

Environmental Approvals Branch
Manitoba Sustainable Development
Environmental Stewardship Division
Environmental Approvals Branch
160-123 Main Street
Winnipeg, MB R3C 1A5



February 9, 2018

Ms. Tracey Braun,

Emergent BioSolutions proposes the addition of two new manufacturing processes and replacement of current aseptic filling machine to the Winnipeg facility at 155 Innovation Drive, Environment Act Licence No. 3138.

In response to the Notice of Alteration submitted to Manitoba Sustainable Development on October 6, 2016, the Environmental Approvals Branch requested a complete Environment Act Proposal, as the Director determined that the proposed alteration would significantly increase the potential emissions to the environment. Please find enclosed copies of Environment Act Proposal for two new processes and filling machine replacement proposed for the facility at 155 Innovation Drive, in accordance with Section 11 of *The Environment Act*.

This document contains confidential and proprietary information of Emergent BioSolutions which shall not be communicated, disclosed, or assessed to or by any persons without the written consent of Emergent BioSolutions. For this reason, two versions of the Environment Act Proposal have been submitted, including a full version and a redacted version excluding proprietary information.

Sincerely,

A handwritten signature in blue ink, appearing to read "Karrie Zonneveld".

Karrie Zonneveld
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Enclosures:

1. Environmental Assessment Report (Proprietary and Public Versions)
2. Environment Act Proposal Form (Submitted November 15, 2017)
3. Reports/plans supporting the EAP (Submitted November 15, 2017)
4. Application Fee Payment (Submitted November 15, 2017)

Environment Act Proposal

Public Version



Original Submission: November 15, 2017

Updated Submission: February 8, 2018

To:

Ms. Tracey Braun
Director, Environmental Approvals Branch
Manitoba Sustainable Development

Prepared by:

Karrie Zonneveld
Environment Specialist
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Environmental Assessment Report

Executive Summary

Emergent BioSolutions Canada Inc. (hereafter referred to as Emergent) submitted a Notice of Alteration to Manitoba Sustainable Development on October 6, 2016, proposing the addition of two new processes to the Winnipeg facility at 155 Innovation Drive. The purpose of this Environmental Assessment Report is to provide an evaluation of the environmental impact of the two new proposed processes, as well as the replacement of the current aseptic filling machine. This report will also be used to provide added information on the operations of our facility that may have not been described in the initial Environment Act Proposal received October 29, 2014 and dated October 30 / 31, 2014.

Emergent (previously Cangene Corporation) has been operating at 155 Innovation Drive for over 30 years, located in the Smart Park on the University of Manitoba Fort Gary Campus. Emergent obtained Environment Act Licence No. 3138 on May 19, 2015.

The facility at 155 Innovation Drive has not been operating at full capacity since 2012. Proposed alterations, consisting of the addition of two new manufacturing processes and replacement of the aseptic filling machine, should serve to decrease the under-utilization of the facility. These proposed alternations do not include any building expansion or new construction.

Additional raw materials will be used in these new processes, creating slight differences in potential environmental impacts and mitigation measures to what was previously assessed for the facility.

An environmental assessment has concluded that the mitigation measures currently in place for the two new processes and new filling machine fully prevent the occurrence of any negative environmental impacts.

1. Introduction and Background

Emergent's facility at 155 Innovation Drive has been manufacturing biopharmaceuticals since 1985. The civic address was changed in 2002 from 104 Chancellor Matheson Drive to 155 Innovation Drive. Environment Act Licence No. 3138 was issued for this facility on May 19, 2015. 155 Innovation Drive specializes in the manufacture of liquid hyperimmunes, biopharmaceutical / bio-defense products and contract manufacturing. The building also houses administration, quality control laboratories, and product development laboratories.

Effective January 1, 2017, Cangene Corporation changed its legal name to Emergent BioSolutions Canada Inc. The company has been managing the development, manufacture, and marketing of licensed specialty hyperimmunes since it first licensed its anti-D immune globulin (WinRho) in Canada in 1980. All products manufactured by the site are outlined in Appendix 1 "List of Products Manufactured at 155 Innovation Drive".

All the human hyperimmune products are manufactured in a nearly identical manner as they differ only by individual antibody of interest, a small proportion of the total IgG fraction.

The site also manufactures investigational products originating from human plasma, and engages in contract manufacturing (CM). The site is licensed by FDA for the manufacture of an equine-based hyperimmune plasma product. This is manufactured in a separate facility from the human hyperimmune products; however, utilities (e.g. purified water, water for injection, clean steam) are shared between both manufacturing platforms. The CM activities occur in the same facility that the hyperimmune products are manufactured; however, manufacturing is done on a campaign basis, meaning only one product can be manufactured at a time, thereby eliminating any chance of cross over or cross contamination. Additionally, all product contact equipment is dedicated for the CM product or single-use disposable technology is employed.

Demand for manufacturing decreased in the years 2012 to 2015. As a result, the building has not been operating at full capacity since 2012. The proposed alterations should result in decreased under-utilization of the building. The proposed alterations do not include any building expansion or new construction.

The addition of two new processes includes: production of topical skin decontamination product and contract manufacturing for an external third party (hereafter referred to as the third-party process). Although these alterations do not include building expansion or new construction, changes to the existing facility layout were required to create additional manufacturing suites. Changes are complete, with the addition of two new manufacturing suites.

The main intent of the replacement of the current filling machine is to replace aging equipment for compliance and business continuity purposes. Emergent Winnipeg will increase its filling capability, which may result in acquiring more customers. This proposed alteration requires changes to the existing facility layout.

1.1 Topical Skin Decontamination Product

This section has been removed due to its proprietary content.

1.2 Third-Party Process

This section has been removed due to its proprietary content.

1.3 Filling Machine

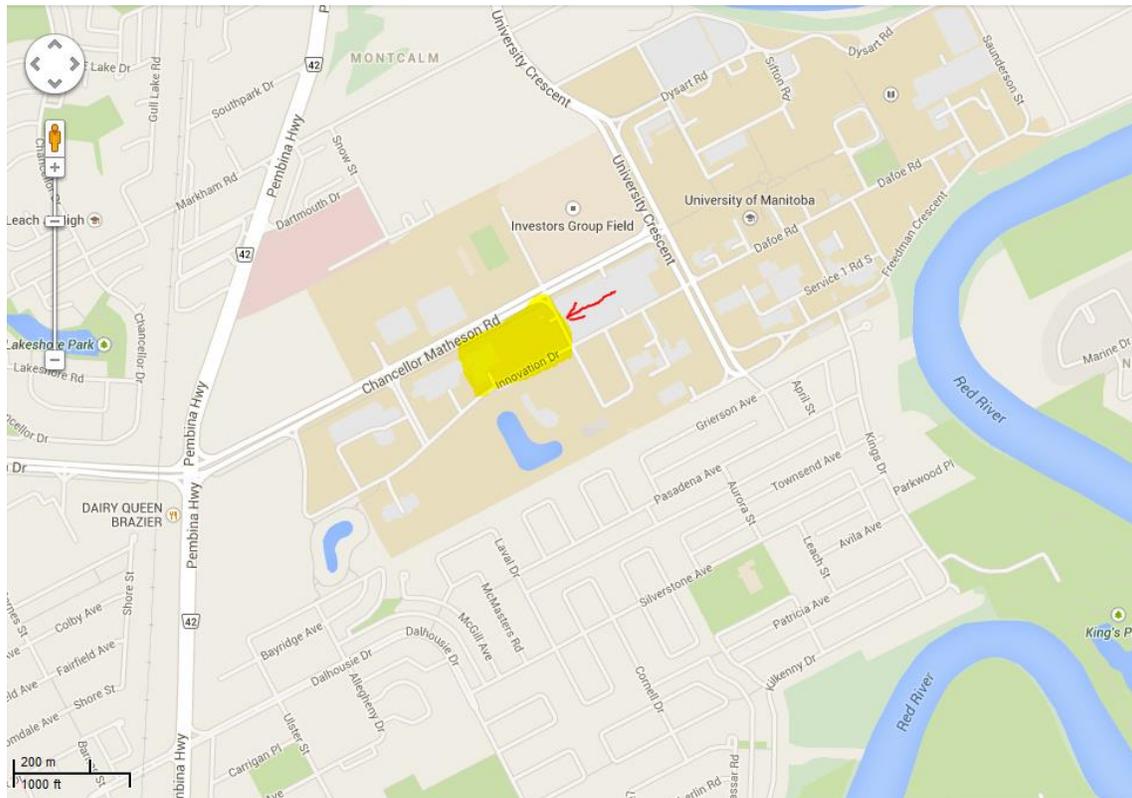
Emergent is investing in its Winnipeg facility, a major capital budget upgrade of the manufacturing facility to replace the current aseptic filling machine.

The new filling machine at Emergent Winnipeg will completely remove human interaction from the filling operation by utilizing robotics within an isolation chamber. The existing conventional filler will remain operational until the new filler is completely qualified and receives full regulatory approval.

2. Status of Title

See Appendix 8.

3. Description of Development



3.1 Description of Existing Development

155 Innovation Drive is comprised of approximately 5 acres of land with 1 facility (consisting of three connected building) and two parking lots. The prime purpose is to house a pharmaceutical manufacturing facility, supporting research and quality control laboratories, as well as administrative offices. Operations include manufacturing of liquid vaccines, quality control testing, packaging, filling, and shipping / receiving. Emergent operates under the North American Industry Classification System (NAICS) of Canada code of 325410.

155 Innovation Drive is owned by Emergent. The property is located in the Smart Park on the University of Manitoba Fort Gary Campus. The facility is a single-tenant building comprised of approximately 250,000 square feet, divided into three connected buildings: Building A, Building B, and Building C. Building B, constructed in 1982, was the first building constructed on the property and includes office, laboratory, and manufacturing space. Building A was constructed in approximately 2002 and includes office, laboratory, warehouse, 2 shipping bays, and packaging areas. Building C was constructed in 2006 and includes manufacturing and laboratory areas. Buildings B and C have a basement and Building A has a crawl space. The listed address of 155 Innovation Drive was previously 104 Chancellor Matheson Road. Features of 155 Innovation Drive include:

- Administrative office area
- Laboratories
- Manufacturing areas
- Packaging
- Warehouse
- Wastewater treatment systems
- Mechanical rooms
- Generators
- Chillers
- Water purification systems
- Boilers
- Chemical storage rooms
- Cafeteria / lunch room
- Loading docks
- Paved parking areas

Asphalt-paved parking lots lie to the north, east, and west of the facility. Paved roads surround the property to the north, south, and east. No additional structures are present on the property.

Approximately 350 employees work out of 155 Innovation Drive.

The property is bordered:

- north by a parking lot, manicured lawn, earthen berm, paved sidewalk, and 4-lane Chancellor Matheson Road before the University of Manitoba outdoor athletic arenas and *Investors Group Field* stadium;
- south by Innovation Drive, office building, a storm water retention pond, and vacant field;
- east by a small paved parking lot, Rh Way service road, and a large paved parking lot owned by the University of Manitoba; and
- west by a paved parking lot and office buildings.

Prior to the 1982 development, the land was vacant and was owned by the University of Manitoba. The property is zoned MMU for Manufacturing – Mixed Use according to the City of Winnipeg Planning, Property and Development Department.

3.2 Description of Proposed Alteration to the Development

There will be no building expansion or new construction resulting from the proposed alteration. Changes to the interior layout of the building were required to create additional cleanroom-grade manufacturing suites (2 suites constructed and commissioned in 2016 for use in 2017) and 1 filling suite, accommodating the new topical skin decontamination product, third-party processes, and new filling machine.

Existing boilers and water purification are sufficient to supply the increased demand by the new processes. An additional rooftop heating and cooling unit (RTU) was installed to accommodate the increased HVAC demand for topical skin decontamination product. A rooftop exhaust fan will be installed to support the filling machine operations.

The current filling process and the new filling process will need to be qualified, operated, and maintained simultaneously for a period before the current filling machine can be decommissioned.

4. Description of Existing Environment in the Project Area

According to a recent EcologERIS report, the ground elevation of 155 Innovation Drive is approximately 745 feet above mean sea level. No water bodies are present on the property. The nearest water body, a storm water retention pond, is adjacent to the property to the south. The Red River is located approximately ½ mile to the east of the property. The site is located on flat land with no observable slope. Based on the topography of the region and the location of the Red River, groundwater flow is presumed to be to the east. No wetlands are present on the property and the site has never flooded.

Winnipeg has an extreme humid continental climate, with great differences between summer and winter temperatures. The openness of the prairies leaves Winnipeg exposed to numerous weather systems including blizzards and cold Arctic high pressure systems, known as the Polar high.

Temperatures as high as 42.2C in July (1936) and as low as –47.8C (1879) have occurred in the city, a 90°C (162°F) difference. The city averages 521.1 mm of precipitation per year, although this can vary greatly from year to year.

Winnipeg has a reputation for being a windy city with average annual wind speeds of 16.9 km/h, predominantly from the south but the city has experienced wind gusts of up to 129 km/h. April is the windiest month, and July the least windy. Tornadoes do occur in the area, particularly in the spring and summer months, however they are not frequent. A Fujita scale F5 tornado struck Elie just 40 km west of Winnipeg in 2007; this was the strongest tornado ever recorded in Canada.

Because of its flat topography and substantial snowfall, Winnipeg is subject to severe flooding. The Red River, located less than 1 km to the east, reached its greatest flood height in 1826, and this event remains the highest flood stage of the last two hundred years.

There are numerous climate and/or weather monitoring stations within the City of Winnipeg; ten within a 10-mile vicinity.

Significant regional and local water bodies include:

- Lake Winnipeg – the eleventh largest freshwater lake on earth.
- Lake Manitoba – the smallest of the province's three large lakes.
- Red River, which rises at Wahpeton, North Dakota and Breckenridge, Minnesota and winds its way north along the North Dakota-Minnesota border into Manitoba. It continues 885 km north to Winnipeg and further to Lake Winnipeg. 155 Innovation Drive location is less than 1km from the Red River as it passes to the east of University of Manitoba Fort Gary Campus.
- Assiniboine River joins the Red River at the Forks (centre of downtown Winnipeg), and after travelling across the prairies from Preeceville, Saskatchewan, and Manitoba for 1,070 km.

One local storm water retention pond is located about 200 meters south of the facility.

This facility is a long-standing resident of the Smart Park industrial setting. The design of this entire development was geared to this type of business so there is nothing notable in the Emergent business plan that would present a risk to public safety and human health or vice versa in the surrounding socioeconomic environment.

5. Environmental and Human Health Effects of the Proposed Development

5.1 Description of the Environmental and Human Health Effects of the Existing Development

The Environment Act Licence (EAL) for 155 Innovation Drive was issued by Manitoba Sustainable Development on May 19, 2015 based on the hyperimmune manufacturing, laboratory, research and development, and administrative activities occurring at this site. A description of the environmental and human health effects of the existing licensed process is provided in this section.

In the application for the EAL, the *University of Manitoba, Phase 1 – Environmental Property Assessment, Proposed Research Park, Winnipeg, Manitoba*, prepared by UMA Engineering Ltd., dated April 1997 was reviewed. The 1997 Phase 1 included the entire property, except for Building B of 155 Innovation Drive. No environmental concerns or suspected contamination were identified and the Phase 1 did not make any recommendation for further investigations.

Air emissions are generated by the facility through natural gas heating, and fugitive air emissions through chemicals used in the manufacturing process on site. Laboratory fume hoods exhausting outside are equipped with HEPA filters, receiving regular preventative maintenance. The buildings are heated by natural gas and cooled by roof-mounted air conditioning units and chillers. No recognized environmental conditions are identified based on a review of the facility's air emission sources.

Raw materials received, stored, and used on site in process related applications are:

- Diesel fuel
- Oils
- Chiller and boiler (physical plant) chemicals
- AC-30 (water chemical additive)
- Compressed gases
- Pharmaceutical product bottles
- Caustic soda
- Caustic potash
- Phosphoric acid
- Sulfuric acid
- Ethanol
- Isopropyl alcohol
- Methanol
- Miscellaneous common laboratory chemicals

Laboratory chemicals, including ethanol, isopropyl alcohol, and methanol are stored in containers and drums ranging from 10 to 205 litres in size located in the Building A chemical storage room. Small containers of laboratory chemicals are stored and used in laboratories throughout the facility. Some laboratory chemicals are stored in a quarantine area of the Building A warehouse prior to being moved to the chemical storage room and individual laboratories.

Chemical handling and storage procedures are subject to Good Manufacturing Procedures and Good Laboratory Procedures (GxP), and comply with Environment, Safety and Health regulations and best practices.

All incoming raw materials are received and distributed by truck. Chemical containers are marked with labels indicating their contents and are inspected to ensure they are in good condition and not damaged, corroded, or leaking. According to related personnel and database review, no reportable spills or releases of raw materials have occurred at the site.

Any accidental release of chemicals or hazardous materials would be contained within the facility. Emergent BioSolutions has an established emergency response plan that contains a specific section on emergency hazardous spills. Small spills are contained, cleaned up, site-remediated, investigated, and reported internally. Larger spills follow external emergency responder notification and protocol before being turned over to the company for remediation and would follow similar procedures as smaller spills.

5.2 Description of the Environmental and Human Health Effects of Proposed Alteration

5.2.1 Topical Skin Decontamination Product

Raw materials for the topical skin decontamination product are listed in Appendix B. None of these materials are classified as hazardous through Transportation of Dangerous Goods (TDG) regulations. Minute quantities of residue remaining in the tank after blending and emptying the tank are rinsed to the City of Winnipeg sewer system. Routine monitoring ensures that process wastewater is below the limits set out in the City of Winnipeg Sewer By-law No. 92/2010.

During the process of addition of raw materials into the blending tank, a dust extraction arm is used to capture airborne particles. The dust extraction arm draws contaminated air through a filter to retain the particles, preventing release to the environment. Human health is protected during this process as all others in operations with the appropriate respirator in case inhalation levels exceed exposure limits. Exposure testing was performed as part of Emergent's (Chemical Safety Program) Environment, Health and Safety assessment of this product to determine required PPE.

5.2.2 Third-Party Process

The third-party process is liquid-based, and very similar to the existing hyperimmune process described in Section 5.1. The raw materials used in the third-party process are listed in Section 5.1, and Appendix B.

Chemicals classified as hazardous chemicals through the TDG regulation are included in Appendix B. Waste acids, along with all process wastewater, is treated for pH adjustment in neutralization tanks, ensuring pH is within the range limits laid out in the City of Winnipeg Sewer By-law No. 92/2010 before process wastewater is released to the city sewer system. All solvents used in the facility are captured in the underground storage tank (UST permit #36847).

Since the third-party process is liquid-based, release of airborne particles into the environment is not a risk.

Raw materials for the third-party process and finished product are shipped in and out of the facility by truck.

The third-party process uses single-use bag liners and tubing which are autoclaved prior to disposal through the regular garbage. The materials used in the process for single use are not approved by recycling vendors in Manitoba at this time but alternative recycling options are being explored.

5.2.3 Filling Machine

Use of raw materials in the filling operation are minimal, and listed in Appendix B. All final products are shipped out via temperature controlled truck.

Vaporized hydrogen peroxide (H₂O₂) is utilized in the filling machine as a decontaminant to destroy or eliminate all forms of microbial life in the inanimate environment. The vaporized H₂O₂ decontaminates the decontamination and staging isolator (DSI) chamber and isolator chamber to ensure a "clean" area for aseptic processing. The main isolator chamber uses vaporized H₂O₂ at the start of the process and the DSI is decontaminated after each loading of the chamber. Each cycle uses approximately 3 mL to 9 mL (closer to the lower end of the range). A continuous-running rooftop exhaust fan will draw all vaporized H₂O₂ fumes out of the filling suite.

Nitrogen gas is used for inert back-filling in stoppering, and integrity testing. The future estimation of nitrogen gas for the filling operation is approximately 715 cubic metres.

Two gas detectors will be installed in the filling suite to measure oxygen and vaporized H₂O₂, to not fall outside of the parameters set in the Manitoba Workplace Safety and Health regulation and ACGIH standard.

Currently, vials, stoppers, and caps are purchased in bulk quantities, and fully prepared and sterilized at the Emergent Winnipeg site. Vials for the new filling machine will arrive to Emergent sterile and ready-to-use, eliminating the extra sterilization step.

Waste generated as a result of the filling process includes vial tubs, tub nests, bags, lids and liners, and disposable garments and gloves. Whenever reasonably possible, Emergent will introduce recycling programs to divert waste from the landfill, such as the newly implemented garment recycling program.

5.2.4 Discussion

There are no adverse environmental or human health effects anticipated as a result of the introduction of the topical skin decontamination product, third-party processes, and new filling machine to 155 Innovation Drive. Effluents to the City of Winnipeg sewer system are monitored as part of Emergent's participation in the Pollution Prevention Program; allowable by-law limits have not been observed surpassing allowable limits to date, but continual monitoring of facilities and assessing any new processes as they arise will ensure compliance is maintained. The Chemical Safety Program and associated training for employees working with chemicals addresses the need to report any spills or issues concerning any chemicals used in processes.

6. Mitigation Measures and Residual Environmental Effects

6.1 The Chemical Safety Program

The Chemical Safety Program at Emergent's Winnipeg site is based on a lifecycle approach to chemical safety. Management system principles are deployed to conform with requirements of the ISO 14001 and OHSAS 18001 standards. Components of the Chemical Safety Program include the following safe work and environmental procedures:

- SWP / ENP00201 Chemicals entering the Facilities
- SWP00202 Safe Chemical Handling
- SWP / ENP00203 Chemical Storage
- ENP00204 Chemical Waste Disposal
- ENP00205 Hazardous Solid Waste Disposal
- SWP / ENP00206 Hazardous Spill Response

These procedures ensure environment risks are avoided from the moment a chemical is received on site to the moment it exits the site (as waste from either expiry, manufacturing waste, or due to a spill that was captured or sent to drain).

All hazardous waste is collected from the site by a company licensed to handle and dispose of hazardous waste. All regulations, including Hazardous Waste Regulation - M.R. 195/2015 and City of Winnipeg Sewer By-law No. 92/2010 are followed in this process.

Any chemicals sent to drain are in concentrations allowed by the City of Winnipeg Sewer By-law No. 92/2010. Emergent participates in the city's Pollution Prevention Program and is continually monitoring processes to ensure by-law compliance.

6.2 Solid Waste and Hazardous Waste

Emergent's facility is registered with Manitoba Sustainable Development under Hazardous Waste Generator Registration Number MBG13485, and updated for 155 Innovation Drive in 2014.

Small quantities of hazardous waste are generated by laboratories, including acids, bases, and solvents. Any hazardous waste generated onsite is collected in accordance with Manitoba Regulation 195/2015 (Hazardous Waste Regulation) and disposed through a company licensed to handle and dispose hazardous waste by Manitoba Sustainable Development and other regulatory bodies as appropriate. Types and quantities of waste generated by laboratories are not significantly affected by the two new process additions and new filling machine. Hazardous waste is stored in

flammable cabinets (where required) in the chemical storage room in Building A and in small containers in the laboratories until picked up by a licensed hazardous waste handler.

Hazardous materials are either bermed or stored on spill pallets or spill decks. Spill kits are available in areas where chemicals are used or stored. Procedures exist for spill response and spill containment, and affected employees have been trained on these procedures.

Plasma waste is autoclaved to remove the biological hazard and remaining solid waste is disposed of in the general trash.

General trash is collected and stored in a roll-off bin located outside to the south of the facility and removed by a solid waste contractor.

6.3 Underground and Aboveground Tanks

Waste solvent is discharged to a 13,300 litre UST (UST Permit #36847) via solvent drains, and vacuum pumped out of the tank by a licensed hazardous waste contractor. The UST is double-walled with stainless steel encased by an outer wall constructed of hot-rolled-sheet mild steel. The tank has interstitial leak monitoring and high-level alert that alarms to the building maintenance system. The tank was installed in 2006, carries a valid permit, and is appropriately inspected and maintained in a preventative maintenance program as required by permit conditions. No tank leaks or releases have ever been identified according to recent database searches. The UST does not pose an environmental concern on the property based on leak history and installation date, leak detection system, and annual inspections.

No tank leaks or releases have ever been identified according to recent database searches.

6.4 Process Wastewater

155 Innovation Drive entered the City of Winnipeg's Pollution Prevention Program in 2015. The facility is in compliance with the City of Winnipeg Sewer By-law No. 92/2010, and is routinely monitored for compliance.

Water for manufacturing and laboratory use is supplied by the City of Winnipeg public water supply and purified via softening and reverse osmosis prior to use. Some water is also distilled prior to use. Purified water is stored in two 60,000 litre ASTs prior to use through the manufacturing and laboratory. All sanitary and process wastewater is discharged to the City of Winnipeg sewer system. No onsite pits, ponds, or lagoons exist on the property.

All process wastewater is treated for pH adjustment in neutralization tanks, ensuring pH is within the range limits laid out in the City of Winnipeg Sewer By-law No.92/2010 before process wastewater is released to the city sewer system.

Process wastewater flows to a concrete sump pit prior to entering the neutralization tanks, providing settling time for any residual solids from the process. Cleaning the sump pit is a part of a routine preventative maintenance (PM) program, preventing potential for residual solids to build up and release into the sewer system.

6.4.1 Topical Skin Decontamination Product

Minute quantities of residue remain in the tank after blending and emptying after recovering as much product as possible; the tank is rinsed to the City of Winnipeg sewer system. Routine

monitoring ensures that process wastewater is below the limits set out in the City of Winnipeg Sewer By-law No. 92/2010.

6.4.2 Third-Party Process

Due to the nature of pharmaceutical manufacturing, production is highly regulated and strictly adheres to detailed manufacturing procedures. Each product run should be the same, therefore there is little variability between runs, and it is known exactly how much of each chemical is used in the process. An assessment of the process wastewater will be conducted via samples taken by the City of Winnipeg in conjunction with involvement in the above-mentioned Pollution Prevention Program.

6.4.3 Filling Machine

A 200 L local tank filled with water for injection (WFI) will be used for the clean-in-place (CIP) process. The WFI tank will be brought into the filling suite and connected to the filler; WFI is pumped through the filler isolator chamber to a floor drain which flows to the onsite neutralization tanks. The filler floor drain has an automatic valve that opens when the CIP program is enabled to allow water to flow out via flex hose. CIP is primarily used for particulate removal as the risk of product spillage is low. Emergent will continue to sample and monitor wastewater in conjunction with the above-mentioned Pollution Prevention Program.

6.5 Air Emissions

Fume hoods are equipped with HEPA filters which undergo routine testing and preventative maintenance.

Dispensing of raw materials is performed in booths with air recirculated through a coarse filter and two stages of HEPA filters, ensuring airborne particles generated during dispensing are captured.

A dust extraction arm has been installed at the point of addition of the solid materials in the topical skin decontamination product process. The dust extraction arm draws contaminated air through a filter.

The third-party process is liquid-based and does not present any additional risk from air emissions, as raw materials are dispensed in the same dispensing booth.

A continuous-running rooftop exhaust fan will remove vaporized H₂O₂ from inside the hood at 600 cfm. There is a fan inside the filling machine which forces the air out and into the hood at the ceiling at a rate less than 600 cfm. See *Figure 1: Fan Schedule* below.

Manufacturer	Location	Fan Model	CAP. (l/s) cfm	E.S.P (Pa) in. W.G.	SPD. (rpm)	BkW BHP	MTR. (kW) HP
Greenheck	Roof	SFD-7.5-VG	354 750	187 0.75	1592	0.24 0.32	0.37 0.50

Table 1: Fan Schedule

6.6 Site Closure

Upon site closure, should that occur, a detailed decommissioning process is followed.

Control technology prevents the possibility of wastewater contamination using underground, aboveground, and wastewater treatment. All processes with the potential for environmental air contamination are HEPA filtered and all systems are continuously monitored.

6.7 Soil and Other

There are no potential recognized environmental conditions or risk to soil contamination based on air emission sources.

The only potential soil contamination source would be above ground release or the UST. Current handling practices / procedures, controls, UST condition, and the PM program monitoring suggests the potential of this form of contamination as very low risk. Area topography suggests simple containment and minimal spread.

Polychlorinated Biphenyls: Electricity is supplied to the facility by Manitoba Hydro. One pad-mounted transformer is located to the south of the 155 Innovation Drive building. There is no evidence of leaks from this equipment. None of the equipment used onsite utilizes hydraulic fluid containing PCBs.

Asbestos: AMEC Earth & Environment conducted an asbestos survey in Building B on August 27, 2010. The survey report did not identify any asbestos containing material (ACM) in the facility.

As good management practice, building materials are analyzed prior to any major maintenance, renovation, or construction projects.

7. Follow-up Plans, including Monitoring and Reporting

This section refers to monitoring during development and therefore is not applicable. However, note that a Pollution Prevention Plan is under development as part of The City of Winnipeg's Phase 2 Pollution Prevention Program for NAICS code 32410 Pharmaceutical and Medicine Manufacturing.

8. Conclusions

EcoLog ERIS was retained to search federal and provincial regulatory databases to identify environmental issues that have been reported for 155 Innovation Drive and properties in close proximity. No spills or releases of hazardous substances or petroleum processes have been reported at 155 Innovation Drive. Full report enclosed as Appendix G.

Federal and provincial databases were also searched to determine the potential for the site to be affected by releases from neighbouring properties. The sites with the greatest potential to have caused environmental contamination are those having had releases or spills of hazardous substances or petroleum products located up gradient or in close proximity to 155 Innovation Drive. The direction of localized groundwater flow is presumed to be to the east and there the sites that are of the greatest potential concern are those having had releases or spills of hazardous substances or petroleum products and are west (up gradient) or in close proximity to 155 Innovation Drive. Three listings within a 0.25 km radius of the facility are recorded on the databases searched. None of these sites have reported any releases or spills; therefore, there is no evidence that these sites pose an environmental concern to Emergent at 155 Innovation Drive.

A Freedom of Information and Protection of Privacy Act (FIPPA) request was submitted to the Winnipeg Fire and Paramedic Services and the Manitoba Health Department to determine if any hazardous substances incidents have been reported for the property. There were no results from these requests.

The searches of a 2013 independent Phase 1 Environmental Audit concluded that no known, suspected, or historically recognized environmental conditions have been identified in connection with the property at 155 Innovation Drive or surrounding area. There were also no *de minimis* conditions identified at the property.

In conclusion, Emergent has conducted the same business in an environmentally friendly manner for the past 30+ years at 155 Innovation Drive. There have been no historical environmental incident occurrences due to process controls that are appropriately implemented, controlled, and monitored. As the business grows year-to-year, various manufacturing runs within the spectrum of products approved for manufacture at this site may or may not be conducted, depending on the customer demand. The nature of this business expects that new products will join the list in the future, thus producing a new Notice of Alteration. Inputs and outputs also fluctuate due to different needs in the research laboratories. These items are used under controlled processes as mentioned in the previous Chemical Safety Program description and should not have an impact on the environment.

Appendix A: List of Products Manufactured Onsite

Product Name	Product Type / Classification
Human plasma derived therapeutic	Bulk Drug Manufacturing, Human Hyperimmune
Equine plasma derived therapeutic	Equine Hyperimmune
Topical skin decontamination product	Medical Device – Bulk Material
Drug Product Component	Bulk Drug Manufacturing, Drug Product Intermediate

Appendix B: List of Chemicals in Manufacturing Processes

TDG Classification	Chemical List
Class 2.2 Non-flammable, non-toxic gas	Nitrogen, compressed
Class 3 Flammable Liquids	Isopropyl Alcohol, 95% Ethanol, 100% Ethanol, Acetone, Dehydrated alcohol ethanol
Class 4 Flammable Substances	Sodium Lauryl Sulfate
Class 5.1 Oxidizing Substances	Hydrogen Peroxide, Aqueous Solution
Class 8 Corrosives	Sodium Hydroxide Pellet, Phosphoric Acid 85%, Sodium Hypochlorite, Hydrochloric Acid, Sodium Hydroxide, Glacial Acetic Acid
Class 9 Miscellaneous	Products listed in this class are considered proprietary information
Non-TDG Regulated	Human Normal Source Plasma, Equine Plasma, Potassium Phosphate Dibasic, Potassium Phosphate Monobasic, Triton X-100, Gold Particle Sol AGP-HA2, Polysorbate 80, Tri N Butyl phosphate, Sodium Chloride, Sodium Acetate, Sodium Acetate Trihydrate, Maltose, Tromethamine, Sodium Citrate Dihydrate, Anhydrous Citric Acid, Sodium Caprylate, Calcium Chloride Dihydrate, Epsilon-Aminocaproic acid, Glycine, Sucrose, Sodium Citrate Dihydrate, Chromatographic Resins, Sodium Cholate, Propylene Glycol, Urea, Citric Acid Monohydrate, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic, Ammonium Sulfate, Methoxypolyethylene Glycol (MPEG), Diacetyl Monoxime (DAM), Potassium 2,3-Butanedione Monoximate (KBDO), colour dyes, proprietary products

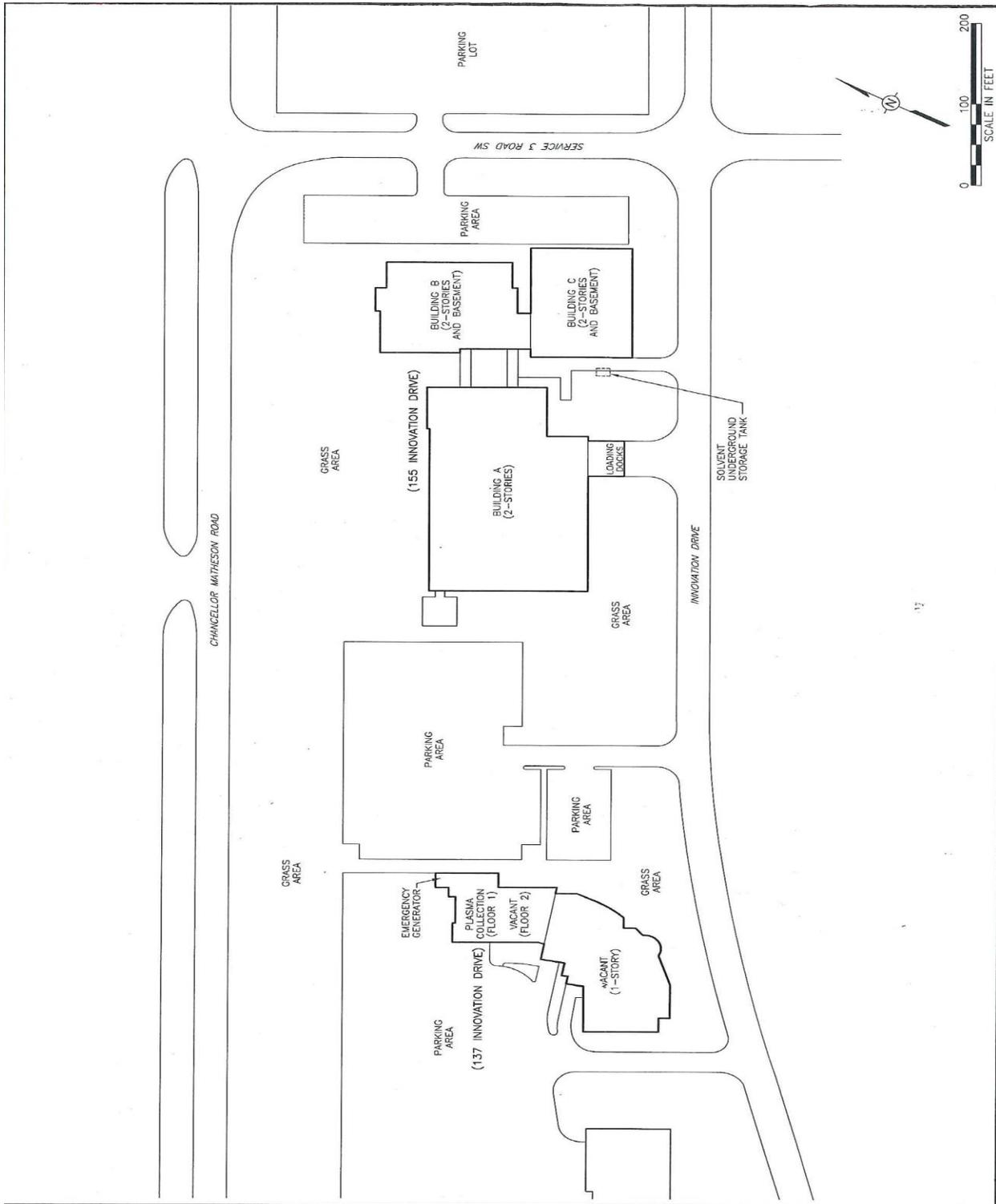
Appendix C: Original Environment Act Proposal Form

Environment Act Proposal Form



Name of the development: Emergent BioSolutions	
Type of development per Classes of Development Regulation (Manitoba Regulation 164/88): Class 1	
Legal name of the applicant: Cangene doing business as Emergent BioSolutions Inc.	
Mailing address of the applicant: Contact Person: Daryl Nielsen City: Winnipeg Province: Manitoba Postal Code: R3T 5Y3 Phone Number: (204) 275-4323 Fax: email: nielsend@ebsi.com	
Location of the development: Contact Person: Daryl Nielsen Street Address: 155 Innovation Drive Legal Description: City/Town: Winnipeg Province: Manitoba Postal Code: R3T 5Y3 Phone Number: (204) 275-4323 Fax: email: nielsend@ebsi.com	
Name of proponent contact person for purposes of the environmental assessment: Daryl Nielsen	
Phone: (204) 275-4323 Fax:	Mailing address: 155 Innovation Drive Winnipeg, Manitoba R3T 5Y3
Email address: nielsend@ebsi.com	
Webpage address: www.emergentbiosolutions.com	
Date: October 9, 2014	Signature of proponent, or corporate principal of corporate proponent:  Printed name: Mark Lobe

Appendix D: 155 Innovation Drive Site Drawing



Appendix E: Topographic Map and Legends

See attached.

Appendix F: Aerial Photograph – 155 Innovation Drive



Appendix G: EcoLog ERIS Report

See attached.

Appendix H: Status of Title

See attached.