

# Evaluation of the National Research Council of Canada's implementation of the Biologics Manufacturing Centre program

**Office of Audit and Evaluation**

March 28, 2024



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Cat. No. NR16-442/1-2024E-PDF

ISBN 978-0-660-71887-3



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# Initialisms and acronyms

<b>BMC</b>	Biologics Manufacturing Centre
<b>CCRM</b>	Centre for Commercialization of Regenerative Medicine
<b>ISI</b>	Innovation, Science and Industry
<b>NRC</b>	National Research Council of Canada
<b>RPPM</b>	Real Property Planning and Management
<b>SEC</b>	Senior Executive Committee
<b>VP</b>	Vice-President
<b>VP SI</b>	Vice-President, Strategic Initiatives

# Introduction

An evaluation of the National Research Council of Canada's (NRC) implementation of the **Biologics Manufacturing Centre (BMC) program** was conducted in fiscal year 2023-24 and covered activities up to July 31, 2023. The evaluation was conducted in accordance with the NRC's Departmental Evaluation Plan and the Treasury Board's Policy on Results (2016).

This report begins by providing a detailed description of the context and world events that led to the development of a vaccine manufacturing centre in Canada. An overview of the model that was used to set up and govern the BMC is also provided. The report then presents findings on:

- the effectiveness of the transition of the BMC from the NRC to its own separate entity, and
- the degree to which the NRC is positioned for its stewardship role of providing oversight of the lease and contribution agreement with the BMC.

**In this report, you may see the following symbols:**



Information that is useful to know to help understand the findings.



Information that supports equity, diversity, inclusion and Gender-based Analysis Plus (i.e., factors that illustrate how diverse groups may experience policies, programs and initiatives).

The report uses the term “**BMC program**” for BMC-related activities that are within the NRC.

The “**BMC**” is used to describe the vaccine manufacturing facility, first established by the NRC and then transferred to a not-for-profit corporation for ongoing operation.



# Evaluation approach

## Scope

A detailed planning phase was conducted prior to commencing the evaluation. The scope of the evaluation was determined in consultation with management with the goal of providing value to the BMC program as well as insight for future similar endeavours.

The evaluation focused solely on the NRC's activities in relation to the BMC program and did not evaluate the BMC. Specifically, the scope of the evaluation included:

- transition from the NRC to the BMC
- the NRC's steady state stewardship and oversight arrangements

The evaluation focused on activities up to July 31, 2023. The evaluation did not examine operations and governance activities that commenced after this date. Project management and facility construction were not examined as part of this evaluation.

## Approach

This is the first evaluation of the BMC program. The evaluation used a mixed-methods approach, incorporating qualitative and quantitative data from several lines of evidence.

## Evaluation questions

1. With regards to the transition from the NRC to the BMC:
  - a. What went well, and why?
  - b. What could have gone better, and why?
  - c. What practices should the NRC sustain for future not-for-profits?
  - d. What could the NRC do differently next time?
2. To what extent is the NRC set up to ensure good stewardship of the BMC program going forward?

## Methods

The evaluation included:

- document and data review
- internal (NRC) interviews (n=15)
- external (BMC) interviews (n=6)



### Interested in the NRC's evaluation

**methodology?** For detailed information on the methods used by the NRC's Office of Audit and Evaluation, including limitations and mitigations, refer to [Appendix A](#) and [Appendix B](#).



# Profile

The Biologics Manufacturing Centre (BMC) is an end-to-end biomanufacturing facility, supporting the growth of domestic biomanufacturing production capacity for the future by ensuring that vaccines and other biologics can be safely manufactured in Canada for Canadians. Designed to produce biopharmaceuticals like viral vector, protein subunit, and virus-like particle vaccines and other biologics, the BMC is an important part of Canada's biomanufacturing infrastructure and a key element of the Government of Canada's Biomanufacturing and Life Sciences Strategy.

Conceived of and built during the COVID-19 pandemic, the business and governance model for the BMC was novel. Initially established and operated by the NRC, the objective was to set up an arms-length, not-for-profit organization, through a public–private partnership arrangement.

Once the not-for-profit was established, the NRC transitioned the operations to the Biologics Manufacturing Centre (BMC) Inc., maintaining an important role as co-founding member, owner of the facility and equipment, holder of the lease and funder. The NRC also participates in BMC oversight and governance, including through its role as observer on the BMC Board of Directors.

# Overview

## Government of Canada announcement

In August 2020, the Government of Canada announced \$126 million in funding over 2 years to build the BMC, a new biomanufacturing facility adjacent to the NRC's Royalmount site in Montreal. An additional investment of \$20 million annually was also announced, to offset the operating costs of the new facility. With the announcement, the Government of Canada also signaled its intention to operate the facility through a public–private partnership in the future.

The process to identify the optimal public–private partnership included consultation with sector stakeholders (i.e., academia, industry and government). After reviewing several types public–private partnership used in Canada and other jurisdictions, the NRC concluded that a not-for-profit governance model was optimal for the BMC. Construction of the new BMC was completed in June 2021, 10 months after breaking ground.

Following their inspection in August 2022, Health Canada issued the facility's drug establishment licence, which demonstrates the facility's compliance with good manufacturing practices.



## Not-for-profit co-founder and incorporation

In July 2022, the NRC sought a co-founder, a partner with whom to create an independent not-for-profit corporation to govern the facility's operations. In October 2022, the Centre for Commercialization of Regenerative Medicine (CCRM) was selected through an independent, transparent process.

The NRC and CCRM proceeded to incorporate Biologics Manufacturing Centre (BMC) Inc. and established the BMC's interim board of directors in December 2022.



For more detailed information on the **BMC facility** and **milestones**, refer to [Appendix C](#) and [Appendix D](#).



# Biomanufacturing and life sciences strategy

The BMC forms an important part of Canada's Biomanufacturing and Life Sciences Strategy, building public capacity and expanding key public assets in support of pandemic preparedness.

## A decades-long decline in Canada's domestic biopharmaceutical industry

Canada did not have the large-scale and flexible biomanufacturing capacity needed to quickly produce a COVID-19 vaccine when the pandemic hit. As a result, the Government of Canada developed Canada's Biomanufacturing and Life Sciences Strategy, which is driven by 2 objectives:

- growing a strong, competitive domestic life sciences sector with cutting-edge biomanufacturing capabilities
- ensuring preparedness for pandemics or other health emergencies

The Strategy consists of 5 pillars:



strong and coordinated governance



laying the foundation



growing businesses



**building public capacity\***



enabling innovation



\*The BMC is a key element in increasing Canada's public biomanufacturing capacity and serves as a foundational element for a proposed broader system of federal capabilities and assets to respond to future pandemics and other health priorities.

# Financial resources

## Funding

In October 2020, the NRC received Treasury Board approval to access new funding (\$100 million in capital and \$26 million in operations) to build the facility and to operate it for its first 2 years. In addition, a 10-year, non-repayable contribution agreement provides \$17 million in annual funding to the BMC to maintain core operations and to keep the facility in a good manufacturing practices readiness state.

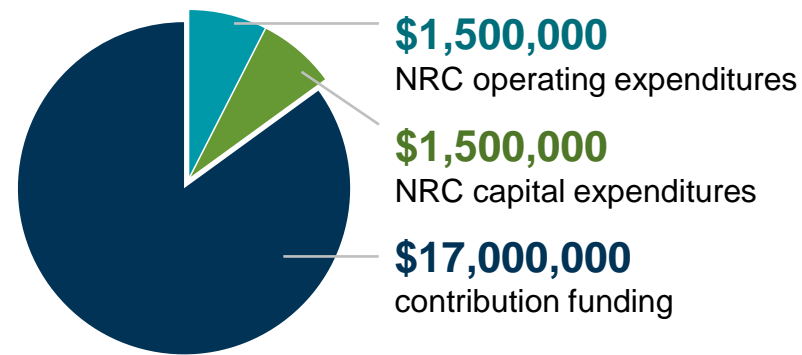
The NRC invested \$2.7 million to set up the BMC and its governance structure. This included funding to develop processes and systems required to transition the facility operations from the NRC to the BMC.

## Revenues

The BMC will use a cost-recovery approach to contribute to the financial sustainability of its operations. This includes generating revenues based on fees for services related to client production. The BMC will also be able to secure other funding sources, such as other public funding and potential funds from private donors.

The BMC will need to use revenues to support public interest projects such as the production of orphan drugs. Any profits remaining will be re-invested into the facility and its equipment.

**Figure 1. Annual funding for the Biologics Manufacturing Centre**



**The NRC's operating expenditures:** include \$1.1 million for building and site maintenance costs. A further \$400,000 of annual operating funding is allocated for oversight and administrative management costs (such as office supplies, tracking and reporting on agreements, secretariat support for governance committees and costs associated with building management).

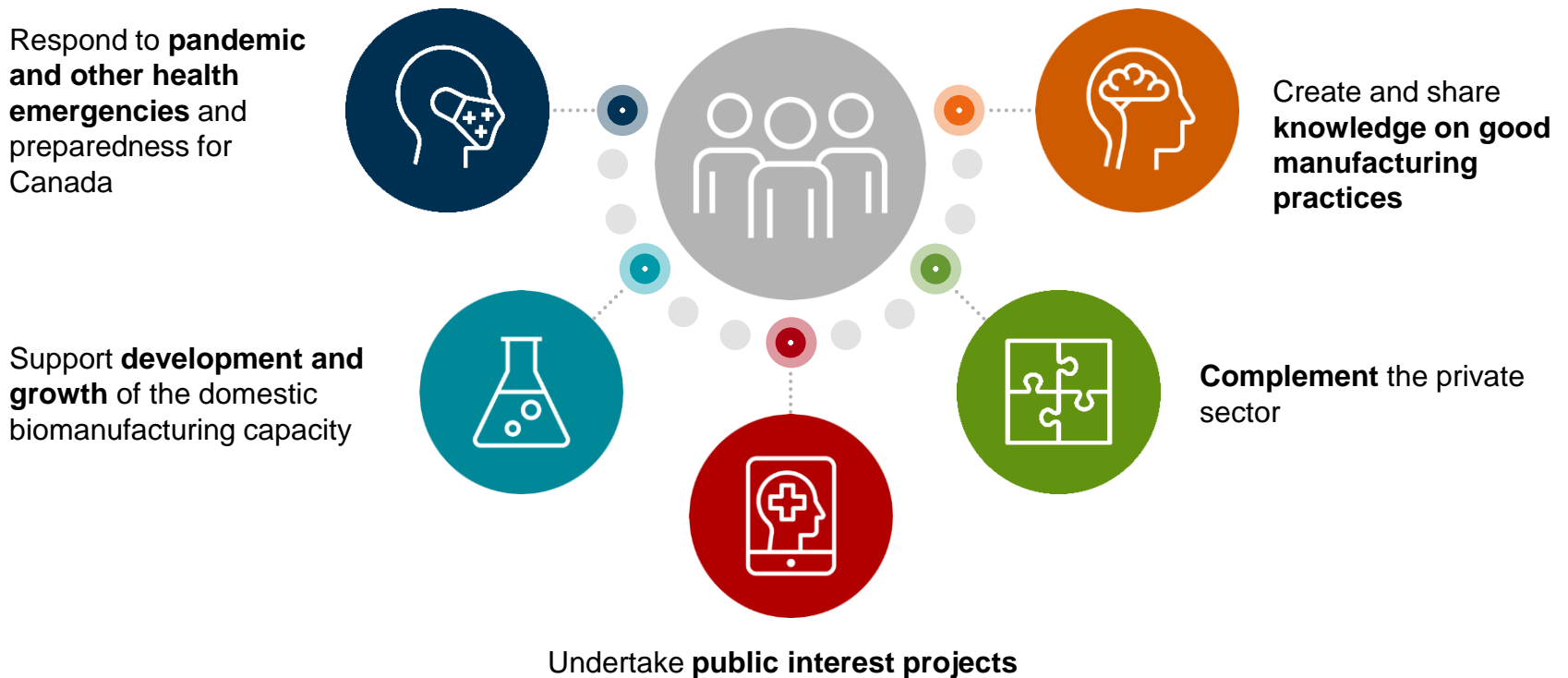
**The NRC's capital expenditures:** used for building recapitalization, based on a fixed asset review recommendation of 2.5% of building costs.

**Contribution funding:** eligible expenditures consist of basic operating costs, including salaries and benefits, utilities, property taxes and other operating costs (including new investments and upgrades within the facility).

# The Biologics Manufacturing Centre's mandate

The NRC provides the BMC with operational funding to support its efforts in complying with its public good mandate. The BMC's dual mandate of emergency preparedness and sector support aligns with Canada's Biomanufacturing and Life Sciences Strategy.

## Public good activities for Canada and Canadians



# Foundational agreements

There were 3 agreements developed to establish and codify the relationship between the NRC and the BMC. The transfer, assignment and transition agreement guided matters related to the handover of the facility from the NRC to the BMC. The contribution and lease agreements guide the steady state relationship.

## Transfer, assignment and transition agreement

This agreement was used to manage the transition of the BMC to the not-for-profit. Between the NRC and the BMC, the agreement covered the assignment of contracts, transfer of assets, representation and warranties, and transition provisions.

## Lease agreement

The lease agreement is a specialised document tailored for the unique context of leasing a biomanufacturing facility with equipment and emphasizes its mission-driven purpose in responding to health emergencies. It codifies the terms by which the BMC will occupy, manage, operate and maintain the NRC-owned biomanufacturing facility.

It includes provisions that make it distinct from a standard lease, relating to the eligible use of the facility, financial arrangements, security, intellectual property rights, and responsibilities for both parties.

## Contribution agreement

The NRC provides operational funding to the BMC through a formal contribution agreement. This agreement supports the operations of the BMC in return for the not-for-profit complying with its public good mandate. It is a 10-year, legally-binding agreement that outlines the terms and conditions for the contribution the NRC provides to the BMC, including requiring the BMC to:

- report on activities involving NRC funds
- develop a business plan describing the BMC's strategic priorities and efforts to maximize the value of the operation of the facility
- report results
- provide signage and public communications in both official languages
- ensure security protections for the building

# Unique health emergency requirement

As a funding and lease condition, the BMC must stop its activities and pivot to address a health emergency requirement if directed by the Government of Canada. The NRC will direct the not-for-profit based on the health emergency triggered by the Minister of Innovation, Science and Industry (ISI), following the recommendation of the Minister of Health.

## Process to trigger health emergency



### **Preliminary health emergency notice**

Minister of ISI directs the NRC to provide notice to the BMC and indicate response requirements (e.g., designated party to work with, type and quantity of product).



### **Feasibility assessment**

Within 15 working days of receiving notice, the BMC works with a designated party to conduct a manufacturing feasibility assessment and provide cost estimates, including penalty costs payable under client agreements.



### **Health emergency response directive**

Based on the feasibility assessment and the Minister of Health's recommendation, the Minister of ISI instructs the NRC to issue a directive to the BMC to respond to the health emergency. Next steps are:

- the designated party negotiates a procurement agreement with the Government of Canada
- the BMC negotiates fair compensation with the Government of Canada for the stoppage of activities and outfitting costs
- the BMC and manufacturer negotiate a production agreement



### **Health emergency manufacturing of product**

Once agreements with the designated party and the Public Health Agency of Canada are in place, the not-for-profit proceeds with manufacturing the product.

# Governance and oversight

Various governance structures exist and play a role in supporting both the NRC and the BMC. The NRC's President and Senior Executive Committee are ultimately accountable for the governance of the BMC program. The BMC Board of Directors and the leadership team are responsible for oversight of the not-for-profit's operations and compliance. The Facilitation Committee and Site Coordination Board are key joint committees that exist to manage and resolve issues between the 2 parties.

## NRC

### Senior Executive Committee:

- acts as the main internal decision-making body in all matters pertaining to the NRC's operations
- ensures the achievement of the NRC's performance, objectives and outcomes
- maintains compliance with policy and regulatory requirements
- maximizes the impact of the NRC's investments, in compliance with the NRC's mandate and priorities

## Joint NRC–BMC committees

### Facilitation Committee:

- addresses issues and risks that arise under the agreements and negotiates resolutions to issues and risk mitigations
- may receive issues for resolution from the Site Coordination Board
- meets quarterly

### Site Coordination Board:

- ensures smooth management of the lease agreement and coordination of activities between the NRC and the BMC
- meets bi-weekly (for members working on operations and maintenance) and quarterly (all members)

## BMC

### Leadership team:

- responsible for managing and operating the facility in a constant good manufacturing practices readiness state
- liable for the performance of all obligations under the agreements, in accordance with applicable laws

### Board of Directors:

- ensures the successful governance of the corporation including acting in the best interests of the BMC

# NRC senior executive roles

Multiple NRC vice-president offices are responsible for different elements of the BMC program.

## Vice-President, Business and Professional Services

- oversight of contribution agreement
- member, NRC–BMC Facilitation Committee
- represents the NRC as a co-founding member of the not-for-profit
- NRC observer to the BMC's board of director meetings

## Vice-President, Corporate Services and Chief Financial Officer

- oversight of lease agreement
- co-chair (with the BMC), NRC–BMC Facilitation Committee

## Vice-President, Life Sciences

- NRC lead on Canada's Biomanufacturing and Life Sciences Strategy
- requesting information about the BMC from the Facilitation Committee as needed to report back to the Biomanufacturing Life Sciences Strategy secretariat on the pillar 4 of the Strategy, building public capacity



# Key NRC enablers

**In addition to providing funding through the contribution agreement, the NRC enables the BMC to realize its objectives through a number of key mechanisms.**

## **NRC secretariat for the BMC program**

Located in the NRC's National Program Office, the secretariat facilitates and supports overall delivery of the BMC program within the NRC. The secretariat serves as a central liaison between parties and:

- liaises and coordinates between the BMC and the NRC branches overseeing agreement management
- conducts a review and follows-up to ensure compliance with obligations under the agreements
- liaises with the NRC's Policy, Strategy and Performance branch and the BMC on Government of Canada performance reporting requirements
- monitors all aspects of the contribution agreement and provides subject matter expertise
- ensures the BMC receives policies related to its obligations on behalf of the NRC
- coordinates the NRC's review of official BMC documents (e.g., business plan)

The secretariat also provides support to the joint NRC–BMC committees and to the NRC observer on the BMC Board of Directors.

## **Real Property Planning and Management service delivery**

Real Property Planning and Management (RPPM) negotiates and fulfills the maintenance standards agreement for the NRC's dedicated and shared infrastructure, including maintenance, repair, removal and replacement.

In collaboration with the Security branch and Health, Safety and Environment branch, RPPM reviews and approves the BMC security plan for potential security, health, and safety events (e.g., major adverse events, threats or terrorism).

RPPM may request a security risk assessment by the BMC and independently conduct one within 3 years of the approved security plan. RPPM also reviews, processes and approves:

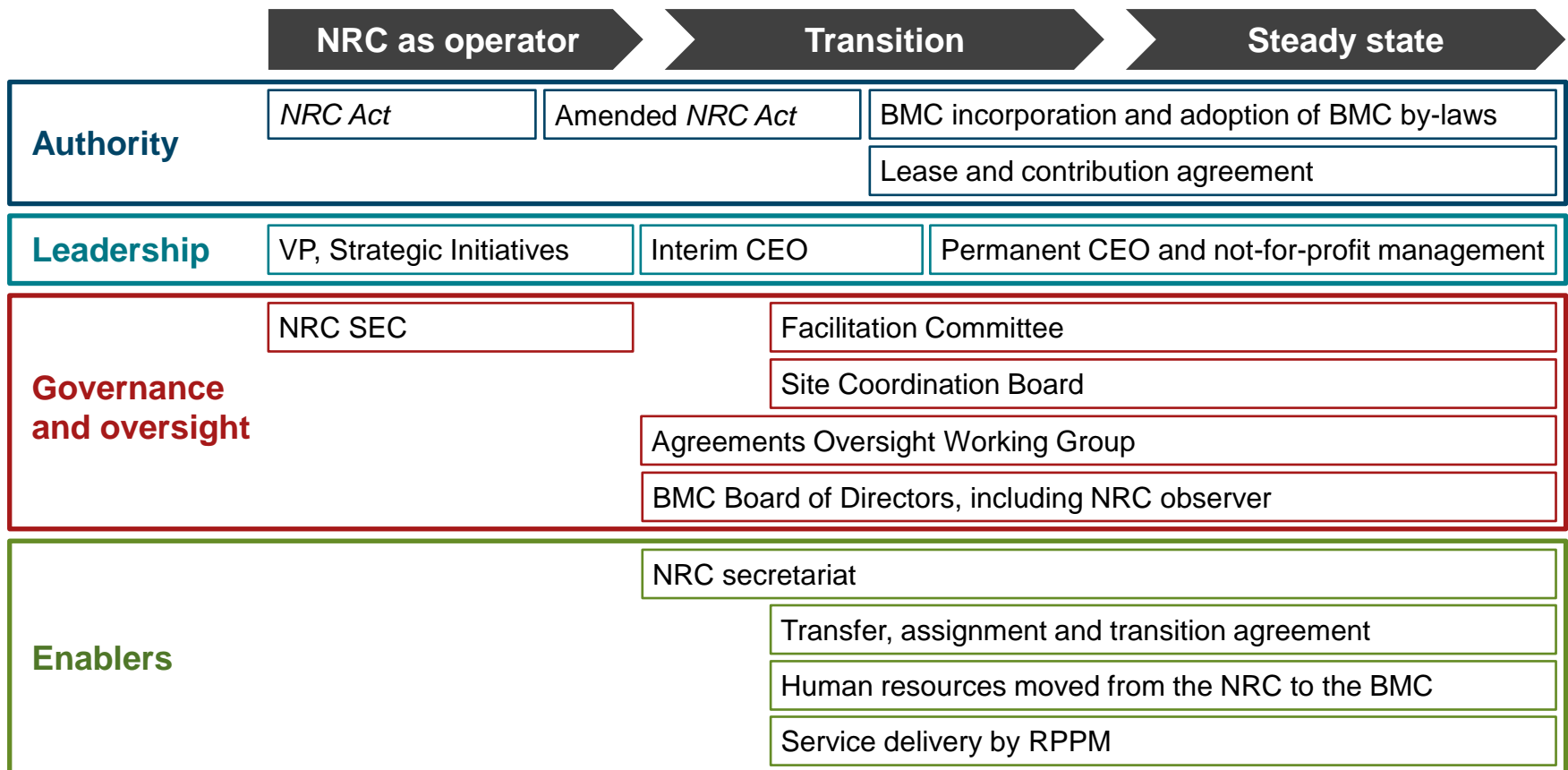
- BMC's renewal requests for individuals' security screenings
- sufficiency of BMC insurance coverage
- BMC's inventory and management of hazardous materials, safety data sheets and chemical management system
- changes to external signage, telecommunications or NRC-owned equipment



# Initial operations and transition

The BMC business and governance model was established through a multi-phased approach. Initially managed by the NRC, it then transitioned to a new not-for-profit management team and board of directors, who assumed operational and governance duties. Authorities, leadership, governance and oversight evolved through the transition.

**Figure 2. Evolution of responsibilities throughout the transition**



# Structure

Figure 3. Pre-transition organizational structure of the Biologics Manufacturing Centre



Figure 4. Biologics Manufacturing Centre organizational structure (as of April 1, 2023)



# Human resources

On March 31, 2023, the NRC's BMC had a total of 98 staff and students on expiring term contracts. Once the contracts expired, the former NRC employees were hired by the not-for-profit on April 1, 2023.

Prior to the end of their term contracts, NRC BMC employees received letters of employment offers from the not-for-profit. On April 1, 2023, 99% of employees accepted the employment offers and began employment with the not-for-profit.

## Biologics Manufacturing Centre staff and students (as of March 31, 2023)



### The representation of women at the BMC was 40% (target was 43 to 57%)

It is expected that the BMC's operations and management teams, and future board of directors (both interim and long term) will have balanced representation that is aligned with the Government of Canada's 50 – 30 Challenge initiative, notably achieving gender parity and 30% of employees and the not-for-profit board of directors being from underrepresented demographic groups.



# Transition from the National Research Council of Canada to the Biologics Manufacturing Centre

The transition of BMC operations from the NRC to the Biologics Manufacturing Centre (BMC) was characterized by tight timeframes, novel approaches and a high degree of complexity. The emergency context within which the BMC was set up and transferred to the not-for-profit partner was a significant source of complexity and extraordinary efforts were made to meet very short timelines.

Many strengths were noted and lessons were learned and captured in a formal lessons-learned report. Notable strengths included leadership, collaboration, a structured framework through which to manage the transition and strategic approaches used to efficiently transfer information technology and human resources to the BMC.

Challenges were also encountered, such as difficulties obtaining timely, easy access to expert legal counsel on unique matters related to the lease. Risks going forward have been identified related to the financial sustainability of the BMC, although more time is needed to assess this.

Change management was effective for the transition of personnel from the NRC to the BMC. In parallel, the NRC needed to establish an oversight function post-transition. This included setting up an NRC secretariat for the BMC program, as well as the Facilitation Committee and Site Coordination Board.

To support this, an internal working group was established in February 2023 to work through the NRC's roles and responsibilities, transfer knowledge and develop and implement an oversight approach. During this early oversight implementation phase, issues and risks should form the basis for arriving at appropriate steady state oversight arrangements, focusing on maximizing effectiveness and efficiency.

# What worked well

**The establishment of a novel business model and its transition to a newly-created not-for-profit was done in a short period of time, with extraordinary effort by the NRC. Success factors included leadership, expertise, and a structured approach to project management, as well as acquiring and transferring essential resources.**

## Dynamic leadership and expertise

Negotiation of the BMC agreements was complex due to the BMC's unique arrangements and novel business model. Broad consultation and specialized expertise were required to ensure all interests of the Crown were appropriately identified. Despite short timeframes, the NRC worked closely with external advisors and various internal working groups to provide advice to the Vice-President, Strategic Initiatives (VP SI) on a wide array of topics.

The background, skills and leadership of the VP SI, who subsequently acted as the interim BMC CEO, were universally cited as critical success factors. This breadth of demonstrated experience and competencies in one leader could be difficult to replicate in the future.

Because the individual played the role of VP SI followed by acting as the interim CEO, there was a risk of perceived conflict of duty. However, this arrangement provided essential knowledge for reaching an appropriate agreement.

## Structured approach

The early determination of 8 key transition pillars served as a solid framework for managing the project. Within this framework, specific strategies for human resources engagement, and information management and technology development facilitated the transfer of crucial resources from the NRC to the BMC, including:

- recruitment of BMC personnel first as NRC term employees, then to the BMC via employment offers enabled retention of 99% of staff
- conducting a compensation study ensured competitive remuneration was offered
- change management, strong communication and transparency related to the transition of employees facilitated trust and retention
- the establishment of a standalone BMC information management and technology infrastructure from the beginning

Care was taken to document these and many other lessons in a formal lessons-learned report, which provides important NRC corporate memory on this initiative.



# Challenges

**In part due to the short time frames and the novel nature of the business model, some challenges were encountered in establishing the agreements and transferring operations to the BMC.**

## **Novel use of lease agreement required specialized legal counsel**

Although the NRC indicated they received strong support from the Department of Justice on most matters, specialized legal expertise on complex leases was needed from external counsel. Due to the urgent timelines imposed by the COVID-19 health emergency and the longer time needed for procurement, the Department of Justice could not hire specialized external counsel.

The BMC eventually retained its own counsel upon its establishment as a new entity. The NRC did not have this expertise available when negotiating its arrangements. In the event that a similar, novel arrangement is pursued, appropriate legal counsel would provide assurance that the NRC's interests are fully protected.

## **Resource transfer and change management: strengths and drawbacks**

As noted, the establishment of the independent BMC information management and technology infrastructure went well. However, the transfer of contracts related to critical software licenses posed some challenges due to the nature of some contractual relationships between Shared Services Canada and vendors. This limited the NRC's ability to sever the contracts and re-establish them independently for the BMC.

Change management efforts to off-board the NRC's BMC team and assets were well done, resulting in a seamless transition. The design and implementation of steady state oversight arrangements are in progress. Change management efforts will be needed to ensure the NRC's role as an oversight body are appropriately implemented and sustained.



# Stewardship

The accountabilities and governance for Biologics Manufacturing Centre (BMC) operations and oversight are new and evolving. The NRC's role expanded from a lessor to include a new mandate for monitoring, overseeing and serving the BMC. Governance structures are in place; however, their focus is currently oriented towards issues identification and management.

As the business model and relationships mature, these bodies are well placed to act as governance for ongoing stewardship and proactive risk and results oversight. In support of this, change management, clear authorities and an adequately resourced organizational structure are needed.

As the NRC finalizes its governance and oversight activities, the role and capacity of the National Program Office secretariat should be monitored to ensure it is sufficiently equipped to support the organization in its stewardship functions. Risk management mechanisms that help to monitor both financial and operational risk will be required to assess results, risk and sustainability of the model over time.

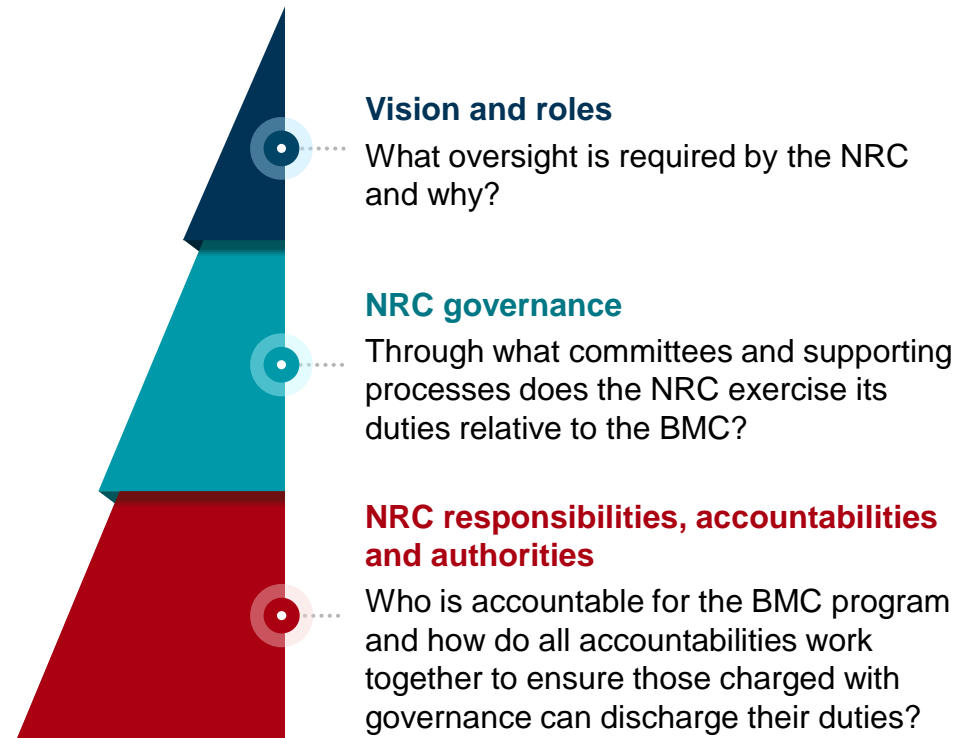
# Understanding stewardship mechanisms

The principle of strong stewardship refers to care, safeguarding and oversight of assets, in support of the interests of the organization and in the pursuit of specific objectives and outcomes.

In the case of the BMC, the NRC is the steward of both the facility and scientific equipment. The NRC also has to enable the success of the BMC in support of broader Government of Canada policy objectives. In this capacity, the NRC has a number of strategic, operational and financial interests that need to be safeguarded.

To this end, the NRC requires efficient, effective and responsive **stewardship mechanisms**, including an agreed upon vision and articulated interests, clear governance structures and efficient, well-aligned roles, responsibilities, accountabilities and authorities.

## Key stewardship mechanisms





# Stewardship going forward

As the BMC business model becomes more established, the NRC will require a more cohesive and formal (but still efficient) stewardship and oversight regime, supported by good internal governance, enabling processes and accountabilities.

## Vision and role for the NRC as an oversight organization needs definition

With the introduction of the new business model, the NRC has expanded from its traditional role of monitoring a standard lease and contribution agreements to also ensuring compliance in support of broader government priorities. This includes responding to the BMC's needs in an expedited manner (e.g., facility maintenance, shared infrastructure repairs) that have a direct bearing on good manufacturing practices certification and commercial success, and playing a coordinating role between the Government of Canada and BMC to be prepared for a future health emergency pivot.

To this end, the NRC must remain arms-length and independent from BMC operations, but must also be responsive to the BMC's needs and risks. For instance, the NRC must be able to efficiently assess and provide feedback on key BMC deliverables required in the agreements, and be able to monitor and quickly respond to the BMC's facilities' needs in support of operational and commercial success.

Although committees and processes are in place to react to needs once identified, proactive monitoring of risks and emerging issues will be important to avoid a “no surprise” environment. To enable this, the NRC needs to establish its vision and role as an oversight organization.

This vision and role should be aligned with the NRC's stewardship obligations, with the interests of the Crown, which the NRC is ideally placed to advance, and should not overlap and duplicate the role of BMC governance (i.e., the BMC Board of Directors).



### Pivoting due to health emergency

In the event of a health emergency and as a direct consequence of a Health Emergency Response Directive, the BMC may delay client work to meet the needs of the emergency. In such an event, the BMC may be required to calculate any penalties they may be obliged to pay to their clients under their existing client agreements (including any agreement termination penalties). Any compensation for potential penalties will be determined between the Government of Canada and the BMC.

# Stewardship going forward (continued)

## Potential to evolve existing NRC committees to proactive oversights

At present, the Facilitation Committee and Site Coordination Board are joint NRC–BMC bodies addressing issues management and issue resolution. NRC representatives on these bodies regularly inform and escalate issues to relevant NRC executives on the NRC–BMC relationship. The current NRC oversight function for the BMC is in its infancy and as these committees evolve, it is expected that they will become more proactive in monitoring performance and risk.

As the NRC matures its BMC processes and relationships, there is opportunity to use the Facilitation Committee and the Site Coordination Board as more holistic governance bodies. They can be used to provide proactive insight and assurance to President of the NRC and Senior Executive Committee on the state of performance and on any emerging issues that could have an effect on the NRC's interests.

New governance bodies are not required. The mandates of the existing governance bodies could be evolved to allow them to play a more proactive oversight role in a steady state.

## Responsibilities, accountabilities and authorities need further refinement

Accountabilities for oversight are split between Real Property Planning and Management for the lease agreement, and the National Program Office for the contribution agreement. Each function reports to different vice-presidents. Tools and processes to codify and align responsibilities are being developed and should continue, anchored on a common vision and clear governance expectations.

The President of the NRC is ultimately accountable for the agreements with the BMC and each of the 2 vice-presidents are responsible for 1 of the 2 agreements. However, there is no single point of accountability at the working or senior level for the BMC relationship, program and related results and risks.



# Enabling effective stewardship activities

**Operational and financial risk monitoring will be critical to measuring appropriateness of the model and results, including those related to the financial sustainability of the BMC.**

## Monitoring needed to determine financial sustainability of the model

Announced by the government in 2020, an investment of \$126 million over 2 years was made in the BMC. Included was an additional \$20 million per year for operating and maintenance costs, of which \$3 million is held by the NRC to fund oversight and other activities. This announcement was based on initial estimates developed prior to a full understanding of the scope of the BMC.

More detailed cost and revenue estimates were developed in 2022 and articulated by the NRC in a funding request, which identified annual operational costs and revenue estimates of \$32 million and \$34 million respectively.

Given the novelty of this business model, more time will be needed to determine if allocated resources are sufficient to sustain effective good manufacturing practices operation and to support the NRC's stewardship and oversight. If allocated resources are not enough, the NRC could be exposed to important financial sustainability and reputational risks, as the owner of the facility and the equipment.

## Sufficient capacity within the NRC secretariat for the BMC program needed

The secretariat, located in the National Program Office, is responsible for the development of NRC processes and governance. The secretariat will also be accountable for steady state coordination.

As the NRC finalizes its governance and oversight activities, the role and capacity of the secretariat should be monitored to ensure it is sufficiently equipped to support the organization in its stewardship functions.



# Areas for consideration

# Rationale and areas for consideration

**The findings from many evaluations typically lead to recommendations to which the program is required to respond. Given the one-time nature of the transition of the BMC from the NRC to its own separate entity, the focus for this evaluation is on lessons learned. Areas for consideration are included to support the ongoing evolution and maturing of the NRC's governance and oversight arrangements relative to the BMC.**

## Rationale emerging from the findings

- The BMC operation carries risks to the NRC's operational, financial and reputational interests. Efficient governance is needed to provide the NRC and its president with assurance that operations are compliant, that risks are appropriately managed and that objectives of the NRC are being achieved.
- The current NRC oversight function for the BMC is in its infancy and has tended to be reactive rather than proactive. Regular and proactive oversight increases the NRC's ability to anticipate and address issues and emerging risks and to course correct as needed.
- The communication of well-defined oversight arrangements, including who is monitoring what, for what purpose and at what frequency, will help the NRC evolve into its newly expanded role. It will also enable the NRC to effectively recalibrate its role as an oversight and enabling organization in support of strong stewardship.
- Lessons will continue to be learned in relation to this novel business model.

Given these points, there are several areas the NRC could consider to enhance its governance and oversight arrangements relative to the BMC.

## Areas for consideration

1. Clarifying and documenting accountabilities for the BMC program and related oversight activities for all levels, to ensure that the NRC's overall accountability for the program is understood.
2. Establishing formal but efficient internal processes and information flows for monitoring the BMC's compliance, operational and financial risks to the NRC, as well as achievement of the NRC's objectives and vision.
3. Mandating the Site Coordination Board and the Facilitation Committee with the proactive oversight of risks, results and emerging issues, ensuring they regularly receive and review the output of the NRC's monitoring activities described in consideration 2.



# Appendices

# Appendix A: methodology



## Document review

Internal documents were reviewed to provide context, to understand the timelines and challenges of the transition of the Biologics Manufacturing Centre (BMC) from the National Research Council (NRC) to the not-for-profit. Documents included:

- various working group, committee and board terms of references
- meeting minutes
- action trackers and deck presentations
- foundational agreements, funding requests and lessons learned documentation



## Data review

Corporate data was sourced from internal documents and included transition and oversight project tracking data, funding information, and financial and human resources data. This information was used to analyse the timeline of project deliverables, information on funding decisions and Gender-based Analysis Plus metrics for BMC staff.



## Key informant interviews

Interviews were conducted to collect information such as personal experiences, opinions and expert knowledge related to the transition from the NRC to the BMC and the extent to which the NRC is set up to ensure good stewardship of the BMC program going forward. Information collected through the interviews provided contextual information and was used in conjunction with the other lines of evidence.

A total of 21 stakeholders were interviewed for this evaluation:

- 15 NRC internal interviewees (representatives from the NRC involved with the transition of the BMC)
- 6 external interviewees (representatives from the BMC's management)

# Appendix B: limitations and mitigation

Although the evaluation encountered minor challenges, methodological limitations were mitigated, where possible, through the use of multiple lines of evidence and the triangulation of data. Details on a limitation and its associated mitigation strategy are described below.

## **Difficulty finding up-to-date documentation due to full access**

The evaluation team was given full access to the project document repository. Due to the high number of documents, it was difficult to find the latest versions of certain documents. As the transition was still ongoing, some documents were updated after being reviewed, leading to out-of-date information.

### **Mitigation:**

A document tracker was used to flag potential out-of-date documents and was used as a reminder to check for more recent versions. Official or final versions of important documents were also requested from the BMC evaluation liaison to ensure the most recent version was reviewed.

In addition, close communication with the client, in particular the National Program Office secretariat, helped to provide clarification on which documents were the most current.

Post completion of the transition, the NRC team reviewed all BMC documents and have retained final versions only.



# Appendix C: facility

## Characteristics

The BMC is a 12,500 square-foot facility located at the NRC's Royalmount site in Montreal, Quebec. The facility is located next to the NRC's Human Health Therapeutics Research Centre and the Clinical Trial Manufacturing Facility.

The BMC contains over 50 rooms, 250 pieces of equipment including 30 critical interdependent essential systems ensuring good manufacturing practices compliance and the safety of vaccines.

## Production

The BMC produces vaccines in 2 clean room suites using billions of microscopic cells cultivated in bioreactors. After undergoing upstream processing in 4 bioreactors ranging from 50 to 2000 liters, the cell mixture is purified through various steps, including chromatography and tangential flow filtration, to obtain the crucial vaccine drug substance.

In the fill and finish areas, the vaccine is aseptically filled into sterile vials using specialized machinery. Following meticulous inspection in dedicated booths, the vials are labeled, packaged in an adjacent room, and stored in an 8400 square-foot warehouse, which also manages critical vaccine-making supplies.



## Ensuring good manufacturing practices compliance

Prior to commercial production at the BMC, the NRC underwent a complex commissioning, qualification, and validation process to ensure good manufacturing practices compliance. Good manufacturing practices regulations guarantee that every aspect of vaccine production adheres to precise standards. This rigorous process involved extensive testing and documentation.

Simultaneously, the facility created more than 300 standard operating procedures to ensure good manufacturing practices compliance. Upon completing these steps, Health Canada conducted an inspection and issued a drug establishment licence in August 2022.

# Appendix D: BMC milestones

