

**Syngene**

**Standard Operating Procedure**

**Department:**  
**Environmental Health Safety and Sustainability**

**Title: TOLLER EHSS ASSURANCE AUDIT**

**Document Number:**  
**SOP-EHSS-EHSS-0056**

**Version Number:**  
**1.0**

**Effective Date:**  
**25-Aug-2021**

**Signature Manifestation**

<b>Responsibility</b>	<b>Department</b>	<b>Signed By</b>	<b>Date</b>
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Nidhi Cs/EHSS/ SYNGENE	19-May-2021 11:53:57 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Sunil Kumar/EHSS/ SYNGENE	19-May-2021 15:08:45 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	25-May-2021 14:39:43 (IST)

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<b>Syngene</b>	<b>Standard Operating Procedure</b>	<b>DEPARTMENT: Environmental Health Safety and Sustainability</b>	
<b>TITLE:TOLLER EHSS ASSURANCE AUDIT</b>			
<b>Document Number: SOP-EHSS-EHSS-0056</b>	<b>Version no.: 1.0</b>	<b>Effective Date: 25-Aug-2021</b>	<b>Next Review Date: 25-Aug-2023</b>
<p><b>1.0 OBJECTIVE:</b></p> <p>To describe the procedure for the Toller EHSS assurance audit in alignment with Syngene EHSS policy. Ensuring sustainable value chain by building a network of responsible business partners committed to environmental stewardship across the product life cycle right from sourcing of raw materials to manufacturing and distribution of Syngene products &amp; services.</p> <p><b>2.0 SCOPE:</b></p> <p>The scope of the procedure covers all the existing and new suppliers, service providers and third-party manufacturing sites of Syngene International Limited.</p> <p><b>3.0 RESPONSIBILITY:</b></p> <p><b>3.1. EHSS Department:</b></p> <p><b>3.1.1</b> Prepare the list service provider and recycler, waste disposal facility to be audited.</p> <p><b>3.1.2</b> To conduct EHSS audit as per the plan along with other stakeholders, provide a documented report with the Action and corrective action with timeline and track the corrective action point to closure with regular follow up visits at predetermined frequency.</p> <p><b>3.1.3</b> Appoint lead auditor to conduct audit. A lead auditor should have completed the IRCA certified lead auditor course on ISO 14001: 2015 or ISO 45001: 2018 and minimum of 10 years' experience in the field of EHSS.</p> <p><b>3.2. SCM Team:</b></p> <p><b>3.2.1</b> To identify the list of suppliers to be audited.</p> <p><b>3.2.2</b> Prepare the audit calendar &amp; circulate along with budgetary planning</p> <p><b>3.2.3</b> To communicate the audit schedule and get questionnaire filled from the supplier</p> <p><b>3.2.4</b> Follow-up with suppliers to ensure the required Action and Corrective Action is in place with timeline</p> <p><b>3.3. Administration Department:</b></p> <p><b>3.3.1</b> To identify admin related service providers like food suppliers, coffee tea vendors, laundry service, &amp; transport service providers to be audited.</p> <p><b>3.3.2</b> Admin may not inform in advance on scheduling the audit to vendors.</p> <p><b>3.3.3</b> Follow-up with suppliers to ensure the required Action and Corrective Action is in place with timeline</p> <p><b>3.3.4</b> Coordinate with EHSS &amp; QA for Audit.</p> <p><b>3.4. Strategic sourcing team:</b></p> <p><b>3.4.1</b> To identify the list of contract manufacturers to be audited.</p> <p><b>3.4.2</b> To communicate the audit questionnaire and schedule to the contract manufacturer</p>	<b>Effective</b>		

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<p><b>3.4.3</b> To ensure follow-up with contract manufacturer and share the action and corrective actions for the audit reports.</p> <p><b>4.0 ABBREVIATIONS:</b></p> <p>Admin : Administration  BU : Business Unit  EF : Enabling Function  EHSS : Environment, Health, Safety and Sustainability  ISO : International Organization for Standardization  IRCA : International Register of Certificated Auditors  QA : Quality Assurance  SCM : Supply chain Management</p> <p><b>5.0 PROCEDURE:</b></p> <p><b>5.1 VENDOR SELECTION FOR AUDIT AND AUDIT PREPARATION</b></p> <p><b>5.1.1</b> Vendor shall be selected based on the criteria such as hazardous material suppliers, bulk chemical manufacturers, key raw material suppliers, Engineering and infrastructure facility service providers, pharmaceutical and intermediate manufacturers, waste recyclers, waste disposal facility, food /Snack suppliers and laundry service provider, drinking water supplier &amp; Transporters.</p> <p><b>5.1.2 Gather relevant information from vendor</b></p> <p><b>5.1.2.1</b> The inspection team to gather the relevant information on as per audit questionnaires such as</p> <p><b>5.1.2.1.1</b> Record of previous interventions, incidents, concerns and enforcement  <b>5.1.2.1.2</b> Information specific to the work activities and process risks  <b>5.1.2.1.3</b> Any agreed contracts between the vendor and Syngene</p> <p><b>5.1.3 Identify the objective of Audit</b></p> <p><b>5.1.3.1</b> The inspection objectives and priorities should</p> <p><b>5.1.3.1.1</b> Align with the audit plans  <b>5.1.3.1.2</b> Take into account relevant guidance  <b>5.1.3.1.3</b> Relate to the most significant hazards known or likely to be present  <b>5.1.3.1.4</b> Focus on the management of health and safety to achieve sustained compliance  <b>5.1.3.1.5</b> To clear about the outcomes to be achieved</p> <p><b>5.1.4 Select an appropriate Inspection method</b></p>			

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<p><b>5.1.4.1</b> Consideration should be given to</p> <p><b>5.1.4.1.1</b> The size and structure of the organization, the level of health and safety risk associated with the work activities and degree of organizational and/or process complexity.</p> <p><b>5.1.4.1.2</b> How to meet the inspection objectives in the most effective and efficient way?</p> <p><b>5.1.4.1.3</b> Based on the above audit shall be conducted either by Desk top audit or site audit. For the small vendors / supplier the supplier audit questionnaire is not mandatory.</p> <p><b>5.1.5     <b>Make preparation for the inspection</b></b></p> <p><b>5.1.5.1</b> EHSS assurance audit shall be carried out for all the suppliers, service providers, laundry service providers, food supply vendors and outsourcing process areas at least once in two years as per annual planner (FORM-EHSS-EHSS-0282).</p> <p><b>5.1.5.2</b> The annual planner shall be prepared in the first week of calendar year by the respective department or based on need &amp; maintained by the concerned department.</p> <p><b>5.1.5.3</b> EHSS assurance audit shall be scheduled on the mutually agreed date from both the parties. (Syngene and the Toller) as per the planner.</p> <p><b>5.1.5.4</b> The pre audit questionnaire (FORM-EHSS-EHSS-0283) along with audit agenda shall be shared to the Toller at least 15 days in advance before the audit date through SCM or Admin or Strategic sourcing department.</p> <p><b>5.1.5.5</b> The Toller has to fill the pre audit questionnaire and send it back to Syngene within 10 days from the date of receipt.</p> <p><b>5.1.5.6</b> Suitable arrangements should be made by audit team</p> <p><b>5.1.5.7</b> Deciding what resources, including any particular knowledge, skills or specialist inputs are required for the inspection</p> <p><b>5.1.5.8</b> Considering when to visit and by prior appointment</p> <p><b>5.1.5.9</b> Making provision for personal health and safety, including referring to relevant safety policy supplements</p> <p><b>5.2     <b>CONDUCTING THE AUDIT</b></b></p> <p><b>5.2.1     <b>Make Introduction</b></b></p> <p><b>5.2.1.1</b> On arrival at the site make contact with supplier safety representative to</p> <p><b>5.2.1.2</b> Explain the reason for the visit and how it will be conducted</p> <p><b>5.2.1.3</b> Provide information about the auditor’s role, give an initial explanation of our policy on health and safety.</p> <p><b>5.2.1.3.1</b> Agree who, from the vendor is best placed to assist during the audit.</p> <p><b>5.2.1.3.2</b> Encourage their representative to take notes, engage in the inspection and describe what they understand as their main hazards and what they do to control them.</p> <p><b>5.2.1.3.3</b> Discuss any specific health and safety precautions or site rules to be observed.</p>			

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<p>5.2.1.3.4 Make contact with at least one employee and/or safety representative wherever possible early in the visit to</p> <p>5.2.1.3.5 Explain the reason for the visit and how it will be conducted.</p> <p>5.2.1.3.6 Find out how they and the workforce are consulted and involved in the management of health and safety.</p> <p>5.2.1.3.7 Provide them with the opportunity to raise health and safety concerns, in private if they wish.</p> <p>5.2.1.3.8 Discuss how they will be provided with relevant information at the conclusion of the inspection</p> <p><b>5.2.2 Assess specific risk control systems and the adequacy of health and safety management arrangements</b></p> <p><b>5.2.2.1 Conduct the audit by:</b></p> <p>5.2.2.1.1 Considering the vendor health and safety policy and procedures.</p> <p>5.2.2.1.2 Identifying and prioritising a sample of risk control systems for inspection to assess how well the vendor is managing health and safety risk.</p> <p>5.2.2.1.3 Auditors should select the most significant hazards known or likely to be present, in accordance with relevant operational guidance.</p> <p>5.2.2.1.4 The number of risk control systems to be audited will depend on factors including: the size and nature of the site or business, the scale or complexity of the risks, the time needed to assess the arrangements for managing health and safety based on the risk control systems selected.</p> <p>5.2.2.1.5 Following up any concerns raised by employee or safety representatives</p> <p>5.2.2.1.6 Identifying key strengths and weaknesses in the risk control systems and management arrangements.</p> <p>5.2.2.1.7 Noting examples of good practice in order to reach a balanced assessment of the vendors' performance.</p> <p>5.2.2.1.8 Continually reviewing the progress of the audit against the emerging findings about the level of compliance, the discovery of any breaches and the effectiveness of the health and safety management arrangements.</p> <p>5.2.2.1.9 Managing the extent and duration of the audit, dependent upon findings</p> <p>5.2.2.1.10 Closing out of audit in a timely manner, and with appropriate explanation, when there is sufficient evidence that risks are being adequately controlled and that appropriate management systems are in place</p> <p><b>5.2.3 Make regulatory decisions</b></p> <p>5.2.3.1 Assess the audit findings and take immediate enforcement action in relation to any risk of serious personal injury.</p>			

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<p><b>5.2.3.2</b> Determine the appropriate level of enforcement both the risk control systems inspected and the health and safety management arrangements.</p> <p><b>5.2.3.3</b> Ensure that the information and evidence gathered during the audit is sufficient to support any proposed enforcement action.</p> <p><b>5.2.3.4</b> Identify any material breaches and/or other breaches and assess them in the context of the vendors' overall arrangements for managing health and safety risks.</p> <p><b>5.2.3.5</b> Decide whether specialist assistance is required to clarify enforcement benchmarks.</p> <p><b>5.2.3.6</b> Decide if it is appropriate to extend the audit beyond a single visit on occasions when all risk control systems justifying inspection cannot be accommodated on the same day. Judgement is required in deciding the timescale for further intervention, for example, to complete promptly because it is suspected that significant risks are poorly controlled, or to resume after an interval in which the vendor is expected to have made improvements, including to their management arrangements.</p> <p><b>5.2.4 Communicating the Audit closer/Concluding meeting</b></p> <p><b>5.2.4.1</b> Inform the vendor or their representative of the audit findings and next steps by</p> <p><b>5.2.4.1.1</b> Indicating whether any product, process or procedures breaches have been observed, and, if so, the consequences in accordance with policies and procedures.</p> <p><b>5.2.4.1.2</b> Explaining the remedial measures required to comply with safety norms.</p> <p><b>5.2.4.1.3</b> Discussing and agreeing timeline to rectify breaches, encouraging prompt action where quick and simple solutions are available.</p> <p><b>5.2.4.1.4</b> Demonstrating where and why management failings have led to breaches and setting expectations for improved performance.</p> <p><b>5.2.4.1.5</b> Explaining immediate or likely enforcement action, including any written confirmation that will be sent and any follow up action to assess compliance.</p> <p><b>5.2.4.1.6</b> Inform the safety representatives of the outcome about the audit and &amp; its consequences from safety front.</p> <p><b>5.3 REPORT, RECORD, FOLLOW UP, CLOSE OUT AND EVALUATE</b></p> <p><b>5.3.1 Reporting and recording</b></p> <p><b>5.3.1.1</b> Complete relevant reports and records by</p> <p><b>5.3.1.1.1</b> Recording the inspection as mentioned in the supplier questionnaire submitted by the vendor in accurate and updated where necessary</p> <p><b>5.3.1.1.2</b> Ensuring that information required by the relevant operational guidance is included in the visit record</p> <p><b>5.3.1.1.3</b> Assigning risk level for the observed notices</p>			

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<p>5.3.1.1.4 The audit report highlights the best practices followed at Toller’s site, the areas of noncompliance, areas for improvement and necessary action to be taken (in case of non-compliance).</p> <p><b>5.3.2 Following up and closing out</b></p> <p><b>5.3.2.1</b> Ensure that nonconformity identified during the audit are followed up and closed out by</p> <p>5.3.2.1.1 Arranging specialist support where necessary and agreed at the appropriate level</p> <p>5.3.2.1.2 Initiating safety /supply chain action where there are potential breaches</p> <p>5.3.2.1.3 Pursuing any issues that have arisen with others e.g. contractors, consultants etc</p> <p>5.3.2.1.4 Scheduling follow-up activity, including further site visits where appropriate, to confirm that remedial action has been taken.</p> <p>5.3.2.1.5 The status of the report either closed if there are no necessary corrective actions or remain open if are in need of improvement</p> <p>5.3.2.1.6 A site visit is not required where written confirmation from the vendor provides sufficient assurance of remedial actions taken</p> <p>5.3.2.1.7 If the existing vendor is blacklisted for two years, then the same vendor shall give the service on post completion of evaluation and audit.</p> <p><b>5.3.3 Evaluating</b></p> <p>5.3.3.1 Consider whether the objectives of the inspection were achieved</p> <p>5.3.3.2 The findings are categorized as follows:</p> <p>5.3.3.2.1 <b>High Risk (Level 1):</b> Legal noncompliance / Unacceptable safety risk exists and action must be taken immediately. like blacklist the vendor for two years.</p> <p>5.3.3.2.2 <b>Medium Risk (Level 2):</b> Work practices are being carried out under a moderate level of risk and corrective action must be taken within seven working days.</p> <p>5.3.3.2.3 <b>Observations (Level 3):</b> An acceptable level of risk exists and must be corrected by expected completion date.</p> <p>5.3.3.3 The audit findings shall be discussed and agreed with the auditees in the closing meeting at the end of the audit date. The formal audit report shall be shared within 15 days of the audit by EHSS.</p> <p>5.3.3.4 The audit team shall share the draft audit report to the supplier (Toller) through SCM or Admin or Strategic sourcing department within 15 days from the date of audit. After the final review and mutual agreement from the auditor and auditee final report shall be shared within 30 days from the date of audit as per FORM-EHSS-EHSS-0284.</p> <p>5.3.3.5 The response for the audit report shall be given by the Toller within 15 days from the date of final report received.</p> <p>5.3.3.6 The EHSS department shall maintain the audit report</p>			

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<p><b>5.3.3.7</b> The final report shall be maintained in EHSS Department and a copy of the same shall be shared with user department.</p> <p><b>5.3.3.8</b> The Toller's to share the corrective action taken to close the audit findings with document evident or photo. The points shall be closed based on the document evident or on site confirmation on need basis.</p> <p><b>6.0 ANNEXURES:</b></p> <p>FORM-EHSS-EHSS-0282 : Annual Planner  FORM-EHSS-EHSS-0283 : Supplier questionnaire  FORM-EHSS-EHSS-0284 : EHSS audit report  FORM-EHSS-EHSS-0285 : SOP Training Questionnaire</p> <p><b>7.0 REVISION HISTORY:</b></p>			
<b>Version no.</b>	<b>Effective Date</b>	<b>Description of Change</b>	
1.0	25-Aug-2021	<u>Reference Change Control Number: - EHSS/CCF/21/0012</u>	

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<b>Syngene</b>		Annexures		Department: Environmental Health Safety and Sustainability									
Reference SOP No.: SOP-EHSS-EHSS-0056													
Title: ANNEXURE - 01 - TOLLER EHSS ASSURANCE AUDIT PLANNER													
Document No: FORM-EHSS-EHSS-0282				Version No.: 1.0				Effective date: 25-Aug-2021					
<b>TOLLER EHSS ASSURANCE AUDIT PLANNER</b>													
Year:										Department:			
Sl.No	Supplier / Vendor Name	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Prepared by: (Sign & Date)							Reviewed by: (Sign & Date)						
Exported By: Nidhi.Cs/EHSS/SYNGENE													

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Document No: FORM-EHSS-EHSS-0282	Version No.: 1.0	Effective date: 25-Aug-2021						
<p>REVISION HISTORY:</p> <table border="1"> <thead> <tr> <th>Version</th> <th>Effective Date</th> <th>Description of Change</th> </tr> </thead> <tbody> <tr> <td>1.0</td> <td>25-Aug-2021</td> <td><u>Reference Change Control Number: EHSS/CCF/21/0012</u></td> </tr> </tbody> </table>			Version	Effective Date	Description of Change	1.0	25-Aug-2021	<u>Reference Change Control Number: EHSS/CCF/21/0012</u>
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<p>Exported By: Nidhi Cs/EHSS/SYNGENE</p>								

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<b>Reference SOP No.: SOP-EHSS-EHSS-0056</b>		
<b>Title: ANNEXURE - 02 - SUPPLIER QUESTIONNAIRE</b>		
<b>Document No: FORM-EHSS-EHSS-0283</b>	<b>Version No.: 1.0</b>	<b>Effective date: 25-Aug-2021</b>
<b>Contents</b>		
Section 1	Company Information	
Section 2	General Information / Personnel	
Section 3	EHSS Management	
Section 4	Plant Installations	
Section 5	Health and Hygiene	
Section 6	Safety and Loss Prevention	
Section 7	Environmental Protection	
Section 8	Sign Off	
<b>Supporting Documentation</b>		
Please provide where appropriate copies of the following documents either at during the audit or with this completed questionnaire:-		
<ol style="list-style-type: none"> <li>1. Site plan</li> <li>2. Location map</li> <li>3. Company brochure</li> <li>4. Organization chart – EHSS reporting structure</li> <li>5. Health, Safety and Environment Policy (or separate policies)</li> <li>6. EHSS-related Authorizations, Permits or Licenses</li> <li>7. Copies of ISO certificates (Eg, Environmental Management System – ISO 14001: 2015, OHSAS 18001: 2007 / ISO 45001: 2018 certificates if applicable)</li> </ol>		

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<b>Document No: FORM-EHSS-EHSS-0283</b>	<b>Version No.: 1.0</b>	<b>Effective date: 25-Aug-2021</b>
<b>SECTION 1 : COMPANY INFORMATION</b>		
<b>Company Name:</b>		
<b>Address:</b>		
<b>Tel No:</b>		
<b>Fax No:</b>		
<b>Email:</b>		
<b>Company status:</b>	Sole trader / Private Ltd / Subsidiary / Partnership / Public	
<b>Company established Since :</b>	<input type="checkbox"/> <1yr <input type="checkbox"/> 1-5yrs <input type="checkbox"/> 5-10yrs <input type="checkbox"/> >10yrs	
<b>Product(s) manufactured for Syngene International Ltd:</b>		
<b>Processing Capability</b>		
Indicate general details of the type of processing/capability available on the site:		
Bulk Chemical Manufacturing	<input type="checkbox"/>	Pharmaceutical Manufacturing <input type="checkbox"/>
Solvent Recovery	<input type="checkbox"/>	Quality, Development Laboratories <input type="checkbox"/>
Wastewater Treatment	<input type="checkbox"/>	Infrastructure & Utilities (steam, electricity) <input type="checkbox"/>
Waste Disposal (incineration)	<input type="checkbox"/>	Warehouse & Distribution <input type="checkbox"/>
If company is member of a group:		

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<b>Document No: FORM-EHSS-EHSS-0283</b>	<b>Version No.: 1.0</b>	<b>Effective date: 25-Aug-2021</b>
<b>Name and Address of Head Office / Parent Company:</b>		
<b>Broad product range:</b>		
<b>SECTION 2 : GENERAL INFORMATION / PERSONNEL</b>		
<b>2.1 Personnel</b>		
Total number of employees at your site:		
Number in manufacturing:		
Number of Female employees		
Number in laboratories:		
Number in administration:		
Number in EHSS:		
Total number of contract staff at your site:		
Please list the name, title and general responsibilities of any full-time/part-time EHSS staff at your site.		
<b>Name</b>	<b>Title</b>	<b>Responsibilities</b>

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<b>2.2 Site Occupation</b>		
What is the facility operation timings / shift timings?		
What shift working pattern is used?		
Who has responsibility for the site on shifts?		
How many operators available on site outside of normal hours?		
<b>2.3 Site Location</b>		
What surface area does the site occupy?		
What distance from site is the nearest housing and social facilities (e.g. school, hospital)?		
What distance from site are the nearest waterways?		
Which natural events represent risk factors in your location (e.g. earthquakes, storms, floods, etc.)?		
Describe the surrounding area:		
Describe any environmentally sensitive areas close to the facility:		
Describe transportation access to the site (e.g. roads, rail, ship):		

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<b>2.4 Neighbourhood Relationships</b>		
Describe relationship and any potential problems that arise with: -		
- <u>Residential neighbours:</u>		
- <u>Industrial neighbours:</u>		
How are complaints dealt with?		
How many complaints have you had in the last two years?		
<b>2.5 Security Arrangements</b>		
Is the site totally fenced and secure?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Are there are installed security systems / intrusion alarms?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
When is there a security presence on site?		

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<p>How are visitors to the site logged and controlled?</p>		
<p>SECTION 3 : ENVIRONMENT, HEALTH, SAFETY AND SUSTAINABILITY</p> <p><b>3.1 Health, Safety and Environment Policy / Management</b></p>		
Does an up-to-date EHSS Policy exist?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
List any EHSS accreditations which your site holds (ISO, OHSAS):		
<p>Describe briefly your EHSS Management System, e.g. with reference to:</p> <ul style="list-style-type: none"> <li>- compliance with regulations</li> <li>- performance monitoring</li> <li>- employee involvement</li> <li>- training</li> <li>- targets and objectives</li> </ul>		

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<p>Explain the structure and scope of activity of your site EHSS Committee(s). Indicate how frequently it meets and how identified improvement actions are progressed.</p>		
<b>3.2 EHSS Manual / EHSS Documentation</b>		
Does the site have an EHSS manual?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Is the manual readily available to all personnel on site?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>3.3 Internal Auditing</b>		
What kind of EHSS audits/inspections are done?		
Who carries these out?		

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How are audit findings recorded?																										
How are any improvement actions followed up?																										
<b>3.4 Training</b> How are staff trained on:- <ul style="list-style-type: none"> <li>- operation of plant equipment</li> <li>- process control</li> <li>- materials handling</li> </ul>																										
Are staff trained on the use of the following? <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>Yes</th> <th>No</th> <th>Frequency</th> </tr> </thead> <tbody> <tr> <td>Fire extinguishers?</td> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Breathing apparatus?</td> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Fork Lift Trucks?</td> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Emergency Response ?</td> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> <tr> <td>General safety equipment?</td> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> <td></td> </tr> </tbody> </table>				Yes	No	Frequency	Fire extinguishers?	Yes <input type="checkbox"/>	No <input type="checkbox"/>		Breathing apparatus?	Yes <input type="checkbox"/>	No <input type="checkbox"/>		Fork Lift Trucks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>		Emergency Response ?	Yes <input type="checkbox"/>	No <input type="checkbox"/>		General safety equipment?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
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How is the training recorded?		
How would operators obtain advice / Instructions for any process / safety deviation outside normal working hours?		
<b>3.5 Contact with External Regulatory Authorities</b> Do you have contact with the following Regulating Authorities:		
		Frequency
Health & Safety Inspector?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
State Pollution Control Board Officer?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Local Authority Officers?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Fire Inspector?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Others (indicate which)?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Have there been any actions/prosecution in the last two years?		Yes <input type="checkbox"/> No <input type="checkbox"/>

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If yes, please give details:			
<b>SECTION 4: PLANT INSTALLATIONS</b>			
<b>4.1 Manufacturing Procedures</b>			
Indicate which manufacturing operations and procedures apply to the Syngene product(s):-			
Synthesis Reaction	Yes <input type="checkbox"/> No <input type="checkbox"/>	Drying - Spray Drier	Yes <input type="checkbox"/> No <input type="checkbox"/>
Centrifuge/Filtration	Yes <input type="checkbox"/> No <input type="checkbox"/>	- Fluid Bed Drier	Yes <input type="checkbox"/> No <input type="checkbox"/>
Milling and Blending	Yes <input type="checkbox"/> No <input type="checkbox"/>	- Paddle Drier	Yes <input type="checkbox"/> No <input type="checkbox"/>
Distillation	Yes <input type="checkbox"/> No <input type="checkbox"/>	- Stove Drier	Yes <input type="checkbox"/> No <input type="checkbox"/>
Others, please give details			
<b>4.2 Manufacture</b>			
Do written production records exist?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
Do process operating procedures include:			
Steps for each operating phase?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
Operating limits?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
Safety and health considerations?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
Safety systems and their functions?	Yes <input type="checkbox"/> No <input type="checkbox"/>		

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Are employees trained in the operation of the process including EHS matters before being allowed to operate on a newly assigned process?		Yes <input type="checkbox"/>	No <input type="checkbox"/>
4.3 Laboratories/Offices/Workshops			
	<b>Labs</b>	<b>Offices</b>	<b>Workshops - NA</b>
Is ventilation equipment regulated and tested?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is protective equipment available and used?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Are safety inspections carried out?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
4.4 Storage			
Are the following storage facilities used on the site:			
Warehouse(s)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Tank Farm(s)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Drum Storage Area(s)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Waste Storage Area(s)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Are any special protective systems included in the storage units?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
How are storage facilities labelled to indicate their contents?			
How do you avoid storage of incompatible materials?			

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<b>4.5 Materials Movements</b>		
Who carries out transport on site?		
Who carries out training on transport issues?		
How are vehicle movements on site controlled?		
Security check, Road hump, speed limit display boards, etc		
Are there restricted areas?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Is a training programme provided for the drivers?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
What test regime is carried out on vehicles?		
Who acts as Dangerous Goods Safety Advisor for the site?		
<b>4.6 Materials Receipt</b>		
Are receipt records produced for each delivery?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
How is material status controlled (e.g. approved/quarantined/rejected)?		

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What are the arrangements for sampling and testing?		
Are rejected materials segregated / easily identifiable?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Describe the storage facilities / warehousing arrangements:		
<b>4.7 Material Acceptance</b>		
Who has responsibility for receipt of materials?		
At what time of day are materials accepted onto site?		
Describe briefly the sequence of events for the acceptance of materials on site:		

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What happens when deliveries arrive on site which are not expected?		
<b>4.8 Tanker Unloading</b>		
How are drivers made aware of the particular tank at which their load is to be discharged?		
Who supervises this activity?		
How are levels in the tank monitored prior to a tanker discharge?		
Are adequate earthing cables provided for each unloading point?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Are tankers provided with handrails or other means to prevent fall from the tanker?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>4.9 Storage in Tanks</b>		
What is the capacity of the tank bunds?		

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Is earth bonding used to minimise the risks from static electricity?		Yes <input type="checkbox"/> No <input type="checkbox"/>
How is pressure build-up in tanks prevented?		
How are tanks cleaned out?		
How frequently are tanks cleaned out?		
Are tank farms protected by fire-fighting systems such as foam/deluge systems?		Yes <input type="checkbox"/> No <input type="checkbox"/>
Are tanks filled from the bottom or the top?		
Are tanks nitrogen blanketed?		Yes <input type="checkbox"/> No <input type="checkbox"/>
Are high level warning systems fitted to tanks?		Yes <input type="checkbox"/> No <input type="checkbox"/>
Are solvents from different sources mixed within the same storage tank?		Yes <input type="checkbox"/> No <input type="checkbox"/>
Who determines which tanks are used for storing which material and what is the basis of this decision?		
Bund construction is:-	Walls	Floor

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Soil / Brick / Concrete		
What is the frequency of bund inspection?		
<b>4.10 Engineering</b>		
Does the site have an engineering department?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Do you have a system for organizing preventive maintenance?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
How are HSE relevant equipment and installations identified in the system?		
What type and how frequently are there energy supply failures?		
Briefly describe your maintenance and calibration systems for HSE critical equipment:-		
- safety protection systems		
- statutory controlled systems (e.g. lifting equipment, pressure vessels, etc.)		

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- ventilation equipment		
<b>SECTION 5 : HEALTH AND HYGIENE</b>		
<b>5.1 Health</b>		
What health monitoring is carried out and by whom?		
How is the health monitoring recorded?		

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What medical services are available on site (e.g. first-aiders; nurse; local doctor)?		
What welfare facilities are available on site?		
<b>5.2 Safety Data Sheets</b>		
Are Safety Data Sheets available on all chemicals?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Who produces the Data Sheets?		
How often are they reviewed?		
How knowledge on SDS transferred to employees / Contractors?		
<b>5.3 Material Handling Assessments</b>		
Have material handling assessments been carried out in the following areas:-		
- Laboratories?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
- Offices?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
- Production / Engineering?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>5.4 Personal Protective Equipment</b>		
Indicate which items of personal protective equipment are normal issue:		
Indicate which items of personal protective equipment are special issue:		

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<p>How is personal protective equipment checked?</p>		
<p>Who is responsible for specifying PPE?</p>		
<p>Who is responsible for maintenance of PPE?</p>		
<b>5.5 Noise</b>		
Are ambient Noise level is monitored at site?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Are Workplace Noise level is monitored?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Describe any noise issues with your operations:		
<p><b>SECTION 6 : SAFETY AND LOSS PREVENTION</b></p>		
<b>6.1 Process Safety</b>		
Does your site have a Process Safety Management System?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does it include the following elements:		
Process Safety Information?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Process Risk Analysis?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

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HAZOP?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Operating Procedures and Safe Practices?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Incident Reporting and Investigation?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Emergency Planning and Response?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Does your site manage accurate process safety information for each process that utilises toxic, flammable or reactive materials? Process Safety includes:			
Chemical information [toxicity, exposure limits, physical data, reactivity data, thermal and chemical stability, .....]	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Process technology information [block flow diagram or process flow diagram, process chemistry, maximum chemical inventories, safe upper and lower limits (pressure, temperature, flow rates, compositions), evaluation of deviations from upper and lower process limits]	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Process equipment information [materials of construction, piping and instrument diagrams, electrical classifications, relief system design basis, ventilation system design, design codes and standards, material balances, energy balances, process interlocks, detection or suppression systems]	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Are risk analysis/HAZOP studies carried out:-			
- internally	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
- by third parties	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
<b>6.2 Thermal Process Safety</b>			
How does the company assess the thermal safety of processes prior to full-scale plant operation?			
Which thermal testing method is used to assess the thermal stability of distillation streams/residues?			

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<p>Is the thermal testing method referred to above carried out internally or by third party testing facilities?</p>		
<p>Who is responsible for carrying out the assessment of the results of thermal stability testing?</p>		
<p>How are operating conditions and alarm limits determined on the basis of the results of the thermal testing?</p>		
<p>Describe the role of interlocks and high and low level alarms in the control of distillation processes.</p>		
<p>What provision is made in case of loss of utilities (e.g. water supply, energy supply,</p>		

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<p>compressed air supply, etc.)?</p> <div style="border: 1px solid black; height: 150px; width: 100%;"></div>					
<b>6.3 Risk Assessment</b>					
<table border="1" style="width: 100%;"> <tr> <td style="width: 60%;">Does the site have a risk assessment programme in place?</td> <td style="width: 20%;">Yes <input type="checkbox"/></td> <td style="width: 20%;">No <input type="checkbox"/></td> </tr> </table>			Does the site have a risk assessment programme in place?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does the site have a risk assessment programme in place?	Yes <input type="checkbox"/>	No <input type="checkbox"/>			
If yes, briefly describe the programme:					
<div style="border: 1px solid black; height: 100px; width: 100%;"></div>					
<table border="1" style="width: 100%;"> <tr> <td style="width: 40%;">Who is responsible for carrying them out?</td> <td style="width: 60%;"></td> </tr> </table>			Who is responsible for carrying them out?		
Who is responsible for carrying them out?					
Explain how identified risks are assessed in terms of severity and probability:					
<div style="border: 1px solid black; height: 200px; width: 100%;"></div>					

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For what type of activity are risk assessments undertaken?		
<b>6.4 Systems of Work</b>		
Do you have a permit to work system?		Yes <input type="checkbox"/> No <input type="checkbox"/>
Do formal procedures exist for the following systems of work:		
- Cold work?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
- Hot work?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
- Confined space entry?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
- Excavation?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
- Working at height?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
- Any other?		
<b>6.5 Alarm Organisation/Installations/Emergency Plans</b>		
Are there alarms/sirens on site?		Yes <input type="checkbox"/> No <input type="checkbox"/>
For which type of incidents are written alarm procedures available?		
How often are site personnel trained in this procedure?		
Give brief details of any on-site and off-site Emergency Plans:		

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Is the plant a major accident hazard site (e.g. Seveso 2 Directive upper tier, Seveso 1 lower tier)?		
		Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>6.6 Notification of Syngene in Case of a Reportable Incident</b>		
How would Syngene be informed about reportable incidents (to the regulatory authorities) on site?		
- if the incident <u>involves</u> Syngene material?		
- if the incident <u>does not involve</u> Syngene material?		
<b>6.7 Contact with Emergency Services</b>		
Do you have regular contact with the following Emergency Services:		
		Frequency
- Fire Brigade?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
- Police?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

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- Ambulance?		Yes <input type="checkbox"/>	No <input type="checkbox"/>		
- Local Authority?		Yes <input type="checkbox"/>	No <input type="checkbox"/>		
<b>6.8 Fire Brigade</b>					
Is there a site fire brigade or is the public service used?					
How long does it take for the fire brigade to arrive at the site?					
How many self-contained breathing apparatus are available?					
How often is training in their use given?					
How many hydrants are available in the plant area?					
Is there a fire-fighting water retention facility?				Yes <input type="checkbox"/>	No <input type="checkbox"/>
If so, what is the capacity in Litres					
<b>6.9 Accidents/Dangerous Occurrences</b>					
Does the site have a formal incident/accident reporting system?				Yes <input type="checkbox"/>	No <input type="checkbox"/>
How are other near-misses reported and investigated?					
How are the findings from these investigations communicated and acted upon?					
Please indicate the following for the last three years:					
Year	No. of LTAs	Frequency Index (= Number of LTAs x 200,000) Hours worked			

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Have there been any fatalities on the site in the last five years?			Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>SECTION 7 : ENVIRONMENTAL PROTECTION</b>			
<b>7.1 Regulatory Aspects</b>			
Do you have a current environmental licence/permit/authorisation?			Yes <input type="checkbox"/> No <input type="checkbox"/>
If no permit is needed, explain how the site is regulated?			
Do you receive inspections/visits on a regular basis from Environment Inspectors?			Yes <input type="checkbox"/> No <input type="checkbox"/>
Please indicate the main environmental consent parameters and limits:			
Have any limits been exceeded in the last three years?			Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, describe:			

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<b>7.2 Air Emissions</b>		
Has the site estimated, measured or calculated air emissions?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If yes, briefly describe:		
Ambient Air Quality Monitoring and Stack monitoring are carried out every month		
Do you have any odour problems on/off site?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Do you operate off-gas scrubbing equipment?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	
If yes, describe:		
Do you operate dust-control equipment?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	
If yes, describe:		

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Does a site plan exist of all vents (release points)?		Yes <input type="checkbox"/> No <input type="checkbox"/>
What vent monitoring is carried out and by whom?		
Provide details of any unauthorised releases to air and any enforcement actions in the last 3 years:		
<b>7.3 Wastewater Discharge</b>		
Has the site estimated, measured or calculated wastewater releases?		Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, briefly describe:		
Is there an on-site wastewater treatment facility?		Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, briefly describe:		

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If yes, does the site discharge treated wastewater to:			
- River?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
- Municipal Sewer?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
- Other?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
If no, does the site discharge untreated wastewater to:			
- River?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
- Municipal Sewer?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
- Other?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Do you check the integrity of your wastewater system?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Are spillage lists available for unplanned losses?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Provide details of any unauthorised releases to water and any enforcement actions in the last 3 years:			
<b>7.4 Waste Disposal</b>			
Do you have:			
- Hazardous Waste?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
- Non-hazardous waste?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Please describe the waste management process:			
- classification of waste			

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- selection of disposal route			
- documentation			
- transport			
Waste stored on site in drums is stored on:			
- a concrete surface	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
- tarmacadam	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
- chipping covering soil	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
- soil	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

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Do you utilise any third parties for storage of waste?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
At which sites is waste disposed?		
Do you have any waste minimisation or recycling programmes?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>7.6 Ground / Groundwater</b>		
Does the site have any history/specific activities that may have caused ground contamination?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Is any water abstracted on site or close to the site?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
If so, what is it used for?		
Is there any ground/groundwater pollution on the site?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
What has been done to investigate any ground pollution?		
What has been done to prevent ground/groundwater pollution?		

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<b>7.7 Other Environmental Issues</b>		
Does any asbestos exist on the site?		Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, how is it managed?		
Do you have any PCB transformers on the site?		Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, do you have a plan to remove them?		Yes <input type="checkbox"/> No <input type="checkbox"/>
Do you have any programme to reduce the use of ozone-depleting substances or reduce greenhouse gas emissions?		Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>SECTION 8 : SIGN OFF</b>		
<b>Action since last Audit by Syngene:</b>		
Describe any actions taken to improve safety and environmental protection on the site since the last audit:		

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<b>Questionnaire completed by:</b>		
<b>Position:</b>		
<b>Date:</b>		
<p data-bbox="542 1766 1076 1797"><i>Thank you for completing this questionnaire</i></p> <p data-bbox="1125 1864 1382 1885">FORM-EHSS-EHSS-0283/1.0</p>		

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<b>REVISION HISTORY:</b>		
<b>Version</b>	<b>Effective Date</b>	<b>Description of Change</b>
1.0	25-Aug-2021	<u>Reference Change Control Number: EHSS/CCF/21/0012</u>

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<b>Reference SOP No.: SOP-EHSS-EHSS-0056</b>		
<b>Title: ANNEXURE - 03 - EHSS AUDIT REPORT</b>		
<b>Document No: FORM-EHSS-EHSS-0284</b>	<b>Version No.: 1.0</b>	<b>Effective date: 25-Aug-2021</b>
<b>REVISION HISTORY:</b>		
<b>Version</b>	<b>Effective Date</b>	<b>Description of Change</b>
1.0	25-Aug-2021	<u>Reference Change Control Number: EHSS/CCF/21/0012</u>

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