

Manitoba Conservation and Water Stewardship
Environmental Approvals
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October 31, 2014

Ms. Tracey Braun,

Our Winnipeg facilities located at 26 Henlow Bay and 155 Innovation Drive were inspected on July 23, 2014, with a follow-up letter of August 20, 2014, to which this response relates.

With respect to 155 Innovation Drive, Cangene operating as Emergent BioSolutions requires licensing under The Environment Act. We respectively submit the attached Environment Act Proposal application in order to bring the facility into compliance with the license requirements.

I trust that you will find all is in order and can process an Environment Act License for this existing facility.

Sincerely,

Daryl Nielsen C.R.S.P.
Manager - Environment Safety and Health
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Enclosures:

1. Development Environmental Assessment Report
2. Environment Act Proposal Form
3. Reports/plans supporting the EAP
4. Application Fee payment

Environment Act Proposal



Submitted: October 30, 2014

To: Ms. Tracey Braun

Manitoba Conservation and Water Stewardship

Environmental Approvals

Prepared by: Daryl Nielsen & Bryan Stadnyk

Emergent BioSolutions

Environment, Safety and Health

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NOTE: *The Environment Act* requires that subject to the Confidential Information clause, Section 47, a proposal shall be filed in the public registry. **Proprietary information, if applicable, should be clearly noted. Separate hard and electronic reports excluding proprietary information should be submitted for the public registry.**

Development Environmental Assessment Report

Executive Summary

There has been some confusion in the past with respect to Cangene Corporation (now operating as Emergent BioSolutions) address by which records are filed with Manitoba Conservation and Water Stewardship. The civic address changed from 104 Chancellor Matheson Drive to 155 Innovation Drive in 2002 with the development of the Smart Park located on the University of Manitoba Fort Gary Campus.

The legal business name remains "Cangene Corporation" while the operating name is "Cangene Corporation doing business as Emergent BioSolutions." Note that we have not moved or changed our principal business over the past 30 years; however Cangene Corporation did acquire 26 Henlow Bay in 1999; Environment Act License #2298.

Introduction and Background

Cangene/Emergent has been manufacturing biopharmaceuticals at the 155 Innovation Drive location since 1985, it is certainly not a new development and many of the license application requirements don't seem applicable. It is from this perspective that the application form has been completed.

Given the information introduced in the Executive Summary above, the purpose of this application is to fulfill the requirement of an Environment Act License pertaining to a 30-year old existing Winnipeg-based business that has not changed its manufacturing role or location in that period.

Emergent Winnipeg is a pharmaceutical company specializing in the manufacture of liquid hyper-immunes, biopharmaceutical / bio-defense products and contract manufacturing. In addition to supporting production, the organization's internal structure is comprised of departments that fulfill laboratory research, development and administrative needs as required.

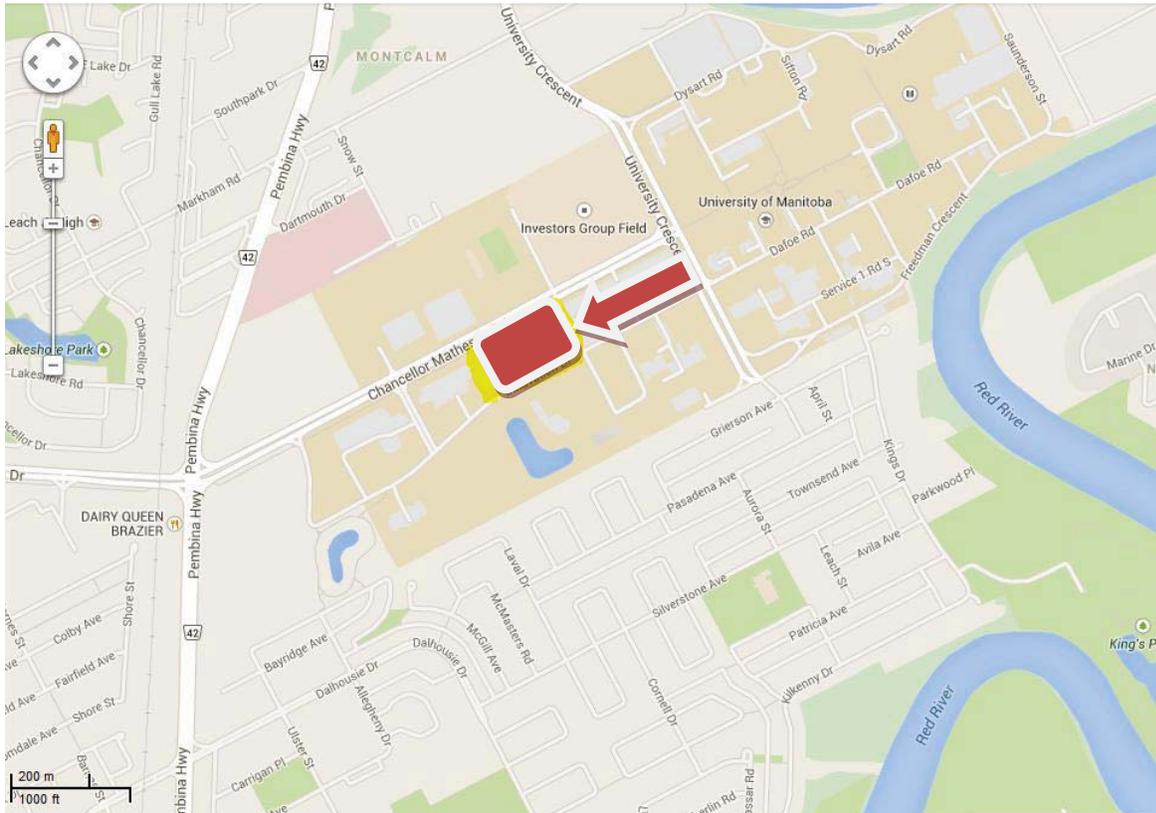
Although there is apparently no Environmental Act License in place for this address, Cangene Corporation at 155 Innovation Drive does hold a valid Hazardous Waste Generator Permit#MBG03262 & Permit to Operate a Petroleum Storage Facility #36847.

Rationale for a "development" at this stage seems irrelevant along with alternatives, population trends, previous studies, project siting and prior government agency authorization.

Status of Title

[See Appendix 2](#)

Description of Development



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

155 Innovation Drive is owned by Cangene Corporation. 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 room
- Cafeteria/lunch room
- Loading docks
- Paved parking areas

Asphalt paved parking lots lie to the 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 25 – 300 employees are stationed at 155 Innovation Drive with approximately 10 employees working out of space leased in an adjacent building (137 Innovation Drive) who operate a plasma collection centre.

The property is bordered:

- north by a 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 then an 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.

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 in that there are 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. According to Environment Canada, Winnipeg was the coldest city in the world with a population of over 600,000 based on the average night-time temperature from December to February, inclusive. 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 still 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 continues to Lake Winnipeg. 155 Innovation Drive location is less than 1km from the Red River as it passes to the east of the 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 to the 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 and 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.

Description of Environmental and Human Health Effects of the Proposed Development

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, with the exception of 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.

Phase 1 Environmental Site Assessment, 137 Innovation Drive, Winnipeg, MB, prepared by Jacques Whitford, dated July 25, 2008 was also reviewed. The Phase 1 only addressed 137 Innovation Drive. No environmental concerns or suspected contamination were identified and the Phase 1 did not make any recommendations for further investigations.

Fugitive air emissions are generated through processes within the facility from cleaners and lubricants used onsite and natural gas heating. Point source air emissions are generated from the autoclaves, laboratory hoods and diesel generators when operational. 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 | Caustic potash |
| Oils | Phosphoric acid |
| Chiller and boiler (physical plant) chemicals | Sulfuric acid |
| AC-30 (water chemical additive) | Ethanol |
| Compressed gases | Isopropyl alcohol |
| Pharmaceutical product bottles | Ethyl alcohol |
| Caustic soda | Methanol |
| And miscellaneous common laboratory chemicals | |

Diesel fuel is stored in three above ground storage tanks (AST) in Buildings A (1,385 liters), Building B (875 liters) and Building C (1,893 liters). Oil, including primarily gear oil and lubricating oil, is stored in small containers of less than 4-liters and 25-liter container in the Building B mechanical shop and the Building C chiller room.

Chiller chemicals are stored in 205 liter drums in the mechanical and chiller rooms in Building B and C. Boiler chemicals are stored in the Building C boiler room in containers ranging from 25 – 205 liters in size. AC-30, used in the water purification system is stored in 205 liter drums throughout the facility including the Building A passivation room and Building C water purification areas. Compressed gases, including nitrogen, argon and carbon dioxide are stored in 100lb compressed gas cylinders primarily in the Building A warehouse. Pharmaceutical product bottles are stored on shelves in the warehouse.

Caustic soda, caustic potash, phosphoric acid and sulfuric acid, used in wastewater treatment and water purification processes are stored 25 liter containers, 205 liter drums and totes in the wastewater treatment rooms, water purification areas and Building A chemical storage room.

Laboratory chemicals, including ethanol, isopropyl alcohol, ethyl alcohol and methanol are stored in containers and drums ranging from 10 liter to 205 liters 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).

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. Cangene operating as 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 would follow external emergency responder notification and protocol before being turned over to the company for remediation and would follow similar procedures as smaller spills.

Mitigation Measures and Residual Environmental Effects

155 Innovation Drive is registered with Manitoba Conservation & Water Stewardship under Hazardous Waste Generator #MBG03262. Primary waste generated is limited to small quantities of laboratory waste including acids, corrosives and alcohols. Hazardous waste is stored in flammable cabinets in the chemical storage room in Building A and in small containers in the laboratories. Waste containers are supplied and rotated by a contracted hazardous waste service contractor. Hazardous waste streams are essentially the same as they have been since operations began in the late 1980's.

Non-hazardous solid wastes generated onsite include plasma waste, nonhazardous laboratory chemicals, used oil, waste solvent, waste AC-30 and general trash. Plasma waste is autoclaved to remove the biological hazard and the remaining solid waste is disposed of in the general trash. Non hazardous laboratory wastes are stored in 205 liter drums and small containers in the Building A chemical storage room and disposed by a registered hazardous waste disposal contractor. Used oil is also disposed through the same contractor. Waste solvent is discharged into a 13,300 liter underground storage tank (UST Permit #36847) and disposed by the same contractor as required. Waste AC-30 is stored in the wastewater treatment room and the Building A passivation room and discharged into a wastewater treatment system before entering the building effluent waste stream. General trash is collected and stored in a rolloff bin located outside to the south of the facility and removed by a solid waste contractor.

No onsite pits, ponds or lagoons exist on the property. A wastewater sump is operated in conjunction with the wastewater treatment system.

Upon site closure, should that occur, there would be a detailed decommissioning process. Process documents enclosed as Appendix 6.

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

Underground and Aboveground Tanks

Waste solvents make their way to a 13,300 liter UST via solvent drains in laboratory clean rooms in Building C. The double-walled tank is 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, is appropriately inspected and maintained in a PM program as required by the conditions of the permit. No tank leaks or releases have ever being identified according to recent database searches. Because there is no history of leaks and based on the installation date, leak detection system and annual inspections the UST does not pose an environmental concern on the property.

Three diesel fuel ASTs associated with emergency generators are present at 155 Innovation Drive. The diesel fuel tank in Building A is a 1,385 liter double-walled steel tank located on the first floor. The diesel fuel tank in Building B is a 985 liter double-walled steel tank located in the basement. The diesel fuel tank in Building C is a 1,893 liter double-walled steel tank located in the basement. No tank leaks or releases have ever being identified according to recent database searches.

Four wastewater treatment ASTs of unknown size are present in 155 Innovation Drive; two are located in Building B and two are located in Building C. the tanks receive wastewater from the building manufacturing process areas. The tanks are constructed of double-walled steel.

The buildings obtain water from the City of Winnipeg public water supply. No water supply wells are located on the property. No septic or cesspools have ever been present onsite.

Two 60,000 liter purified water ASTs are located in Building C. The tanks feed ASTs of varying sizes located throughout the manufacturing and laboratory spaces of the buildings.

Water for laboratory use is supplied by the public water supply and purified via reverse osmosis and salt softener prior to use. The City water passes through the water purification system and is stored in the two 60,000 ASTs prior to use through the laboratory and manufacturing processes.

Sanitary and domestic grey water is discharged directly into the City sewer system, which is directed to a City of Winnipeg wastewater treatment plant.

Laboratory sinks and floor drains, process and manufacturing sinks and floor drains, boiler blowdown and compressor condensate discharge to a wastewater treatment system prior to being discharged to the City sewer system. Wastewater is discharged via concrete sumps to two wastewater treatment systems. The treatment rooms are located in Building B and Building C. Each treatment room contains two steel ASTs of unknown size. Wastewater is pH and temperature treated by adding caustic potash, caustic soda, sulfuric acid or phosphoric acid. After treatment the wastewater is discharged to the municipal sanitary sewer. No spills or releases from the treatment system have ever occurred. The City of Winnipeg conducts periodic inspection of the wastewater treatment system and wastewater discharge. No violations have been issued by the City however at the time of writing this application a Pollution Prevention Plan is being prepared for January 2015 submission to the City.

Air and Soil

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

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

Other

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.

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.

Conclusions:

EcoLog ERIS was recently 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 were reported at 155 Innovation Drive. Full report enclosed as [Appendix 5](#).

Federal and provincial databases were also searched to determine the potential for the site to be affected by releases from neighboring properties. The sites that have the greatest potential to have caused environmental contamination are those that have 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 that have 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 .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 Cangene operating as Emergent BioSolutions at 155 Innovation Drive.

Searches were unsuccessful in determining the existence of environmental cleanup liens against the property. There are no engineering or institutional controls issued against the property.

A FIPPA request was submitted to the Winnipeg Fire & Paramedic Services and the Manitoba Health Department to determine whether any hazardous substances incidents have been reported for the property. There were no results from these requests.

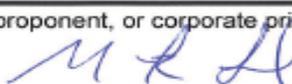
The exhaustive searches of a 2013 independent Phase 1 Environmental Audit concluded that no known, suspect or historically recognized environmental conditions have been identified in connection with the property at 155 Innovation Drive or surrounding area. There were also no *de minimis* conditions identified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

In conclusion, Cangene, operating as Emergent BioSolutions 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.

Environment Act Proposal Form

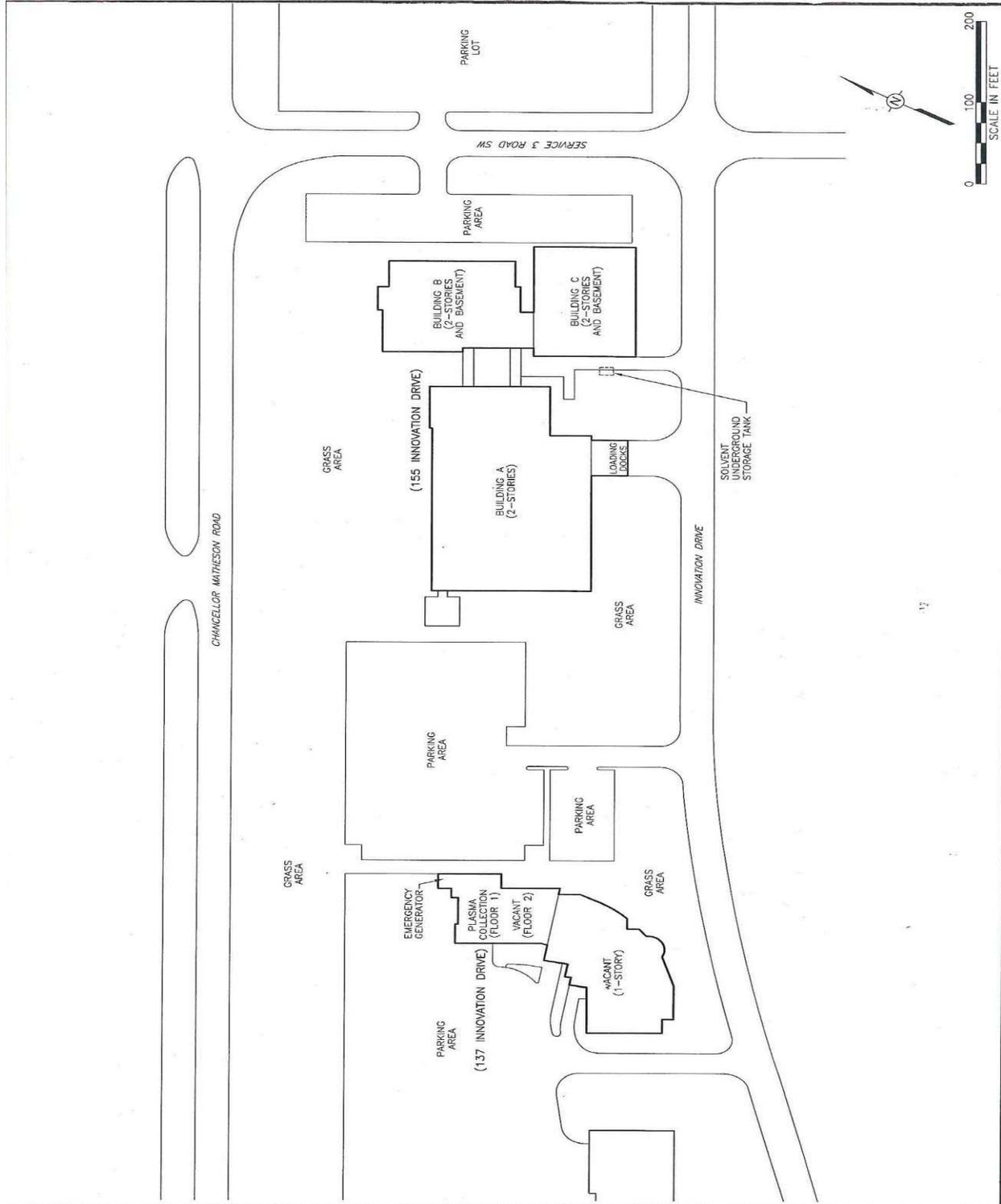
Environment Act Proposal Form



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

Appendices: Reports/plans supporting the EAP

Appendix 1: 155 Innovation Drive Site Drawing



Appendix 2 – Status of Title

Appendix 3 – Topographic Map and Legends

Appendix 4 – Aerial Photographs

Appendix 5 – EcoLog ERIS Report

Appendix 6 – Decommissioning Process Documents