3 Non-Technical Summary

Following the pre-application guidance, form Part A and Part C2 and C3 are provided as part of this application. The documents are referenced:

PP3439GG_FOL_V008_Form Part A
PP3439GG_FOL_V008_Form Part C2
PP3439GG_FOL_V008_Form Part C3

3.1 Reason for variation

In 2025, the process 'FCM' was introduced on site, with the intention of starting commercial manufacture mid-2026. Due to the low customer demand of the product (up to 200kg/year), the product will be manufactured in the development laboratories on site, which doesn't currently have a registered environmental monitoring point. Therefore, this application is not suitable for inclusion under the currently Multi-Product Protocol (MPP).

FCM is a second-generation anticoagulant rodenticide derived from 4-hydroxycoumarin, developed in response to the emergence of warfarin-resistant rats. The process involves undertaking the last step of a multi-stage chemical synthesis, consisting of reaction of a tetralol ether with 4-hydroxycoumarin to yield the FCM. The final step is the process is to filter and mill the product into a fine powder, that is then packaged into ~4.15kg bags and shipped to the customer site for final formulation.

The process is outside the range of products previously manufactured on site and the volumes are too small for current manufacturing assets. Therefore, the intention is to manufacture FCM in a modified laboratory area, which will be customised to handle the potent and toxic nature of FCM and also EDC.

3.2 Key changes and impact of change

3.2.1 The FCM manufacturing process

This is a new product introduction for the Lianhetech Seal Sands (LSS) facility, with a proposed start date of July 2026. FCM is a potent active ingredient (AI), classified as highly toxic (LD_{50} = 250 µg/kg; OEL <100 ng/m³ based on single-dose rat studies), and falls outside the range of compounds previously handled at the site. To meet customer demand, Development Laboratories 1 and 2 will be upgraded to support commercial manufacture of FCM using ~50 L scale equipment. The process is designed to produce up to 200 kg per annum.

The FCM process consists of 7 stages:

- Stage 1 – Condensation Reaction
- Stage 2 – Neutralisation and Phase Separation (including waste treatment)
- Stage 3 – EDC Removal by Vacuum Distillation
- Stage 4 – Methanol Solvent Exchange by Atmospheric Distillation
- Stage 5 – Crystallisation
- Stage 6 – Filtration and Drying
- Stage 7 – Milling

Detailed chemistry and process flow diagrams are provided in **Section 10** of this report.

The manufacture of the FCM process will be carried out in existing lab facilities, there is no significant changes that would impact the energy consumption and therefore expected energy efficiency changes are considered minimal.

Further energy efficiency choices in the design, equipment selection and operation are further discussed in **Section 10** of this report.

The project for the FCM process is intended to produce up to 200 kg of FCM per annum, in 2 batches per week loads of approximately 2.5 kg per batch, to fulfil the customer requirements.

This will be the first time the process has been operated commercially at the Seal Sands, and the operating conditions will be monitored and optimized where possible within the regulatory constraints to minimize the usage of raw materials and generation of effluent streams to reduce the environmental impact of the process.

Further details of efficient use of raw materials, waste recover and disposal are provided in **Section 10** of this report.

Due to the commissioning of a new stack and therefore, a new established point source emission to air, referenced A1/5, an air quality impact assessment was commissioned to determine the impact to pollution dispersion from the point source emission and the impact on sensitive receptors. The assessment concluded that process contributions are insignificant and there are no predicted exceedances of the EALs for the protection of human health at the point of maximum ground level impact or any human exposure location outside the site boundary.

The installation has one permitted release point for emission to sewer or effluent treatment plant; this is referenced as release point D1 and is described as discharges to Bran Sands Treatment Works operated by Northumbrian Water. From this change, there are no process waste transfers to Bran Sands via D1 and therefore the current agreement with Bran Sands will remain unchanged.

The site has no existing point sources of emissions to land and does not propose to add a point source to land as part of this project.

The operator is located in an area of significant and similar industrial use, with extensive chemical manufacturing and processing operations. Raw materials and intermediates involved in the new manufacturing process are of low odour potential therefore environmental impact from odour, noise and vibration are considered as low.

There are no nearby residential receptors within 3.5km of the site.

3.2.2 Schedule 3 amendment

For this change, current permit conditions require a Schedule 3 amendment to introduce a parameter limit to be agreed with the Agency for the emission of EDC and methanol from the new stack, with reference emission point, A1/5.

3.2.3 Infrastructure changes

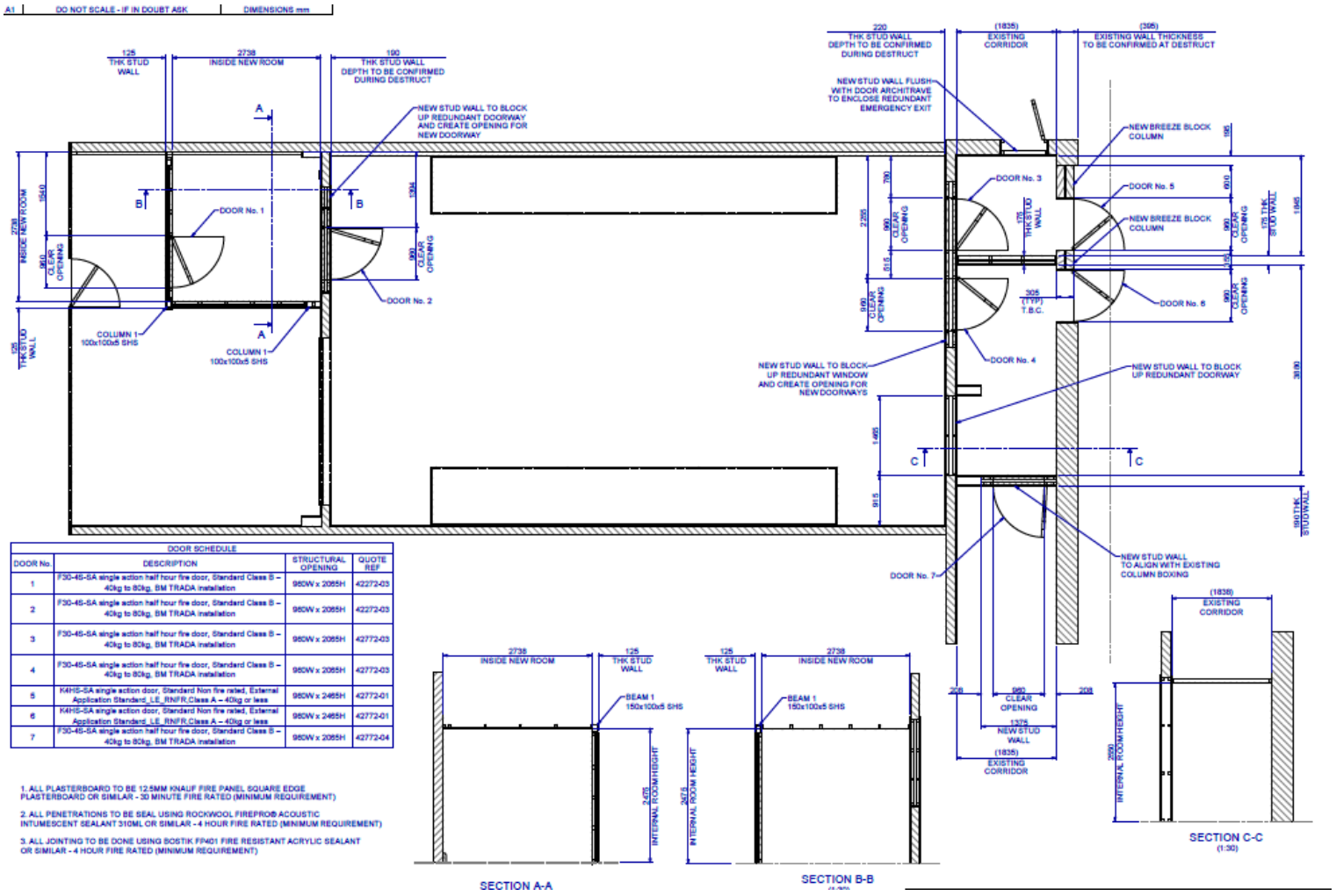
The design and operation of the FCM process will have minimal infrastructure changes, limited to a small modification to the Laboratory 1 & 2 spaces as described below:

- The existing laboratory 1 & 2 main processing area footprint will remain the same, with a minor change of installing new floor-to-ceiling fume cupboards. NOTE: Only half of lab 2 is required for FCM and only 3 out of 11 fume cupboards are being replaced across both labs
- All fume cupboards have secondary containment, in line with CIRIA C736 key requirements, which specifically requires bunds to have a minimum capacity of 110% of the largest tank. The bund capacities are demonstrated below in comparison to the volume within the fume cupboard.

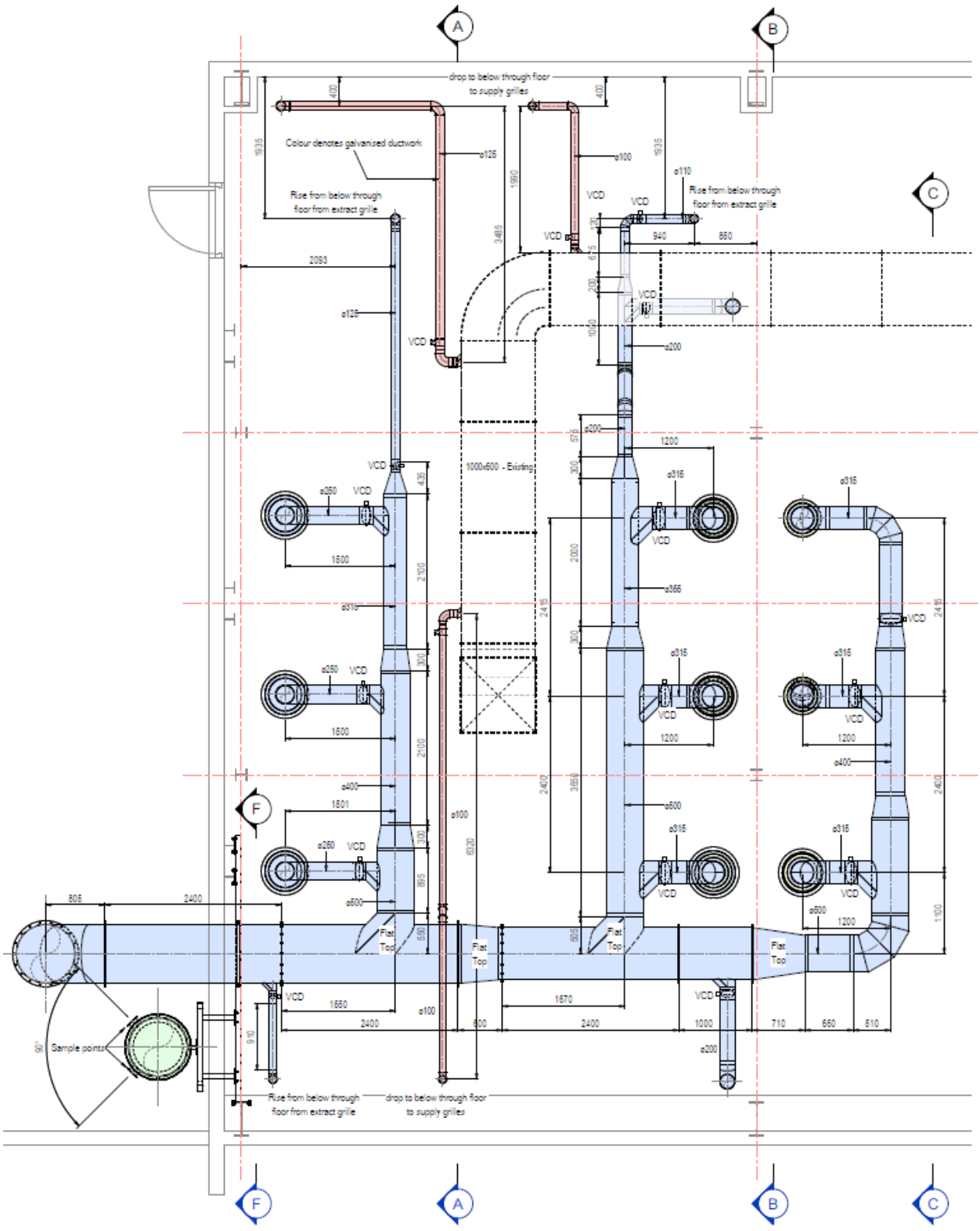
Maximum EDC volumes per fume cupboard

Fume Cupboard	Vessel	EDC Content	Max EDC content per FC	Bund capacity
1	R5	~1.5 kg / 1 L (5-10% EDC in ~20 L of MeOH / FCM mix)	14 L	146.5L
	R3	17.5 kg / 14 L		
	R4	11 kg / 9 L		
2	V3	~20 kg / 18 L (conc. Residues from R1, ~28 kg total)	18 L	100L
	V4	~1.5 kg / 1 L (5-10% EDC in ~20 L of MeOH / FCM mix)		
3	R7	5L	5L	70.6L
	R8	5L		
4	R2	~18 kg / 14 L	56 L	70L
	R6	~70 kg / 56 L		
5	V1	30-34 L (~40 kg)	35 L	130L
	V2	30-34 L (~40 kg)		
	R1	30-34 L (~40 kg) + 2 kg = ~42 kg (~35 L)		
6	V5	Negligible (aqueous washes)	Negligible	65.5L
	Scrubber	Negligible		

- At both ends of Laboratory 1, ancillary areas to create material and personnel airlocks to maintain a negative pressure differential within the main processing room will be incorporated into the current footprint of the building by erecting walls and doors, as shown in the Engineering drawing below.



- The air supply for all FCM areas will come from the existing supply. A new dedicated extract fan and environmental stack system will remove the air from Lab 1 main processing room and associated ancillary rooms, x6 fume cupboards and Lab 2 x3 fume cupboards, as shown in the Engineering drawing below.



- The process equipment will be vented through a carbon bed, prior to the connection to the environmental stack.

As the volumes being handled are small, current site infrastructure is acceptable.