IPC Licence Application

Site Operational Report
1. Introduction

Beckman Coulter Inc. (BC) is a Danaher Corporation company that develops, manufactures and markets products that simplify, automate and innovate complex biomedical testing. It is operating in two industries: Diagnostics and Life Sciences. With a history of more than 80 years the company helps healthcare and laboratory professionals, pharmaceutical and biotechnology companies, universities, medical schools, and research institutions worldwide. BC products help laboratories support optimal patient care with efficient diagnostic testing while addressing community health concerns such as antibiotic resistance, throughout the world.

BC’s objective is to provide the right patient insights at the right time with our clinically impactful clinical chemistry and immunoassay menu addressing prevalent and expensive health risks.

Our priority is to deliver accurate results with rapid, consistent TAT, fewer pre-analytical errors, and more efficient workflows designed to fit today’s laboratory. BC’s total laboratory automation solutions can reduce TAT outliers by 30%, which can contribute to shorter patient stays, which in turn improves efficiency of hospitals worldwide.

Our standardization support provides consistency across locations and networks for patients and physicians. Customers can save time, increase productivity and make informed decisions with solutions such as REMISOL Advance middleware and the DxONE Information Management Solutions.

Founded by Caltech professor Arnold O. Beckman in 1935 as National Technical Laboratories to commercialise a pH meter that he had invented, the company eventually grew to employ over 12,000 people, with $5.8 billion in annual sales by 2017. Its current headquarters are in Brea, California. Beckman Coulter was acquired by Danaher Corporation in 2011. BC has manufacturing facilities in Chaska, (Minnesota), Mishima, (Japan), Suzhou, (China) and in Co. Clare, Ireland.

In 2009, BC acquired Olympus Diagnostics, including its Clinical Chemistry production facility in Clare. In 2018, BC approved the development of 2 new, large scale projects at this facility: the development of additional Immunoassay production and the introduction of Urinalysis production. Both projects are well underway and employment at the site as increased significantly to 400 plus. In January 2020, BC announced Clare will now be the main Research & Development Centre for CC reagents, which will see additional employment at the site.

The company is committed to operating in an environmentally sustainable and responsible manner. This is reflected by their accreditation to ISO 14001.

The company will potentially operate the following working hours:

- 24/7 - Main factory.
- 7am-6pm – Office.
2. Process Flow Diagrams

### Urinalysis

<table>
<thead>
<tr>
<th>Operation / Description</th>
<th>Flow Chart</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production of urine test strips: The process starts with mixing 12 unique solvent &amp; water based chemical formulations which are soaked (impregnated) into paper &amp; dry. This paper is cut into long thin rolls. The 12 types of paper are glued with a hotmelt glue onto a plastic backing material. This glued paper &amp; plastic roll is then cut into small parts which become the urine test strips which have 12 test pads for testing urine. Depending on the colour changes can be used to indicate different properties of the urine sample.</td>
<td>Flow Chart</td>
</tr>
</tbody>
</table>

### FILL/包装

<table>
<thead>
<tr>
<th>Operation / Description</th>
<th>Flow Chart</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filling of containers such as bottles/valves/Packs with formulated Product. Containers are filled with product, labelled and kitted into shipper boxes for delivery to distribution centers worldwide.</td>
<td>Flow Chart</td>
</tr>
</tbody>
</table>

### Warehouse

Chemical shipment arrives. Approximately 10 shipments per week, average 25 pallets. Approximately 300 different spares allocated for chemicals in Coldroom, Ambient and Room Temp Warehouses. 5 outside containers held Acid and Flammable products.

### VA

VA Agrement of Beckman controls and calibrators, controls for Bionol and Controls and Calibration for Beckman 14 for serum urine.

### QC Process

- Raw Materials: Fuel/Feed Water, Environmental Exposure Buffers, Final product products
- To facilitate product traceability (papers, 300 products of batch, 20 products in an identification stage, connected by bar code labelling, each with their own unique number, product specific test instruments.

<table>
<thead>
<tr>
<th>Operation / Description</th>
<th>Flow Chart</th>
</tr>
</thead>
<tbody>
<tr>
<td>In AU CSCA formulation we manufacture nearly 200 different types of batch. Batch size range from 1L to 20,000L. Batch time range from 4 hours to 6 week’s.</td>
<td>Flow Chart</td>
</tr>
</tbody>
</table>

### AU CSCA Formulation

- Planning tool formulation when batch time requirement is required
- Batch is planned on the formulation schedule, Oracle is updated. Individual procedure are followed as per batch specific procedures. IQP, general cleaning guidelines etc are followed
- Batch is processed testing for Batch specific procedure's
- Batch is stored under required storage temperature until being filled

### IA BV Formulation

- In IA BV formulation we manufacture nearly 250 different types of batch. Batch size range from 1L to 1,000L. Batch time range from 4 hours to 6 week’s.
- Planning tool formulation when batch time is required
- Batch is planned on the formulation schedule, Oracle is updated. Individual procedure are followed as per batch specific procedures. IQP, general cleaning guidelines etc are followed
- Batch is processed testing for Batch specific procedure's
- Batch is stored under required storage temperature until being filled

---

Consent of copyright owner required for any other use.
3. Emergency Incidents

There has never been any environmental emergency incident at the facility which would have generated any significant pollution incident.

4. Reason for Licence Application

Beckman have expanded the process operations on site to accommodate a new UA project which will be commercialised in 2020. As part of this process, solvent consumption will increase to above 10 tonnes per year for coating activities. All solvent storage arrangements are in place in line with EPA guidance and an RTO has been commissioned in 2019 for treatment of emissions.

5. Abatement Systems

The facility has process water emissions that are totally controlled by a sequential system that can be shut down immediately and no process water from the factory would be discharged beyond holding tanks. That protection systems prevents any shock to the reed beds from any process water. The routine protection applied, is that the process water is analysed and verified as compliant with control parameters prior to been manually discharged to reed bed 2 for further polishing. Abnormal operation would consist of process water not meeting the criteria set out for this water prior to discharge. In such an event, the water is held in storage and a licenced contractor would be commissioned to remove the water off site to an alternative plant for additional treatment.
5-1: Process Wash Water Flow Diagram

The sewage effluent treatment plant was upgraded in 2019 to accommodate additional effluent to be treated from employees on site as part of the site expansion. The treatment plant installed is a parallel system, with two treatment systems capable of operating alongside each other. The treatment plant expansion was designed in a way that if one section of the plant was to go offline for maintenance or service, the second plant would still be capable of treating effluent albeit at a slower rate and for a limited period of time. Final effluent can be shut off from discharging to the reed beds at any stage and effluent collected / removed off site for additional treatment in the event of abnormal operation, malfunction or interruption of services required to operate the system. The treatment plant process flow diagram is outlined below:

Fig 5-1 Process Wash Water Flow Diagram
Fig 5-2 Wastewater Treatment Plant Flow Diagram
Solvent emissions from the UA project are collected from the specific equipment which is located inside a purpose built room. There are no fugitive emissions from the equipment, therefore all waste solvent is diverted from the process to the Regenerative Thermal Oxidiser (RTO). The system was installed and commissioned in 2019 and deemed to comply with the emissions limit values that are allowable under the Solvent Regulations and that applied under BAT for the sector. The process flow for the RTO is outlined below:

Fig 5-3: RTO
In the event of abnormal operations the following would be carried out on site.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole factory loss power</td>
<td>The RTO and the Impregnation machine would shut down, the emergency bypass would open venting all gas to atmosphere and the emergency backup will kick in within a specific time period to turn the fans on which will pull the gas out of the drying ovens and also vent to atmosphere, preventing any gas entering the work area.</td>
</tr>
<tr>
<td>RTO power loss</td>
<td>It would send a fault to the Impregnation machine and it would go into an alarm which would cause emergency bypass to open and vent to atmosphere. The emergency bypass units are spring loaded to open and close for this reason.</td>
</tr>
<tr>
<td>RTO malfunction</td>
<td>It will give an alarm and the sounder would go off on the machine, if the alarm was interfering with the solvent processing or was deemed serious enough based on the risk and the way the RTO is programmed, it would cause emergency bypass to open and vent to atmosphere.</td>
</tr>
<tr>
<td>Impregnator malfunction</td>
<td>The vapours or gases will still be vented to the RTO as the RTO fan is independent.</td>
</tr>
</tbody>
</table>

6. Raw Materials

All raw materials which are deemed to have potential environmental significance are stored in line with best guidance and BAT for storage. All liquid raw materials which are potentially polluting are stored in containers as supplied by the agents within bunded areas. The bunds are inspected weekly and emptied weekly or more frequently as required. There are management procedures for acceptance, storage, use, maintenance, transport and usage of the solvents and chemicals on site. Solvents are signed in and out of storage as required and only by authorised personnel. Environmentally significant raw materials are transported on site in volumes that are required for use. Stocks are maintained at levels that are suitable for company requirements and in line with capacity and availability for adequate storage. External bunds are certified and covered to prevent ingress of rainwater.

Intermediates and final products would not be considered as potentially environmental pollutants.

7. Waste

There is a designated waste management area at the installation which is used for segregation and management of solid waste prior to collection by authorised contractor on a routine basis. All liquid waste is collected in large, sealed storage tanks or drums which are bunded. An excerpt to illustrate an example of the standard of waste management procedures is outlined in the procedure below:
PROCEDURE FOR HANDLING, SEGREGATION, STORAGE, DISPOSAL & TREATMENT OF HAZARDOUS WASTE STREAMS AT BCII

1. OVERVIEW

1.1 Purpose: The purpose of this procedure is to specify how BCII segregates, stores, disposes of and treats all hazardous waste streams resulting from its processes.

1.2 Scope: This procedure covers all sections of BCII where various types of hazardous wastes result as a by-product of processes on site. It is the responsibility of all those involved in such processes to ensure that all types of hazardous wastes are treated in accordance with legislative requirements and do not enter non-hazardous waste streams where such wastes could end up at landfill or get released as chemical effluent into the environment.

1.3 Responsibilities: The relevant Area Manager is responsible for ensuring their teams of people adhere to the environmental protocols as outlined in this procedure. Any updates of this procedure must be pre-approved by EHS.

1.4 Process Owner: Environmental Health and Safety Manager.

2. PROCEDURE

2.1 HAZARDOUS MATERIALS: 

1. BCII, resulting from its processes, produce the following by-products which are classified as hazardous waste streams:

   - Aqueous Chemical Waste
   - Biohazardous/Clinical Waste
   - Contaminated raw material, finished product & cleaning agent containers
   - Waste Absorbent Material from Hazardous Spills
   - Contaminated Glass
   - Contaminated Sharps
   - Obsolete/Expired Raw Materials
   - Obsolete/Expired reagents
   - Waste Oil
   - Fluorescent Tubes
   - Waste electrical & electronic equipment
   - Waste Toners, Cartridges & Ribbons
   - Batteries
   - Empty Paint, Stripper & Thinner Containers, etc.
   - Sludge from Effluent Treatment Plant
   - Cyanide containing waste e.g. Lyse III and Vitamin B 12
   - Miscellaneous hazardous waste

2. Each of the above hazardous waste streams must be segregated and stored separately using the appropriate bins which are all labeled. If hazardous waste needs to be removed from a department please contacts BCII’s Waste officer.
2.17 Sludge Removal from Effluent Treatment Plant:
1. In the unlikely event that sludge needs to be taken off site for treatment or disposal, a licensed waste contractor will be contacted and the relevant waste license & collection permit will be requested for review & approval.
2. The contractor in question will provide BCII with all relevant information relating to how the sludge was treated or disposed of.

2.18 Cyanide Waste Stream:
1. The sources of Cyanide waste are from the use of Potassium Cyanide as a raw material and the products containing Potassium Cyanide such as Lyse III and Vitamin B12. This includes the water washings from the Tanks and Lines which process these products. This waste is diverted to a separate waste drain sump and pumped out to an individual dedicated Cyanide waste tank. This waste is then removed off site by an approved waste vendor following all local waste regulations and controlled by the EHS dept.
2. Each Department's Waste Management Plan is displayed within that particular area for all employees, contractors, visitors to observe and adhere. Should any changes in an area's waste stream take place, the plan will then be reviewed by EHS Manager / Specialist and updated by the area manager.
3. The Environmental, Health & Safety Manager/Officer records BCII's waste metrics on a monthly basis and displays same on BCII's EHS Notice Board.

3. APPENDICES
Appendix 1 – Aqueous Waste Streams at BCII

4. REFERENCE DOCUMENTATION
List of Approved Hazardous Waste Contractors
IRL-ENVIRO-PCD-0002– Hazardous Waste Contractor Selection & Control
FQA 193, Obsolete Electrical & Electronic Equipment Form
Waste Metrics
FQA 185, BCII's Waste Management Plan
FQA 165, Obsolete Raw Material Form
WTF Forms
Certificates of Disposal