introduction and Purpose

12.1.1 Introduction

Section 7.3.7 of the Bylaws of Engineers and Geoscientists BC mandates that professionals authenticate documents, containing information related to regulated practice, that they prepare or are prepared under their direct supervision, before those documents are delivered to others who will rely on the information contained in them. This professional obligation is further described in the Engineers and Geoscientists BC's *Guide to the Standard for the Authentication of Documents*.

Section 7.3.7 of the Bylaws of Engineers and Geoscientists BC also mandates that all authenticated documents display the registrant firm's permit to practice number. To satisfy the requirements set out in this Bylaw, only a Responsible Registrant or individuals authorized by the Responsible Registrant may apply the permit to practice number. Professionals authenticating a document are responsible for confirming that all permit to practice requirements have been met prior to authenticating the document.

The seal may be a manual seal which is an ink stamp, or a digital image of a seal accompanied by an approved digital certificate. A document is authenticated when the manual seal is applied, signed, and dated with the date the seal is applied, by the professional whose name is on the seal, or when the approved digital certificate is applied to the digital version of the seal, by the professional whose name is on the seal.

During compliance audits, auditors will be confirming policies and procedures for the appropriate authentication of professional documents are being adhered to and that all professional documents are being appropriately authenticated prior to them being delivered to parties who will be relying upon them.

12.1.2 Purpose

The Engineers and Geoscientists BC seal is used to authenticate documents related to regulated practice. When signed and dated, or when an approved digital certificate is applied, a professional's seal indicates to the user of the document that the document has been prepared and delivered in the professional capacity of, or directly supervised by, a qualified professional, who is taking responsibility for the contents of the document for it's intended use.

The professional's seal indicates that the document has not been altered, and that it contains the original information for which the professional accepted responsibility. The seal is a mark of reliance, an indication that others can rely on the fact that the opinions, judgments, or designs in the sealed

documents were provided by a professional held to high standards of knowledge, skill, and ethical conduct. It is not a warranty.

The application of the permit to practice number is a confirmation that all permit to practice requirements have been met.

Legal liability is different from professional responsibility. Whether or not professional's authenticate documents they prepare or directly supervise, they are liable for the content. However, if they issue an unauthenticated professional document to others who will be relying on the engineering content, they will be in breach of the Bylaws of Engineers and Geoscientists BC.

This section describes how professional documents will be authenticated in LMBME.

12.2 Policy

Any professional document that a professional prepares or directly supervises must be authenticated before it is issued to others who will rely on its engineering content.

LMBME has not identified any documentation which engineers routinely produce that requires authentication. In some circumstances, documentation related to medical device modifications or development of custom-made medical devices, may require authentication.

LMBME's permit to practice number (1001931) must appear on all authenticated documents. The Responsible Registrant(s) is responsible for, and the only individual who can authorize the application of the permit to practice number on professional documents issued by LMBME. The Responsible Registrant must set or agree to policies regarding the application of the permit to practice number in professional documents for the area(s) of practice for which they are responsible.

The seal must remain in the care and control of the professional to whom it was issued and may only be signed and dated, or digitally certified, by that individual.

12.3 Guiding Principles for Detailed Practice Area Procedures

This high-level procedure applies across the firm and will inform any more detailed procedures for authenticating documents in LMBME.

Professionals of record will:

- Maintain the care and control of their professional seal.
- Review all professional documents to the extent they deem necessary to take professional responsibility for the engineering content.
- Confirm that all permit to practice requirements have been met and that the permit to practice number is included on all authenticated documents.
- Decide when and whether a professional document is ready to be authenticated.

- Use a signed and dated manual seal or apply a digital seal with digital certification approved by Engineers and Geoscientists BC to authenticate all professional documents that they prepare or directly supervise before those documents are delivered to others who will rely on them.
- For manual seals, the date must be the date the seal was applied.
- Authenticate all professional documents that:
    - the professional has prepared in their professional capacity or has been prepared under their direct supervision,
    - contain content related to the regulated practice, and
    - will be relied on by others.
- Authenticate all record drawings that contain changes to the engineering content not previously issued in an authenticated document.
- Any email correspondence which contains professional engineering advice, or decisions issued in a professional capacity will be followed up with an appropriately authenticated document.
- Retain a record copy of all authenticated documents in the project file.

13. Direct Supervision

13.1 Introduction and Purpose

13.1.1 Introduction

As required by section 7.3.8 of the Bylaws of Engineers and Geoscientists BC, professionals must meet the requirement of Direct Supervision in all areas of regulated practice where there is delegation to subordinates. This professional obligation is further described in the Engineers and Geoscientists BC's *Guide to the Standard for Direct Supervision*.

Delegating means to undertake certain activities, work, or decisions related to the regulated practice on behalf of a professional who takes professional responsibility for the work of the subordinate. To directly supervise work delegated to a subordinate means to control and conduct the activities, work, or decisions related to the regulated practice that have been delegated to a subordinate. A subordinate may be any individual who engages in the regulated Practice under the direct supervision of a professional. Typically, these individuals are engineers-in-training, technologists, another non-professional or less experienced professionals.

During compliance audits, auditors will be confirming professionals are directly supervising any engineering work that they delegate to subordinates who are non-professionals or professionals whose level of experience is insufficient for the activity or work.

13.1.2 Purpose

When professionals authenticate documents, or otherwise take professional responsibility for professional engineering work, they are exposing themselves to personal liability for the work. When they delegate engineering work, they remain responsible for that work. Adequate and appropriate direct supervision mitigates their risk and ensures that professionals retain appropriate control of that work. Direct supervision also allows more experienced professionals to assist in the professional development of those less experienced.

This section describes the delegation and direct supervision of engineering work in LMBME.

13.2 Policy

Professionals must directly supervise any engineering work that they delegate to a subordinate. When doing so, professionals must retain appropriate control of and take professional responsibility for that work.

A subordinate may be an engineer-in-training (EIT), technologist, a non-professional, or a less experienced professional to whom a professional delegates engineering work.

13.3 Guiding Principles for Detailed Practice Area Procedures

This high-level procedure applies across the firm and will inform any more detailed procedures for direct supervision in LMBME.

To delegate work to a subordinate, professionals of record will:

- Assess the work that may be delegated to confirm the knowledge, experience and capabilities required, and any tools or resources (e.g., standards, codes, etc.) that can be used to successfully implement the work.
- Assess the subordinates to confirm that they have the required knowledge, capability and experience and to identify any gaps that must be addressed.
- Make required tools and resources available and address any gaps in them, including identifying subject matter experts to be consulted during the work.
- Address gaps in the subordinate's knowledge, skills and experience by setting up a monitored learning experience.
- Establish the subordinate's scope of work, duties, responsibilities, authorities, and limits on acting alone.
- Create a plan defining when and how the subordinate's work will be reviewed.
- Delegate the work to the subordinate and communicate the scope of work, duties, responsibilities, authorities, limits on acting alone, and the timing and process for required reviews.
- Be available to answer questions.
- Be involved in all engineering decisions.
- Review the subordinate's work, as planned.
- Retain documentation to demonstrate that professional reviews of the subordinate's work took place.

14. Appendixes

- **Clinical Engineer Continuing Education Plan Assessment**
- **Checklist and Signoff for Independent Review of High-Risk Activities and Work**

14.1.1 Clinical engineer continuing education plan assessment (EGBC template)

REGISTRANT INFORMATION				
Name and Designation:			**User ID:**	
Job Title:				
Industry of Practice:				
Area(s) of Practice (including any anticipated changes):				
Dates that this CE Plan applies to:	**From:**		**To:**	

REVIEW OF PREVIOUS YEAR'S ACTIVITIES	
In reviewing your development plan for the previous year, did you complete all of your planned activities? Why or why not?	

PRACTICE RISK ASSESSMENT		
By which method have you assessed your practice risks?	☐ Engineers and Geoscientists BC Practice Risk Assessment Tool (attached)	☐ Other risk assessment
If you have used another risk assessment, please briefly describe the method and outcomes.		
☐	I have assessed the risks of my practice and will use continuing education opportunities to learn about and reduce those risks where necessary.	

REVIEW OF LEARNING NEEDS		DEVELOPMENT PLAN		
In what area of my practice do I need to improve my performance, skills, or knowledge?	What do I need to learn to achieve or maintain Competency in this area?	What activities do I need to obtain this learning?	How will I evaluate a successful outcome?	What is my deadline for meeting this outcome?
Area 1:				
Area 2:				
Area 3:				
Based on the above development plan, please list at least three activities you plan to complete in the upcoming Three-Year Rolling Period.		Activity 1:		
		Activity 2:		
		Activity 3:		
		Activity 4:		

List at least one Ethical Learning activity or topic you plan to pursue this year.	

REVIEWER INFORMATION (IF APPLICABLE):

Note: All registrants are highly encouraged, but not required, to review their CE Plan with another person, such as a peer or manager. Please refer to Section 3.3.1 for more information.

Name of Reviewer:	
Position/Relationship: (e.g. Manager, Supervisor, Mentor, Peer)	

CE PLAN DECLARATION

I hereby declare that the information presented above is true to the best of my knowledge.

Signature:		**Date:**	

CHECKLIST AND SIGNOFF FOR an INDEPENDENT REVIEW of High-Risk Professional Activities or Work

[Print clearly and legibly]

PROFESSIONAL OF RECORD

RE:

Name of project, activity, or work	Name of professional and designation (P.Eng., P.L.Eng.)
Address of project, activity, or work	Firm name
	Permit to Practice number
	Address of firm

ITEM	REVIEWED INITIALS	REMARKS
1. Assumptions for Professional Activities or Work		
2. Concept for Professional Activities or Work		
3. Criteria for carrying out Professional Activities or Work		
4. Calculations or Analysis		
5. Representation or Output (e.g., drawings, reports, spreadsheets, models, etc.)		

6. Design check of representative elements		
7. Review of representative details		
8. Applicable codes, standards and regulations		
9. Review of Risk Assessment		
10. Qualifications of Reviewer for Type 2 Review		
11. Concerns discussed with the Engineer of record		

INDEPENDENT REVIEWER

Name of professional and designation

(P.Eng., P.L.Eng.)

Firm name

Permit to Practice number

Address of firm

Date: (yy/mm/dd)

Signature

CHECKLIST AND SIGNOFF FOR an INDEPENDENT REVIEW of High-Risk professional Activities or Work

[Print clearly and legibly]

TO: **ENGINEER OF RECORD** DATE (yy/mm/dd): _____

Name of professional and designation (P.Eng., P.L.Eng.)

Firm name Permit to Practice number

Address of firm

RE: Name of project, activity, or work

Address of project, activity, or work

The undersigned hereby records that an Independent Review of the professional activity or work, based on the Documentation prepared by the Engineer of record for the professional activity or work, has been completed by this Independent Reviewer.

I am a member of the firm

_____
(Name of Firm)

with the Permit to Practice number

_____
(Permit to Practice Number)

and I sign this letter on behalf of the firm.

I certify that I am a Professional Registrant as defined below.

DATE
(yy/mm/dd): _____

_____

Name of professional and designation

(P.Eng., P.L.Eng.)

_____

Signed

_____

Address

_____

_____ (Affix PROFESSIONAL SEAL here)

Telephone

NOTE:

1. The above letter must be signed by a Professional Registrant (professional engineer, professional licensee engineering, licensed to practice by Engineers and Geoscientists BC) qualified to conduct an Independent Review of the professional activity or work being reviewed.

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