

THE ENGINEERING PROFESSION'S POSITION

- Biomedical engineering is a critical and rapidly expanding discipline that holds significant potential to greatly enhance healthcare and the quality of life of Canadians.
- The regulation of biomedical engineers and biomedical engineering recognizes the importance of ensuring the safety and efficacy of medical devices and treatments developed through this field, as well as the need to protect the public from any potential harm.
- Incorporating biomedical engineers' accountability into federal, provincial, or territorial legislation and regulations related to biomedicine weaves the engineering regulatory process into the fabric of government and thereby keeps Canadians safe and the country prosperous.
- To safeguard the public and prevent unlicensed individuals in biomedical engineering from performing duties that require a licensed engineer, it is crucial for all stakeholders—the public, engineers, governments, regulators and decision-makers—to comprehend the regulated scope of biomedical engineering and the benefits of its regulation by provincial and territorial engineering licensing bodies.

The challenge(s)

Biomedical engineering is the application of engineering principles and practices to medicine and biology for healthcare purposes.¹ Biomedical engineers use their knowledge of engineering and biological sciences to plan, design, develop, and evaluate medical devices, systems, materials, and equipment, as well as to create new technologies and therapies.² The vast field can be broken down into several subfields, that include (i) biomedical devices and instrumentation, (ii) medical imaging, (iii) biomechanics and rehabilitation engineering, (iv) biomaterials and tissue engineering, and (v) biomedical signal and image processing. Biomedical engineers therefore play an important role in the development of new technologies and therapies that can improve the diagnosis, treatment, and understanding of human health and disease.

Medical devices developed through the application of engineering are used widely. The associated medical devices industry is heavily

regulated in Canada. Like other regulated industries, software is used to drive or control biomedical devices such as radiation (imaging) devices, surgical robots, and non-invasive instruments. In some cases, medical devices interact directly with humans and must be safely controlled. The overall system including the associated software must be designed not only to function in an appropriate manner, but to prevent malfunction and inappropriate or unsafe operation, even in the presence of failures. Defective hardware and software could lead to direct harm to the patient in the use of the medical devices or to the incorrect processing of data, and consequently poor decisions or actions on the part of health care providers impacting future patient health. Erroneous processing on the part of such a system could result in a false negative (which incorrectly indicates that a disease condition or attribute is absent) or in a false positive (a result that incorrectly indicates that a particular condition or attribute is present). The need for safety in such systems is clear: failure

¹ Enderle, J. & Bronzino, J. (2012). *Introduction to Biomedical Engineering*. Academic Press. pp. 16-. ISBN 978-0-12-374979-6.

² *IBID*

or erroneous behaviour can result in injury to patients. Because of this risk, medical device design, production, operation, and maintenance are subject to industry specific regulation. Concerns about the development and use of medical devices also exist in other subfields of biomedical engineering.

Biomedical engineering is a rapidly evolving field, and there is an increasing need for licensed biomedical engineers who can apply their knowledge of engineering principles and practices to the planning, design, development, and evaluation of medical devices, equipment, materials, and therapies. As the population continues to age, there is increased demand for medical devices and associated treatments that can help older individuals maintain their independence and quality of life. Additionally, advancements in technology enable the development of new therapies and devices. Together this drives demand for licensed biomedical engineers who can help to plan, design, develop, and evaluate these new therapies and devices. The regulation of biomedical engineering is therefore crucial for ensuring the safety and efficacy of medical devices and associated therapies developed through this field and protecting the public from any potential harm.

How Engineers Canada has contributed

Engineers Canada actively participates in federal consultations regarding legislation and regulations that impact the work of engineers and address initiatives that require the expertise of an engineer.

Biomedical engineering programs at Canadian post-secondary institutions that apply for accreditation are subject to an accreditation process, developed and administered by Engineers Canada through the Canadian

Engineering Accreditation Board (CEAB). The CEAB ensures these biomedical engineering programs are current and relevant to Canadian needs.

With licensure tools developed by Engineers Canada, the provincial and territorial engineering regulatory bodies can assess the qualifications of all applicants to determine whether they are eligible for licensure and to determine requirements that need to be satisfied to achieve professional engineer status.

In addition, the Canadian Engineering Qualifications Board (CEQB) has developed the [Biomedical Engineering Syllabus](#) to further define the requirements for biomedical engineering. The CEQB, in consultation with the provincial and territorial engineering regulators, has also prepared a national document that provides guidance to regulators regarding the scope and depth of the software engineering discipline, which is closely related to biomedical engineering in some cases. This [national paper on professional practice in software engineering](#) provides an introductory rationale that addresses the nature of practice in software engineering, including the use of software in biomedical devices and their applications.

Provincial and territorial engineering regulators play a crucial role in ensuring the safe and ethical practice of biomedical engineering. They do this by setting standards and guidelines for the practice of engineering and by enforcing these standards through licensing and disciplinary processes. Most engineering regulatory bodies regulate engineering businesses to ensure that companies without a Permit to Practice are prohibited from practicing engineering, including biomedical engineering, and from using reserved titles. This helps to protect the public and ensure that new technologies and therapies are developed and used in a responsible and effective manner.

Recommendations to the federal government

The federal government should continue to recognize that the Canadian public are best served when the jurisdiction of the 12 provincial and territorial engineering regulators is recognized and respected. These regulators have been delegated the authority to regulate the engineering profession by their respective provincial and territorial governments. They maintain high professional and ethical standards, establish codes of conduct, and ensure timely, transparent, objective, impartial, and fair admissions and licensing practices. By overseeing and supporting the practice of professional engineering in their jurisdictions, they help ensure the protection of the Canadian public.

The licensing of biomedical engineers by one of the 12 provincial and territorial engineering regulators ensures that only qualified and competent individuals can practice in the field and provides a mechanism for disciplining those who engage in unethical or unsafe practices. This helps maintain the integrity of the profession and protects the public. Engineers are also responsible for upholding ethical and safety standards and ensuring that their products and services meet these standards, as well as for the safety, performance, and reliability of their designs.

To ensure proper consultation and collaboration in accordance with provincial and territorial engineering acts, the federal government should involve professional engineers when developing or amending legislation and regulations related to biomedical engineering or biomedical engineers.

How Engineers Canada will contribute

Engineers Canada will continue to contribute in the following ways:

- Ensure Canadian standards for the accreditation of biomedical engineering in Canadian universities are current and reflect Canadian needs.
- Support the work of provincial and territorial regulators to enforce the engineering acts as they pertain to the practice of biomedical engineering.
- Monitor the federal government's agenda, legislative initiatives, and proposed biomedical regulations to bring recommendations on emerging areas to the attention of the federal government.