

**Annex I: Comments regarding the IPPC application – Crystal Pharma Ltd.**

**Form A**

Section	Duly Made?	ERA Comments 9 October 2017	Crystal Pharma replies 5 December 2017	Duly Made?	ERA Comments 23 January 2017	Crystal Pharma replies 29 January 2018	Duly Made?	ERA replies 31 January 2018	Crystal Pharma replies 6 February 2018
A1.1	✘	Noted. In the box requesting the input of the application reference number kindly input the permit reference number; IP 0005/07/C.	Done.	✓	Noted.		✓		
A1.2	✓	Noted.					✓		
A1.3	✓	Noted.					✓		
A1.4	✘	<b>Doc Reference: IP 0005/07/C: IPPC Permit type C, 05/October/2015</b>  Noted.					✓		
		<b>Doc Reference: IP 0005/07/B: IPPC Permit type B, 21/July/2011</b>  Kindly remove from section as permit B is superseded.	Ok. Noted. Modified in Form A and in Section 3 of the Final Site Closure Plan (V.1. Dated 05122017).	✓	Noted.				
		<b>Doc Reference: IP 0005/07/A: IPPC Permit type A, 27/November/2008</b>  Kindly remove from section as permit A is superseded	Ok. Noted. Modified in Form A and in Section 3 of the Final Site Closure Plan (V.1. Dated 05122017).	✓	Noted.				
		<b>Doc Reference: CP11306 Permit to transfer Solid waste containing hazardous substances, 28/August/2017.</b> [Permit Valid till 27 February 2018]  Noted.							
		<b>Doc Reference: CP11307 Permit to transfer absorbents, filter materials, wiping cloths, protecting clothing contaminated</b>	Ok. Modified to include the “Request for Permit to transfer absorbents, filter materials, wiping cloths, protecting	✓	Noted.				

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		<p><b>by hazardous substances; 16/May/2017</b> [Permit Valid till 16 November 2017]</p> <p>Kindly note that this permit has expired. The Operator is to whether an application for a consignment permit for this waste has been submitted.</p>	<p>clothing contaminated by hazardous substances; Applicants' copy, 27/November/2017". Modified in Form A and in Section 3 of the Final Site Closure Plan (V.1. Dated 05122017).</p>						
		<p><b>Doc Reference: CP 11309 Permit to transfer packaging containing residues of or contaminated by hazardous substances, 16/May/2017.</b> [Permit Valid till 16 November 2017]</p> <p>Kindly note that this permit has expired. The Operator is to whether an application for a consignment permit for this waste has been submitted.</p>	<p>Ok. Modified to include the "Request for Permit to transfer packaging containing residues of or contaminated by hazardous substances; Applicants' copy, 27/November/2017". Modified in Form A and in Section 3 of the Final Site Closure Plan (V.1. Dated 05122017).</p>	✓	Noted.				
		<p><b>Doc Reference: DMU 5897 Public sewer discharge permit, 03/October/2016</b></p> <p>Kindly provide a valid sewer discharge permit.</p>	<p>Ok. DMU 5897 Public sewer discharge permit, 08/November/2017 included in Form A and modified in Section 3 of the Final Site Closure Plan (V.1. Dated 05122017).</p>	✓	Noted.				
				✗	<p><b>Doc Reference: Site Closure Plan (Section 4); Annex 1. Lease Agreement</b></p> <p>Kindly ensure that this document is a 'standalone document' and is included in the section A1.4. Kindly ensure that a signed copy of the MIP inspection report is provided. Moreover,</p>	<p>The Lease agreement has been deleted from the Site Closure Plan and is included as A.4.1. Document 6 "Lease agreement".</p> <p><i>Document 7 includes MIP inspection report. Crystal Pharma has requested a signed copy of MIP inspection report and is awaiting the</i></p>		<p><b>Doc Reference: Document 6: Lease Agreement</b></p> <p>Noted.</p> <p><b>Document Reference: Document 7: MIP inspection report.</b></p> <p>Noted. Signed inspection report is to</p>	<p><b>Noted. As soon as received from MIP it will be sent to ERA by email.</b></p>

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					page 3 of the same report seems to imply that certain maintenance works are needed. Should this be understood that Crystal Pharma will have to carry out such tasks prior to final closure?	<i>reception. We will send it to ERA as soon as it is received.</i>  No maintenance works have been required by the MIP. Evidence of this communication is provided under A.4.1. Document 8.		be provided at the earliest.  <b>Document Reference: Document 8: Communication between MIP and Crystal Pharma concerning the maintenance works.</b> Noted.	
A2.1	✘	Kindly fill in the missing information in continuation with section A2.1 on page 3 of the application.	Done.	✓	Noted.		✓		
A2.2	✓	Noted					✓		
A3.1	✓	Noted					✓		
A3.5	✓	Noted					✓		
		<b>Doc Reference:</b> (Document 8) Register of Companies: Solea Pharma Limited							
		<b>Doc Reference:</b> (Document 9) Change of Name from Solea Pharma Limited to Crystal Pharma Limited							
		<b>Doc Reference:</b> (Document 10) Board of Directors resolution dated 24/August/2015							
		<b>Doc Reference:</b> (Document 11) Form K: Change of Directors and Secretary							
		<b>Doc Reference:</b> (Document 12) Form K: change of Directors							
A3.6	✓	Noted					✓		
A 4	✓	Noted.					✓		

Form E

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E1.1	✓	Noted					✓		
E2.1	✗	Kindly fill in appropriate in this case given the application is a full surrender the box indicating <i>No</i> should be ticked.	Done.	✓	Noted.		✓		
E3.1	✗	<p>Doc reference: <b>Report re Submission of a land and groundwater risk assessment, and if required, a monitoring strategy and baseline report-October 2015</b></p> <p>As agreed upon in the meeting held on the 11.10.17, document is to be replaced by a site report which describes the current condition of the site. Sections of the land &amp; groundwater risk assessment which describe the site may in be included.</p> <p>Moreover as also mentioned in earlier communications kindly provide a 'programme of works/gantt chart' which details the timeframes</p>	Noted. As Agreed in the referred meeting, version 1 of Form E refers to the Final Site Closure Plan which includes the description of the Site just after operational cease, and includes specific section (Section 5 V2) on soil and groundwater conditions and proposed site investigation.	✗	<p><b>Doc reference: Final Site Closure Plan V1 dated 05122017</b></p> <p>'Report resubmission of a land and groundwater risk assessment' has been replaced by <i>Document 1 Final Closure Plan</i> which includes:</p> <ol style="list-style-type: none"> <li>1. Site Closure Plan (Section 1 &amp; 2)</li> <li>2. Site Closure Plan (Section 3)</li> <li>3. Site Closure Plan (Section 4)</li> <li>4. Site Closure Plan (Section 5)</li> <li>5. Site Closure Plan (Section 6)</li> </ol> <p>Kindly ensure that only Site Closure Plan (Section 1 &amp;2) and (Section 3) are referenced in section E3.1 of Form E. It is imperative that that only the relevant information is cross-referenced in the appropriate IPPC form section.</p> <p>Kindly note Site Closure Plan (Section 6) can be omitted completely as it serves no particular purpose. Comments on the other Subdocuments referred</p>		✓	<p><b>Doc reference: Document number 1: Final Site Closure Plan dated 29012018 Section 1&amp;2 and Section 3.</b></p> <p>Noted.</p>	

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		envisioned for the completion of the decommissioning operations together with timeframes for disposal of any residual wastes from such operations.	Final site closure plan V1 dated 06122017 included an updated Gantt chart as agreed in the referred meeting.		<p>to collectively as <i>Document 1 Final Closure Plan</i> will be tackled in section below.</p> <p><b>Document: Site Closure Plan (Section 3)</b></p> <p>Kindly remove the section titled Annex 1. Site Protection and Monitoring Programme (SPMP) from this section.</p> <p>With regards to the comment on the Gantt chart being inputted in V1 dated 06122017 it is understood that this implies 'Site Closure Plan (Section 4) Annex 7. Programme of works' With reference to this document kindly ensure that the timeline uses the MM/YY format as opposed to the weeks with no time reference. Kindly ensure this document is reference as a 'standalone document' in section E3.1</p>	<p>Noted. Section 6 has been deleted from the Site Closure Plan.</p> <p>Noted. Final Site Closure Plan Section 3 Annex 1 has been deleted.</p> <p>Noted. The Gantt chart modified to use MM/YY is provided as standalone document Form E, section E.3.1. document 2, and it has been deleted from Site Closure Plan (Section 4) Annex 7. Programme of works.</p>		<p>Noted.</p> <p>Noted.</p> <p><b>Doc reference: Document number 2: Program of works.</b></p> <p>Noted.</p>	
E.3.2	✓	<b>Doc reference 2: Spillage management</b>  Noted.		*	<b>Document number 2: Spillage management. Two procedures</b>  Noted. With regards to section E 3.2 of the IPPC form E the Operator is being requested to either make reference to <i>Annex 9: Spill Management Procedures of the Site Closure Plan (Section 4)</i> or <i>Document no.2 Spillage</i>	Noted. Spill Management procedures included as <i>Annex 7: Spill Management Procedures of the Site Closure Plan (Section 4)</i> and deleted as <i>standalone document to avoid confusion. Spillage records are also provided in the same Annex 7.</i>	✓	<b>Document reference: Document number 3: Final Site Closure Plan V2 dated 290118: Section 4 V2 and Section 5 V3</b>  <b>Subdocument: Site Closure Plan (Section 4) Annex 8: Spill Management Procedures</b>	

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					<i>management procedures</i> as these two documents are identical.			Noted.	
	×	<p><b>Doc reference 3: Spillage records</b></p> <p>Kindly provide spillage records for all previous years. Crystal Pharma to confirm whether than been any major spill other than the minor spills listed.</p>	<p>Crystal Pharma implemented a formal spillage procedure on 18/10/2011. According to this, in the case of a mayor spillage an investigation was to take place but minor spillages were no recorded. No mayor spillages have occurred on site. Please find included former procedure as Annex in Section 4 Site closure plan V1 dated 05122017.</p> <p>Spillage procedure was modified on 17/01/2017 to include a logbook for recording all spillages. This is the information already submitted and also included in V1 of the Final Site Closure plan dated 06122017.</p>	✓	<p><b>Document number 3: Spillages records</b></p> <p>Noted.</p>			As indicated above <i>'Document number 3: Spillages records'</i> has been removed as consolidated with Site Closure Plan (Section 4) Annex 8: Spill Management Procedures.	Agreed.
	×	Kindly ensure that the <i>'Site Closure Plan'</i> is cross-referenced within this section.		×	As mentioned previously kindly ensure that the appropriate section/s of the Site Closure is referenced in this section.	As discussed during conference call held on 26/01/2018, Form E, Section 3.2 will only refer to Site closure plan Sections 4 and Section 5.		Amendment in Form E has been noted.	
		1. With reference to section 3.2, the Operator is to clarify whether there will be any decontamination treatment of the underground sump, reservoir and connecting pipework.	1. Sump has been cleaned and its content analyzed. It meets specifications (evidence sof such have been included as Annex in Section 4 Site closure plan V1 dated 05122017).		1. Kindly identify section in which such results are located.	Evidence of the latests analytical results dated 6/11/2017, from the Water Service Corporation have been included as Annex 3 Section 4 of the Site closure plan (E.3.2, Document 1, Section 4, Annex 3).		<p><b>Document reference: Site Closure (Section 4)</b></p> <p><b>Subdocument: Annex 3: Latest Analytical results by Water Services Corporation</b></p> <p>The WSC report has been noted. Nonetheless, the operator is to indicate when the reservoir will be cleaned.</p>	<b>Noted. As soon as the reservoir is cleaned, evidence will be sent to ERA by email.</b>

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			<p>Reservoir is going to be cleaned by an external company.</p> <p>Connecting pipework-drainage procedure (attached) has been followed to ensure the cleaning of the pipes.</p> <p>Pipes connecting the warehouse and the external area with the reservoir were sealed in 2012.</p>		<p><b>Document reference: Site Closure (Section 4); Annex 2: Drainage Procedure.</b></p> <p>The procedure provided in Annex 2 seems to tackle superficial cleaning of drain gutters/entry point. ERA is however requesting submission for the internal cleaning of pipelines which were utilised for transfer of hazardous materials. Kindly clarify whether any cleaning was carried out prior to sealing such pipelines.</p>	<p>Crystal pharma is working to hire the external company to clean the reservoir. As soon as this is done, we will inform ERA by email.</p> <p>As discussed in the calls and email correspondence, all drainage is connected to the sump. All drainage were cleaned and evidence of the latests analytical results are provided (E.3.2, Document 1, Section 4, Annex 3).</p>		<p>Additionally the sump the sump may require certification and/or remediation subject to the land and groundwater test results.</p> <p>Noted. WSC to provide feedback if there are any issues in this regard.</p>	
		<p>2. With regards to the hardstanding and impermeable treatment in the production area and storage area will the coating be removed as part of the surrender?</p>	<p>2. No. According to termination agreement between CP and MIP the coating remains as it is. (Included as Annex in Section 4 Site closure plan V1 dated 05122017).</p>		<p><b>2. Document: Site Closure Plan (Section 4) Section 1.3 Plant and Equipment</b></p> <p>With regards to the following statement;</p> <p><i>‘As per ERA request for clarification dated 9th October 2017, please note that hardstanding and impermeable treatment in the production area and storage area will remain in place. As agreed with the Land Owner (MIP).’</i> Kindly provide evidence/communication of such an agreement made with MIP.</p>	<p>Noted. Evidence of the communications with MIP regarding hardstanding status is provided as <u>Form E, E3.2, Document 1: Site Closure Plan Section 4, Annex 1.</u></p>		<p><b>Document Reference: Site Closure Plan (Section 4)</b></p> <p><b>Subdocument: Annex 1. Communication with MIP</b></p> <p>Noted.</p>	
		<p>3. With reference to section 4.3 in, with regards to the equipment which will be</p>	<p>3. See attached Termination agreement between CP and MIP.</p>		<p>3. Noted.</p>				

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		retained on site (Scrubber, cooling tower, chilled water equipment) is this the comprehensive list of equipment which will be retained on site? Moreover for all items/equipment which will remain on site requires authorization from Malta Industrial Parks.	The list of equipment that is retained or removed is specified within the agreement.						
		4. With reference to section 4.5.2 isolation and removal of chemicals kindly explain the disposal procedure for such chemicals.	4. The chemicals that could be found were oil and glycol. Glycol was drained for the system and stored in IBC's. The system was cleaned with water and bleach and this stream was joined with the previous one. Waste was labelled as non-halogenated organic waste and managed through the authorised contractor PTMatic. Oil has been removed for the pumps and tanks and stored in IBC's. Tanks have been cleaned by an external company with water (Falcan) and waste managed through authorised contractor (/Waste Oil Company LTD) Evidences have been included as annex in Section 4 Site closure plan V1 dated 05122017).		<p><b>4. Document: Site Closure Plan (Section 4) Section 1.5.2 Plant and Equipment</b></p> <p>Noted. Kindly ensure that Annex 5 (PTMatic Waste Carrier Authorization) and Annex 11 (Documents from Falzon group of companies and waste oils company limited) which are included in Site Closure Plan (Section 4) are to be removed.</p> <p>With reference to the Annex 13: Waste Logbook and another waste log on page 17 of the Site Closure Plan (Section 4) it is imperative that only one comprehensive table is used. Moreover kindly ensure that those waste streams which are hazardous are labeled appropriately. The asterisk symbol implies the waste is hazardous. The following codes need to be amended.</p> <p>07 05 01* 07 05 04* 07 05 13* 13 07 03* 14 06 01* 14 06 03*</p>	<p>Noted. Annex 5 and 11 have been deleted.</p> <p>Noted. The waste logbook table has been deleted from page 17 of Section 4 of the Site Closure Plan and is only provided as Annex 11. The codes have been amended to reflect those hazardous waste streams with an *.</p>		<p>The removal of <i>Annex 5 (PTMatic Waste Carrier Authorization)</i> and <i>Annex 11 (Documents from Falzon group of companies and waste oils company limited)</i> has been noted.</p> <p><b>Document: Site Closure Plan (Section 4)</b> <b>Subdocument: Annex 11 Waste Logbook</b></p> <p>Noted, however wastes which were listed in the waste logbook on page 17 were not included in Annex 11. The waste-streams listed hereunder are missing from Annex 11.</p> <ul style="list-style-type: none"> <li>○ Non-Contaminated litter</li> <li>○ Ferrous metal</li> <li>○ Oil</li> <li>○ Electronic devices</li> </ul>	<p>Oil was included as waste number- W 70. Ferrous metal waste has not been generated yet, but has been included in the table (W85). Gas reagents were included as waste number – W 71. Solid reagents were listed as laboratory reagents and were included as waste numbers- W 68 and W 81</p>



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					<p>16 05 06* 20 01 21*</p> <p>Following permit issuance an updated waste log will be requested in which waste streams of identical EWC codes are grouped together.</p>			<ul style="list-style-type: none"> <li>○ Glass</li> <li>○ Plastic</li> <li>○ Fluorescent tubes</li> <li>○ Paper and cardboard</li> <li>○ Solid reagents</li> <li>○ Gas reagents</li> </ul> <p>Additionally kindly ensure acetic acid (W52) 06 01 06 also needs to be marked as *.</p>	<p>Electronic devices and fluorescent tubes has been included as waste number – W 82 and W83</p> <p>Non-contaminated litter, glass, plastic, paper and cardboard has been collected by NATS on a weekly basis. NATS is not providing any differentiated collection record, not specific amounts per type of waste. Therefore we have included all under Waste number- W 84. W52 marked with *.</p>
		<p>5. With reference to section 4.4 <i>Decommissioning Team</i> it is to be ensured that all local occupational &amp; health safety shall be adhered to.</p>	<p>5. Noted. Specific reference has been included in Section 4 of Final Site Closure Plan V1 dated 06122017. Compliance to H&amp;S regulations will be supervised by the local external specialist Resolve Consulting Limited</p>		<p>5. With Regards to this section, kindly be advised that this will be assessed by the OHSA as part of the regulatory consultation. Further feedback may be provided at a later stage.</p> <p>Reference is made to <i>Section 1.5.1 Preparation of risk assessments and method statements</i> in Document reference Site Closure Plan (Section 4). The following is statement is mentioned:</p> <p><i>‘Of particular importance is that all activities shall be covered by specific risk assessments and methods statements (RAMS), thus ensuring that the contractors have identified the hazards the dismantling process is likely to pose. These assessments shall include the evaluation of the potential impact posed to the environment, and determine the necessary mitigation measures to prevent environmental harm. For</i></p>	Noted.			

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					<p><i>guidance, a non-exhaustive list of OHS hazards and environmental impacts that are likely to materialize during the dismantling process is included in Annex 4.”</i></p> <p>Kindly note that Annex 4 does include any method statements. It is understood that the method statements can be found on pages 11-13 of the Site Closure Plan (Section 4) and in Annex 6 of the same document.</p>	<p>Note that Pages 11 to 13 describe the dismantling procedures. In section 1.5.1 Crystal Pharma refers to the future Health and Safety Plan that Resolve Consulting will design to ensure that all risks are identified and managed during dismantling operations. The Annex 6 is only a non-exhaustive list of OHS hazards and environmental impacts that are likely to materialize during the dismantling process.</p>		Noted.	
		<p>6. With regards to the following statement, ‘<i>Specific procedures have been prepared to decommission reactors, centrifuges, stainless steel vacuum ovens, air forced oven, lyophiliser, mills and micronizers. Decommissioning procedure templates are included in appendix 3 and records will be maintained. Equipment shall also be disposed of in accordance with appendix 2, Equipment disposal schedule.</i>’</p> <p>Kindly provide the indicated method statements for ERA’s assessment.</p>	<p>6. Detail sequent of actions included in Section 4 Site closure plan V1 dated 05122017</p>		Noted.				

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		7. With reference to point “ <i>that due to building constraints, the external wall adjacent to the clean room technical area of the Lyophiliser will be demolished to allow for the removal of the equipment. This will be carried out under the professional guidance of an architect and reconstructed once equipment has been remove. Any building waste shall be disposed of in licenced landfills.</i> ” Kindly indicate whether PA & MIP approval have been granted in this regard.	7. Request for PA confirmation for not needing specific permit and justification have been included as Annex in Section 4 Site closure plan V1 dated 05122017		7. Noted.				
		8. With regards to the liquid waste generated from the dismantling operations kindly provide more details of the waste disposal including the final disposal location	8. Equipment liquid chemicals have been explained in point 4. Water to rinse pipework was stored in IBC’s and disposed as non-halogenated aqueous waste through the authorized waste contractor PTmatic.		8. Noted.				
		9. With regards to the removal of the refrigerant from HVAC equipment kindly provide qualifications and details of technician.	9. The technician in charge of this removal was Mr. Johan Tabone. Certificate of qualifications has been included as Annex Final Site Closure Plan Section 4 V1 dated 06122017		9. The certificate has been noted. However kindly remove the green skips permit in Annex 10 of the Site Closure Plan (Section 4)	Noted. Annex 10 of Section 4 Site closure plan has been deleted.		Noted.	
		10. With regards to the waste emanating from the diesel tank and waste liquid process tank,	10. Both tanks will remain on site.		10. Noted. It should however be noted that according to Document A in Annex I. Lease Agreement, there is no indication	Noted. Communication with MIP regarding the diesel tank has been included as Form E, E3.2,		Noted.	

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		kindly clarify whether such structures will be retained on site.			that the diesel tank must remain on site. However this has been mentioned in section 1.5.4 Decommissioning and removal of plant and ancillary equipment of the Site Closure Plan (Section 4).	Document 1: Site Closure Plan Section 4, Annex 1.			
		11. With reference to section 4.6 decommissioning for existing materials, given that the majority of raw materials have been removed off site and disposed off as waste as noted during the 20.10.17 inspection. Kindly submit an update to table labelled as the following 'raw materials inventory at 31 <sup>st</sup> August 2017 with the date of removal and disposal location.	11. As noted during the inspection most chemicals have been disposed of through authorized contractors. Updated Waste logbook has been included as Annex XYZ of the Final Site Closure Plan Section FFF V1 dated 06122017.		11. It is understood that 'Annex XYZ' should refer to <b>Annex 13: Waste logbook of the Site Closure Plan (Section 4)</b> . Kindly see point 4 above.  With reference to the ' <b>Annex 12: updated raw materials inventory + evidences of final destiny of the Site Closure Plan</b> ', kindly note that the list of invoices is not necessary. Moreover with reference to the table under the column disposal location those entries labeled as "see invoice" should be changed to sold to third party or as deemed necessary.	Noted. See clarification above. Waste Logbook is now only included as Annex 11. (Form E, E3.2. Document 3, Final Site Closure Plan Section 4 annex 11).  Noted. Invoices have been deleted from Annex and table has been amended as required.		Noted.  Noted.	

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		12. With reference to table with the caption (the waste presents on site are registered in the following table). Table 4 kindly provide full names for wastes W1 and W2 and provide waste carrier and waste broker permit number as well as the permitted disposal facility.	12. ok. Noted. Updated Waste logbook has been included as Annex XYZ of the Final Site Closure Plan Section FFF V1 dated 06122017. Waste Carrier is PTMatic. Associated documentation included as Annex XYZ of the Final Site Closure Plan Section FFF V1 dated 06122017		12. Noted. Kindly see point 11 above.	Noted. See response above.			
					13. Reference is made <i>section 1.6 Decommissioning for Existing Materials of the Site Closure Plan (Section 4)</i> , the following statement is made; “ <i>Further waste will be generated through the decommissioning process, specifically from washing and flushing of equipment. The existing waste disposal procedures will continue to be followed: aqueous based waste with a relatively low level of contamination (such as water rinses including cleaning agents, scrubber liquors and general wash-down water) will be controlled to ensure that are below discharging limits. In this case would be sent to the sewer. If not, the stream would be collected and sent for third party disposal. Organic solvent based streams will be collected and sent for third party disposal; highly concentrated aqueous streams will be collected and sent for third party disposal.</i> ”	The Water Service authority was on site on 12/10/2017 and was informed on the cease of production activities. Discussion on the wastewater discharge during the operational cease were verbally discussed and discharge permit granted. The valid wastewater discharge permit will be cancelled with the Water Service Authority once all cease operations have been completed.		Noted. WSC to provide feedback in this regard.	

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					Kindly note the WSC authorization pre-approval will be required for such a procedure.				
					<p>14. With reference to <b>Annex 6: Decommissioning</b> procedure kindly explain and indicate the location of the <b>chemical drain</b> which is mentioned in the following procedures:</p> <ul style="list-style-type: none"> <li>• Air Force Oven decommissioning Record</li> <li>• Micronizer decommissioning Record</li> <li>• Vacuum oven decommissioning record</li> <li>• Vacuum filter decommissioning record</li> <li>• Cold room decommissioning record</li> <li>• Key product warehouse decommissioning records</li> <li>• Clean area decommissioning record</li> </ul>	The procedures for “Equipment Use and Cleaning” refer to the cleaning and collection of cleaning liquids into secondary containments that are then pumped into IBCs and managed as Non halogenated organic waste through PTMatic. The ,mention to drains in the decommissioning records is therefore incorrect and should be understood to the secondary containments.		Noted. Procedures to be corrected.	The cleaning of the equipment took place on September 2017. Documents have been already completed by the operators. No changes are therefore feasible in the records.

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	x	<p><b>Doc reference: Site Closure Plan (Section 5) submitted on 16.10.17</b></p> <p>1. With reference to section 5.2.1 <i>Design of the sampling plan</i>.</p> <p>All shallow boreholes for soil sampling shall be drilled to 3m depth and 3 samples shall be taken from each borehole. The 3m samples shall be retained in cool conditions, and only require testing if contamination is found in the 2m sample of the respective borehole. The same practice may be applied for the drilling and sampling from the monitoring wells in case groundwater is not encountered at 12m. ERA reserves the right to change the requested depth of boreholes and the number of required samples per borehole depending on the land conditions observed on site during the coring exercise.</p> <p>The following sampling locations shall be retained as originally proposed: MW-1, MW-3, BH-4, BH-5.</p> <p>The remaining sampling locations shall be shifted as per the <b>attached plan</b>:</p> <p>BH-1: to be shifted closer to the sump to provide more representative samples covering potential leakages/spills from the sump</p>	<p>Ok, noted.</p> <p>Sampling locations (Sampling location Plan modified in Section 5 Final site closure plan V2 dated 06122017):</p> <p>BH-1: It will be moved closer to the sump, as long as no underground utilities or access limitations are present.</p> <p>BH-2: Given the accessibility constraints inside the boiler room for the drilling rig, we propose keeping the original location of BH-2 outside the facility. This will enable a deeper drill in case of identifying impacts.</p> <p>BH-3: Ok, noted: This borehole will be advanced by means of hand auger soil samplers. Location shifted</p>	x	<p><b>Doc reference: Site Closure Plan (Section 5) V2 submitted on the 15.12.18</b></p> <p>All comments and amendments were noted. The land and groundwater monitoring plan was approved by the Authority on 18.12.17. Nonetheless, as stated in the communication, ERA reserves the right to request additional monitoring it deems necessary.</p> <p>Kindly ensure that specifically the Site Closure Plan (Section 5) is made reference to in this section.</p> <p>Noted.</p> <p>Noted, however note please be advised that the Authority reserves the right to request additional monitoring on site it deems necessary on site, this includes but is not limited to observations made during the drilling and/or the eventual test results. This is especially the case for the BH-2 in which the original position will be kept. Moreover, following the removal of structures as delineated in the IPPC application, the Authority still reserves the right to request additional monitoring.</p>	<p>Noted. Site Closure Plan (Section 5) is referred in Form E, E.3.2 as Document 1.</p> <p>Noted.</p>	✓		

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		<p>and associated pipework.</p> <p>BH-2: to be shifted to the area of the boiler room.</p> <p>BH-3: to be shifted to the location of the former fuel storage area.</p> <p>MW-2: to be shifted closer to the reservoir.</p> <p>In case difficulties arise regarding the accessibility of sampling locations BH-2 and BH-3, such boreholes may be drilled and sampled after the removal of the specific equipment in these locations.</p>	<p>as close as feasible to former fuel storage area.</p> <p>MW-2: Ok, noted. It will be moved closer to the reservoir, as long as no underground utilities or access limitations are present</p>		<p>Noted.</p> <p>Noted.</p>				
		<p>2. With reference to section 5.2.2.1. <i>Field methodology for drilling works and soil sampling</i></p> <p>Kindly note that dry-drilling is mandatory to avoid flushing and dispersion of the contaminants which may be present. Water shall only be used to clean the drilling and sampling equipment before each subsequent sampling activity. Cleaning of the equipment shall be carried out away from any of the sampling locations. These methods have to be followed during sampling to ensure cross-contamination does not occur.</p> <p>Samples shall be taken from all 8 boreholes from directly underneath the current</p>	<p>Dry drilling will be preferentially used in order to avoid dispersion of the contaminants.</p> <p>However, the opinion of the environmental consultant company (ERM) is that the use of water for drilling purposes will probably be necessary because of the though unit geology (Limestone).</p>		<p>2. Noted</p>				



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		<p>hardstanding and tested for asbestos.</p> <p>Samples shall be taken from 2 boreholes from directly underneath the current hardstanding and tested for dioxins and PCBs. Justification is to be provided for the 2 proposed sampling locations.</p> <p>All samples shall be photographed, labelled, and logged before being sent to the laboratory. Additionally, a record shall be kept of any visual or olfactory evidence of contamination (e.g. stains, hydrocarbon odours).</p>	<p>Ok, noted. Modified in Section 5 Final Site closure Plan V2 dated 06122017.</p> <p>Ok, noted. Modified in Section 5 Final Site closure Plan V2 dated 06122017.</p> <p>We understand that no additional boreholes are needed to collect these 2 soil samples</p> <p>Ok, noted. Modified in Section 5 Final Site closure Plan V2 dated 06122017.</p>						
		<p>4. With reference to section 5.2.2.2. <i>Analytical Program</i></p> <p>TOC shall be added to the list of analytes for both soil and groundwater samples. BOD and COD shall be added to the list of analytes for groundwater samples.</p> <p><b>Two separate set of standards</b> (EPA, ISO or EN) and detection limits shall be submitted for all contaminants to be analyzed for both <b>soil samples and groundwater samples</b>. This is requested in view that these 2 set of samples represent 2 different environmental matrixes. Also the laboratory</p>	<p>Ok, noted. Modified in Section 5 Final Site closure Plan V2 dated 06122017.</p> <p>Ok, all analytical methods are covered under the ISO 17025, modified USEPA or both. Modified in Section 5 Final Site closure Plan V2 dated 06122017.</p>		<p>Noted.</p> <p>Noted.</p>				

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		guidance shall be quoted for the pre-treatment and stabilization operations to be carried out on the field for the groundwater samples.							
E4	✓	Noted.					✓		