

	Standard Operating Procedure	Department: Environmental Health Safety and Sustainability
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Title: ANNUAL/HALF YEARLY HEALTH CHECKUP

Document Number: SOP-GMP-EHSS-0002	Version Number: 3.0	Effective Date: 24-Jan-2022
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Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Arundhati Chavan/ EHSS/SYNGENE	21-Jan-2022 11:11:16 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Vinod Jyothikumar/ EHSS/SYNGENE	21-Jan-2022 11:58:43 (IST)
QA Approval	CONTINUOUS IMPROVEMENT & INTERNAL AUDIT	Harendra Sinha/QA/ SYNGENE	21-Jan-2022 12:45:23 (IST)

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	<p align="center">Standard Operating Procedure</p>	<p>DEPARTMENT: Environmental Health Safety and Sustainability</p>	
<p>TITLE:ANNUAL/HALF YEARLY HEALTH CHECKUP</p>			
<p>Document Number: SOP-GMP-EHSS-0002</p>	<p>Version no.: 3.0</p>	<p>Effective Date: 24-Jan-2022</p>	<p>Next Review Date: 24-Jan-2024</p>
<p>1.0 OBJECTIVE: To have a documented procedure to periodically monitor the Occupational Health of all employees and contract workers through annual/half yearly health checkup.</p> <p>2.0 SCOPE: This procedure is applicable to all Employees and Contract workers of Syngene International Limited.</p> <p>3.0 RESPONSIBILITY:</p> <p>3.1 Environment, Health, Safety and Sustainability: For coordinating annual/half yearly health checkup</p> <p>3.2 Clinical Development: For Clinical Tests</p> <p>3.3 Administration: Transportation, breakfast and facility arrangement for the employees as well as the doctors</p> <p>3.4 HR: Planning, registration and communication</p> <p>3.5 Legal: Prepare AHC agreement between Syngene and third party vendor.</p> <p>4.0 ABBREVIATIONS:</p> <p>BUN : Blood Urea Nitrogen EHSS : Environment, Health, Safety and Sustainability FBS : Fasting Blood Sugar HC : Health Checkup HDL : High Density Lipid HR : Human Resources IT : Information Technology API : Active Pharmaceutical Ingredients LDL : Low Density Lipoprotein OHC : Occupational Health Centre SGOT : Serum Glutamic Oxaloacetic Transaminase SGPT : Serum Glutamic Pyruvate Transaminase SOP : Standard Operating Procedure VLDL : Very Low-Density Lipoprotein AHC : Annual Health Checkup</p>			

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<p>5.0 DEFINITION: NA</p> <p>6.0 EHSS : NA</p> <p>7.0 PROCEDURE: Health Checkup shall be conducted in three different forms such as</p> <p>7.1 Pre-employment health checkup:</p> <p>7.1.1 It shall be carried out for all employees prior to their joining the organization and those reports shall be maintained by HR department</p> <p>7.1.2 Employees who qualify in the pre-employment health checkup shall only be considered for joining</p> <p>7.2 Annual Health Checkup:</p> <p>7.2.1 It shall be conducted for all the employees and contract workmen of Syngene</p> <p>7.2.2 AHC is carried out annually to help detect occupational illness and health abnormalities.</p> <p>7.2.3 Annual health checkup shall be conducted with all necessary facilities of medical care. The basis of checkup is dependent on the person's age, occupation and any other case-specific examinations on the advice of director of factories</p> <p>7.2.4 The Syngene Legal department shall prepare the AHC agreement between Syngene and third-party vendor for conducting AHC and it shall be reviewed yearly prior to conducting AHC</p> <p>7.2.5 Annual health checkup shall be conducted in coordination and with involvement of HR, IT, Admin, EHSS and third-party vendor (who shall have an agreement with Syngene for conducting AHC)</p> <p>7.2.6 AHC communication shall be sent to all employees and contract workmen 15 days (± 10 days) prior, to register online, with suitable date and time</p> <p>7.2.7 AHC handouts shall be provided to employees and contract workmen to indicate voluntarily their consent for undergoing the checkup as given in FORM-GMP-EHSS-0012 'Annual/half yearly health checkup handout' on scheduled date and time (as selected)</p> <p>7.2.8 Annual/half yearly health checkup shall be conducted in two phases</p> <p>7.2.8.1 Phase - 1: General checkup and sample collection followed by clinical testing. The following tests are recommended for all employees</p> <p>7.2.8.1.1 Height and weight</p> <p>7.2.8.1.2 Pulse and Blood pressure</p>			

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<p>7.2.8.1.3 Urine analysis</p> <p>7.2.8.1.4 CBC (Complete Blood Count)</p> <p>7.2.8.1.5 FBS (Fasting Blood Sugar)</p> <p>7.2.8.1.6 Lipid profile: Triglycerides, HDL, LDL, VLDL & Total cholesterol</p> <p>7.2.8.1.7 Liver function: Bilirubin (Total), SGPT/SGOT</p> <p>7.2.8.1.8 Kidney Function: BUN, Creatinine</p> <p>7.2.8.1.9 HbA1c</p> <p>7.2.8.1.10 PFT (Pulmonary Function Test)</p> <p>7.2.8.1.11 Skin examination</p> <p>7.2.8.1.12 Eye Test</p> <p>7.2.8.1.13 ECG for employees older than 35 years</p> <p>7.2.8.1.14 All the rescuer and fire fighter team in the ERT should undergo ECG</p> <p>7.2.8.1.15 Audiometric Test (Personnel exposed to high noise area)</p> <p>7.2.8.2 Phase - 2: Doctor consultation</p> <p>The physician’s consultations are conducted in respective Syngene facilities in coordination with qualified doctors</p> <p>7.3 Half yearly health checkup:</p> <p>7.3.1 Health checkup shall be conducted half yearly for employees who are involved in handling of *finished API at Syngene (Biocon Park). Department heads shall communicate the name of the employees who are involved in handling of finished API at Syngene Manufacturing facilities. <i>Note: * Half yearly health checkup is applicable for personnels/employees who are working for CD manufacturing facilities.</i></p> <p>7.3.2 Half yearly health checkup shall be conducted in an establishment with all necessary facilities of medical care on the advice of director of factories</p> <p>7.3.3 Half yearly health checkup shall be conducted in coordination and with involvement of HR, IT, Admin, EHSS and third-party vendor (who shall have an agreement with Syngene for conducting annual/half yearly health checkup)</p> <p>7.3.4 Half yearly health checkup communication shall be sent to selected employees who are subject to undergo medical checkup. This communication shall be sent out at least 7 days prior to the actual exam.</p>			

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<p>7.3.5 Half yearly health checkup handout shall be provided for employees to indicate voluntarily their consent for undergoing the checkup as given in FORM-GMP-EHSS-0012 ‘Annual/half yearly health checkup handout’ on scheduled date and time (as selected)</p> <p>7.3.6 Half yearly health checkup shall be conducted in two phases</p> <p>7.3.6.1 Phase - 1: General checkup and sample collection followed by clinical tests. The following tests are recommended</p> <p>7.3.6.1.1 Height and weight</p> <p>7.3.6.1.2 Pulse and Blood pressure</p> <p>7.3.6.1.3 Urine analysis</p> <p>7.3.6.1.4 CBC (Complete Blood Count)</p> <p>7.3.6.1.5 PFT (Pulmonary Function Test)</p> <p>7.3.6.1.6 Skin examination</p> <p>7.3.6.1.7 Eye Test</p> <p>7.3.6.2 Phase - 2: Doctor consultation</p> <p>The physician consultations will be conducted in Biocon Park</p> <p>7.4 Annual/half yearly health checkup organogram is as given in FORM-GMP-EHSS-0010 ‘Annual/half yearly health checkup Organogram’</p> <p>7.5 Appropriate personal protective equipment while handling blood and urine samples shall be ensured during annual/half yearly health checkup.</p> <p>7.6 The waste generated from the annual/half yearly health checkup will be disposed as per biomedical waste management handling rules; refer SOP-EHSS-EHSS-0019 ‘Handling Of Liquid and Solid Waste’</p> <p>7.7 Annual/half yearly health checkup reports (E reports as well as hard copy) shall be maintained with OHC and the retention period of annual/half yearly health checkup reports is 5 years.</p> <p>7.8 The results from the annual/half yearly health checkup are reviewed by qualified medical doctors. Abnormalities will be highlighted to HR and the respective HOD for further action and follow up.</p> <p>7.9 With respect to health checkup reports, HR department will follow-up where necessary.</p> <p>7.10 Any employee or contract workmen who fails to appear for annual/half yearly health checkup (as applicable) should provide the report of health checkup conducted outside with the same tests as prescribed above. The report should be handed over to HR within one week of the AHC completion.</p>			

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<p>Note: In case of pandemic or natural calamities, not limited to, if annual/half yearly health checkup is not performed for any possible reason, prior action has to be handled through QMS.</p>			
8.0 REFERENCES : NA			
9.0 ANNEXURES:			
FORM-GMP-EHSS-0010	Annexure - 01	Annual/half yearly health checkup Organogram	
FORM-GMP-EHSS-0011	Annexure - 03	SOP Training Questionnaire	
FORM-GMP-EHSS-0012	Annexure - 04	Annual/half yearly health checkup handout	
FORM-GMP-EHSS-0013	Annexure - 05	Annual/half yearly health checkup flow chart	
10.0 REVISION HISTORY:			
Version no.	Effective Date	Description of Change	
3.0	24-Jan-2022	<p><u>Reference Change Control Number: - SYN/GMP/CC/2022-0006</u></p> <p>1. Updated section 7.3.1 Half yearly health checkup 2. Health checkup word is captured in Note after section 7.10 3. Included the title of all the annexure in SOP</p>	
2.0	27-Sep-2021	<p><u>Reference Change Control Number: - PR # 46734</u></p> <p>SYN/GMP/CC/2021-2407</p> <p>1. Included Note SOP prepared as per SOP-GMP-QA-0060 ‘Electronic Document management system’</p>	
1.0	16-Apr-2021	<p><u>Reference Change Control Number: - PR 37139</u></p> <p>As part of transition from manual to Electronic document management system SOP-GMP-EHSS-0002 ANNUAL/HALF YEARLY HEALTH CHECKUP has been revised</p>	

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	Standard Operating Procedure	Department: Environmental Health Safety and Sustainability
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Title: ASPECT- IMPACT IDENTIFICATION THROUGH RISK BASED APPROACH

Document Number: SOP-EHSS-EHSS-0021	Version Number: 2.0	Effective Date: 16-Feb-2023
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Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Nidhi Cs/EHSS/ SYNGENE	11-Feb-2023 11:19:10 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Satish Birajdar/EHSS/ SYNGENE	13-Feb-2023 10:58:58 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	13-Feb-2023 15:55:24 (IST)

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<p>Document Number: SOP-EHSS-EHSS-0021</p>	<p>Version no.: 2.0</p>	<p>Effective Date: 16-Feb-2023</p>	<p>Next Review Date: 15-Feb-2025</p>
<p>1.0 OBJECTIVE: To have a documented procedure for identification, evaluation and review of aspect-impact on the environment, and evaluation of risk and opportunities for Significant Aspects Identified.</p> <p>2.0 SCOPE: This procedure covers all the activities carried inside Syngene International Limited which gives guidelines for the following:</p> <ul style="list-style-type: none"> • To identify Environmental aspects and associated impacts associated with products, activities and services. • Methodology to evaluate and determine the significant Environmental aspects. • To determine and rank risks and opportunities related to environmental aspects, compliance obligations and other issues and requirements. <p>3.0 RESPONSIBILITY:</p> <p>3.1 Department Head: Department Heads are responsible for the following:</p> <p>3.1.1 To ensure the environment aspect identification and Impact assessment is reviewed in the management review meetings.</p> <p>3.1.2 To take up Objectives and Targets, Management Programme(s) for significant aspects having severe consequence to minimize significance.</p> <p>3.1.3 To approve the AIM register for the department.</p> <p>3.2 EHSS Core Team: They are responsible for the following:</p> <p>3.2.1 To ensure that all activities, products and services are listed and related environmental aspects.</p> <p>3.2.2 To guide personnel during aspect-impact assessment</p> <p>3.2.3 To assess the significant aspects</p> <p>3.2.4 To ensure the risk and opportunities assessment for significant aspects identified.</p> <p>3.2.5 To co-ordinate between EHSS Head, Environment leader, Department Heads and ensure the identification of aspect-impact assessment is assessment is periodically reviewed.</p> <p>3.2.6 Review of AIM records once in 6 months and if any changes in work practices/addition of new activity/major incident pertaining to any activity etc. to be revised prior to review period.</p> <p>3.3 EMS leader: EMS Leader is responsible for the following:</p> <p>3.3.1 To ensure the environment aspect identification and Impact assessment is reviewed in the management review meetings.</p> <p>3.3.2 To review and update the procedure at least once in two years or as and when required.</p>			

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<p>3.4 EHSS:</p> <p>3.4.1 Authorized personnel from EHSS shall be responsible check the AIM Register of all the departments.</p> <p>3.4.2 To coordinate with departments during AIM assessment.</p> <p>4.0 ABBREVIATION:</p> <p>AIM : Aspect Impact BC : Business Concern CO : Compliance Obligation EHSS : Environment, Health, Safety and Sustainability EMS : Environment Management System EOP : Equipment Operating Procedure Ex : Example IPC : Interested Party Concern IPN : Impact Priority Number LCP : Life Cycle Perspective MA : Management Appointee MS : Management System OCP : Operation Control Procedure QA : Quality Assurance RBO : Risk Based Opportunities SOP : Standard Operating Procedure</p> <p>5.0 DEFINITION:</p> <p>5.1 Environment: Surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelation.</p> <p>5.2 Environmental aspect: Element of an organization's activities, products or services that can interact with the environment, and change to the environment whether adverse or beneficial, wholly or partially resulting from an organization's environmental aspects</p> <p>5.3 Significant environmental aspect: An environmental aspect that has or can have significant environmental impact.</p> <p>5.4 Environmental impact: Any change to the environment whether adverse or beneficial, wholly or partially resulting from an organization's activities, products or services.</p> <p>5.5 Environment Management System: Part of an organization's management system manage environmental aspects and fulfil compliance obligations and risk & opportunities.</p> <p>5.6 Environmental policy: Intentions and direction of an organization related to its environmental performance as formally expressed by top management.</p> <p>5.7 Risk and Opportunities: Potential adverse effects (threats) and potential beneficial effects.</p>			

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<p>5.8 Outsource: Make an arrangement where an external organization performs part of an organization’s or Process.</p> <p>5.9 Normal activity: The activity carried out regularly.</p> <p>5.10 Abnormal activity: The activity carried out apart from regular activities. Ex: Break down activities or De -chocking of solvents etc.</p> <p>5.11 Environmental Emergency situation: A sudden - onset disasters or accidents resulting from natural, technological or human-induced factors, or a combination of these, that causes or threatens to cause severe environmental damage as well as loss of human lives and property. Such situations call for immediate actions.</p> <p>5.12 Compliance Obligation: Legal requirement that the organization has to comply with and other requirement that an organization has to or choose to comply with. Compliance obligations include mandatory requirements, such as applicable laws and regulations, or voluntary commitments, such as organizational and industry standards, contractual relationships, codes of practice and agreements with community groups or non-governmental organizations.</p> <p>5.13 Aspects which can be controlled: Products / Activities / Services directly under the control of the Organization Example: Procurement, Manufacturing, Inspection, Test activities, Packing, dispatch activities.</p> <p>5.14 Aspects which can be influenced: Aspects which may not be under the direct control of the Organization Example: Goods and services provided by external providers such as Transportation, Canteen/Cafeteria.</p> <p>5.15 Life cycle: Consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources to final disposal.</p> <p>5.16 Interested Party Concern: It is applicable when the Aspect/Impact or is having a concern expressed by Employees, Neighbors or Local Residents. (Note: Aspect Impact assessment should be carried out for any complaint received from any employee or interested party and if the assessor feels that the impact is Significant then the same is considered as interested party concern and the impact is treated as Significant).</p> <p>5.17 Business Concern: Events which affect Operational interruption Organization’s reputation / image (such as Compliance obligations) and Events which results in serious damage to environment / serious injuries / fatal accidents / loss of property / huge financial implications and Areas where there is a considerable resource saving / potential to alter the quality or quantity of waste generated / business continuity.</p>	<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Declaration - **Document Electronically Signed** This document is Valid for 24 hrs. from 01-Jun-2023 12:24:39</p>		

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6.0	EHSS: NA	
7.0	PROCEDURE:	
7.1	Individual department Head/Managers/Executives/Junior Executives shall be trained in methodology of aspect Identification and Impact assessment during in house EHSS training program by authorized EHSS department personnel.	
7.2	EHSS Core Team / Department Head shall be involved in area wise Aspect identification and Impact assessment in coordination with EHSS personnel.	
7.3	Determine the environmental aspects of Products, activities and services that can controlled and those that can be influenced taking into consideration a life cycle perspective. Syngene shall ensures that following are considered while identifying the environmental aspects: <ul style="list-style-type: none"> • Results of previous environmental incidents/accidents • Change, including planned or new developments, and new or modified activities, products and services • Compliance obligations • Design and development of facilities, processes, products and services • Acquisition of raw materials • Operational, manufacturing processes, including warehousing • Operational and maintenance of facilities, assets and infrastructure • Processes and practices of external providers • Packaging, product transportation and service delivery • Storage, use and end of life treatment of products • Waste Management, including re-use, refurbishing, recycling, recovery and disposal • Other issues and requirements identified in the context of the organization. • Understanding the needs and expectations of interested parties 	
	Note: This information can be used in the establishment and improvement of environment management system such as identifying trainings, competency, monitoring and measurement needs.	
7.4	Aspect-Impact Methodology:	
	Following steps are involved in Aspect-Impact Methodology:	
7.4.1	Identification of activity	
7.4.2	Aspect Identification	
7.4.3	Impact identification	
7.4.4	Assessment of condition of the activity	
7.4.5	Assessment of activity for Control and Influence	
7.4.6	Assessment of Overriding Factors	

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<p>7.4.7 Assessment of Impact Priority Number</p> <p>7.4.8 Determination of Significance</p> <p>7.4.9 Assessment of Existing Controls</p> <p>7.5 Identification of the Activity: All activities, Products and Services which are under the scope of Environment Management system shall be identified.</p> <p>7.6 Aspect Identification: During Environmental Aspect Identification following points shall be considered:</p> <p>7.6.1 Emissions to air</p> <p>7.6.2 Releases to water</p> <p>7.6.3 Waste Management including disposal of waste</p> <p>7.6.4 Local environmental issues</p> <p>7.6.5 Current environmental management practices and procedures</p> <p>7.6.6 Results of previous environmental incidents/accidents</p> <p>7.6.7 External Communication related to environmental issues</p> <p>7.6.8 Other relevant issues such as green belt development</p> <p>7.6.9 Resource Depletion</p> <p>7.7 Impact Identification: Some of the following impact(s) shall be considered during the identification.</p> <p>7.7.1 Air pollution</p> <p>7.7.2 Water pollution</p> <p>7.7.3 Soil pollution</p> <p>7.7.4 Noise pollution</p> <p>7.7.5 Natural resource depletion</p> <p>7.8 Assessment condition of the activity: The condition of the activity shall be identified such as</p> <p>7.8.1 Normal: Conditions that are normal other than specified above</p> <p>7.8.2 Abnormal: Start up, shut down or break down conditions.</p> <p>7.8.3 Emergency: Foreseeable/emergency condition.</p> <p>7.9 Assessment of activity for Control and Influence: The activity shall be assessed for whether it is under the control of the organization or Influenced by the organization.</p> <p>7.9.1 Controlled: Identify the environmental aspects and associated impacts associated with the activities, products or services that can be directly controlled by the Organization (Examples explained in the definition).</p>			

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<p>7.9.2 Influenced: Aspects which can be influenced by the Organization. (Examples explained in definition).</p> <p>7.10 Assessment of Overriding Factors:</p> <p>7.10.1 Compliance Obligation (CO): Identified Environmental aspect shall be assessed for Legal Concern (as defined in the definition). If CO is rated as ‘YES’ then those impact(s) related to the aspect(s) shall be considered as Significant by default.</p> <p>7.10.2 Interested Party Concern (IPC): Identified Environmental aspect shall be assessed for Interested Party Concern (as defined in the definition). If Interested Party Concern is rated as ‘YES’ then those impact(s) related to the aspect(s) shall be considered as Significant by default. Example of Interested Party: Concerns expressed directly or indirectly by one or more of the following are considered under this category:</p> <table border="1" data-bbox="456 981 1136 1420"> <thead> <tr> <th>S.No</th> <th>External Interested Parties</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Customers</td> </tr> <tr> <td>2</td> <td>Stakeholders</td> </tr> <tr> <td>3</td> <td>Suppliers</td> </tr> <tr> <td>4</td> <td>Non - Government Organisation (NGOs)</td> </tr> <tr> <td>5</td> <td>Legal Bodies</td> </tr> <tr> <td>6</td> <td>Public</td> </tr> <tr> <td>7</td> <td>Local Panchayat</td> </tr> <tr> <td>8</td> <td>Visitors</td> </tr> </tbody> </table> <p>7.10.3 Business Concern: Identified Environmental aspect shall be assessed for Business Concern (as defined in the definition). If Business Concern is rated as ‘YES’ then those impact(s) related to the aspect(s) shall be considered as significant by default.</p> <p>7.11 Assessment of Impact Priority Number and Significance: The environmental impacts which do not fall under above categories are evaluated with “SSPD” quantitative analysis as given below. Impact Priority Number shall be assessed by considering Scale, Severity, Probability and Detection and the criteria of assessment is as given below.</p> <p>7.11.1 S1: Scale - It is the extent/area of environmental impact rated on a scale of 1 to 4</p> <p>7.11.2 S2: Severity - It is the degree of impact (damage) on environment rated on a scale of 1 to 4</p> <p>7.11.3 P: Probability /Likelihood - It shows the chances of occurrence of an aspect rated on a scale of 1 to 4.</p> <p>7.11.4 D: Duration - It indicates the duration of Impact on environment and is rated on a scale of 1 to 4.</p>				S.No	External Interested Parties	1	Customers	2	Stakeholders	3	Suppliers	4	Non - Government Organisation (NGOs)	5	Legal Bodies	6	Public	7	Local Panchayat	8	Visitors
S.No	External Interested Parties																				
1	Customers																				
2	Stakeholders																				
3	Suppliers																				
4	Non - Government Organisation (NGOs)																				
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Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability
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TITLE:ASPECT- IMPACT IDENTIFICATION THROUGH RISK BASED APPROACH

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Scale: Scale shall be assessed by the following criteria,

Scale (S1)		
Rating	Criteria	Description of criteria
1	Impact is Isolated.	Impact is contained within the work station / work area (restricted within the work area)
2	Confined to Shop floor / Dept.	Impact is restricted / contained within the Department / Shop floor.
3	Confined to Plant	Impact is restricted within the plant premises.
4	Regional / global	Impact migrates outside the Company premises / region in which the company is located

Severity: Severity shall be assessed by following criteria,

Rating	Category	Severity of the impact (Resources)	Severity of the impact: (Releases or exposure)
1	Negligible Impact	Resource consumed is negligible. Renewable / abundant resource	Bio-degradable. Effect on environment is negligible or tolerable. Does not have any legal concerns. Zero effect on interested party concerns / Organization's image.
2	Moderate	Resource consumed is moderate. Renewable resource; may take 1 to 5 Years for regeneration	Releases or wastes generated can be treated / re-cycled. Potential for internal noncompliance. May affect performance standard aspiration.
3	Serious	Resource consumed is considerable. Renewable resource; may take 5 - 10 Years for regeneration	Affects human health, vegetation; contributes to resource depletion over time (land / water source). May affect compliance obligations. Potential for external complaint.
4	Severe / Catastrophic	Resource consumed is high. Depletion of non-renewable resources such as Coal, oil, Gas etc / a global issue.	Releases are of global concern - ozone depletion, global warming etc. Ill effects extend to community around. Not meeting Compliance obligations. Serious complaints / Affects Company's image or reputation.

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Probability: Probability shall be assessed by following criteria,

PROBABILITY (P)		
Rating	Criteria	Description of criteria
1	Seldom	No evidence of occurring / occurrence under extreme situations only.
2	Occasional	Possibly may occur annually (average). May occur due to human error or equipment failure. Event has happened in another place.
3	Likely	Intermittent in normal conditions (Monthly /weekly) / 2 to 3 times in month (on an average) or repeat event.
4	Routine / Continuous	More frequent occurrence / Constant in normal conditions. Something that always happens.

Detection: Detection of Impact shall be assessed by following criteria,

DURATION OF DETECTION OF IMPACT (D)		
Rating	Criteria	Description of criteria
1	Short Term	Less than 1 hr
2	Medium Term	Less than 24 hrs
3	Long Term	More than one day
4	Very long Term	More than a month

7.12 Determination of significant aspects:

- 7.12.1 IPN (Impact Priority number) is defined as the product of the scores assigned for Scale (S1), Severity (S2), Probability (P) and Duration (D). Thus, $IPN = S1 \times S2 \times P \times D$.
- 7.12.2 All Environmental aspects with IPN score of 18 and above shall be considered as significant aspects.
- 7.12.3 If the score of severity is 4 (Severe / Catastrophic), it shall be considered as Significant by default
- 7.12.4 If CO, IPC, BC is rated as 'YES' then those impact(s) related to the aspect(s) shall be considered as Significant by default.

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<p>7.13 Assessment of Existing Controls: In case if the Environment aspect is significant, Existing Controls assessed. Recommendations shall be considered for all significant aspect as per the following hierarchy:</p> <p>7.13.1 Elimination 7.13.2 Substitution 7.13.3 Engineering 7.13.4 Administrative control</p> <p>7.14 Evaluation of Risk and Opportunities: 7.14.1 The risks and opportunities associated with significant environmental aspects, compliance obligations, potential emergency situations and other issues and requirement identified related to all activities, products and services shall be evaluated in order to: 7.14.2 Prevent or reduce, undesired effects, including the potential for external environmental conditions to affect the Company. 7.14.3 Achieve continual improvement.</p> <p>7.15 Risk and Opportunity Evaluation Methodology: 7.15.1 Consideration of Significant Aspect 7.15.2 Identification of Risk and Opportunity 7.15.3 Risk Rating and Classification 7.15.4 Risk Mitigation and Action Plan 7.15.5 Risks and opportunities can affect the ability to achieve the intended outcome of the EMS. Examples of Risks and opportunities are given below.</p> <table border="1" data-bbox="191 1496 1401 2007"> <thead> <tr> <th>Risks</th> <th>Opportunities</th> </tr> </thead> <tbody> <tr> <td>Non-fulfilment of Compliance obligations which can result in fines, or costs of implementing actions or Cancellation of license to operate. A customer need for rapid expansion of manufacturing capacity without considering the need for storage facility of generated wastes may lead to environmental non-compliances. Adverse publicity about the organization. Affects Organization’s reputation / image.</td> <td>Identifying new technology such as Control equipment that can reduce polluting discharges. Optimizing conservation of resources such as re-cycling water. Working with interested parties to defuse opposition to a proposed waste disposal method. Reduce operating expenses. Identifying methods for recycling of generated wastes.</td> </tr> </tbody> </table>				Risks	Opportunities	Non-fulfilment of Compliance obligations which can result in fines, or costs of implementing actions or Cancellation of license to operate. A customer need for rapid expansion of manufacturing capacity without considering the need for storage facility of generated wastes may lead to environmental non-compliances. Adverse publicity about the organization. Affects Organization’s reputation / image.	Identifying new technology such as Control equipment that can reduce polluting discharges. Optimizing conservation of resources such as re-cycling water. Working with interested parties to defuse opposition to a proposed waste disposal method. Reduce operating expenses. Identifying methods for recycling of generated wastes.
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<p>7.16 Consideration of Significant Aspect: All the significant aspects Identified by the Aspect Identification and Impact assessment methodology shall be considered for the Evaluation of Risk and Opportunities.</p> <p>7.17 Identification of Risk and Opportunity: Potential adverse Effect (Risk) and Potential beneficial Effect (Opportunity) of significant aspects shall be identified.</p> <p>7.17.1 The risks and opportunities associated with compliance obligations, potential emergency situations and other issues and requirement identified related to all activities, products and services shall also be identified and the Risk mitigation and action plan shall be maintained for the same.</p> <p>7.18 Risk Mitigation and Action Plan:</p> <p>7.18.1 Mitigation plan shall be assessed based on High risk and Unacceptable risk.</p> <p>7.18.2 Person or the team responsible for addressing the mitigation plan shall be identified and the risk and opportunity shall be communicated.</p> <p>7.18.3 Target date shall be defined based on the mitigation plan identified.</p> <p>7.18.4 Status of the Mitigation Plan shall be evaluated during the review of AIM Register and Evaluation of Risk and Opportunity of the same.</p> <p>7.19 AIM Record:</p> <p>7.19.1 Environmental Aspect – Impact Register shall be maintained as per FORM-EHSS-EHSS-0142(Annexure-01).</p> <p>7.19.2 Risk and Opportunity Register shall be maintained as per FORM-EHSS-EHSS-0143(Annexure-02).</p> <p>7.19.3 Environmental Aspect / Impact and Risk / Opportunities Summary sheet shall be maintained as per FORM-EHSS-EHSS-0144(Annexure-03).</p> <p>7.19.4 FORM-EHSS-EHSS-0142(Annexure-01) to FORM-EHSS-EHSS-0144(Annexure-03) along with summary of changes (for easy tracking) shall be maintained as a soft copy in a excel sheet. The excel file shall be forwarded to respective blocks EHSS Core team members and department Heads.</p> <p>7.19.5 Once the assessment is done, all the annexures shall be maintained in soft copy and printing will be done on need basis.</p> <p>7.19.6 The next review date of the register shall be 6 months from the date of Effective. The next review shall be done ± 15 days from the “Next review date”.</p> <p>7.19.7 Environmental Aspect – Impact Register and Risk and Opportunity Register shall be prepared by EHSS Core team member of the department in co-ordination with department head. The same shall be reviewed and checked by Dept. Line Manager and the EHSS Co-</p>			

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<p>coordinator of the respective block. Dept. Head/ OU head of the respective block/function will approve it.</p> <p>7.19.8 Review of AIM records once in 6 months and if any changes in work practices/addition of new activity/major incident pertaining to any activity etc. to be revised prior to review period.</p> <p>7.19.9 Individual department EHSS core team personnel shall raise the change control if any addition of new activity/Modification/Major Incident pertaining to any activity prior to the review period.</p> <p>7.19.10 Risk and Opportunity Register reviewed as and when the significant aspect, compliance obligations, potential emergency situations and any other issues and requirement identified.</p> <p>7.19.11 Soft copy of AIM shall be uploaded in “Syngconnect” by EHSS department for reference.</p> <p>8.0 REFERENCES: NA</p> <p>9.0 ANNEXURES:</p> <table border="1"> <tr> <td>FORM-EHSS-EHSS-0142</td> <td>Annexure – 01 Environmental Aspect – Impact Register</td> </tr> <tr> <td>FORM-EHSS-EHSS-0143</td> <td>Annexure – 02 Risk and Opportunities Register</td> </tr> <tr> <td>FORM-EHSS-EHSS-0144</td> <td>Annexure – 03 AIM Summary sheet</td> </tr> <tr> <td>FORM-EHSS-EHSS-0145</td> <td>Annexure – 04 List of controls</td> </tr> <tr> <td>FORM-EHSS-EHSS-0146</td> <td>Annexure – 05 SOP Training Questionnaire</td> </tr> </table> <p>10.0 REVISION HISTORY:</p> <table border="1"> <thead> <tr> <th>Version no.</th> <th>Effective Date</th> <th>Description of Change</th> </tr> </thead> <tbody> <tr> <td>2.0</td> <td>16-Feb-2023</td> <td><u>Reference Change Control Number: - EHSS/CCF/23/0004</u></td> </tr> <tr> <td>1.0</td> <td>02-Feb-2021</td> <td><u>Reference Change Control Number: - EHSS/CCF/20/0022</u> As part of transition from manual to Electronic document management system SOP-EHSS-EHSS-0021 ASPECT-IMPACT IDENTIFICATION THROUGH RISK BASED APPROACH has been revised</td> </tr> </tbody> </table>				FORM-EHSS-EHSS-0142	Annexure – 01 Environmental Aspect – Impact Register	FORM-EHSS-EHSS-0143	Annexure – 02 Risk and Opportunities Register	FORM-EHSS-EHSS-0144	Annexure – 03 AIM Summary sheet	FORM-EHSS-EHSS-0145	Annexure – 04 List of controls	FORM-EHSS-EHSS-0146	Annexure – 05 SOP Training Questionnaire	Version no.	Effective Date	Description of Change	2.0	16-Feb-2023	<u>Reference Change Control Number: - EHSS/CCF/23/0004</u>	1.0	02-Feb-2021	<u>Reference Change Control Number: - EHSS/CCF/20/0022</u> As part of transition from manual to Electronic document management system SOP-EHSS-EHSS-0021 ASPECT-IMPACT IDENTIFICATION THROUGH RISK BASED APPROACH has been revised
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Title: CHEMICAL HYGIENE MANAGEMENT

Document Number: SOP-EHSS-EHSS-0071	Version Number: 1.0	Effective Date: 30-Dec-2022
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Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Nidhi Cs/EHSS/ SYNGENE	29-Dec-2022 12:35:28 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Sunil Kumar/EHSS/ SYNGENE	29-Dec-2022 12:57:33 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	29-Dec-2022 16:10:26 (IST)

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	<p align="center">Standard Operating Procedure</p>	<p>DEPARTMENT: Environmental Health Safety and Sustainability</p>	
<p>TITLE:CHEMICAL HYGIENE MANAGEMENT</p>			
<p>Document Number: SOP-EHSS-EHSS-0071</p>	<p>Version no.: 1.0</p>	<p>Effective Date: 30-Dec-2022</p>	<p>Next Review Date: 29-Dec-2024</p>
<p>1.0 OBJECTIVE:</p> <p>The purpose of Chemical Hygiene Management is to minimize employee’s health hazard exposure associated with “Hazardous Chemicals” that are handled in the laboratories through hygiene practices. The procedure provided harmonized process, guidance and practices to manage the employee interference with Hazardous chemicals.</p> <p>2.0 SCOPE:</p> <p>This procedure provides mandatory requirements and guidance on Hazardous Chemical hygiene practices in Syngene R&D operations.</p> <p>Harmonized process for new Hazardous chemical procurement, hazard communication including the chemical labelling and SDS (Safety Data Sheets) as per GHS (Global Harmonized System) system, minimum requirements for Hazardous chemical handling (storage, distribution and use), fume hood controls and safe practices.</p> <p>The basis for this procedure is a determination that laboratories differ from industrial or manufacturing operations in their use and handling of Hazardous chemicals and that a different approach as per OSHA and R&D best practices warranted to protect workers. This standard does not establish new occupational exposure limits (OELs) but sets other performance provisions designed to protect laboratory workers from Hazardous chemicals potential hazards in their work environment.</p> <p>Note: The procedures do not cover the radioactive materials, chemicals of manufacturing scale or used in manufacturing, engineering design standards, mechanical integrity and safety technologies. However, the references to regulatory and safety technologies will be provided as and when required. The common practices like SDS (Safety Data Sheet) and GHS labelling can be extended or adopted across Syngene including manufacturing</p> <p>3.0 Roles and Responsibilities:</p> <p>3.1 Line Management:</p> <p>Line management is responsible for effective implementation of the procedure and sustaining through:</p> <p>3.1.1 The new hazardous chemicals are assessed before procurement and necessary safety controls are in place.</p> <p>3.1.2 EHSS review and consent for new hazardous chemicals from regulatory or restricted use perspective.</p> <p>3.1.3 The employee and contractor awareness in handling the Hazardous chemicals safely. Chemical hazard communication training is conducted initially during new employee orientation or new Hazardous chemical procurement and at annual frequency.</p>			

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<p>3.1.4 Minimize inventories and ensure proper controls like fume hoods, safety showers and PPEs in place.</p> <p>3.2 OU Tech. team: OU Tech. team is responsible for the following:</p> <p>3.2.1 To ensure material status checks i.e. verification of material received from SCM (Supply Chain Management) team for material content and hazards labels on the containers against the purchase request.</p> <p>3.2.2 Monitoring inventory and storage.</p> <p>3.2.3 SDS and chemical labelling system.</p> <p>3.2.4 Chemical distribution and chemical sweep program.</p> <p>Note: Tech. team from OU includes OU operation team or nominated representatives.</p> <p>3.3 Environment Health Safety and Sustainability (EHSS): EHSS team is responsible for providing guidance and support overall Chemical Hygiene Management by:</p> <p>3.3.1 Hazardous chemical reviews and statutory compliance guidance to the line management e.g. Narcotic, Hazardous /poisons chemicals, banned or restricted chemicals by various authorities.</p> <p>3.3.2 Support line management and other functions for new Hazardous chemicals reviews by hazard assessment and mitigation/controls.</p> <p>3.3.3 Monitor the change in SDS like exposure limits, hazards categories, change in GHS system and requirements.</p> <p>3.3.4 Periodic audits to ensure compliance to the procedure.</p> <p>3.3.5 Review the procedure periodically and ensure that the procedure is current and updated.</p> <p>3.4 Engineering and Maintenance Team (EAM): EAM is responsible for proper design, installation and integrity of engineering controls like lab ventilation (includes fume hoods and spot exhaust), safety showers, chemical storage cabinets and electrical fixtures.</p> <p>4.0 ABBREVIATION:</p> <p>GHS - Global Harmonized System OELs - Occupational Exposure Limits SCM - Supply Chain Management ALARP - As Low As Reasonably Possible MSIHC - Manufacturing Storage And Import Of Hazardous Chemicals</p>			

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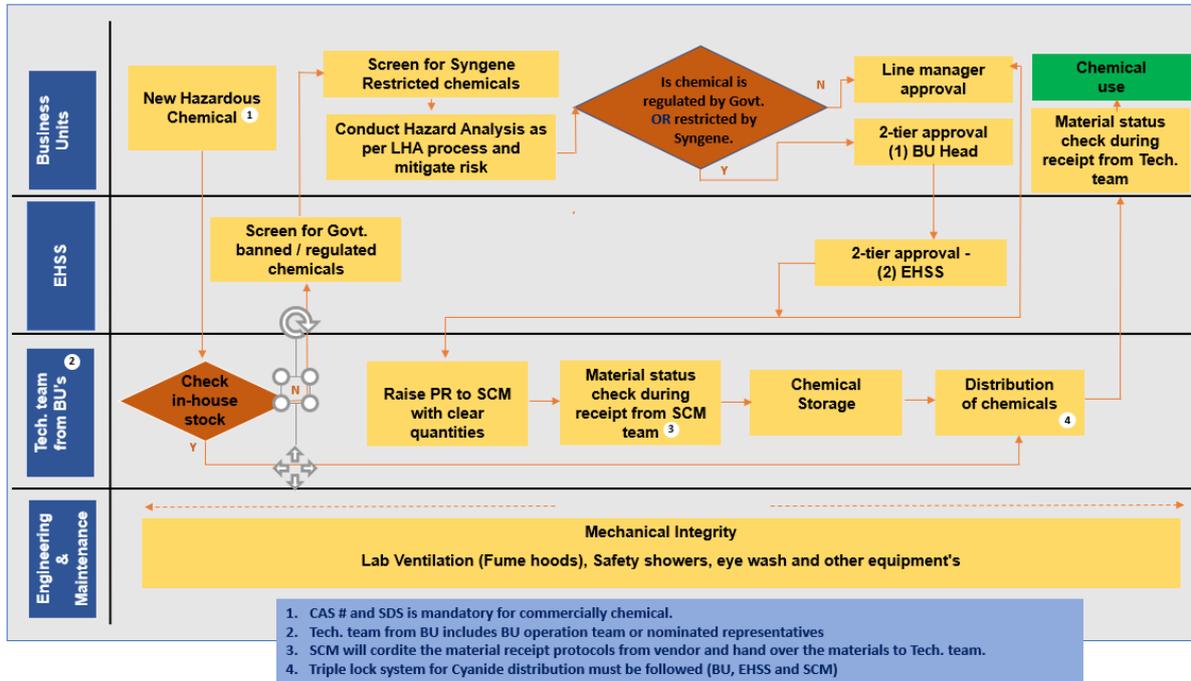
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<p>CAS - Chemical Abstracts Service LHA - Lab Hazard Analysis IBC - International Building Code SDS - Safety Data Sheet NBC - National Building Code IECEs - International Electro technical Commission for Explosive Atmospheres ATEX - Atmosphere Exposable OSHA - Occupational Safety & Health Administration PPE - Personal Protective Equipment SOP - Standard Operating Procedure</p>			
<p>5.0 DEFINITION:</p>			
<p>These definitions are provided to describe the intent of this procedure, the terms may be defined differently in other contexts.</p>			
<p>5.1 Breathing zone - is defined as the zone within a 0.3 m (or 10 inches) radius of a person /worker's nose and mouth, and it has been generally assumed that a contaminant in the breathing zone is homogeneous and its concentration is equivalent to the concentration inhaled by the worker.</p>			
<p>5.2 Hazardous Chemicals / substance - Any substance that can pose significant physical, health affect and environmental impact because of the substance’s extreme or high acute toxicity (including asphyxiation), flammability, explosivity (from flammables), chemical reactivity, or corrosiveness (strong acids/bases).</p>			
<p>5.3 Prohibited chemicals - Chemicals that pose an inherent, immediate, and potentially life-threatening risk, injury, or impairment due to toxicity or impact on environment.</p>			
<p>5.4 Restricted chemicals - Chemicals that are restricted from manufacturing or use and/or quantities. These chemicals may pose potential life threatening risk, injury, toxicity or impact on environment.</p>			
<p>5.5 Syngene Prohibited or Restricted Chemicals - Chemicals that are prohibited from use or restricted for use by Syngene management under Product Stewardship or Sustainability program.</p>			
<p>6.0 EHSS:</p>			
<p>6.1 Precautionary measures for Chemical Hygiene Management: NA</p>			
<p>7.0 PROCEDURE:</p>			
<p>7.1 Chemical Hygiene Process and procedure:</p>			

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7.1.1 The Chemical Hygiene Management is intended to serve as an operational guide for the incorporation of prudent safety practices into the day-to-day use of Hazardous chemicals within laboratories. The *Seven Element program* is developed as a harmonized process which must be adapted and expanded by Operating units at Syngene laboratories to meet their specific needs.

The seven (07) element chemical Hygiene Management program are:

- 7.1.1.1 New Hazardous Chemical Procurement Review.
- 7.1.1.2 Chemical Hazard Communication.
- 7.1.1.3 Safety Data Sheet (SDS) Management.
- 7.1.1.4 Chemical Labelling System (GHS – Globally Harmonized System).
- 7.1.1.5 Chemical Handling Safe Practices.
 - 7.1.1.5.1 Chemical Inventory Management.
 - 7.1.1.5.2 Chemical Storage.
 - 7.1.1.5.3 Chemical Distribution.
 - 7.1.1.5.4 Chemical usage and Personal Hygiene.
- 7.1.1.6 Engineering Controls and its use – Fume Hoods and Safety Showers.
- 7.1.1.7 Chemical protective clothing – Gloves.

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<p>7.2 New Hazardous Chemical Procurement Review:</p> <p>Hazards of hazardous chemicals must be recognized and controlled before procurement. All new hazardous chemicals should be reviewed, and review should include the following:</p> <p>7.2.1 Regulated or restricted chemicals as per law of the land (Regulation).</p> <p>7.2.2 Syngene regulated or restricted chemicals.</p> <p>7.2.3 Quantity of chemicals.</p> <p>7.2.4 Hazards associated with the chemical.</p> <p>7.2.5 Facilities required for handling – storage conditions, ventilation and PPEs.</p> <p>7.2.6 The regulator requirements screening should be done by referring the Govt. Acts and Rules such as (Non-exhaustive list):</p> <p>7.2.6.1 Narcotic chemicals/drugs or Psychotropic substance rules.</p> <p>7.2.6.2 Drug control department for materials like Cyanide.</p> <p>7.2.6.3 Poisons Rules – Drug controller department for materials like Cyanide.</p> <p>7.2.6.4 Banned chemicals or pesticides by Director of Plant Protection, Govt. of India.</p> <p>7.2.6.5 MSIHC (Manufacturing, storage and import of Hazardous chemicals) rules</p> <p>7.2.7 The regulatory screening should be conducted by the EHSS team and the provide clearance to the OU's for the new Hazardous chemical procurement.</p> <p>7.2.8 Syngene EHSS should maintain the list of prohibited and restricted chemicals by Syngene Organization in the template as per FORM-EHSS-EHSS-0444(Annexure – 01).</p> <p>7.2.9 The Lab Hazard Analysis – LHA software must be used for reviewing the new Hazardous chemical hazards. The review templates #14 and subsequent review templates for the Hazardous materials #14A to 14H must be used to analyze the new material hazards.</p> <p>7.2.10 The hazard analysis should include the quantity of the chemical and procuring more than 20 liters should be avoided. The chemical hazard mitigation measures should include engineering controls like ventilation /fume hoods, storage conditions like temperature, storage cabinets and specific PPEs.</p> <p>7.2.11 The following step by step process must be followed for procuring the commercially available new chemical:</p> <p>7.2.11.1 Review new Hazardous chemicals for any regulatory or Syngene restrictions for procurement. Seek EHSS help to review regulatory restricted chemicals and obtain clearance.</p> <p>7.2.11.2 Refer SDS from “chemwatch” software or other Syngene approved genuine sources.</p> <p>7.2.11.3 CAS # (Chemical Abstracts Service) and SDS (Safety Data Sheet) is mandatory. Employees should not initiate the request for procurement if commercially available material does not have CAS # and SDS. Employees must contact OU head and EHSS for advice.</p>			

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<p>7.2.11.4 Analyze the chemical hazards using LHA software template #14 and subsequent template depending on the material hazard category like pyrophoric, peroxides etc.</p> <p>7.2.11.5 Review facilities and engineering controls available and additional control required with support from the EAM team like fume hoods, spot exhaust, safety showers & eye wash, storage cabinets etc.</p> <p>7.2.11.6 Review with line manager and align on quantities (ALARP - as low as reasonably possible) and obtain approval from line manager for new Hazardous chemical procurement</p> <p>7.2.11.7 Follow <i>2-tier approval process</i> i.e. approval from OU head and EHSS for the following chemicals:</p> <ul style="list-style-type: none"> • Regulated chemical by Govt. regulatory body (e.g. Cyanide and Narcotic chemicals). • Regulated by Syngene organization (OU Specific also). <p>7.2.11.8 Raise the purchase request with OU Tech. team.</p> <p>7.2.12 The materials (samples and chemicals) which are under development or unknown may <i>not</i> have proper SDS or CAS # are always at high risk. The samples or materials may be from clients, competitors’ samples from market and as well as from Syngene cross OU’s transfers. This material hazard information should be requested in advance before initiating the analysis and the following information from material/sample issuer/supplier should be requested:</p> <ul style="list-style-type: none"> • Material hazard assessment conducted, if any. • Exposure hazard information like toxicity, reactivity and other hazards. • The protection measures like equipment’s and controls used e.g. fume hoods, glove box or any other. • Specific PPEs like gloves type and respirator type. • Safe practices that are followed by the issuer. • Special precautions that must be adopted. <p>7.2.13 FORM-EHSS-EHSS-0445(Annexure-02) template should be followed to seek material hazard information for under development or unknown materials or client samples. Once the hazard information is gathered, a Lab hazard analysis (LHA) process should be followed to mitigate the hazards.</p> <p>Important Note:</p> <ul style="list-style-type: none"> • Where the toxicity, reactivity, or other hazards of a substance used in laboratory are not well established by SDS and are not available from other sources or technical literatures, line manager must develop specific, precautionary practices and guidance to handle the material(s) safely to prevent employee exposure, releases, or other hazards. • Where there is no proper hazard information available, materials should be treated as <i>“Hazardous by default”</i> and safety measures should be taken. The measures should 			

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<p>include handling of material under controlled conditions (fume hoods or glove boxes or spot exhaust) with selection of gloves and respirators.</p> <p>7.3 Chemical Hazard Communication:</p> <p>7.3.1 All employees and contractors having exposure to Hazardous chemicals have the “Right to Know”, the health and physical hazard information of the materials. The hazards of the materials must be communicated to personnel initially and annually thereafter, including new personnel before initial assignment and personnel transferred to new assignments.</p> <p>7.3.2 Chemical hazard communication should be covered under new the safety induction program by EHSS and as well as line management. Every year, all employees must receive training about the chemical hazards and the practices to be followed in the laboratories. Any combination of face to face, LMS or field training modes can be used. The chemical annual training must cover following topics:</p> <p>7.3.2.1 Significant hazards of the chemicals.</p> <p>7.3.2.2 Routes of entry.</p> <p>7.3.2.3 Chemical labelling system – GHS.</p> <p>7.3.2.4 SDS management.</p> <p>7.3.2.5 Handling safe practices - storage, distribution, use and disposal.</p> <p>7.3.2.6 Protective control measures - engineering controls like lab ventilation fume hoods, ventilation and selection of PPEs and its use.</p> <p>7.3.2.7 Emergency - spill management, emergency equipment use like safety showers.</p> <p>7.3.3 Hazard communication mainly includes two primary sources and hence it must be made readily available to each employee handling the chemicals. The two-primary source of chemical hazard information are:</p> <p>7.3.3.1 SDS (Safety data sheet).</p> <p>7.3.3.2 Chemical labelling</p> <p>Both the SDS and chemical labelling <i>must meet GHS (Global Harmonized System) requirements</i>. GHS system describes the nature and severity of a chemical hazard by hazard class and hazard category.</p> <p>7.3.4 Safety Data Sheet (SDS) Management:</p> <p>As per Global Harmonised System, SDS covers 16 sections and the details of sections are provided in Figure – 01.</p>			

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Figure – 01: 16 sections of SDS

1. Identification and supplier	9. Physical and Chemical Properties
2. Hazards Identification	10. Stability and Reactivity
3. Composition	11. Toxicological Information
4. First Aid Measures	12. Ecological information
5. Firefighting Measures	13. Disposal considerations
6. Accidental Release Measures	14. Transport Information
7. Handling and Storage	15. Regulatory information
8. Exposure Controls/Personal Protection	16. Other Information

7.3.5 SDS provides Hazard (H) and Precaution (P) codes and statements for ease understanding of material hazards. Under Hazard (H) code, there are 29 categories or classes (Ref: GHS, Rev.8 2019) and they are:

- Code 2 - Physical hazards and it has 17 classes/categories
- Code 3 - Health hazards and it has 10 classes/categories
- Code 4 - Environmental hazards and it has 02 classes/categories

7.3.6 Precaution (P) code covers 05 categories and they are:

- Code 1 - General precautions
- Code 2 - Prevention
- Code 3 – Response
- Code 4 – Storage
- Code 5 - Disposal

7.4 Mandatory Requirements of SDS management:

The following are the mandatory SDS requirements in Syngene:

7.4.1 The SDS should be obtained from genuine source and readily made available to employees for use, it includes:

- SDS from supplier i.e. from chemical manufacturer.
- Reliable and Syngene approved SDS database (say Chemwatch database or tool).

Important Note: SDS sourcing from unreliable source (say generic or incomplete SDS from google) is not recommended practice.

7.4.2 The Syngene EHSS team must monitor the change in SDS like exposure limits, hazards categories, change in GHS system and requirements. New information received must be communicated to line management and should be incorporated into the Syngene hazard communication training program.

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<p>7.4.3 If the SDS database is not in place at Syngene, OU’s must have a list of the chemicals with SDS (soft or hard copy) and maintain for the respective business.</p> <p>7.4.4 Syngene must make sure a process is in place to ensure SDSs are up-to-date. SDS management process must cover that all materials / chemicals and must be reviewed once in <i>three years</i> to ensure that they are accurate and up-to-date.</p> <p>7.5 Chemical Labelling – GHS (Global Harmonized System):</p> <p>All chemicals must have the GHS labels and Syngene SCM team must insist chemical suppliers to adhere to the GHS labelling compliance. The GHS pictograms reference is provided in (Figure – 02) for recognizing the chemical hazards based on pictograms. The following chemical labelling practices should be followed in Syngene lab operations:</p> <p>7.5.1 Original Container: The existing GHS labels on purchased Hazardous chemicals from the manufacturer must not be defaced or removed.</p> <p>7.5.2 Reagents and solutions: Common solvents and reagents that are transferred from their original container to another container or prepared solution or buffers should have a proper label affixed to the container to clearly identify the contents. The prepared solutions also should be labelled as per GHS.</p> <p>7.5.3 Special labelling for Peroxide Forming Chemicals: Additional peroxides labels will be provided for the peroxide forming chemicals along with GHS labels.</p> <p>7.6 GHS Labelling process:</p> <p>All chemical containers will be checked for GHS labelling as per SDS by the OU Tech team in the warehouse during receipt of materials. The new GHS Labels will be printed and posted on the chemical containers by the OU Tech team if the container label does not meet GHS labelling and if the label is not in good condition. As required under Rule 20 of Insecticide Rule 1971, due care must be taken to avoid any alteration or deface on the manufacturer label provided on insecticide containers.</p> <p>GHS labelling can be provided to the primary or secondary containers in case chemical containers are too small and not able to paste the labels. The guidance for preparing the GHS labels is provided in FORM-EHSS-EHSS-0446(Annexure-03).</p>			

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Figure – 02: GHS Pictograms



7.7 Peroxides Labelling process:

Peroxidizable compounds are divided into the following four groups, based up on the manner in which peroxides are formed.

- 7.7.1 **Group A:** Chemicals that form explosive levels of peroxides spontaneously upon exposure to air and/or light or motion and can explode without further concentration. They can be Hazardous even if not opened. The validity for Group A peroxides is 12 months from date of receipt or 03 months from the date of opening the container, whichever comes first.

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<p>7.7.2 Group B: Chemicals require external energy for spontaneous decomposition, forming explosive peroxides when distilled, evaporated or otherwise concentrated. The validity for Group A peroxides is <i>12 months from date of receipt or 06 months from the date of opening the container, whichever comes first</i>. If uninhibited, dispose after 03 months (opened or unopened).</p> <p>7.7.3 Group C: Chemicals are highly reactive and can auto-polymerize as a result of internal peroxide accumulation. The peroxides formed in these reactions are extremely shock and heat sensitive. The validity for Group A peroxides is <i>12 months from date of receipt or 03 months from the date of opening the container, whichever comes first</i>. If uninhibited, dispose after 24 hours (opened or unopened).</p> <p>7.7.4 Group D: Potential Peroxide Forming Chemicals but cannot be clearly categorized in Class A, B, or C. Over 200 organic and inorganic compounds are capable of forming peroxides. The employee/investigator should refer to the SDS, contact the chemical manufacturer, to determine if chemicals are potential peroxide formers. This group peroxides should be discarded only if the peroxide crystals are formed and there is visible discoloration or stratification</p> <p>All peroxide reagents must have the label containing (a) Received date (b) container opened date and (c) Expiry date. The peroxides labelling process is Syngene will be as followed:</p> <p>7.7.4.1 Four label color codes will be followed for peroxide forming chemicals</p> <ul style="list-style-type: none"> ○ Red Labels for Group peroxide reagents/chemicals ○ Yellow Labels for Group B peroxide reagents/chemicals ○ Blue Labels for Group C peroxide reagents/chemicals ○ Green Labels for Group D peroxide reagents/chemicals <p>7.7.4.2 Warning labels will be pasted by the OU Tech team in the warehouse and will enter the received date on the label upon receipt. The peroxides standard label pictogram for four groups of peroxides are provided in (Figure – 03).</p> <p>7.7.4.3 The laboratory personnel receiving peroxides from the warehouse should check the date of receiving for validity. Lab personnel must enter date of opening and expiry date of peroxides depending on the group (A, B, C and D).</p> <p>7.7.4.4 Expiry of peroxide reagents should <i>be checked on monthly by assigned employee</i> both in stores and in lab and, should maintain the register of tracking.</p> <p>7.7.4.5 The list of potential peroxide forming chemicals are provided in FORM-EHSS-EHSS-0447(Annexure-04) for reference. This is a non-exhaustive list and line management must ensure a complete list for the respective OU.</p>			

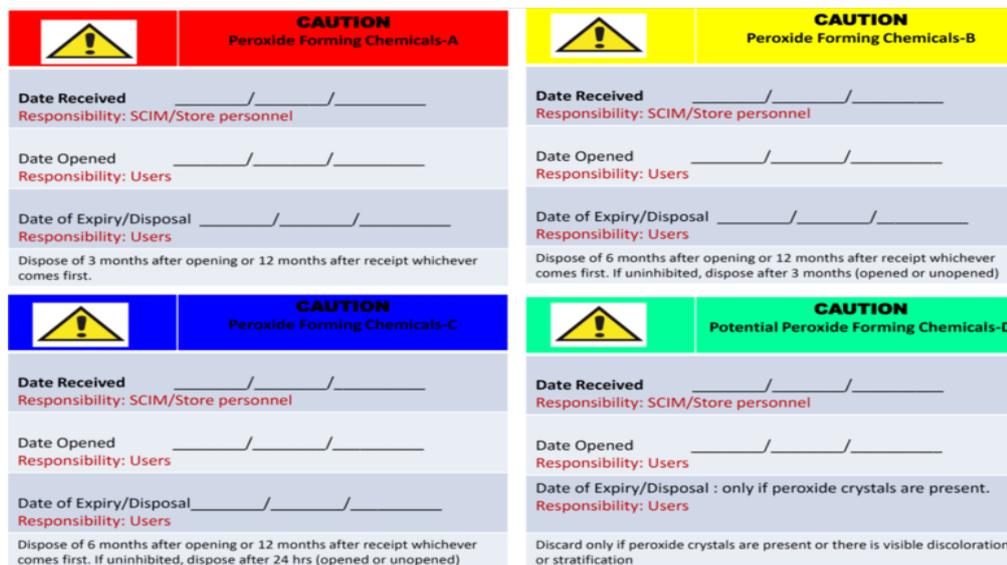
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Figure – 03: Peroxides label pictogram



7.8 Chemical handling - Inventory, Storage, Distribution and Use:

7.8.1 Inventory Management System:

Good chemical inventory management is the best hazard prevention control in chemical management. Syngene should adopt chemical inventory system (CIS) to manage the chemicals and it should include:

- 7.8.1.1 **JIT (Just in Time)** – receiving materials as and when required with proper planning of experiments/process in lab operations will reduce the safety risk.
- 7.8.1.2 **FIFO (First in and First Out)** – chemicals procured first must be issued and consumed first. This process will help to minimize the chemical expiry and waste.
- 7.8.1.3 **Purchase Control** - The inventory should be controlled at procurement stage and bulk ordering must be avoided. Any bulk ordering of flammables more *than 20 liters in plastic containers* and other Hazardous chemical like peroxides, pyrophoric etc. must be restricted to smaller volumes as much as possible. Only working stock of small quantities should be stored in the working area or lab. The working stock recommended not be more than 05 days as a good laboratory practice.
- 7.8.1.4 **Real-time Inventory** – Real time inventory helps issues the materials/chemicals available in stock in warehouse or from other OU which are unused or no more required. This will help in minimizing the new chemical procurement and chemical risk overall.
- 7.8.1.5 **Material Shelf Life Tracking** – Chemical shelf life and expiry tracking should be done to ensure the materials are removed from the workplace and disposed of safely. Tracking the chemicals well in advance before expiry will help to issue the chemicals required by the OU

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instead of new chemical procurement. The chemical shelf life must be tracked by OU Tech. team as per the guidance provided in the FORM-EHSS-EHSS-0448(Annexure-05), Chemical Zoning, Compatibility and Shelf Life. Any *chemical storage for more than the specified storage shelf life duration should be discouraged* and OU Tech team should coordinate with management and OU heads for mitigation plans.

7.8.1.6 Chemical Sweep – is a chemical sharing practice to minimize the chemical risk and waste. The unused or no longer needed chemical(s) from one OU can be distributed to other OU who are in need. OU Tech. team must monitor chemicals and coordinate the sweep program at every six months interval across Syngene. OUs should also track the inventory and share the list of chemicals which can go for chemical sweep.

7.8.1.7 Chemical inventory or storage limits for laboratories – Several codes like NBC (National Building Code), IBC (International Building Code) and NFPA (National Fire Protection Association) provide guidance for storage of materials in buildings. NFPA Code 45 (Fire Protection for Laboratories Using Chemicals) goes further in describing maximum permissible quantities of flammable and combustible materials for laboratories.

NFPA recommends limits per lab unit as well as per 100 square feet (9.3 Sq. Mts.) of laboratory unit in sprinklered and unsprinklered units/labs. Laboratory line managers must ensure periodic chemical inventory checks to meet the compliance. The Max. allowable flammable quantities for the lab area are provided in Table - 01 as per NFPA 45 and the Max. allowable flammable quantities for the store attached to lab building as per NFPA 30 is provided in the Table - 02.

Table - 01: Max. allowable flammable inventory inside the lab area:

NFPA 45: Fire Protection for Laboratories Using Chemicals					
Laboratory unit Fire classification	Flammable & Combustible liquid class	Quantities in Use		Quantities in Use & Storage	
		Max. Quantity per 9.3 m ² of laboratory unit (L)	Max. Quantity per laboratory unit (L)	Max. Quantity per 9.3 m ² of laboratory unit (L)	Max. Quantity per laboratory unit (L)
A High Fire Hazard	I	38	1820	76	1820
	I, II and IIIA	76	3028	150	6060
B Moderate Fire Hazard	I	20	1136	38	1820
	I, II and IIIA	38	1515	76	3028
C Low Fire Hazard	I	7.5	570	15	1136
	I, II and IIIA	15	757	30	1515
D Minimal Fire Hazard	I	4	284	7.5	570
	I, II and IIIA	4	284	7.5	570

Permitted only if
sprinklers system installed

Permitted without
sprinklers system installed

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Table - 02: Max. allowable flammable inventory in lab attached storeroom

Storeroom Area	Fire Sprinkler Lts. / Sq. Ft.	Non-Fire Sprinkle Lts. / Sq. Ft.
< 150 Sq. Ft.	19	7.6
> 150 & < 500 Sq. Ft.	38	15.2

The flammables storage quantities storage will also *vary based on the building floor* as per IBC (International Building Code). IBC recommends limiting storage, use in-open/closed inside the lab building by floor wise. For example, flammables quantities (usage + storage) in the *second floor must be 50% less compared to ground floor. Hence lab design during set up and lab operations must consider these standards to minimise the risk.* This is for controlled areas as per IBC standard i.e. where the lab is having 02 Hours fire rated wall and flooring, water-based sprinkler system and mechanically ventilated system.

Important Note: Any individual chemical container capacity should not be cross 20 liters as per lab best practices and NFPA 30 standard (includes waste containers).

7.9 Chemical Storage:

The chemical storage principles should be applied to minimize the risk of laboratory chemicals in storage. These are physical or engineering controls that are intended to contain or control the risk at source so are high up on the desired hierarchy of safety precautions. The following are the *three principles* for chemical storage:

- Segregation
- Separation and
- Ventilation

7.9.1 Segregation: The incompatibles from each other like strong acids from strong bases and strong oxidisers from organic or flammable materials. Mixing of these incompatible materials due to spillage, breakage of containers or leakage may lead to reactions which can generate heat, toxic vapours, fire and even explosion. FORM-EHSS-EHSS-0448(Annexure-05) Provides guidance on Syngene chemical storage zoning to manage the chemical compatibility as well as chemical storage shelf life guidance.

7.9.2 Separation: The Hazardous chemicals from unsuitable conditions for the purpose of their toxicity, flammability or reactivity (e.g. preventing exposure to heat / temperatures, air, moisture, sources of ignition and unauthorized access should be separated. The separation can be achieved by “physical separation” and “separation by distance” *by having proper storage facilities.*

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<p>7.9.3 Physical separation: This can be achieved by means of storage cupboards and cabinets which physically divide incompatible classes of Hazardous chemicals e.g. Flammable should be stored in dedicated fire rated flammables cabinets and acids (inorganic and some organic acids) in a dedicated acid cabinet.</p> <p>7.9.4 Separation by distance: Separation by distance practices adopted to the store's rooms (includes lab or building stores), dedicated flammables or peroxides stores which should be away from the lab building to minimize the risk. The separation by distance should be based on the volumes and risk.</p> <p>Separation by distance can also be applied to chemicals in laboratories as a means of keeping incompatibles a safe distance apart or minimizing risk from more than one flammable cupboard becoming involved in a fire. However, this requires additional storage space in the lab.</p> <p>7.9.5 Ventilation: Ventilation is often an essential requirement for safe storage of Hazardous chemicals. Its main function is to allow dilution and extraction of vapours or gases that may escape / seep out from containers during storage, so they no longer present problems from the viewpoint of noxious smell, Hazardous personal exposure or creation of an explosive atmosphere. Materials that should be stored in a ventilated cupboard includes (non-exhaustive list):</p> <p>7.9.5.1 Malodorous or noxious substances such as mercaptans and mercaptoethanol (which should be in well-sealed containers in sealed secondary containers which are only opened in a fume cupboard).</p> <p>7.9.5.2 Volatile non-highly flammable substances such as chlorinated solvents.</p> <p>7.9.5.3 Formaldehyde.</p> <p>7.9.5.4 Volatile, malodorous amines (in secondary containers).</p> <p>Important Note: Ventilating cupboards should not be used for storing highly flammable liquids unless they meet the requirements for highly flammable liquid storage cupboards and have fire dampers fitted to the extract and any inlets that will shut off the ventilation in the event of a fire.</p> <p>7.10 Storage of Different Class of Materials:</p> <p>7.10.1 Acids: Concentrated acids must be safely stored inside an acid storage cabinets cabinet. Day stock of dilute acids, such as used with pH meters, may be stored on the lab bench or in fume hoods with proper labels. Fuming acids, acids chlorides should be stored in ventilated enclosures.</p> <p>Inorganic and some organic acids can be stored in a dedicated acid cabinet in a separate/independent secondary container. Oxidizing acids must be isolated from other acids (i.e., each in its own separate secondary containment).</p>			

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<p>7.10.2 Alkalis (corrosive acids): Must be stored separately from acids since any accidental mixing of the concentrated materials will generate large quantities of heat and fumes.</p> <p>7.10.3 Flammables: Must be stored in dedicated fire rated flammables cabinets. Acetic acid and acetic anhydride must be stored in a flammable cabinet.</p> <p>7.10.4 Peroxide formation: A significant number of laboratory solvents can undergo auto-oxidation under normal storage conditions to form unstable and potentially dangerous peroxide by-products. These solvents are sufficiently volatile that multiple openings of a single container can result in significant and dangerous peroxide concentration. Peroxidizable chemicals should be stored in sealed, airtight in a dark, cool and dry place. Containers should be kept away from light (light can initiate peroxide formation) in a dark amber glass bottle with a tight-fitting cap is generally appropriate. To minimize the rate of decomposition, peroxides and peroxidizable materials should be stored at the lowest possible temperature consistent with their solubility and freezing point. Liquid or solutions of peroxide should not be stored at or lower than the temperature at which the peroxide freezes or precipitates, becoming extremely sensitive to shock and heat.</p> <p>7.10.5 Chlorinated solvents - are best stored in ventilated cabinets separately from flammable solvents, because there are violent reactions when certain flammable solvents and chlorinated solvents are allowed to mix. Also, when chlorinated solvents are involved in a fire they can generate toxic gases such as phosgene. They should not be stored with alkali metals such as lithium, potassium or sodium, since any mixing may cause an explosion. They can be stored in metal bins if ventilated storage is not available.</p> <p>7.10.6 Noxious chemicals: Ventilating cabinets are designed to safely hold chemicals which give off noxious fumes and smells. Often these are located under fume cupboards. Free-standing or independent ventilated storage units/cabinets can also be used to store materials such as mercaptans and amines which have a strong smell. They can also be used to store lachrymators. If you do not have a ventilated cabinet, containers of these noxious materials can be stored in sealed secondary containers which should only be opened in a fume cupboard.</p> <p>7.10.7 Oxidizers: Best to be stored separately from other materials. Ideally, they should be stored in a cabinet made from metal or other non-organic material. Oxidizing agents must never be stored with flammable solvents or reducing agents since fires and explosion can result after any spillage, even without a naked flame or heat. E.g. peroxides, perchlorates and nitrates.</p> <p>7.10.8 Highly Toxic material – should be kept in a dedicated cabinet under control locking provision e.g. Cyanide and register should be maintained.</p>			

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7.11 Storage Facilities:

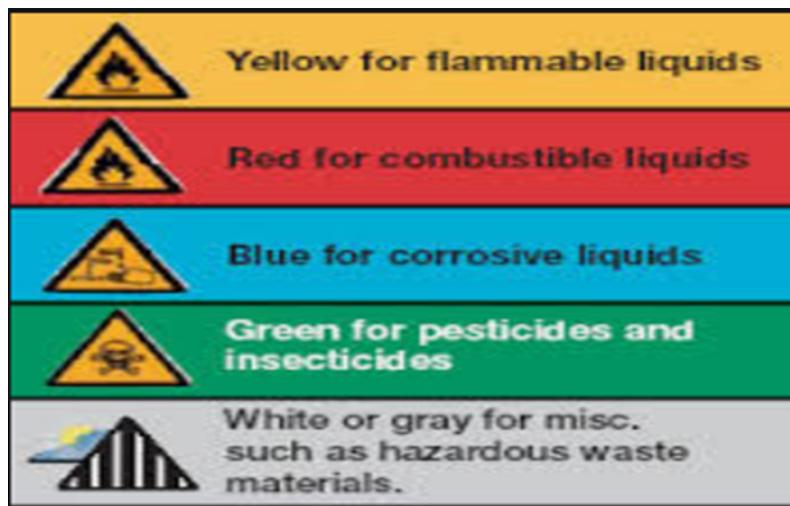
7.11.1 **Shelving:** properly designed storage shelves or racks should be provided for storing Hazardous materials. The following practices should be followed in relation to storage on shelves:

- 7.11.1.1 Storage capacities should be marked and should not be overloaded. If the shelves are bowed, they are overloaded.
- 7.11.1.2 All storage shelves / racks should be fastened to wall or structure to avoid fall.
- 7.11.1.3 Store breakable containers, particularly of liquid and Hazardous chemicals below 5.5 feet and solid chemicals below 6.5 feet.
- 7.11.1.4 Store large heavy containers at low level.
- 7.11.1.5 Where items are stored above this level ensure they are lightweight/infrequently used and that there is a safe means of access e.g. step stool or ladders.
- 7.11.1.6 Shelves must have raised edges/lips to prevent items being pushed off the other side and are not easily knocked off.

7.11.2 **Storage Cabinets:** standard (NFPA / FM global / others) and rated cabinets should be used for the storage of chemicals. The fire rating varies from 30mins to 2 hours fire rated for flammables with safety features like vent with flame arrestor, secondary containers, bonding provision etc. Similarly, acid cabinets must have an interior of moulded polyethylene or alternate that is impervious to acids.

The storage cabinets must meet the standards like NFPA or FM Global requirements. NFPA 30 flammable storage cabinets and cans/containers should be used for flammables. The color codes for the identification of storage cabinets is provided in (Figure – 04).

Figure – 04 : Storage cabinets color codes :



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<p>7.11.3 Ventilated cabinets: These are cabinets which are fitted with mechanical/forced ventilation. They can be independent or may be situated beneath a fume hood cupboard. They are designed to safely store chemicals that give off noxious fumes and smells to be sucked away by the forced ventilation.</p> <p>7.11.4 Refrigerators, Freezers and Cold Rooms - used for storing certain Hazardous substances at material desired temperature and humidity. The features vary depending on the material stored and hazards associated with it. The following engineering controls should be considered while deciding the Hazardous material refrigerators, freezers and cold rooms.</p> <p>7.11.4.1 Flame proof / Intrinsically safe wiring and fixtures</p> <p>7.11.4.2 4 hour fire rated structure / panels</p> <p>7.11.4.3 Explosive relief structure / panels</p> <p>7.11.4.4 Flame and smoke detection</p> <p>7.11.4.5 Fire suppression</p> <p>7.11.4.6 Spill containment provision</p> <p>7.11.4.7 Gas detection system</p> <p>7.11.4.8 Multi sensor temp. and RH monitoring / alarms</p> <p>7.11.4.9 Data loggers and remote monitoring and alert</p> <p>7.11.4.10 Audio visuals, alarms and hooters</p> <p>7.11.4.11 Door unlock provision inside for walk in cold room</p> <p>7.11.4.12 Emergency alarm / Bell for walk in cold room</p> <p>Note: where the substances are flammable, the units must meet the Ex d – Explosive protection, Ex i – Intrinsic safe, Ex n – Non-sparking as per ATEX (atmosphere exposable) and IECEx (International Electro technical Commission for Explosive Atmospheres) standards</p> <p>7.11.5 Fume cupboards: are not designed or intended to be used as storage areas and they should be kept clear of materials and containers to avoid air flow disruption and fume hood functioning. However, the provisions can be made beneath a fume hood for ventilated cabinets, acid or flammables for storage purpose.</p> <p>7.11.6 Secondary Containers: all Hazardous chemicals must be stored using secondary containers to minimize the risk of spill and container damage. Secondary container material (material of construction) should be compatible with the chemical class. The guidance on secondary container selection is provided in FORM-EHSS-EHSS-0449(Annexure-06).</p> <p>Important Note: The storage facilities and its safety features must be based on process hazard analysis and engineering design.</p> <p>7.11.7 Storage good practices by employees working in Lab:</p> <p>The following good practice should be adopted in labs for chemical storage by employees.</p>			

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<p>7.11.7.1 The minimum amounts of chemicals should be stored in labs area. Only working stock.</p> <p>7.11.7.2 Store chemicals as per compatibility zoning only and incompatible materials must be segregated.</p> <p>7.11.7.3 Floors, bench tops, and fume hoods should not be used as storage areas.</p> <p>7.11.7.4 Ensure labelling all chemicals under storage.</p> <p>7.11.7.5 Stored chemical containers must be examined periodically (at least once in 15 days) for deterioration and container integrity.</p> <p>7.11.7.6 Ensure compatible secondary container for all chemicals.</p> <p>7.11.7.7 Must be stored or placed Secondary containers.</p> <p>7.11.7.8 Multiple bottles / containers of same the chemical should never be opened for use. First container in the front line should be opened and other containers in the storage line should not be opened unless the first in the line is consumed. It is deemed practice that only the first container in the line is opened for use.</p> <p>7.11.7.9 Ensure all containers are closed properly to minimize the VOCs.</p> <p>7.12 Chemical Distribution:</p> <p>The chemicals distribution from stores to labs or lab to lab must be checked and verified. The checks must include:</p> <p>7.12.1 Chemical container integrity checks: chemical containers should be physically checked for container integrity like container damage, cracks, spill traces etc.</p> <p>7.12.2 GHS Labelling: check for right label as per SDS or provide GHS label</p> <p>Note: The same process should be adopted during the receipt of chemicals from suppliers.</p> <p>7.12.3 The following practices should be followed during distribution of chemicals:</p> <p>7.12.3.1 The small quantity of chemicals (say up to 2-3 liters, 1 or 2 bottles) can be carried by hand and the container should be placed in a secondary container. Unbreakable containers, such as solvent buckets, should be used for movement of chemicals.</p> <p>7.12.3.2 The bigger volumes (say multiple bottles of 1 / 2 / 5 liters) should be carried using a steady trolley (stainless steel or HDPE) of suitable capacity. The trolley must have wheel locking provision and compatible secondary containers should be used.</p> <p>7.12.3.3 <i>Only material lifts should be used for chemical movement to the different floors in the building.</i> Use of passenger lift is prohibited.</p> <p>7.12.3.4 The PPEs should be used for the transportation or distribution of chemicals e.g. Safety glass, Safety shoe, Gloves (specific to chemical) and apron.</p> <p>7.12.3.5 Cyanide distribution practice at Syngene Reference(PROCEDURE FOR CYANIDE MANAGEMENT SOP-EHSS-EHSS-0060).</p>			

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<p>7.12.4 Chemical usage and Hygiene Practices:</p> <p>The chemical must be used as per safe work procedure based on the hazard analysis LHA process. The hazard analysis covers the (1) chemical physical & chemical hazards, (2) quantity and concentration of materials (3) process conditions like temperature, pressure, flow etc. and (4) lab equipment involved in the process.</p> <p>The LHA analysis outcome should determine the safe work procedure for chemicals or processes involving chemicals safe handling /use. The chemical handling/use procedure should cover the protection equipment's requirements like fume hoods, glove boxes, spot exhaust etc., PPEs like specific gloves & respirators and safety precautions like quenching, decontamination.</p> <p>Syngene has developed general handling procedures (SOPs) for each category of the Hazardous chemicals e.g. pyrophoric, Cyanide, Peroxides etc. The index for Hazardous chemical procedures / SOPs are provided in FORM-EHSS-EHSS-0450(Annexure-07).</p> <p>7.12.5 Personal Hygiene (Exposure and Contamination):</p> <p>All employees and contractors must follow hygiene practices to minimize the exposures and contaminations.</p> <p>7.12.5.1 No Food and No Drink in the lab, includes "<i>Temple Prasadam</i>".</p> <p>7.12.5.2 Chemicals should never be touched without proper gloves irrespective of hazard of the chemical.</p> <p>7.12.5.3 Wash hands and all areas of exposed skin thoroughly before leaving the laboratory or work area.</p> <p>7.12.5.4 Wash hands and clean up thoroughly before eating, drinking or other activities.</p> <p>7.12.5.5 Do not store food or drink in lab refrigerators and use lab microwave or lab ware for food and drink.</p> <p>7.12.5.6 Remove lab coats and/or uniforms immediately if they become contaminated with any chemicals and do not use the contaminated aprons.</p> <p>7.12.5.7 Never smell or taste the chemicals.</p> <p>7.12.5.8 Do not use mouth suction for pipetting or for start of siphoning.</p> <p>7.12.5.9 Remove gloves that have been exposed to Hazardous chemicals before touching anything not normally exposed to chemicals (e.g. telephones, door knobs, and computers).</p> <p>7.12.5.10 Handle Hazardous chemicals only under fume hood and keep the fume hood sash closed all the time.</p> <p>7.12.5.11 Inspect the gloves every time before use.</p> <p>7.12.5.12 Clean and decontaminate the lab work bench and equipment at the end of the day to minimize contamination and exposure.</p>			

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<p>7.12.5.13 Clean and decontaminate the equipment before realizing to repair and maintenance to minimize chemical exposure to service personal.</p> <p>7.12.5.14 Avoid contact lens and cosmetics.</p> <p>7.12.5.15 Always use PPEs like safety shoe/toe covered shoe, lab apron, gloves and respirator as required for the work.</p> <p>7.13 Engineering Controls – Fume Hoods and Safety Showers:</p> <p>7.13.1 Laboratory Ventilation and Fume Hoods:</p> <p>Laboratory ventilation and fume hoods are a critical engineering control to minimize Hazardous chemical exposure and provide basic protection from explosions and fires in laboratories. The use of ventilation and fume hoods is considered a prudent practice for controlling exposure to chemicals in laboratories and hence its proper functioning is essential. The laboratory ventilation system comprises mainly Two sub-systems:</p> <p>7.13.1.1 Dilution Ventilation system: this system brings clean air to push down air contaminant concentration in the area. This system is suitable where:</p> <ul style="list-style-type: none"> • Quantity of contaminant is low. • Person is not near the emission source. • Toxicity is LOW. • Contaminant generation is uniform. <p>The no. of air changes is 8-12 per hour depending on the nature of lab operations which will meet the ventilation requirement of any accidental spill or release of any fumes or gases (like nitrogen) immediately. The temperature of ~24 deg. C will be maintained. Lab or workplace room ventilation is the example of dilution ventilation.</p> <p>7.13.1.2 Local Exhaust Ventilation (LEV) System: This system is used to remove air contaminants at or near the source of release and away from the breathing zone. This system is suitable where:</p> <ul style="list-style-type: none"> • Quantity of air contaminants are high. • Person/Worker is near the emission source. • Toxicity is HIGH. • Contaminant generation is varying. <p>The air contaminants are removed before they dispersed into the work environment, or before the employee is exposed to harmful contaminants. This system is energy efficient and cost effective. Fume hoods, spot exhaust / elephant trunks, glove box etc. are the examples of local ventilation systems.</p>			

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<p>7.13.2 Fume Hoods:</p> <p>A laboratory fume hood is a ventilated, enclosed workspace designed to contain and exhaust fumes, gases, vapors and particulate matter generated or released within the enclosure. The objectives of chemical laboratory ventilation are:</p> <p>7.13.2.1 To contain and exhaust the chemical fumes, vapors, gasses, dust, mist and aerosol.</p> <p>7.13.2.2 Employee protection against inhalation exposure.</p> <p>7.13.2.3 Physical barrier between chemicals reactions and the laboratory.</p> <p>7.13.2.4 Contain and protect against chemical spills, run-away reactions and fires.</p> <p>7.13.3 Hood and Ventilation System Design and Performance:</p> <p>Fume hoods and lab ventilation performance should be ensured through proper engineering design and periodic evaluation of its performance against design. The design and operation performance measurement of the hood must cover the following:</p> <p>7.13.3.1 In general, a fume hood’s face velocity is recommended to be between <i>0.3 m/s (60 FPM) and 0.5 m/s (100 FPM)</i> as per OSHA guidelines. As per ANSI/AIHA Z9.5 hood face velocity should be between 80 FPM and 120 FPM.</p> <p>7.13.3.2 Fume hood average face velocity <i>must be at least 60 FPM</i> (feet per minute) with sashes at maximum operating opening. Hoods should be <i>provided with alarm for low face velocity</i>.</p> <p>7.13.3.3 Air is exhausted from the hood through adjustable slots in a plenum at the back of the hood. It is important that those slots be adjusted properly to give uniform air flow velocity at the face (the plane of the sash) of the hood. The uniformity must be such that, when reading face velocity in a grid pattern, <i>no individual reading must be lower than 45 FPM</i>.</p> <p>7.13.3.4 Hoods must have a magnehelic gauge or digital FPM instrument to check the face velocity mounted on the hood, with an indicator showing what the differential static pressure is when operating the hood.</p> <p>7.13.3.5 The hood must have the following instrumentation and alarms provisions:</p> <ul style="list-style-type: none"> • Magnehelic gauge or digital FPM instrument with an indicator showing what the differential static pressure when operating the hood. • Low face velocity alarm (<60FPM). • Power failure or ventilation failure alarm (Note: its mandatory to have ventilation failure alarm for Hazardous process). <p>7.13.3.6 Fume hoods should be suitably sited to ensure maximum containment. Locate hoods to avoid crosscurrents at the hood face due to pedestrian traffic, doors and supply air diffusers. Sufficient laboratory supply air must be available to allow hoods to operate at their specified face velocities.</p> <p>7.13.3.7 A fume hood is not designed to contain high velocity releases of particulate contaminants unless the sash is fully closed. The hood is not capable of containing explosions, even</p>			

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<p>when the sash is fully closed. If an explosion hazard exists, the user should provide anchored barriers, shields or enclosures of sufficient strength to deflect or contain it. Such barriers can significantly affect the airflow in the hood.</p> <p>7.13.3.8 A conventional fume hood must not be used for perchloric acid. <i>Perchloric acid</i> vapours can settle on ductwork, resulting in the deposition of perchlorate crystals. <i>Perchlorates</i> can accumulate on surfaces and have been known to detonate on contact, causing serious injury to researchers and maintenance personnel. Specialized perchloric acid hoods, made of stainless steel and equipped with a wash down system must be used for such work.</p> <p>7.13.3.9 Hood and spot exhaust testing should be performed as per OEM / ASHRAE requirements.</p> <ul style="list-style-type: none"> • Typical tests include face velocity measurements, smoke tests and tracer gas containment. Tested required initially after installation and prior to first use. • Additional testing may be necessary if the flow indicator is out of range, after any changes / modifications is done on the hood or blower. • Dry ice test performance can also be performed whenever the equipment configuration in a hood is changed significantly or to ensure proper functioning of hood. The dry ice test should be done during any change or at least once in two years by the lab team. <p>7.13.4 Guidelines for Using a Fume Hood Effectively:</p> <p>The level of protection provided by a fume hood is affected by the manner in which the fume hood is used. No fume hood, however well designed, can provide adequate containment unless good laboratory practices are used and as follow:</p> <p>7.13.4.1 Ensure the exhaust is operating before beginning work. Check the baffles for obstructions and check an airflow monitor for face velocity and it should be within 60 to 100 FPM. Even while working, be alert to changes in airflow.</p> <p>7.13.4.2 When using the fume hood, keep your face outside the plane of the hood. Use the sash for protection during Hazardous work. Work at least 6 inches back from the face of the hood. A stripe on the bench surface is a good reminder.</p> <p>7.13.4.3 When using large apparatus inside the hood, place the equipment on blocks, when safe and practical, to allow air flow beneath it.</p> <p>7.13.4.4 The hood sash should be kept closed, except during apparatus set-up or when working within the hood is necessary. Keep the hood sash closed as much as possible to maximize the hood's performance. Keep the sash closed when not in use to maximize energy conservation.</p> <p>7.13.4.5 If hood performance is suspected, or an airflow alarm is triggered, pause the work and close the sash completely and plan for securing the experiment as appropriate.</p>			

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<p>7.13.4.6 Use appropriate personal protective equipment such as splash goggles and gloves. This enhances safety in case of catastrophic spills, run-away reactions or fire. Wear a full-face shield if there is possibility of an explosion or eruption.</p> <p>7.13.5 Risks Involved with the Improper Use of Fume Hoods:</p> <p>A fume hood is a safety equipment that can be misused to the extent that they can be less effective than expected. Injury/illness from misuse can arise from the causes like:</p> <p>7.13.5.1 Risk of hood sash lowering or not closing during operation of hoods: This will increase risk of employee exposure to Hazardous fumes / vapors due to inadequate air flow that reduces the containment of noxious substances. A secondary purpose is to serve as a protective shield when working with potentially explosive or highly reactive materials.</p> <p>7.13.5.2 Electrical power Outages: In case of a power outage of 15-20 mints, the hood sash should be lowered within an inch to maintain a chimney effect to keep some air flowing into the hood. Secure the experiment and evacuate the place.</p> <p>7.13.5.3 Exhaust block: Care: should be taken with use of tissue paper products, aluminum foil, and other lightweight materials within a hood. For example, a single paper tissue towel or chemical wipe can potentially decrease the airflow into the hood if it restricts exhaust flow.</p> <p>7.13.6 Good Housekeeping Practices in a Laboratory using Fume Hoods:</p> <p>7.13.6.1 Do not use the hood as a waste disposal mechanism. Apparatus used in a hood should be fitted with condensers, traps, or scrubbers to contain and collect waste solvents, toxic vapors or dust.</p> <p>7.13.6.2 Limit chemical storage in fume hoods. Keep the smallest amount of chemicals in the hood needed to conduct the procedure at hand.</p> <p>7.13.6.3 Do not use the hood as a storage area. Items can block airflow and interfere with containment. Store Hazardous chemicals such as flammable liquids in an approved safety cabinet.</p> <p>7.13.6.4 Do not leave uncapped bottles of reagents in a hood. Although a hood is used to exhaust fumes out of the laboratory, minimizing the amount of evaporation and fuming is desirable for the environment and operator safety.</p> <p>7.13.6.5 Always use good housekeeping techniques to maintain the hood at optimal performance levels. Excessive storage of materials or equipment can cause eddy currents or reverse flow resulting in contaminants escaping from the hood.</p> <p>7.13.7 Testing and maintenance of Fume hood:</p> <p>7.13.7.1 Hoods should be evaluated by the user before each use to ensure adequate face velocities and the absence of excessive turbulence (60-100FPM).</p>			

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<p>7.13.7.2 Fume hoods should be certified, at least annually, to ensure they are operating safely. Typical tests include face velocity measurements, smoke tests, tracer gas containment and electromechanical checks. Tracer gas containment tests are especially crucial, as studies have shown that face velocity is not a good predictor of fume hood leakage. This can be achieved through internally (EAM team) or through Annual maintenance contracts.</p> <p>7.13.7.3 Hood and spot exhaust testing should be performed by the EAM/maintenance Team. Face velocities of fume hoods must be tested, and the results clearly posted</p> <ul style="list-style-type: none"> • Fume hoods face velocity checks on monthly basis. • Spot exhaust or local exhaust like elephant truck once in three months (check with respect to design). <p>7.13.7.4 Quarterly fume hood testing and maintenance shall be followed as per EAM SOP, SOP-DQA-DS-EAM-0003 using the check list FORM-DQA-DS-EAM-0007.</p> <p>7.13.8 Misconceptions / myths Associated with Fume Hoods:</p> <p>7.13.8.1 When working with highly Hazardous materials, the higher the face velocity the better.</p> <p>While it is important to have a face velocity between 0.3 m/s (60 fpm) and 0.5 m/s (100 fpm), velocities higher than this are harmful. When face velocity exceeds 0.6 m/s (125 fpm) eddy currents are created which allow contaminants to be drawn out of the hood, increasing worker exposures.</p> <p>7.13.8.2 A chemical hood can be used for storage of volatile, flammable, or odiferous materials when an appropriate storage cabinet is not available.</p> <p>While it is appropriate to keep chemicals that are being used during an experiment inside the chemical hood, hoods are not designed for permanent chemical storage. Each item placed on the work surface interferes with the directional airflow, causing turbulence and eddy currents that allow contaminants to be drawn out of the hood. Flammable materials storage cabinets provide additional protection in the event of a fire and hence fume hoods should not be used for storage.</p> <p>7.13.8.3 The airfoil on the front of a hood is of minor importance. It can safely be removed if it interferes with my experimental apparatus.</p> <p>Air foils are critical to efficient operation of a chemical hood. With the sash open an airfoil smoothest flow over the hood edges. Without an airfoil eddy currents form, causing contaminates to be drawn out of the hood. With the sash closed, the opening beneath the bottom airfoil provides for a source of exhaust air.</p>			

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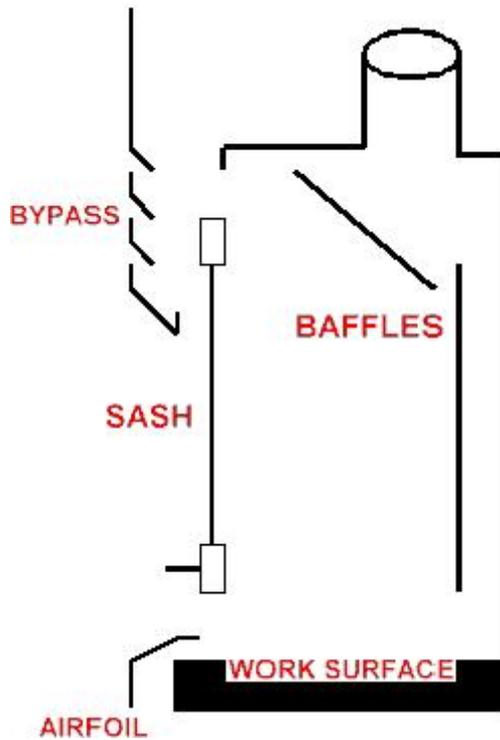


FIGURE - 05

7.13.9 Safety Showers and Eyewash:

Where the eyes or body of any person may be exposed to injurious Corrosive, toxic, high temperature, dust/particulate or flammable Materials, suitable facilities for quick drenching or flushing of the eyes and body must be provided within the work area for immediate emergency use.

Safety showers and eyewash must be *reachable within 50 feet* travel distance from any exposure source and the path of travel must be free of obstructions that may inhibit the immediate use of the equipment.

7.13.10 Safety Showers and Eyewash standard requirements:

Safety body was showers and eye wash fountains must meet the standards like IS and ANSI. The standardized practices for safety showers and eyewash are:

7.13.10.1 Location: The safety showers and eyewash fountains must be installed at every 15 Mts. (Say 50 feet), on the same level (floor) with an unobstructed travel path where Hazardous materials are being handled. Eye wash fountain unit type or drench hose unit

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<p>type <i>eye wash fountains should be installed adjacent to the Hazardous chemical handling area.</i></p> <p>7.13.10.2 Identification: highly visible signs should be provided for ease identification. Safety shower and eye wash and its surrounding area must have good lighting with backup power.</p> <p>7.13.10.3 Water temperature: Water temperature should be between 60-100 deg. F (say ~15 – 38 deg. C).</p> <p>7.13.10.4 Water pressure / quantity – the water pressure should be enough to provide the required quantity of the water continuously.</p> <ul style="list-style-type: none"> • Safety shower - The water volume must be at least 20 Gallons/mins. (76 Lits./mins.) for a minimum of 15 minutes. • Eye and face wash fountains - The water volume must be at least 3 Gallons/mins. (11.4 Lits/mins) for a minimum of 15 minutes. • Eye wash fountains: The water volume must be at least 0.4 Gallons/mins. (1.5 Lits/mins) for a minimum of 15 minutes. <p>7.13.10.5 Water Quality: the water should meet portable water requirements as per IS standards and should be tested for water quality at least annually.</p> <p>7.13.10.6 Inspection and Testing: The inspections and testing must be conducted at least weekly by users and annually by maintenance team.</p> <p>7.13.10.7 Portable eye wash: All portable eye wash should meet the criteria of 0.4 Gallons/mins. (1.5 Lts/mins) for a minimum of 15 minutes. Although plumbed safety showers and eyewashes are preferable to portable units, properly equipped and maintained portable units are acceptable in low hazard or temporary work locations. Any installation of portable safety showers and eyewash units must be approved by SHE personnel.</p> <p>7.13.11 Safety Shower Use:</p> <p>7.13.11.1 Get under the shower as quickly as possible and promptly remove contaminated clothing while showering and call/seek for assistance.</p> <p>7.13.11.2 Remain under the shower until all affected body areas have been thoroughly flushed. This varies with the type of material and exposure. Minimum 15 mins under shower is recommended.</p> <p>7.13.11.3 After showering, do not put on contaminated clothing or footwear, Obtain medical attention from the medical centre.</p> <p>7.13.12 Eyewash Use:</p> <p>7.13.12.1 Time is vital, get your eyes directly into the stream of water. Get your eyes directly into the stream of water.</p> <p>7.13.12.2 If you have contacts, gently remove them while flushing.</p>			

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<p>7.13.12.3 Hold your eyes open with your fingers and gently roll your eyes to ensure complete flushing.</p> <p>7.13.12.4 Flush for minimum 15 minutes and more as necessary and time varies with the type/hazard of material and exposure.</p> <p>7.13.12.5 Seek medical centre help.</p> <p>7.13.13 Safety Shower and Eyewash Inspection and testing: A safety shower and eyewash should be checked and tested to ensure proper functioning and available for ready use during emergencies. The following inspections and tests must be carried out.</p> <p>7.13.13.1 Safety shower and eyewash functional test: This will be the <i>responsibility of line management</i> and must nominate team members to inspect <i>on weekly basis</i> and employees can be engaged on a rotational basis. The inspection and test should include:</p> <ul style="list-style-type: none"> • Shower and eyewash is visible (proper light) and sign board is available. • Check shower and eyewash head is clean. • Valve are functioning properly. • Check for uninterrupted water flow and pressure. • Flushing the water to minimize the contamination <p>Additionally, the eye wash fountains should be checked for:</p> <ul style="list-style-type: none"> • Proper and sufficient pressure of water streams and height. More pressure may damage the eyeball. • Eye wash fountain - between 6 to 8 inches height. Two streams meet approximately the centre line of the unit at this height. • Drench hose type eye wash – between 4 to 10 inches. • Verify spray pattern so that both eyes would be flushed simultaneously. • Check that drench hose is unobstructed (this is specific to drench hose type eye wash). • The checklist for Safety shower and eyewash fountain weekly inspection should be followed as per “Operation and maintenance of emergency eye washer and shower”(SOP-EHSS-EHS-0017) and its annexure “Inspection report of emergency shower/eye washer”(FORM-EHSS-EHSS-0111). The checklist should be used, and results should be recorded. All deficiencies noted during the testing of eye or body wash stations must be reported immediately to the EAM for rectification. All deficient body showers and eye wash should be tagged and communicated to employees working in the area. 			

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<p>7.13.13.2 Safety Showers and eyewash integrity checks: The integrity checks must be carried out by the EAM team on an annual basis to check the overall integrity of the system and performance. FORM-EHSS-EHSS-0451(Annexure – 05) should be used to conduct the annual integrity checks of safety showers and eyewash.</p> <p>7.14 Chemical protective clothing – Gloves:</p> <p>Several Personal Protective Equipment’s (PPEs) must be used during laboratory activities. The safety shoes (or toe covered shoes), apron, safety glass, gloves and respirators are used depending on the hazard associated with Hazardous materials. As a prudent lab practice, most of the time employees working in lab fail to use the right type of gloves due to lack of awareness, too many chemicals handled in lab operations and several gloves in the market without permeability data. The risk of thermal exposure to Hazardous material is very high and hence this section is focused on chemical protection gloves guidance and harmonized practice in selection of gloves across Syngene.</p> <p>7.14.1 Factors should be considered while selecting the chemical gloves:</p> <p>Chemical gloves are made from Chemical protective clothing’s (CPC) and No single chemical protective clothing (CPC) or material of construction can offer adequate protection against all Hazardous chemicals e.g. neoprene, nitrile or PVC etc. Hence the following factors must be considered while selecting the chemical protective gloves:</p> <p>7.14.1.1 Chemical physical and chemical properties.</p> <p>7.14.1.2 Concentration of chemical.</p> <p>7.14.1.3 Nature and severity of the potential exposure.</p> <p>7.14.1.4 How chemical might permeate, penetrate, and degrade the gloves (CPC materials).</p> <p>7.14.1.5 Duration of work / exposure or protection required.</p> <p>7.14.1.6 Thickness of CPC material.</p> <p>7.14.1.7 Length of gloves – small, medium and large.</p> <p>7.14.1.8 One time use or multiple use.</p> <p><i>Gloves come in different thicknesses. Thicker glove provides better chemical resistance and durability than a thinner glove of the same material. Thinner glove provides more dexterity.</i></p> <p>Hazard analysis must be conducted to select the right chemical gloves (LHA) and the lab team must consult Industrial Hygiene experts in EHSS function. <i>No gloves should be purchased without having permeability data of the gloves from manufacturer/supplier.</i> The qualitative based gloves selection is provided in the Table - 03 to improve compliance in gloves selection. Line management and the EHSS team</p>			

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must ensure branded and good permeable rated gloves for Hazardous chemicals are made available.

Table – 03: Qualitative gloves selection guidance

Glove material	Gloves Features
Latex (natural rubber)	<ul style="list-style-type: none"> • <i>Good for biological and water-based materials.</i> • Poor for organic solvents. • Little chemical protection. • Hard to detect puncture holes. • Can cause or trigger latex allergies
Nitrile	<ul style="list-style-type: none"> • Excellent general use glove. <i>Good for solvents</i>, oils, greases, and some low concentration acids and bases. • Clear indication of tears and breaks. • Good alternative for those having latex allergy issues
Neoprene	<ul style="list-style-type: none"> • <i>Good for acids</i>, bases, alcohols, fuels, peroxides, hydrocarbons, and phenols. • Poor for halogenated and aromatic hydrocarbons. • Good for most Hazardous chemicals.
Viton	<ul style="list-style-type: none"> • <i>Good for chlorinated and aromatic solvents.</i> • Good resistance to cuts and abrasions. • Poor for ketones. • Expensive.
Polyvinyl chloride (PVC)	<ul style="list-style-type: none"> • Good for acids, bases, oils, fats, peroxides, and amines. • Good resistance to abrasions. • Poor for most organic solvents.
Polyvinyl alcohol (PVA)	<ul style="list-style-type: none"> • Good for aromatic and chlorinated solvents. • Poor for water-based solutions.
Butyl rubber	<ul style="list-style-type: none"> • Good for ketones and esters. • Poor for gasoline and aliphatic, aromatic, and halogenated hydrocarbons.
Kevlar	<ul style="list-style-type: none"> • Cut-resistant gloves. • Sleeves are also available to provide protection to wrists

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	<p>and forearms.</p> <ul style="list-style-type: none"> • If potential for biological or chemical contamination, wear appropriate disposable gloves on top of your cut-resistant gloves and discard after use. • Cut resistance gloves coated with nitrile or Neoprene can also be used to protect from cuts and chemical hazards
Cryogenic	<ul style="list-style-type: none"> • For use with cryogenic materials. • Designed to prevent frostbite. Note: Never dip gloves directly into liquid nitrogen.

Important Note: Gloves must be inspected before every use. The reusable gloves should be cleaned and stored properly. The damaged gloves should not be used.

7.15 Training:

All employees and contractors having exposure to chemicals through primary or secondary means must be trained initially and annually. The following category of employees, contractors and service providers should be trained and communicated on the chemical hazards:

- 7.15.1 Syngene employee and contractors working inside lab.
- 7.15.2 SS team involved in receipt of chemicals from supplier.
- 7.15.3 OU Tech. team involved in chemical ordering, storage and distribution.
- 7.15.4 EAM team involved in lab equipment and facility service and maintenance.
- 7.15.5 Equipment AMC (annual maintenance contract) agency / contractors.
- 7.15.6 Lab coat laundry service vendor / contractors.

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7.16 Key Performance Indicators:

Following key performance indicators should be monitored by OUs for their area

	Parameters	UOM
Chemical Hazard Procurement	New Hazardous chemical requested by OU	No.
	Hazard assessment conducted for new hazardous chemical	No.
	Review of unknown or under development	No.
Chemical Hazard Communication	GHS Labels for all chemical containers (including water)	No.
	Inventory monitoring – no of expired chemicals available for disposal	No.
Chemical Handling	Deviations while storing chemicals as per zoning practices	No.
	Deviations in Fume hoods/ spot exhaust functional test (PM overdue, less face velocity)	No.
	Deviations in safety showers and eye wash stations functional test (adequate water pressure)	No.
	Availability/Deviations while selection, usage of Gloves	No.
Engineering Controls & Gloves Selection		

8.0 REFERENCES: SOP-EHSS-EHSS-0060
SOP-EHSS-EHSS-0017

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9.0 ANNEXURES:

FORM-EHSS-EHSS-0444	Annexure – 01 LIST OF PROHIBITED AND RESTRICTED CHEMICALS AT SYNGENE
FORM-EHSS-EHSS-0445	Annexure – 02 UNKNOWN / UNDER DEVELOPMENT CHEMICAL HAZARD INFORMATION TEMPLATE
FORM-EHSS-EHSS-0446	Annexure – 03 GUIDANCE FOR PREPARING THE GHS LABELS
FORM-EHSS-EHSS-0447	Annexure – 04 LIST OF PEROXIDES FORMING CHEMICALS
FORM-EHSS-EHSS-0448	Annexure – 05 CHEMICAL ZONING, COMPATIBILITY AND STORAGE SHELF LIFE
FORM-EHSS-EHSS-0449	Annexure – 06 CHEMICAL SECONDARY CONTAINER SELECTION GUIDANCE
FORM-EHSS-EHSS-0450	Annexure – 07 LIST OF HAZARDOUS CHEMICALS PROCEDURE AVAILABLE IN SYNGENE FOR REFERENCE
FORM-EHSS-EHSS-0452	Annexure – 08 KEY PERFORMANCE INDICATORS
FORM-EHSS-EHSS-0453	Annexure – 09 SOP TRAINING QUESTIONNAIRE

10.0 REVISION HISTORY:

Version no.	Effective Date	Description of Change
1.0	30-Dec-2022	<u>Reference Change Control Number: - EHSS/CCF/22/0022</u> Newly introduced procedure

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Title: EMERGENCY PREPAREDNESS AND RESPONSE

Document Number: SOP-EHSS-EHSS-0020	Version Number: 2.0	Effective Date: 26-Apr-2022
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Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Nidhi Cs/EHSS/ SYNGENE	13-Apr-2022 16:08:31 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Vinod Jyothikumar/ EHSS/SYNGENE	13-Apr-2022 16:38:16 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	13-Apr-2022 17:21:29 (IST)

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<p>Document Number: SOP-EHSS-EHSS-0020</p>	<p>Version no.: 2.0</p>	<p>Effective Date: 26-Apr-2022</p>	<p>Next Review Date: 25-Apr-2024</p>
<p>1.0 OBJECTIVE:</p> <p>An emergency plan specifies procedures for handling sudden or unexpected situations. The objective is to be prepared to:</p> <ol style="list-style-type: none"> 1.1 Improve state of preparedness for meeting contingencies. 1.2 Reduce response time in organizing the ERT. 1.3 Identify major resources, manpower, material, and equipment needed to make the ERT operational. 1.4 Clearly define roles and responsibilities. 1.5 Establish clear chain of command. 1.6 Reduce damage to buildings, stock, and equipment. 1.7 Protect the environment and the community. 1.8 Accelerate the resumption of normal operations. 1.9 Protect and rescue of employees from the affected building. <p>2.0 SCOPE:</p> <p>This procedure is applicable to all the areas of Syngene International Limited with regard to environmental impact and occupational health & safety risks arising out of the industrial activities and to develop, conduct, review and ensure corrective action regarding emergency preparedness and response to comply for all applicable regulations. This SOP applies to:</p> <ol style="list-style-type: none"> 2.1 Emergency response planning 2.2 Emergency response training and drills 2.3 Responding to emergencies 2.4 Corrective action and preventive actions (CAPA) of drill observations. <p>This SOP describes the essential features of response to emergencies that are initiated either by an on-site event that affects the Syngene International Ltd site. These emergencies include fire, explosions, toxic and flammable spills or releases, medical, confined space, severe weather, civil disturbances with site potential, flooding, electrical, and other site emergencies.</p> <p>This SOP does not include or apply to transportation emergencies that occur off-site Also, this standard does not include global disasters (e.g., pandemics and large-scale natural calamities).</p> <p>3.0 RESPONSIBILITY:</p> <ol style="list-style-type: none"> 3.1 All employees, contract workers and interested parties shall adhere to this procedure. 3.2 The individual ERT roles and responsibilities are defined in ERCP document. 3.3 Role of Non ERT in general: <ol style="list-style-type: none"> 3.3.1 Initiate shutdown procedure (bring your activities to safe level) as per your standard procedure. 3.3.2 Switch off all the heating apparatus. 			

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3.3.3 Do's and Don'ts in general:

Do's:	Don'ts
In case, you notice fire or any emergency : pull MCP and raise alarm.	Do not panic.
Use only Emergency door / staircase for evacuation.	Do not use lift during evacuation.
Assemble in the assembly point with calm & brisk walking.	Need not de-gown inside the lab.
Need to assemble at designated assemble point.	Do not assemble other designated assembly point.
Assist people with special needs.	Do not enter the incident spot if you are not an ERT member.
Coordinate for head count.	Taking photos and videos not allowed.
Enter the building once emergency all clear.	Do not swipe access card while exit and entering back after all clear

3.3.4 Role of observer in case of any abnormalities observed:

List of abnormalities	Action required
1. Pressure buildup: <ul style="list-style-type: none"> • More than process expected pressure • Rate of raise in pressure (rapid) • Activation of emergency safety relief system (Rupture disc, Pressure relief valves, Pressure safety valves) 2. Temperature : <ul style="list-style-type: none"> • More than process expected temperature • Rate of raise in temperature (rapid) 3. Leakage/rupture of process and utility pipelines 4. Spark/smoke/fire 5. Chemicals spillage Leakage/release of any gases (fumes, vapours and any types of gases) 6. Activation of local fixed sensors (Lower Explosive Limit (LEL), Oxygen (O2), Hydrogen (H2), Carbon monoxide)	1. Activate the manual call point and evacuate the building by using the nearest emergency exit 2. Process operators close the addition valve, 3. Press the reactor emergency puss button 4. Evacuate the building by using the nearest emergency exit

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<p>(CO), etc).</p>			
<p>4.0 ABBREVIATIONS:</p> <p>BC : Building Controller BERT : Building ERT CAPA: : Corrective action and preventive action ECC : Emergency Control Centre EHSS : Environment Health Safety and Sustainability EMR : Emergency EMS : Emergency management system ERT : Emergency response team ERCP : Emergency response and contingency planning HCC : Head count coordinator HOD : Head of the Department IC : Incident Controller NFPA : National Fire Protection Association RBTM : Role based training matrix. RD: Rapture disc SC : Site Controller SERT : Site ERT SOP : Standard operating procedure</p> <p>5.0 DEFINITIONS:</p> <p>5.1 Assembly point: The designated and properly identified point that evacuees from a building or area go to and are accounted for; this is also called an “Assembly Area”.</p> <p>5.2 Building Controller (BC): A person responsible for overall control measures, rescue operation and mitigation of emergency at respective building and get additional resources required for emergency mitigation from Site ERT, Site Controller and external support as needed.</p> <p>5.3 Building ERT (BERT): A building level team responsible to act on emergency mitigation as instructed by IC/ BC inside the effected building</p> <p>5.4 Confined space: A space or location that meets all three of the following characteristics:</p> <p>5.4.1 It is large enough to allow full-body entry. 5.4.2 It has a restricted means of entry and exit. 5.4.3 It is not designed for continuous human occupancy.</p> <p>5.5 Dangerous goods: Articles or materials capable of posing significant risk to people, health, property, or the environment. Dangerous goods include items of common use, such as</p>			

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<p>radioactive, flammable, explosive, or corrosive oxidizers or asphyxiants; biohazardous, toxic, pathogenic, or allergenic substances and organisms; Level 2 and 3 aerosols; and flammable and combustible liquid-based paints. This term is like “hazardous substances.”</p> <p>5.6 Drill: An exercise involving a simulated emergency that includes personnel performing emergency response operations for the purpose of evaluating the effectiveness of the training, the education programs, and the competence of personnel in performing response duties and functions as defined in the site emergency response and contingency plan (ERCP).</p> <p>5.7 Emergency: Event / incident happens unexpectedly and represents a clear threat or risk of damage to people, environment, reputation, or assets linked to the company.</p> <p>5.8 Emergency Response and Contingency Plan (ERCP): A written document that describes what physical action might be taken at the scene of the incident to limit the consequences.</p> <p>5.9 Emergency Response Team (ERT): An organized group of Syngene International Ltd employees and contractor employees at a facility who are knowledgeable, trained, and skilled in responding to emergencies as described in the site ERCP. This response can include, but is not limited to, fire, medical, confined space rescue, high angle rescue, and dangerous goods response. SERT and BERT form ERT organization.</p> <p>5.10 First observer: The first person who observes the situation that poses an immediate risk to health, life, property, or environment</p> <p>5.11 Non ERT: An organized group of Syngene International Ltd employees and contractor employees at a facility who are not in Emergency response team (ERT).</p> <p>5.12 Incident controller (IC): The individual at the scene of the incident who implements the strategies and tactics to achieve the goals set by the building controller. This individual report to the building controller.</p> <p>5.13 Silent hours: The time during the period beyond A, B and general shift hours on working days and on all holidays including Sundays.</p> <p>5.14 Site ERT (SERT): A Site level team responsible to act on emergency mitigation as instructed by IC/BC, (For Biocon Park this team is located at S14, manufacturing facility and working 24x7 and readily available to respond emergencies for any Syngene buildings).</p> <p>5.15 Site Controller: A person who has ultimate control over the affairs of the organization during emergencies inside the premises.</p> <p>5.16 Site: The location of a complex or facility that includes all property within the property lines or lease limits of the company (e.g., all or any portion of buildings, structures, facility improvements, elements, and pedestrian or vehicular routes located at a facility).</p> <p>5.17 Training: The process of achieving proficiency through instruction in a classroom, by electronic media, or hands-on practice in the operation of equipment and systems that are expected to be used in the performance of assigned response duties.</p> <p>6.0 PROCEDURE:</p>			

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<p>6.1 This SOP describing appropriate personnel response in the event of an emergency and address the hazardous events specific to that site, including, but not limited to, those listed in this procedure.</p> <p>6.2 This SOP describes activity being carried out for strengthening the emergency preparedness and response as follows;</p> <p>6.2.1 Selection of Emergency Response Team members: The members of the building and site ERT shall be selected as per ERT SELECTION CRITERIA guidelines: GUI-EHSS-EHSS-0006.</p> <p>6.3 ERT battle plan:</p> <p>6.3.1 This section contains information for organizing and conducting building and site level battle plan before starting of shifts (Shift A, B, C, and General shift).</p> <p>6.3.2 The purpose of battle plan is to timely respond to any emergency and mitigate incidents to minimize adverse effect to life, property, and the environment. In battle plan shall be discussed.</p> <p>6.4 At Building level (Building ERT):</p> <p>6.4.1 Every day, before starting of each shift, all ERT members must meet at ground floor (building emergency control center) for 5 - 10 minutes.</p> <p>6.4.2 Confirm on ERT strength (ERT headcount) at present in the building.</p> <p>6.4.3 This meeting shall be led by Building Controller / ERT lead of the building.</p> <p>6.4.4 The team discuss on the clarity on role to be performed in case there is activation of building alarm/emergency.</p> <p>6.4.5 Members are expected to have clarity who is Building controller, Incident Controller, Fire fighter, Rescuer, First aider, Head counter and Utility coordinator.</p> <p>6.4.6 In addition, any update from the previous shift related to Building alarm / Emergency equipment impairment, any support required from EHSS / EAM for upkeep of emergency infrastructure.</p> <p>6.4.7 Get acquaintance to escalate for activation of Site ERT for the required support (including silent hours).</p> <p>6.5 At Site Level (Site ERT (S14): In addition, all the above mentioned at building battle plan points at the building level, include in-house fire tender driver (Aerial ladder platform vehicle) as part of battle plan.</p> <p>6.5.1 The details of discussion shall be recorded as per below table:</p>			

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ERT BATTLE PLAN							
Date:		Shift name (✓):		A	B	C	G
Building Controller for the day:						Alternative building controller for the day:	
EMERGENCY RESPONSE TEAM BATTLE TRACKING PLAN							
S. No.	Points discussed in ERT Battle Plan	Total number of ERT present for the shift	ERT Lead for the shift (during silent hours)	Incident Controller for the shift	Utility coordinator for the shift		
Signature of BC/IC/ERT Lead							

6.6 Trainings to Non ERT, visitors and contract workers.

- 6.6.1 All new joiner shall be trained before onboarding (New joiners’ induction).
- 6.6.2 Non ERT members Do’s and Don’ts in general trained yearly once as mentioned in point 3.3.3
- 6.6.3 Role of observer in case of any abnormalities observed yearly once as mentioned in point 3.3.4
- 6.6.4 Visitors are trained by showing video on site safety rule including ERP at security gate before issuing visitor pass.
- 6.6.5 Contract workers are training as part contractor safety induction.
- 6.6.6 Role based and credible scenario specific training to BERT, SERT and Site EMS team as per ERCP documents.
- 6.6.7 The members of the building and site ERT shall be trained as per ERT SELECTION CRITERIA guidelines: GUI-EHSS-EHSS-0006 FORM-EHSS-EHSS-0102 ANNEXURE - 01 and FORM-EHSS-EHSS-0103 ANNEXURE - 02.
- 6.6.8 Site EMS team trained by conducting tabletop exercise by yearly once.
- 6.6.9 Credible emergency scenario preparation for each operational unit and enable functions: Preparation of possible credible emergency scenario refer ERCP standard document.
- 6.6.10 Conduct the emergency Mock drill as per the planner FORM-EHSS-EHSS-0140 ANNEXURE -01 and
- 6.6.11 Mock drill shall be conducted considering all shifts and buildings of the site shall participate in a mock drill.
- 6.6.12 Emergency mock drills shall be conducted by selecting scenario from credible emergency scenario document from ERCP.
- 6.6.13 The result of mock drill shall be recorded as per FORM-EHSS-EHSS-0359 ANNEXURE - 02 (Mock drill report).

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<p>6.6.14 Observations of mock drill shall be recorded as per FORM-EHSS-EHSS-0138 ANNEXURE - 03. (Emergency Mock drill observations and Corrective actions form). Note: If ERT and Non ERT members score is <85% as per FORM-EHSS-EHSS-0359 ANNEXURE - 02, then emergency mock drill shall be repeated within same planned week.</p> <p>6.6.15 Emergency assembly point area: All Syngene buildings at Biocon park are divided into seven clusters of assembly point area (Refer FORM-EHSS-EHSS-0360 ANNEXURE - 04) to assemble employees in case of any emergency building alarm activated.</p> <p>6.6.16 Emergency Telephone Numbers:</p> <p style="margin-left: 40px;">Syngene Emergency Contact Number : 4001 S12 Emergency Contact Number : 4400</p>			
7.0 ANNEXURES:			
FORM-EHSS-EHSS-0140	ANNEXURE – 01	MOCK DRILL ANNUAL PLANNER	
FORM-EHSS-EHSS-0359	ANNEXURE – 02	MOCK DRILL REPORT	
FORM-EHSS-EHSS-0138	ANNEXURE - 03	EMERGENCY MOCK DRILL OBSERVATIONS AND CORRECTIVE ACTION FORM	
FORM-EHSS-EHSS-0360	ANNEXURE - 04	BIOCON PARK CLUSTER WISE ASSEMBLY POINT AREA	
FORM-EHSS-EHSS-0141	ANNEXURE - 05	SOP TRAINING QUESTIONNAIRE	
8.0 REFERENCES :			
<p>Syngene Emergency response contingency plan (ERCP) document. ERT SELECTION CRITERIA guidelines: GUI-EHSS-EHSS-0006</p>			
9.0 REVISION HISTORY:			
Version no.	Effective Date	Description of Change	
2.0	26-Apr-2022	<p><u>Reference Change Control Number: - EHSS/CCF/22/0002</u></p> <p>1. Included building in Mock drill annual planner 2. FORM-EHSS-EHSS-0359 ANNEXURE - 02 has been included 3. FORM-EHSS-EHSS-0138 ANNEXURE – 03 has been revised 4. FORM-EHSS-EHSS-0360 ANNEXURE – 04 has been included</p>	

	<p align="center">Standard Operating Procedure</p>	<p>DEPARTMENT: Environmental Health Safety and Sustainability</p>	
<p>TITLE:EMERGENCY PREPAREDNESS AND RESPONSE</p>			
<p>Document Number: SOP-EHSS-EHSS-0020</p>	<p>Version no.: 2.0</p>	<p>Effective Date: 26-Apr-2022</p>	<p>Next Review Date: 25-Apr-2024</p>
<p>1.0</p>	<p>06-Oct-2021</p>	<p><u>Reference Change Control Number: - EHSS/CCF/20/0022</u> As part of transition from manual to Electronic document management system SOP-EHSS-EHSS-0020 EMERGENCY PREPAREDNESS AND RESPONSE has been revised</p>	

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	Standard Operating Procedure	Department: Environmental Health Safety and Sustainability
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Title: HAZARDOUS MATERIALS MANAGEMENT

Document Number:
SOP-EHSS-EHSS-0009

Version Number:
2.0

Effective Date:
16-Feb-2023

Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Nidhi Cs/EHSS/ SYNGENE	11-Feb-2023 11:24:01 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Satish Birajdar/EHSS/ SYNGENE	13-Feb-2023 10:55:35 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	13-Feb-2023 15:44:48 (IST)

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	<p align="center">Standard Operating Procedure</p>	<p>DEPARTMENT: Environmental Health Safety and Sustainability</p>	
<p>TITLE:HAZARDOUS MATERIALS MANAGEMENT</p>			
<p>Document Number: SOP-EHSS-EHSS-0009</p>	<p>Version no.: 2.0</p>	<p>Effective Date: 16-Feb-2023</p>	<p>Next Review Date: 15-Feb-2025</p>
<p>1.0 OBJECTIVE: To have a documented procedure for Hazardous Materials Management which includes toxic chemicals, flammable materials, explosives, radioactive substances, biological, controlled substances and wastes associated with it.</p> <p>2.0 SCOPE: The scope of the procedure covers all areas of Syngene International Limited.</p> <p>3.0 RESPONSIBILITY:</p> <p>3.1 Supply Chain and Stores: To ensure proper procurement, storage and dispatch of materials.</p> <p>3.2 User departments: To ensure proper handling, storage, transportation and removal of all hazardous materials and wastes associated with it.</p> <p>3.3 Environment, Health, Safety and Sustainability department personnel:</p> <p>3.3.1 To develop Hazardous Materials Management Program.</p> <p>3.3.2 To conduct inspections in compliance with the procedure.</p> <p>4.0 ABBREVIATION:</p> <p>EHSS : Environment, Health, Safety and Sustainability Kg : kilogram LD : Lethal Dose LC : Lethal Concentration l : liter mg : milligram PPE : Personal Protective Equipment</p> <p>5.0 DEFINITION: NA</p> <p>6.0 EHSS: NA</p> <p>7.0 PROCEDURE: All hazardous material and waste shall be managed as per the relevant national and state laws.</p> <p>7.1 Procurement of hazardous chemicals:</p> <p>7.1.1 Users: In order to procure any chemicals, the user department should review the list of chemicals as provided in the list available [Refer: The Major Accident Hazards Control (Karnataka) Rules, 1994, Schedule 1 part II]. If not, users have to coordinate with the</p>			

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Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability																	
TITLE:HAZARDOUS MATERIALS MANAGEMENT																			
Document Number: SOP-EHSS-EHSS-0009	Version no.: 2.0	Effective Date: 16-Feb-2023	Next Review Date: 15-Feb-2025																
<p>Purchase as well as EHSS department to verify if the chemical requested comes under the purview of the following acts / rules (prevalent at the time).</p> <p>7.1.2 EHSS:</p> <p>7.1.2.1 EHSS/Supply Chain shall audit the vendor/supplier as per FORM-EHSS-EHSS-0198(Annexure-02).</p> <p>7.1.2.2 Ensure that relevant hazards are identified, and adequate steps for prevention and control of hazards are suggested.</p> <p>7.1.2.3 Provide information, training, equipment including antidotes information to personnel on handling hazardous materials.</p> <p>7.1.3 Supply Chain and stores:</p> <p>7.1.3.1 Records of the hazardous chemicals imported should be available for inspection.</p> <p>7.1.3.2 Relevant information for chemicals which are imported, (Name and address of the person receiving the consignment in India, port of entry in India, mode of transport from the exporting country to India, quantity of chemical(s) imported and complete product safety information) should be obtained at the time of import.</p> <p>7.2 Classifications of hazardous Chemicals:</p> <p>7.2.1 Toxic Chemicals:</p> <p>Chemicals having the following values of acute toxicity and which, owing to their physical and chemical properties, are capable of producing major accidents/hazards.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>S.No</th> <th>Degree of Toxicity</th> <th>Medium lethal dose by the oral route (oral toxicity) LD50 (mg/kg) body weight of test animals</th> <th>Medium lethal dose by the dermal route (dermal toxicity) LD 50 (mg/kg) body weight of test animals</th> <th>Medium lethal concentration by inhalation route (four hours) LC 50 (mg/l) inhalation on test animals</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Extremely toxic</td> <td>1 - 50</td> <td>1 - 200</td> <td>0.1 - 0.5</td> </tr> <tr> <td>2</td> <td>Highly toxic</td> <td>51 - 500</td> <td>201 - 2000</td> <td>0.5 - 2.0</td> </tr> </tbody> </table> <p>7.2.2 Flammable chemicals:</p> <p>7.2.2.1 Flammable gases: Chemicals which are in the gaseous state at normal pressure when mixed with air become flammable and the boiling point of which at normal pressure is 20°C or below.</p>					S.No	Degree of Toxicity	Medium lethal dose by the oral route (oral toxicity) LD50 (mg/kg) body weight of test animals	Medium lethal dose by the dermal route (dermal toxicity) LD 50 (mg/kg) body weight of test animals	Medium lethal concentration by inhalation route (four hours) LC 50 (mg/l) inhalation on test animals	1	Extremely toxic	1 - 50	1 - 200	0.1 - 0.5	2	Highly toxic	51 - 500	201 - 2000	0.5 - 2.0
S.No	Degree of Toxicity	Medium lethal dose by the oral route (oral toxicity) LD50 (mg/kg) body weight of test animals	Medium lethal dose by the dermal route (dermal toxicity) LD 50 (mg/kg) body weight of test animals	Medium lethal concentration by inhalation route (four hours) LC 50 (mg/l) inhalation on test animals															
1	Extremely toxic	1 - 50	1 - 200	0.1 - 0.5															
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	<p align="center">Standard Operating Procedure</p>	<p>DEPARTMENT: Environmental Health Safety and Sustainability</p>	
<p>TITLE:HAZARDOUS MATERIALS MANAGEMENT</p>			
<p>Document Number: SOP-EHSS-EHSS-0009</p>	<p>Version no.: 2.0</p>	<p>Effective Date: 16-Feb-2023</p>	<p>Next Review Date: 15-Feb-2025</p>
<p>7.2.2.2 Flammable liquids: Chemicals which have a flash point lower than 65°C- and which remain liquids under pressure, where particular processing conditions, such as high pressure and high temperature, may create major accident hazards. Highly flammable liquids are chemicals which have a flash point lower than 23°C and the boiling point of which at normal pressure is above 20°C.</p> <p>7.2.3 Explosives: Chemicals which may explode under the effect of flame, heat or photo-chemical conditions or which are more sensitive to shocks or friction than dinitrobenzene.</p> <p>7.2.4 Radioactive substances/materials: Substances or materials which spontaneously emits radiation in excess of the levels.</p> <p>7.2.5 Biologicals: Any preparation made from organisms or microorganisms or product of metabolism and bio- chemical reactions intended for use in the diagnosis, immunization or the treatment of human being or animals or in research activities.</p> <p>7.2.6 Controlled substances: A controlled substance is generally a drug or chemical whose manufacture, possession, or use is regulated by a government, such as illicitly used drugs or prescription medications that are designated a controlled drug.</p> <p>7.3 Storage of hazardous materials:</p> <p>7.3.1 Storage considerations may include temperature, ignition control, ventilation, chemical compatibility, segregation and identification.</p> <p>7.3.2 Proper segregation is necessary to prevent incompatible materials from inadvertently coming into contact.</p> <p>7.3.3 If incompatible materials come into contact, it may lead to fire, explosion, violent reactions or release of toxic gases.</p> <p>7.3.4 General storage practices for chemicals:</p> <p>7.3.4.1 Store chemicals in designated areas only.</p> <p>7.3.4.2 Ensure all containers are appropriately labeled.</p> <p>7.3.4.3 Check for damaged labels, outdated chemicals, damaged containers and peroxide forming compounds.</p> <p>7.3.4.4 Store all the chemicals below shoulder/eye level, if in case the chemical are sought to store above shoulder/eye level, ensure appropriate ladder and/or material handling equipment, recommended PPEs and administrative control in place</p> <p>7.3.4.5 Do NOT store incompatible chemicals in a common cabinet (e.g., corrosives with solvents, acids with bases, oxidizing agents with organic compounds such as sulfuric acid with acetic acid).</p>			

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<p>7.3.4.6 Flammable chemicals should be stored in appropriate areas within the laboratory and away from any potentially incompatible materials.</p> <p>7.3.4.7 All sources of ignition (e.g., hot plates, oil bath and electrical equipment) should be eliminated from areas in which flammable or combustible chemicals are used.</p> <p>7.3.4.8 Use adequate ventilation and scrubbing system while transferring hazardous chemicals.</p> <p>7.3.4.9 Keep containers of flammable chemicals closed at all times when not in use.</p> <p>7.3.4.10 Store corrosives in secondary trays so as to keep any spills contained.</p> <p>7.3.4.11 Inspect periodically for damaged containers.</p> <p>7.3.5 Storage practices for radioactive materials and biologicals:</p> <p>7.3.5.1 Radioactive materials to be handled should follow the norms of the regulatory authorities.</p> <p>7.3.5.2 Proper protection like lead shield, lead apron to be used while handling radioactive materials</p> <p>7.3.5.3 All biologicals/ biological samples should be stored as per the required storage conditions which may not change its efficacy.</p> <p>7.3.5.4 Proper ventilation should be used to prevent contamination of the materials and human exposure.</p> <p>7.3.6 Controlled Substances:</p> <p>7.3.6.1 In conducting research with controlled substances, personnel have to contact EHSS department for guidance in handling the same.</p> <p>7.3.6.2 Personnel should comply with rules and regulations regarding their uses, including relevant permissions/registrations/approvals, storage requirements, inventory maintenance and substance disposal.</p> <p>7.4 Transportation of Chemicals:</p> <p>7.4.1 Transporting chemicals in personal vehicles is restricted.</p> <p>7.4.2 Material lifts should be used for transfer of chemicals.</p> <p>7.4.3 Unbreakable secondary containers should be used to transfer chemicals.</p> <p>7.4.4 Do not transport incompatible chemicals in the same secondary containment.</p> <p>7.4.5 During transportation of chemicals, appropriate personal protective equipment (Safety glasses, lab coat or other appropriate lab attire and safety shoes) should be worn</p> <p>7.4.6 Appropriate gloves shall be kept in the vehicle for protection of transporter in case of a spill during transit.</p> <p>7.4.7 Spills should not be left unattended.</p> <p>7.4.8 Do not attempt to clean up any spill if the following conditions apply:</p> <p>7.4.8.1 More than one chemical has spilled.</p> <p>7.4.8.2 If quantity spilled is more than the available absorbent provided.</p> <p>7.4.8.3 If the chemical is classified as a toxic/poison.</p>			

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<p>Document Number: SOP-EHSS-EHSS-0009</p>	<p>Version no.: 2.0</p>	<p>Effective Date: 16-Feb-2023</p>	<p>Next Review Date: 15-Feb-2025</p>
<p>7.4.8.4 If the chemical is highly flammable or explosive.</p> <p>7.4.8.5 The substance is unknown or you are uncertain of the hazards of the substance.</p> <p>7.4.8.6 A secondary emergency situation exists (e.g., fire).</p> <p>7.5 Hazardous Waste Disposal: Waste generated should be stored in appropriately labeled containers with secondary containment and disposed off properly. (Refer: SOP-EHSS-EHSS-0073, Waste Management).</p> <p>7.5.1 Labeling:</p> <p>7.5.1.1 All hazardous waste containers shall be properly labelled to indicate the type of material contained in the container.</p> <p>7.5.1.2 If bottles are reused, remove the old chemical name and hazards completely and indicate the type of chemical waste on the container.</p> <p>7.5.2 Packaging: All hazardous waste shall be packaged in accordance to the following:</p> <p>7.5.2.1 Use a leak-proof container that will safely contain the contents. Chemical flasks, plastic bags or culture dishes shall not be accepted.</p> <p>7.5.2.2 The container shall not be overfilled with liquid waste. Empty space of at least five percent of the container volume shall be left to allow for thermal expansion.</p> <p>7.5.3 Empty Chemical Containers:</p> <p>7.5.3.1 For volatile organic solvents (e.g., acetone, ethanol, ethyl acetate, ethyl ether, hexane, methanol, methylene chloride, petroleum ether, toluene, xylene), the emptied container can be air-dried in a ventilated area (e.g., a chemical fume hood) without triple rinsing.</p> <p>7.5.3.2 If the material is known to have high acute toxicity, the washings shall be collected and disposed off as hazardous. In many circumstances it may advisable to dispose off the empty chemical container as waste rather than triple rinsing the container.</p> <p>Note: It is improper to dispose off volatile liquids by evaporating.</p> <p>7.5.4 Glass Wares:</p> <p>7.5.4.1 Broken laboratory glassware free from any bio hazardous, radioactive and chemical contamination shall be disposed of by packing in designated broken glass receptacle, cardboard box, or other rigid container.</p> <p>7.5.4.2 This includes the disposal of the following uncontaminated items:</p> <p>7.5.4.3 Broken glass</p> <p>7.5.4.4 Pasteur pipettes</p> <p>7.5.4.5 Glass slides</p> <p>7.5.4.6 Glass vials</p>			

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<p>7.5.4.7 To minimize various potential hazards when discarding broken or unserviceable glassware, the following procedures to be followed:</p> <p>7.5.4.8 Dispose broken laboratory glassware in designated broken glass containers only. These shall be puncture proof, double-lined cardboard box. When the box is full, securely seal with tape to prevent any leaks.</p> <p>7.5.4.9 Label the container as ‘Glassware waste’.</p> <p>7.5.4.10 Never use broken glassware boxes for the disposal of sharps, medical/bio hazardous materials or liquid wastes.</p> <p>7.5.4.11 All personnel handling broken glass containers shall:</p> <p>7.5.4.12 Check the weight and integrity of the container prior to lifting.</p> <p>7.5.4.13 Wear safety glasses and cut resistant gloves when handling the container.</p> <p>7.5.4.14 Do not remove the box if you see a red or orange liner.</p> <p>7.5.4.15 Do not remove the box if open, compromised, wet or suspected of containing chemicals.</p> <p>7.5.4.16 Immediately contact your supervisor if any issues.</p> <p>7.5.5 Metal Containers:</p> <p>7.5.5.1 Metal containers must be triple rinsed with water or other suitable solvent and air-dried. If the container is free of hazardous chemical residues, it may be placed in the regular laboratory trash.</p> <p>7.5.5.2 Secondary Containers that were used as a covering for the primary chemical container may be placed in regular trash or recyclable trash.</p> <p>7.5.5.3 Any packing materials, such as perlite, clay, Styrofoam, etc., may be placed in the regular waste unless it was contaminated with the chemical as a result of container breakage or leak.</p> <p>7.5.5.4 Packing materials contaminated with hazardous materials shall be disposed of as hazardous waste.</p> <p>7.5.5.5 Biomedical waste should be handled as per Bio Medical Wastes (Management and Handling) Rules prevalent at that time.</p> <p>7.6 Handling Compressed Gas Cylinders: Handling compressed gas cylinders shall be in accordance with Procedure for Handling and Storage of Compressed Gas Cylinder (Refer SOP: SOP-EHSS-EHSS-0045).</p> <p>7.7 Spill Control: All spills shall be cleaned up in accordance with Procedure for Operation and Maintenance of Spill Control Kit (Refer SOP: SOP-EHSS-EHSS-0029).</p> <p>7.8 Dissemination of information:</p> <p>7.8.1 Material Safety Data Sheets should be available for chemicals used.</p>			

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<p>7.8.2 Every container of hazardous chemicals should be clearly labeled (tagged or based on the size of the container, accompanying documents) or marked to identify: contents, name and address of manufacturer or importer of hazardous chemical, physical, chemical and toxicological data.</p>			
<p>7.8.3 Chemicals transferred to other containers (including glassware’s viz. conical flasks and so on) should be labeled appropriately.</p>			
<p>7.9 Emergency plan: An on-site emergency plan available with details related to handling major accidents. It also includes name of the person responsible for safety and those who are authorized to take action in accordance with the plan in case of an emergency. The plan should be updated as and when there are new industrial activity identified (prior to the activity being commenced).</p>			
<p>8.0 REFERENCES: SOP-EHSS-EHSS-0073 SOP-EHSS-EHSS-0029 SOP-EHSS-EHSS-0045</p>			
<p>9.0 ANNEXURES:</p>			
<p>FORM-EHSS-EHSS-0197</p>	<p>Annexure – 01 SOP Training Questionnaire</p>		
<p>FORM-EHSS-EHSS-0198</p>	<p>Annexure – 02 Vendor Evaluation Form</p>		
<p>10.0 REVISION HISTORY:</p>			
<p>Version no.</p>	<p>Effective Date</p>	<p>Description of Change</p>	
<p>2.0</p>	<p>16-Feb-2023</p>	<p><u>Reference Change Control Number: - EHSS/CCF/23/0004</u></p>	
<p>1.0</p>	<p>05-Apr-2021</p>	<p><u>Reference Change Control Number: - EHSS/CCF/20/0022</u></p>	

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	Standard Operating Procedure	Department: Environmental Health Safety and Sustainability
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Title: HAZARD IDENTIFICATION AND RISK ASSESSMENT

Document Number: SOP-EHSS-EHSS-0022	Version Number: 2.0	Effective Date: 16-Feb-2023
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Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Nidhi Cs/EHSS/ SYNGENE	11-Feb-2023 11:20:17 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Satish Birajdar/EHSS/ SYNGENE	13-Feb-2023 10:58:21 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	13-Feb-2023 15:53:38 (IST)

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	<p align="center">Standard Operating Procedure</p>	<p>DEPARTMENT: Environmental Health Safety and Sustainability</p>	
<p>TITLE:HAZARD IDENTIFICATION AND RISK ASSESSMENT</p>			
<p>Document Number: SOP-EHSS-EHSS-0022</p>	<p>Version no.: 2.0</p>	<p>Effective Date: 16-Feb-2023</p>	<p>Next Review Date: 15-Feb-2025</p>
<p>1.0 OBJECTIVE: To have a documented procedure for ongoing hazard identification, risk assessment, determination and implement of necessary control measures.</p> <p>2.0 SCOPE: This procedure is applicable to Syngene International Limited which covers the following:</p> <ul style="list-style-type: none"> • Procedure for identifying occupational health and safety hazard and risk assessment. • Mechanism for review and evaluation of occupational health and safety risks. • Periodic review or review as and when there is a change in the process / activity, or when a new process / activity is added or planned. <p>3.0 RESPONSIBILITY:</p> <p>3.1 EHSS core team:</p> <p>3.1.1 To guide personnel during hazard identification and risk assessment.</p> <p>3.1.2 To co-ordinate between EHSS Head, Management Appointee and respective Department Heads and ensure the identification of hazard identification and risk assessment is periodically reviewed.</p> <p>3.1.3 Review of HIRA records once in 6 months and if any changes in work practices/addition of new activity/major incident pertaining to any activity etc. to be revised prior to review period.</p> <p>3.2 Head of the Department:</p> <p>3.2.1 To ensure that all hazards and corresponding unacceptable risks have been identified and sufficiently addressed.</p> <p>3.2.2 To take up Objectives and Targets, Management Programme(s) for unacceptable risks having severe consequence to minimize significance.</p> <p>3.2.3 To approve the HIRA for the department.</p> <p>3.3 Management Appointee: To ensure the Hazard Identification and Risk Assessment is reviewed in the management review meetings.</p> <p>3.4 EHSS Department:</p> <p>3.4.1 Authorized personnel from EHSS shall be responsible to check the HIRA of all the departments.</p> <p>3.4.2 To coordinate with departments during HIRA assessment.</p>			

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<p>4.0 ABBREVIATION: Admin.: Administrative BC : Business Concern OU : Operating Unit EC : Engineering Controls EHSS : Environment, Health, Safety and Sustainability Engg. : Engineering Ex : Example HIRA : Hazard Identification and Risk Assessment IPC : Interested Party Concern IPN : Impact Priority Number LC : Legal Concern LOC : Level of Control MI : Major Incident MP : Management Appointee OCP : Operational Control Procedure RPN : Risk Priority Number SOP : Standard Operating Procedure WS : Worksheet</p> <p>5.0 DEFINITION:</p> <p>5.1 Environment: Surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelation.</p> <p>5.2 Environmental aspect: Element of an organization's activities, products or services that can interact with the environment.</p> <p>5.3 Significant environmental aspect: An environmental aspect that has or can have significant environmental impact.</p> <p>5.4 Environmental impact: Any change to the environment whether adverse or beneficial, completely or partially resulting from an organization's activities, products or services.</p> <p>5.5 Hazard: Source or situation where a potential for harm in terms of injury or ill health.</p> <p>5.6 Hazard Identification: Process of recognizing that a hazard exists and defining its characteristics.</p> <p>5.7 Risk: Combination of the likelihood and consequences of a specified hazardous event occurring.</p> <p>5.8 OHS Risks: Risks pertaining to Occupational Health and Safety at Workplace</p> <p>5.9 Risk Assessment: Overall process of estimating the magnitude of risk and deciding whether or not the risk is acceptable.</p>			

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<p>Document Number: SOP-EHSS-EHSS-0022</p>	<p>Version no.: 2.0</p>	<p>Effective Date: 16-Feb-2023</p>	<p>Next Review Date: 15-Feb-2025</p>
<p>5.10 Interested Party: <i>(defined internally)</i>: Comprises of employees, investors, customers, general public, non-government organizations, regulatory authorities and local community</p> <p>5.11 Acceptable Risk: Risk that can be reduced to a level that can be tolerated by the organization having regard to its legal obligations and its own Occupational, Health & Safety policy.</p> <p>5.12 First aid injury: First aid injury is the one in which the person is administered only the first aid and does not have any significant loss time beyond the period of treatment.</p> <p>5.13 Minor injury: Injury requiring medical treatment for less than 24 hrs.</p> <p>5.14 Major injury: An injury causing disablement extending beyond the day on which the accident occurred.</p> <p>5.15 Reportable injury: Any injury causing disablement for a period of 48 hours or more.</p> <p>5.16 Occupational illness: A disease or illness caused by repeated or prolonged exposure to a workplace hazard as well as acute & chronic illness or diseases caused by inhalation, ingestion, absorption or direct contact.</p> <p>5.17 Fatal injury: An injury, which results in death.</p> <p>5.18 Routine activity/Normal activity: The activity carried out regularly.</p> <p>5.19 Non-Routine/Abnormal activity: The activity carried out apart from regular activities. Ex: Break down activities or De-chocking of solvents etc.</p> <p>5.20 Emergency activity: The activities carried out during emergency. Ex: Operation of Emergency Safety Equipment.</p> <p>5.21 Legal Concern: It is applicable when the Hazard/Risk is addressed by applicable and specifically relevant legal requirements (Factories Act / State factory rules, etc.), regulations or permit requirements. This will likely include aspects associated with processes and activities if (1) safety regulations specify controls and conditions, (2) information must be provided to the authorities, and/or (3) there are, or may be, periodic inspections or enforcement actions taken by the authorities. Safety regulations in the event of incidents will be recognized as Unacceptable” when such an event had occurred in the last 2 years.</p> <p>5.22 Interested Party Concern: It is applicable when the Hazard/Risk is having a concern expressed by Employees, Neighbors or Local Residents.</p> <p>5.23 OH & S Management: Part of an organization’s management system used to develop and implement its OH&S policy and manage its OH&S risks.</p> <p>6.0 EHSS: NA</p>			

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<p>7.0 PROCEDURE:</p> <p>7.1 Individual department Head/Managers/Executives/Junior Executives shall be trained in methodology of Hazard Identification & Risk assessment during in house EHSS training program by authorized EHSS department personnel.</p> <p>7.2 EHSS core team/individual department head shall be involved in area wise Aspect/Hazard identification in co-ordination with EHSS personnel.</p> <p>7.3 HIRA shall take into an account of:</p> <ul style="list-style-type: none"> • Routine and non-routine activities. • Activities of all persons having access to the workplace (including contractors and visitors). • Human behavior, capabilities and other human factors. • Identified hazards originating outside the workplace capable of adversely affecting the health and safety of persons under the control of organization within the workplace. • Hazards created in the vicinity of the workplace by work-related activities under the control of organization. • Infrastructure, equipment and materials at the workplace, whether provided by organization or others. • Changes or proposed changes in the organization, its activities or materials. • Any applicable legal obligations relating to risk assessment and implementation of necessary controls. • The design of work areas, processes, installations, machinery/equipment, operating procedures and work organization, including their adaption to human capabilities. <p>7.4 Hazard Identification and Risk Assessment Methodology: Following steps are involved in Hazard Identification and Risk Assessment,</p> <p>7.4.1 Identification of activity</p> <p>7.4.2 Hazard Category and Hazard Identification</p> <p>7.4.3 OHS Risk Identification</p> <p>7.4.4 Assessing Probability, and Severity</p> <p>7.4.5 Assessing Risk Level – Probability and severity (Risk Priority Number) without controls</p> <p>7.4.6 Assessment of Existing controls</p> <p>7.4.7 Assessment of Risk Level - (Risk Priority Number) with existing controls</p> <p>7.4.8 Other Risks Identification</p> <p>7.4.9 Risk Level</p> <p>7.4.10 OHS Opportunities</p> <p>7.4.11 Other Opportunities</p>			

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<p>7.4.12 Action plan for high risk and very high risk (Unacceptable Risk) for OHS risks and Other risks</p> <p>7.4.13 Responsibility</p> <p>7.4.14 Target Date</p> <p>7.5 Identification of Activity: All the routine/non-routine/emergency activities of the respective department shall be identified.</p> <p>7.6 Hazard category and Hazard Identification: During hazard identification, hazards likely to be considered are:</p> <p>7.6.1 Physical Hazards</p> <p>7.6.2 Chemical Hazards</p> <p>7.6.3 Biological Hazards</p> <p>7.6.4 Physiological Hazards</p> <p>7.6.5 Mechanical Hazards</p> <p>7.6.6 Noise Hazards</p> <p>7.6.7 Electrical Hazards</p> <p>7.6.8 Ergonomic</p> <p>With respect to all the hazard categories given above, specific hazards shall be identified. Examples of hazards which can likely be considered are listed in FORM-EHSS-EHSS-0150(Annexure-04) for reference.</p> <p>7.7 OHS Risk Identification: Some of the following risk (s) should be considered during the identification.</p> <p>7.7.1 Headache</p> <p>7.7.2 Eye Irritation</p> <p>7.7.3 Temporary Sickness</p> <p>7.7.4 Long term health problems</p> <p>7.7.5 Occupation illness</p> <p>7.7.6 Minor cuts</p> <p>7.7.7 Skin disease/allergies</p> <p>7.7.8 Respiratory problems</p> <p>7.7.9 Minor injury</p> <p>7.7.10 Burns</p> <p>7.7.11 Fatal.</p>			

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7.8 Assessing probability, Detection and Severity without any controls: The Probability /Likelihood of occurrence of Risk, Consequence of the risk (Severity) and Persons affected shall be calculated by below tables.

Scale		Probability (P)	
Unlikely	1	Occurs only at exceptional circumstances	Once in 5 years
Possible	2	Not likely to occur in most circumstances	Once in a year
Likely	3	Might occur at some circumstances	Quarterly/Monthly
Almost Certain	4	Will probably occur in most circumstances	Weekly/ Daily/ Shift wise

Scale	Severity (S1)
1	Near miss
2	First Aid Injuries
3	Non reportable injury/Occuapational illness
4	Reportable injury/Dangerous occurrence/Fatal

Scale	Person Affected (S2)
1	Nil
2	Less than or equal to two
3	More than two but not entire department
4	Total department

7.9 Assessment of Risk Level:

Risk Level shall be calculated from Scale.

Scale = Probability (P) x Severity (S1) x Person affected (S2).

Risk Rating shall be considered as given in the table on basis of scale.

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Risk Rating	Risk Level	Scale	Actions
≤ 4	Low	1	Give consideration to further action to reduce the risk (Monitor existing controls)
5 to ≤ 9	Medium	2	Action required to control the risk. Interim measures are necessary in the short term.
10 to ≤ 24	High	3	Action required urgently to control risks. Interim measures required in the short term (contingency plan)
25 to ≤ 64	Very High	4	Risk unacceptable. Immediate action required to reduce the risk.

7.10 Assessing of Existing controls:

The existing controls as per the Hierarchy of Controls viz. Elimination, Substitution, Engg Controls, Admin controls and PPE controls available at the organization will be factored and evaluated.

7.11 Assessing of Probability and Severity with Existing controls:

The Probability /Likelihood of occurrence of Risk, consequence of the risk (Severity) and Persons Affected shall be calculated considering the existing controls as per the table mentioned under point (7.4.5) and (7.4.6).

7.12 Other Risks Identification: The other risk(s) are as below

- 7.12.1 Legal or Regulatory Concerns related risks
- 7.12.2 Interested Party Concerns related risks
- 7.12.3 Business Interruptions/Business Concerns related risks
- 7.12.4 High Severity

7.13 Assessing Risk Level: Hazard - Risk shall be assessed further by two methods such as

- 7.13.1 Other Risks
- 7.13.2 Risk Priority Number based on OHS risks

7.14 Assessment of Other Risks:

7.14.1 **Legal Concern:** Identified hazard shall be assessed for Legal Concern (as defined in the definition). If Legal Concern is rated as ‘YES’ then those risk (s) related to the hazard(s) shall be considered as High risk by default

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<p>7.14.2 Interested Party Concern: Identified hazard shall be assessed for Interested Party Concern (as defined in the definition). If Interested Party Concern is rated as ‘YES’ then those risk(s) related to the hazard(s) shall be considered as High risk by default</p> <p>7.14.3 High Severity: If the Severity (S1) and person affected (S2) any of these scale rated as 4, risks considered as High risk. If the hazard has the potential of impacting multiple departments or more than one block, then it will be considered as Very High Risk.</p> <p>7.14.4 The Risk Priority Number (RPN) is greater than or equal to 12 (\geq) shall be considered as High Risk and below 12 shall be considered as acceptable Risk. The RPN falls between 25 to \leq 64 shall be considered as very high risk (Unacceptable Risk)</p> <p>7.14.5 The control measures shall be considered for high risk and very high risk (unacceptable risk). List of Controls are given in FORM-EHSS-EHSS-0151(Annexure-05). If any other controls apart from the list shall be given separately in others column.</p> <p>7.14.6 Interested Party Concern: Identified hazards shall be assessed for Business Interruptions/Business Continuity. If the Business Interruptions/Business continuity is rated as ‘YES’ then those risk(s) related to the hazard(s) shall be considered as High risk by default.</p> <p>7.15 Action Plan:</p> <p>7.15.1 High risk shall be considered for Opportunities (OHS Opportunity and Non OHS Opportunity). These opportunities will be translated into Action plans</p> <p>7.15.2 Responsible person for the action plans should be clearly assigned.</p> <p>7.15.3 Recommendations shall be considered for all high and very high risks (Unacceptable) as per the following hierarchy of control:</p> <p>7.15.4 Elimination</p> <p>7.15.5 Substitution</p> <p>7.15.6 Engineering</p> <p>7.15.7 Administrative control</p> <p>7.15.8 Personal protective equipment</p> <p>7.15.9 Action plan status for each hazard shall be given during the review of HIRA.</p> <p>7.16 HIRA Record:</p> <p>7.16.1 Hazard Identification and Risk Assessment Register shall be consolidated in FORM-EHSS-EHSS-0147(Annexure-01).</p> <p>7.16.2 HIRA summary sheet shall be maintained as per FORM-EHSS-EHSS-0148(Annexure-02).</p> <p>7.16.3 FORM-EHSS-EHSS-0147(Annexure-01) and FORM-EHSS-EHSS-0148(Annexure-02) shall be maintained as a soft copy in a excel sheet. The excel file shall be forwarded to respective block’s EHSS Core team members and department Head.</p>			

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<p>7.16.4 Once the assessment is done, the annexures shall be maintained in soft copy and printing will be done on need basis.</p> <p>7.16.5 The next review date of the register shall be 6 months from the date of Effective. The next review shall be done ± 15 days from the “Next review date”.</p> <p>7.16.6 Hazard Identification and Risk Assessment Register shall be prepared by EHSS Core team member of the department in co-ordination with department head. The same shall be reviewed and checked by Dept. Line Manager and the EHSS Co-coordinator of the respective block. Dept. Head/ OU head of the respective block/function will approve it.</p> <p>7.16.7 Review of HIRA records once in 6 months and if any changes in work practices/addition of new activity/major incident pertaining to any activity etc. to be revised prior to review period.</p> <p>7.16.8 As and when any changes in process, new modification individual department EHSS Core team personnel shall raise the change control.</p> <p>7.16.9 Soft copy of latest revised HIRA shall be uploaded in “Syngconnect” by EHSS department for reference.</p> <p>8.0 REFERENCES: NA</p> <p>9.0 ANNEXURES:</p>													
<table border="1"> <tr> <td data-bbox="248 1288 662 1400">FORM-EHSS-EHSS-0147</td> <td data-bbox="662 1288 1422 1400">Annexure - 01 Hazard Identification and Risk Assessment Register</td> </tr> <tr> <td data-bbox="248 1400 662 1512">FORM-EHSS-EHSS-0148</td> <td data-bbox="662 1400 1422 1512">Annexure – 02 Hazard Identification and Risk Assessment Summary Sheet</td> </tr> <tr> <td data-bbox="248 1512 662 1568">FORM-EHSS-EHSS-0149</td> <td data-bbox="662 1512 1422 1568">Annexure – 03 SOP Training Questionnaire</td> </tr> <tr> <td data-bbox="248 1568 662 1624">FORM-EHSS-EHSS-0150</td> <td data-bbox="662 1568 1422 1624">Annexure – 04 List of Hazards</td> </tr> <tr> <td data-bbox="248 1624 662 1680">FORM-EHSS-EHSS-0151</td> <td data-bbox="662 1624 1422 1680">Annexure – 05 List of Controls</td> </tr> </table>				FORM-EHSS-EHSS-0147	Annexure - 01 Hazard Identification and Risk Assessment Register	FORM-EHSS-EHSS-0148	Annexure – 02 Hazard Identification and Risk Assessment Summary Sheet	FORM-EHSS-EHSS-0149	Annexure – 03 SOP Training Questionnaire	FORM-EHSS-EHSS-0150	Annexure – 04 List of Hazards	FORM-EHSS-EHSS-0151	Annexure – 05 List of Controls
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10.0 REVISION HISTORY:

Version no.	Effective Date	Description of Change
2.0	16-Feb-2023	<u>Reference Change Control Number: - EHSS/CCF/23/0004</u>
1.0	03-Feb-2021	<u>Reference Change Control Number: - EHSS/CCF/20/0022</u> As part of transition from manual to Electronic document management system SOP-EHSS-EHSS-0022 HAZARD IDENTIFICATION AND RISK ASSESSMENT has been revised

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	Standard Operating Procedure	Department: Environmental Health Safety and Sustainability
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Title: INCIDENT REPORTING AND INVESTIGATION

Document Number:
SOP-EHSS-EHSS-0055

Version Number:
2.0

Effective Date:
28-Mar-2023

Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Pooja Naik	16-Mar-2023 16:12:21 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Satish Birajdar/EHSS/ SYNGENE	16-Mar-2023 16:18:50 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	16-Mar-2023 19:26:20 (IST)

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<p>TITLE:INCIDENT REPORTING AND INVESTIGATION</p>			
<p>Document Number: SOP-EHSS-EHSS-0055</p>	<p>Version no.: 2.0</p>	<p>Effective Date: 28-Mar-2023</p>	<p>Next Review Date: 27-Mar-2025</p>
<p>1.0 OBJECTIVE:</p> <p>1.1 To lay down the framework so as to ensure that all incidents are reported, Classified, investigated, and lessons learnt therein are understood, action items implemented, and learnings shared in order to realize the following benefits:</p> <p>1.1.1 Prevent Recurrence of incidents, which will strengthen belief that all injuries can be prevented.</p> <p>1.1.2 Spot deficiencies in EHSS management systems.</p> <p>1.1.3 Demonstrate the commitment of the EHSS management system.</p> <p>1.1.4 Promote the atmosphere of openness and transparency of reporting the incidents.</p> <p>1.2 To develop the communality of understanding regarding incident reporting and investigation processes with the emphasis on the following eight steps:</p> <p>1.2.1 Make initial response and report.</p> <p>1.2.2 Form investigation team.</p> <p>1.2.3 Determine the facts.</p> <p>1.2.4 Determine the key factors.</p> <p>1.2.5 Determine systems to be strengthened.</p> <p>1.2.6 Recommend corrective and preventive actions.</p> <p>1.2.7 Document and communicate the findings.</p> <p>1.2.8 Follow up and closure of incident.</p> <p>1.2.9 Ensuring the learnings to be communicated to stakeholders.</p> <p>2.0 SCOPE:</p> <p>This procedure is applicable to all Syngene establishments including incidents related to material transportation (Safety relating to Distribution systems) and incidents occurred during outdoor duties. Off the job incidents and Disaster or Emergency Management are not covered under this procedure. Also note that, in case of personal health issues, if it is endorsed by HR (as per Syngene HR policy) and approved by a medical professional that the particular incident is not related to workplace activities, then that incident is outside the scope of this procedure.</p> <p>3.0 RESPONSIBILITIES:</p> <p>3.1 Management Responsibility:</p> <p>3.1.1 Syngene Extended Leadership Team has the following responsibilities.</p> <p>3.1.2 To create an atmosphere of trust and respect that leads to openness, resulting in reporting of all incidents.</p>			

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<p>3.1.3 Ensure that a system for Incident Management is established across Syngene.</p> <p>3.1.4 Provide resource and prioritize all related activities.</p> <p>3.1.5 Ensure the system for communication is effective, specially sharing of learning across all OUs.</p> <p>3.1.6 Communicate value of conducting incident investigation.</p> <p>3.2 OU Head/Enabling Function Head Responsibilities:</p> <p>3.2.1 Ensure that all incidents and observations (unsafe acts/conditions and safe acts) are reported in the portal.</p> <p>3.2.2 Establish systems & processes within the respective OU/EF so that requirements as specified in this procedure are adhered to.</p> <p>3.2.3 Arrange resources and prioritize all related activities.</p> <p>3.2.4 Ensure that the critical mass of incident management experts (IMEs) are available within the OU/EF.</p> <p>3.2.5 Implement follow-up system to prevent recurrence.</p> <p>3.2.6 Ensure the system for communication within the OU/EF is effective.</p> <p>3.2.7 Communicate value of conducting incident investigation within the OU/EF.</p> <p>3.2.8 Create an atmosphere of trust and respect that leads to openness.</p> <p>3.2.9 Conducting periodic review of incidents and observations for closure. Discussion of status in the monthly kavach implementation meeting.</p> <p>3.3 Incident Investigation Team Leader (Hereafter referred to as Team Leader) Responsibility:</p> <p>The vice-chair of implementation team will work as ex-officio Team Leader of the investigation team for all incidents within his/her OU/EF. However, OU head can choose another person to lead the Team if the situation so demands. Team Leader has the following responsibilities:</p> <p>3.3.1 Work as a conscious keeper within the OU/EF so as to ensure that all incidents get reported.</p> <p>3.3.2 Consult EHSS OU/EF SPOC whether the incident needs to be investigated through Team formation according to the 8-step process or can be concluded and closed without any Team formation.</p> <p>3.3.3 Form the investigation team as needed as per the guidance outlined in this procedure</p> <p>3.3.4 Organize the team meeting, coordinate for the data collection, and ensure that quality investigation is done.</p> <p>3.3.5 Ensure that the lessons learnt are shared within the OU in consultation with the OU/EF head.</p> <p>3.3.6 Ensure that every incident is closed in consultation with EHSS after ensuring that recommendations are implemented.</p> <p>3.3.7 Keep the OU/EF head informed on what is going on well and the opportunities for improvement.</p>			

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<p>3.3.8 Support OU/EF head to prepare the monthly report.</p> <p>3.4 Incident Management Expert (IME) Responsibilities: IMEs are trained persons from across OUs with full knowledge of the 8-steps of incident management process, particularly with respect to the Root Cause Failure Analysis (RCFA). As an IME, s/he has the following responsibilities:</p> <p>3.4.1 Should undergo Incident management training internally from the Team leaders and/or EHSS SPOC to be certified as an expert to carry out IM functions within the respective OU/EF.</p> <p>3.4.2 Work with all cases of Incident management with the respective OU/EF to understand the issues from each incident and mitigate risks as necessary</p> <p>3.4.3 Work as a conscious keeper within the OU so as to ensure that all incidents get reported.</p> <p>3.4.4 Consult EHSS OU SPOC whether the incident needs to be investigated through Team formation according to the 8-step process or can be concluded and closed without any Team formation.</p> <p>3.4.5 Should share incident knowledge and opinion/information with other OUs/EFs if the necessity arises.</p> <p>3.4.6 Work with the Team leader of the specific OU/EF and apprise the OU/EF head as and when the case may be.</p> <p>3.5 Investigation Team Members’ Responsibilities:</p> <p>3.5.1 Undergo Incident management awareness training as per prevailing procedure.</p> <p>3.5.2 Actively participate in the Incident investigation team meetings and provide data/evidence/document whichever necessary.</p> <p>3.5.3 Provide suggestions/inputs to help the investigation team to correctly identify the contributing causes.</p> <p>3.6 Administration responsibilities for Common shared areas: Common areas are cafeteria, restrooms, staircase, and landing area, corridors, parking areas, garden areas and like, which are used by Syngene and not controlled directly by any of the OUs/EFs. Responsibility for leading the investigation team for the incidents occurring in these areas lies with administration department. In doing so, Administration can seek support from EAM, EHSS or from any OU/EF as necessary.</p> <p>3.7 EHSS Responsibilities:</p> <p>3.7.1 Coordinate & support the implementation of incident management system across Syngene.</p> <p>3.7.2 Support OUs/EFs in competency development so as to ensure that appropriate number of incident management experts (IMEs) are available across all OUs/EFs.</p>			

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<p>3.7.3 Monitor the implementation of incident management system across Syngene & report to Management the opportunities for improvement (OFI).</p> <p>3.7.4 Compile the data on leading and lagging indicators across Syngene & report to the Management as needed.</p> <p>3.7.5 Participate in the Incident investigation suo motu or as a team member when called for.</p> <p>3.7.6 Help the OUs/EFs in classifying every incident.</p> <p>3.7.7 Help the team leader to facilitate closure of incident.</p> <p>3.7.8 Maintain the incident management portal.</p> <p>4.0 ABBREVIATION:</p> <p>OU : Operation Unit</p> <p>EF : Enabling function</p> <p>IME : Incident Management Expert</p> <p>SPOC : Single Point of Contact</p> <p>RCFA : Root Cause Failure Analysis</p> <p>IM : Incident Management</p> <p>EHSS : Environment Health Safety and Sustainability</p> <p>EAM : Engineering and Maintenance</p> <p>OFI : Opportunities for Improvement</p> <p>NM : Near Miss</p> <p>FAC : First Aid Case</p> <p>MTC : Medical Treatment Case</p> <p>RWC : Restricted Workday Case</p> <p>LTI : Loss Time Injury</p> <p>OHC : Occupational Health Center</p> <p>LTI-R : Loss Time Injury- Recordable</p> <p>DISH : The Directorate- Industrial Safety and Health</p> <p>FC : Fatal Case</p> <p>TRC : Total Recordable Cases</p> <p>LTI-FR : Loss Time Injury-Frequency Rate</p> <p>IS : Indian Standards</p> <p>DFE : Dangerous Occurrence, Fire and Environmental release</p> <p>PI : Process Incidents</p> <p>HIPO : High Potential</p> <p>OSLT : Operational Safety Leadership Team</p> <p>FIR : First Information Report</p> <p>CAPA : Corrective and Preventive Action</p> <p>FPR : First Point of Responsibility</p>			

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<p>IMTT : Incident Management Task Team WPS : Workplace Safety LIFE : Learning Incident from Experience LMS : Learning Management System PSM : Process Safety Management LOPC : Loss of Primary Containment IRMS : Incident reporting management system</p>			
<p>5.0 DEFINITIONS:</p>			
<p>5.1 Incident:</p>			
<p>Incident is an event that could have resulted or did result in:</p>			
<ul style="list-style-type: none"> • Injury or illness • Environment release • Adverse community reaction • Property Damage • Business Interruption 			
<p>5.2 Classification of Incidents:</p>			
<p>Incidents are to be classified as injury related and non-injury related (other incidents).</p>			
<p>Injury and non-injury related incidents can further be classified as follows:</p>			
<p>5.2.1 Near Miss (NM): Near Miss is an incident that could have resulted into injury or illness, property damage, environment release, adverse community reaction or business interruption.</p>			
<p>5.2.2 First Aid Case (FAC): First Aid Case is an incident in which an injured person/s gets the first aid treatment either in a plant or Occupational Health Centre (OHC) and no follow up is required or done. The injured person does not remain absent from his normal duty.</p>			
<p>5.2.3 Medical Treatment Case (MTC): Medical Treatment Case is an incident in which an injured person/s gets the treatment either in a plant or Occupational Health Centre (OHC) and follow up is requested and/or done. The injured person does not remain absent from his normal duty.</p>			
<p>5.2.4 Restricted Workday Case (RWC): Restricted Workday Case is an incident in which an injured person after the treatment either in plant or Occupational Health Centre or outside clinic/hospital comes back to duty but advised to be given a light duty as s/he is unable to perform her/his normal duty. The injured person does not remain absent from duty.</p>			
<p>5.2.5 Loss Time Injury (LTI): Loss time injury is an incident in which an injured person does not attend the duty as per the next schedule shift assigned.</p>			
<p>5.2.6 Loss Time Injury Recordable (LTI-R): As per The Karnataka Factories Rules, 1969 (mentioned as Annexure-1 in this document) an incident “which cause such bodily injury as will prevent or will probably prevent the person injured from working for a period of 48 hours immediately following the accident” is defined as Loss Time Injury Recordable and to be</p>			

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<p>reported in prescribed format to The Directorate – Industrial Safety and Health (DISH) Department. Refer FORM-EHSS-EHSS-0271 (Annexure -01). This should be filled by the concerned OU/EF Head and sent to the EHSS Department).</p> <p>5.2.7 Fatal Case (FC): Fatal Case is an event causing a loss of life immediately on the spot or subsequently arising out of that incident.</p> <p>5.2.8 Occupational Illness: A health condition caused, precipitated or aggravated by exposure to workplace over a period of time. According to the WHO, Chronic respiratory diseases, musculoskeletal disorders, noise-induced hearing loss and skin problems are the most common occupational diseases. Work-related noncommunicable diseases (NCDs) as well as cardiovascular diseases and depression caused by occupational stress result in increasing rates of long-term illness and absence from work. Occupational NCDs include occupational cancer, chronic bronchitis and asthma caused by air pollution in the workplace and radiation.</p> <p>5.2.9 HIPO: A HIPO incident is an event that, under different circumstances, might have resulted in a major loss.</p> <p>5.2.10 Total Recordable Cases (TRC): This is the sum of MTC, RWC, LTI, Fatality and Occupational Illness cases.</p> <p>a) Frequency Rate: It is defined as numbers of incidents per 200,000 man-hours worked (As per OSHA guidelines) .For example: If one takes only number of loss time injuries occurred per 200,000 man-hours, then it is called as loss time injury frequency rate (LTI-FR).</p> <p>b) Severity Rate: It is defined as man-days lost per 200,000-man hours worked. For fatality as per IS Code 3786, the man-days lost shall be considered as 6000.</p> <p>It can be seen from the above that the categorization is primarily based on the extent of injury. However, there can be cases where there is no injury to any person but there are/could be damages to property and/or environment and/or adverse effect on the community and/or business interruption. Such incidents are categorized as Fire, Environmental release and Dangerous Occurrence (FED) incidents as per the definition given below.</p> <p>5.3 FED incidents:</p> <p>FED incidents include fire, Environment release and Dangerous occurrence.</p> <p>5.3.2 Fire: Any event of un-intended combustion, regardless of the extent, with or without flame. For more details on fire, refer to FORM-EHSS-EHSS-0273 (Annexure-03).</p> <p>5.3.3 Environment Release: All incidents which have potential adverse impact on the environment; normally those incidents where prescribed limits, if any, are exceeded.</p> <p>5.3.4 Dangerous Occurrence: The schedule of Dangerous Occurrence as per The Karnataka Factories Rules, 1969 is attached under FORM-EHSS-EHSS-0271 (Annexure-01). If the dangerous occurrence falls within this schedule, then these incidents are to be reported to Factory Inspectorate (Directorate of Industrial Safety and Health). EHSS will decide whether the incident falls within this schedule.</p>			

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<p>5.4 Process and Distribution safety incidents (PSM incidents):</p> <p>5.4.1 Process Incidents (PI): An incident that directly involves process equipment and materials, including on-site storage and handling of process materials, involving the release of hazardous substances or involving the release of the energy of hazardous substances that directly involves or could involve process equipment and materials, including on-site storage and handling of process materials. It essentially indicates loss of containment. Refer FORM-EHSS-EHSS-0273 (Annexure-03) for further information to decide whether the incident falls under the category of Process Safety Management).</p> <p>5.4.2 Transportation/Distribution safety Incidents: Any incidents related to transportation or distribution of raw materials, finished goods, intermediates, any hazardous or non-hazardous goods, scrap or material of any kind, excluding transport of employee during shift hours and official out door duties. Refer FORM-EHSS-EHSS-0273 (Annexure-03).</p> <p>5.4.3 For classification of incidents, refer to FORM-EHSS-EHSS-0273 (Annexure-03). Depending on severity, EHSS can take a final call regarding classification.</p> <p>5.5 High Potential (HIPO) incident: A HIPO incident is an event that, under different circumstances, might have resulted in a fatality or major injury or permanent disability or major loss. HIPO incidents can be injury related or non-injury related incidents. This is an overarching classification to invite the attention of the management on priority. After the incident is logged, whether it qualifies to be HIPO or not, will be decided in consultation with EHSS, whose decision is final. Since it is an overarching category, any incident including near miss, any injury or non-injury incident can be HIPO if it satisfies the criteria given here.</p> <p>5.6 Observation (Unsafe Act, Unsafe Condition and Safe Act):</p> <p>Unsafe Condition: Unsafe condition is a set of circumstances, not directly caused by the actions or inactions of one or more employees in an area, that may lead to an injury or incidents if uncorrected. It may be caused by faulty design incorrect fabrication or construction or inadequate maintenance and subsequent deterioration.</p> <p>Unsafe Act: Unsafe act is a conduct [whether witnessed or not] that unnecessarily increases the likelihood of injury, violates established safety rules, or is contrary to expected conduct.</p> <p>Safe Act: Safe act is a conduct [whether witnessed or not], Following established safety rules and doing right thing when no one is watching.</p>			

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5.7 Injury categorization workflow:



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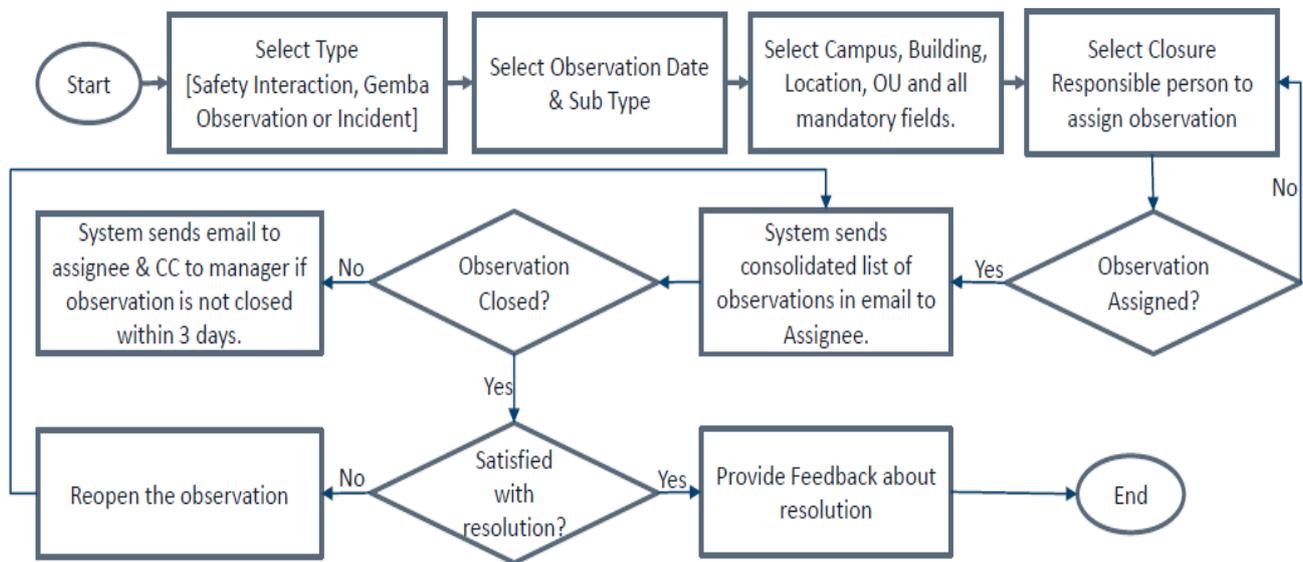
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6.0 EHSS: NA

7.0 PROCEDURE:

7.1 Reporting of GEMBA / Observation / Safety interaction and Incident in portal:

7.1.1 GEMBA /Observation and Safety interaction workflow:



- On raising incident in Synzero portal, the system shall trigger mail notification to all IMEs of the specific OU and EHSS officers.
- The notified IME of the specific OU shall categorize the incident based on the injury categorization workflow in IRMS portal and form investigation team with cross functional team for further action.

7.2 Time Frame for Incident Investigation:

The team is expected to complete the investigation within the time frame as follows:

- All the incidents including LTI as early as possible but not beyond 15 working days.
- Fatality incidents – as early as possible as per the time frame agreed by OSLT.

7.3 Initial Response and Reporting Requirements:

7.3.1 Initial response is most important in bringing the incident under control and minimizing its after effect. It is of paramount importance to ensure that the injured persons get the necessary help at the earliest.

7.3.2 All incidents must be reported, including Near Miss. OU/EF Heads/Functional Managers are responsible to ensure that incidents in their own area get reported.

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<p>7.3.3 For all incidents, the FIR to be submitted through portal within 24 hours of occurrence of incidents.</p> <p>7.3.4 Anybody who witnesses the incident can file the FIR as per template given under FORM-EHSS-EHSS-0279 (Annexure-02). If the incident is witnessed by those who do not have the access to the portal, then they will immediately bring to the notice of their direct reporting officer who is responsible for logging the incident in the portal.</p> <p>7.3.5 It is important that the concerned site person takes all necessary measures to secure the scene of the incident so as to preserve all types of evidences as far as possible which can be used later by the investigation team.</p> <p>7.3.6 Occupation Health Centre shall maintain the record of all those who are reported in OHC and communicates to Syngene EHSS, EHSS team will review the incident and ensures that same is captured in the portal within 24 hours of occurrence.</p> <p>7.3.7 If multiple injuries had happened, the details of victims need to add separately during incident submission by selecting injured persons tab along with its category employee/Casual labor/3rd party.</p> <p>7.3.8 If any incidents/near miss/observation by contract employees shall be informed to the respective line manager and the same will be registered within 24 hours of its occurrence.</p> <p>7.4 Formation of Team for Incident Investigation:</p> <p>7.4.1 The need for team formation depends on the impact or the potential impact of the incident. For RWC, LTI, Fatality, Dangerous occurrence and for HIPO incidents investigation must be done through a team formation.</p> <p>7.4.2 For rest of the categories like FAC, MTC, Process, Distribution, Fire and Environment incidents, the decision whether the investigation is to be done through team formation is to be taken in consultation with EHSS, whose decision is final.</p> <p>7.4.3 FAC, MTC, Process, Distribution, Fire and Environment incidents, which are not categorized as HIPO and which do not require team formation can be closed in consultation with EHSS after recommending the necessary actions.</p> <p>7.4.4 Near Misses can be investigated and closed by the concerned line-manager provided they are not classified as HIPO.</p> <p>7.4.5 The formation of the team is the responsibility of the concerned OU/EF Head. Vice-chair of concerned implementation team works as a team leader. Other members are minimum one IME, representative/s from the concerned area to be selected by IME, EHSS representative and any subject specialist as needed. Apart from this, other members can be invited on an ad-hoc basis. For fatal incidents, the leader of the Investigation team should be OU Head, supported by EHSS Head.</p> <p>7.4.6 The team leader and the team shall be nominated by the concerned OU/EF head or its representative at the earliest but not later than 48 hours of the incident.</p>			

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<p>7.5 Determine Facts, key factors and systems to be strengthened:</p> <p>7.5.1 It is important to understand that the whole process of investigation should be based on <i>fact-finding</i> and not <i>fault-finding</i>. It is only through this approach; can an atmosphere of openness/transparency be promoted.</p> <p>7.5.2 The process of investigation should focus to:</p> <ol style="list-style-type: none"> i) determine the facts ii) determine the key factors both direct and contributing; and iii) determine the systems to be strengthened. <p>7.5.3 For determining the facts, visiting the incident sites immediately after the incident, preservation of the incident scene and potentially relevant evidences to the maximum extent possible are important aspects. After gathering all the data, the team should carefully separate out opinions from fact/s. For doing so, writing a good chronology of the event helps.</p> <p>7.5.4 For determining the key factors, viz. physical, human and operating systems, evidences are important.</p> <p>7.5.5 While focusing on direct factors is important, equal focus shall also be maintained on the contributing factors.</p> <p>7.5.6 One of the most important aspects of incident investigation is to determine the systems to be strengthened. The real benefits of incident investigation can be reaped only through identifying the weakness in the system. The correct system factors can be identified through RCFA, for which it is recommended to follow the WHY TREE technique. The systems are related to:</p> <ol style="list-style-type: none"> i) Personnel ii) Facilities iii) Technology iv) Operating Discipline v) Management systems viz. <ul style="list-style-type: none"> • Process Safety culture • Compliance with Standards • Process safety competency • Workforce Involvement • Safety interaction • Process Safety Information • Process Risk Assessment (PRA) • Operating Procedures • Permit to work (PTW) • Asset integrity and reliability (AIR) • Contractor safety management 			

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<ul style="list-style-type: none"> • Trainings & Communications • Management of Change (MOC) • Pre-Start Safety Review (PSSR). • Emergency Management • Incident Management • Conduct of Operations • Audits • Measurement & metrics • Safety leadership <p>7.6 Recommendations of Corrective and Preventive Action (CAPA):</p> <p>7.6.1 The investigation team has the responsibility to recommend CAPA based on the facts gathered and RCFA done. The hierarchy of recommendations should be elimination, reduction or substitution, engineering control, administrative controls, and finally the PPE in order of decreasing priority</p> <p>7.6.2 For every recommendation, a clear responsibility (First Point of Responsibility - FPR) and target date must be mentioned.</p> <p>7.6.3 The recommendation suggested must be actionable and measurable.</p> <p>7.6.4 Recommendations should be written in such a way that the compliance can be validated by third-party.</p> <p>7.7 Documentation & Communicate Finding:</p> <p>7.7.1 All incidents are to be reported through the portal, however hard copies of the necessary supporting documents as may be required for various purposes including legal shall be retained as per the company policy.</p> <p>7.7.2 Internal Communication:</p> <p>7.7.2.1 The significant lessons learnt from the incidents should be compiled by the IMTT of WPS as per the current system of LIFE (Learning Incident From Experience) and should be shared with all implementation teams. Implementation teams are expected to implement the recommendations.</p> <p>7.7.2.2 Awareness program, safety competitions, safety quizzes and such other initiatives involving cross-section of employees to emphasize the importance of reporting and investigating near misses and all incidents should be organised by WPS work stream in consultation with corporate communication.</p>			

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<p>7.7.3 External Communication: The external communication shall be done as per norms set up by Corporate Communications.</p> <p>7.8 Follow-Up: 7.8.1 The person responsible (FPR) has to ensure the completion of recommendations within the target date. 7.8.2 Implementation team will review the status of compliance of recommendations till closure as part of structured agenda.</p> <p>7.9 Closure of Incident Report: 7.9.1 The team leader has the responsibility to close the Incident Investigation report in the portal after ascertaining that all recommendations have been implemented.</p> <p>7.10 Training: Trainings are of 2 types: Awareness Training & Training for IMEs. The Awareness Training is for all employees at Syngene through the LMS system. The Training for IMEs will be for 2 days which will mainly cover RCFA (Root Cause Failure Analysis through WHY Tree analysis). The pre-requisite for the IME Training is to complete the Awareness Training through LMS. Refresher training shall be given to all IMEs at least once in 2 years. For inducting any new IME, the process defined here is to be followed. Incident Management Task Team Members will work as trainers for IMEs. The schedule for the training for IMEs will be prepared by Workplace Safety Work stream and Implementation Teams will nominate IMEs accordingly for the Training Program.</p> <p>7.11 System Audit: 7.11.1 The Audit shall be carried out to check the effectiveness of implementation of incident reporting and investigation process by multi-functional team once in 2 years. 7.11.2 Management report shall be prepared on monthly basis (26th of previous month to 25th of current month), this report shall be prepared by extracting data from incident portal by shift EHSS officer and same shall be ratified by the EHSS shift manager for the authenticity of the data before sharing to the management. This will works on principle of 4 eye evaluation (maker-checker process). 7.11.3 Incident analysis will be undertaken on monthly basis and shared to respective EHSS SPOC for closures of incidents. Periodic review of data analysis will be made with EHSS and data will be validated of incident portal.</p>			

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7.12 Deviation:

Deviation from this IM procedure should be approved by the OU/EF head in consultation with the EHSS head or his representative.

8.0 REFERENCES: NA

9.0 ANNEXURES:

FORM-EHSS-EHSS-0271	ANNEXURE - 01	Notice of Accident or Dangerous Occurrence-Form 17.
FORM-EHSS-EHSS-0279	ANNEXURE - 02	First Information Report
FORM-EHSS-EHSS-0273	ANNEXURE – 03	Incident Investigation Report Format
FORM-EHSS-EHSS-0272	ANNEXURE – 04	Event Determination Decision Logic tree
FORM-EHSS-EHSS-0280	ANNEXURE – 05	Incident Management RACI Chart
FORM-EHSS-EHSS-0281	ANNEXURE – 06	SOP Training Questionnaire

10.0 REVISION HISTORY:

Version no.	Effective Date	Description of Change
2.0	28-Mar-2023	<p>Reference Change Control Number: - EHSS/CCF/23/0006</p> <ol style="list-style-type: none"> 1. In section 3.2.9, Conducting periodic review of incidents and observations for closure has been added. 2. In section 5.6, Observation (Unsafe Act, Unsafe Condition and Safe Act) has been added. 3. In section 5.7, Injury categorization workflow has been added. 4. In section 7.1 and 7.1.1 Reporting of GEMBA / Observation / Safety interaction and Incident in portal has been added. 5. In section 7.3.3, For all incidents, the FIR to be submitted through portal within 24 hours of occurrence of incidents has been added. 6. In section 7.3.6, Occupation Health Centre shall maintain the record of all those who are reported in OHC and communicates to Syngene EHSS, EHSS team will review the incident and ensures that same is captured in the portal within 24 hours of occurrence has been added. 7. In section 7.3.7, If multiple injuries had happened, the details of victims need to add separately during incident submission by

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		<p>selecting injured persons tab along with its category employee/Casual labor/3rd party has been added.</p> <p>8. In section 7.3.8, If any incidents/near miss/observation by contract employees shall be informed to the respective line manager and the same will be registered within 24 hours of its occurrence has been added.</p> <p>9. In section 7.11.2, Management report shall be prepared on monthly basis (26th of previous month to 25th of current month), this report shall be prepared by extracting data from incident portal by shift EHSS officer and same shall be ratified by the EHSS shift manager for the authenticity of the data before sharing to the management. This will works on principle of 4 eye evaluation (maker-checker process) process has been added.</p> <p>10. In section 7.11.3, Incident analysis will be undertaken on monthly basis and shared to respective EHSS SPOC for closures of incidents. Periodic review of data analysis will be made with EHSS and data will be validated of incident portal has been added.</p>	
<p>1.0</p>	<p>01-Jul-2021</p>	<p><u>Reference Change Control Number: - EHSS/CCF/21/0010</u></p>	

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Title: INDUSTRIAL HYGIENE MANAGEMENT

Document Number: SOP-EHSS-EHSS-0004	Version Number: 2.0	Effective Date: 09-Mar-2023
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Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Nidhi Cs/EHSS/ SYNGENE	20-Feb-2023 10:38:16 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Satish Birajdar/EHSS/ SYNGENE	21-Feb-2023 13:01:16 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	21-Feb-2023 14:09:43 (IST)

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<p>Document Number: SOP-EHSS-EHSS-0004</p>	<p>Version no.: 2.0</p>	<p>Effective Date: 09-Mar-2023</p>	<p>Next Review Date: 08-Mar-2025</p>
<p>1.0 OBJECTIVE: Industrial Hygiene (IH) Program is established to safeguard employee health and well-being by ensuring that exposures to harmful chemical, physical, and biological agents and ergonomic stresses are within acceptable limits and to establish standards that ensures the associated risks are communicated, anticipated, identified, evaluated and controlled.</p> <p>2.0 SCOPE: This procedure applies to all functional areas, operations, offices, including employees, vendors, visitors and contractors within the scope of Syngene and focuses on Syngene’s Industrial hygiene methodology in relation to health and safety of its employees and people that may be affected by its activities/operations.</p> <p>3.0 RESPONSIBILITY: Line management in businesses, locations and functions has the responsibility to implement and adhere to this standard.</p> <p>3.1 Industrial Hygienist:</p> <p>3.1.1 Identification, recognition and evaluation of occupational health hazards at workplace.</p> <p>3.1.2 To conduct various levels of Industrial Hygiene training program like Awareness Level, Skill Level and Knowledge Level to all employees.</p> <p>3.1.3 To Ensure IH equipment’s are tested, calibrated, labeled, and maintained in accordance with manufacturer’s recommendations.</p> <p>3.1.4 Develop and execute Annual Exposure Monitoring program and sampling strategies to evaluate occupational exposure assessment.</p> <p>3.1.5 To ensure the Industrial hygiene exposure monitoring as per the plan and review the monitoring report.</p> <p>3.1.6 To Evaluate and interpret monitoring and sampling results and provide recommendation to improve safe and healthy work to eliminate/reduce workplace health hazards.</p> <p>3.1.7 Demonstrate an expert level knowledge of health stressors that may be found in the workplace.</p> <p>3.1.8 To demonstrate a familiarity level knowledge of the principle external committees, agencies, and associations relating to the field of industrial hygiene.</p> <p>3.2 EHSS Building or Cluster Representative:</p> <p>3.2.1 Identifying the potential for exposure to contaminants and evaluate the types of exposures that may require ongoing monitoring.</p>			

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<p>3.2.2 To conduct industrial hygiene exposure monitoring like Noise Survey and contour mapping, Heat Stress Monitoring, Chemical Exposure Assessment, Indoor Air Quality (IAQ) Study, and Ergonomic Assessment etc.</p> <p>3.2.3 To conduct qualitative & quantitative exposure assessment to evaluate workplace conditions.</p> <p>3.2.4 To anticipate and minimize exposure to health stressors during the planning and design phases of a work activity or from an occupational description.</p> <p>3.2.5 To undertake and implement various industrial hygiene projects.</p> <p>3.2.6 To generate reports to comply applicable statutory requirement.</p> <p>3.2.7 Conducting qualitative and quantitative health risk assessments to assess individual health risk exposure.</p> <p>3.2.8 Development of data collection and storage system</p> <p>3.2.9 Establishment of system to validate the quality of data collection.</p> <p>3.2.10 Ensure illumination survey is carried out as per standards at sites.</p> <p>3.3 Area Owner:</p> <p>3.3.1 Understand the potential health hazards of the work being done and in the areas worked.</p> <p>3.3.2 Evaluate these potential health hazards as part of a pre-job safety review.</p> <p>3.3.3 Ensure workers are aware of the potential hazards and the controls in place to minimize potential exposures.</p> <p>3.3.4 Request assistance from IHs personnel as needed in evaluating conditions.</p> <p>3.3.5 Maintain a basic level of IH hazard awareness.</p> <p>3.3.6 Evaluate jobs for potential health hazards utilizing prior training, PPE assessments, and exposure evaluations.</p> <p>3.3.7 Ensure controls needed to minimize exposures remain effective.</p> <p>3.3.8 Reporting workplace occupational health/hygiene related hazards</p> <p>3.3.9 Participating in the identification and implementation of risk controls</p> <p>3.3.10 Complying with contaminant monitoring and risk control programs.</p> <p>4.0 ABBREVIATION:</p> <p>ACGIH -American Conference of governmental Industrial Hygienists</p> <p>AIHA -American Industrial Hygiene Association</p> <p>HSE - Health Safety Environment</p> <p>HVAC - Heating Ventilating and Air Conditioning</p> <p>IAQ - Indoor Air Quality</p> <p>IARC - International Agency for Research on Cancer</p> <p>IH - Industrial Hygiene</p> <p>IHs - Industrial Hygienists</p> <p>SDS - Safety Data Sheet</p>			

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<p>NIOSH - National Institute of Occupational Safety & Health OH - Occupational Health OSHA - Occupational Safety & Health Administration PEL - Permissible Exposure Limit PEM - Particulates Exposure Monitoring PPE - Personal Protective Equipment RH - Relative Humidity SOP - Standard Operating Procedure STEL - Short Term Exposure Limit TLV - Threshold Limit Value TWA - Time Weighted Average WBGT - Wet Bulb Globe Temperature</p> <p>5.0 DEFINITION:</p> <p>5.1 Exposure Assessment – Determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure.</p> <p>5.2 NIOSH - Part of the Centers for Disease Control and Prevention within the U.S. Department of Health and Human Services. Responsibilities include research and recommending occupational health and safety standards.</p> <p>5.3 OSHA – Part of the U.S. Department of Labor; the regulatory and enforcement agency for safety and health for most U.S. business and industrial sectors.</p> <p>5.4 Industrial Hygienist (IHS) – Individuals by virtue of adequate experience, training, education, board certification or a combination of these factors are competent to provide industrial hygiene related services.</p> <p>5.5 Industrial Hygiene: According to American Industrial Hygiene Association (AIHA), Industrial Hygiene is the science and art devoted to the anticipation, recognition, evaluation, and control of those environmental factors or stresses arising in or from the workplace, which may cause sickness, impaired health and well-being, or significant discomfort among workers or among the citizens of the community.</p> <p>5.6 Personal Sample: A sample collected in an employee’s breathing zone, in front of and within 12 inches of an employee’s nose, for the purpose of assessing the air quality that an employee is breathing. Personal IH samples are sometimes referred to as lapel samples.</p> <p>5.7 Area Sample: A sample collected in a work area for the purpose of assessing the air quality in the area where employees are working or will need to work.</p> <p>5.8 Qualitative Exposure Assessment: A qualitative assessment is an essential first step that helps on Evaluation of POTENTIAL personal exposure to workplace chemicals, physical and/or biological agents based on personal experience and professional judgement.</p>			

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<p>5.9 Quantitative Exposure Assessment: A quantitative assessment is an essential step for Evaluation of ACTUAL personal exposure to workplace chemicals, physical and/or biological agents using accredited numerical and mathematical analysis.</p> <p>5.10 TLV: According to American Conference of Governmental Industrial Hygienist (ACGIH), Threshold Limit Values (TLVs) refer to airborne concentration of chemical substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed, day after day, over a working lifetime, without adverse health effects.</p> <p>5.11 TLV-TWA: According to American Conference of Governmental Industrial Hygienist (ACGIH), The TWA concentration for a conventional 08 hours workday and a 40-hour workweek, to which it is, believes that nearly all workers may be repeatedly exposed, day after day, for a working lifetime without adverse effect.</p> <p>5.12 TLV-STEL: According to American Conference of Governmental Industrial Hygienist (ACGIH), A 15 minute TWA exposure that should not be exceed at any time during a workday, The TLV-STEL should not occur more than four times per day, and there should be at least 60 minutes between exposure period.</p> <p>5.13 TLV-Ceiling: According to American Conference of Governmental Industrial Hygienist (ACGIH), the concentration that should not be exceed during any part of the working exposure.</p> <p>5.14 Action Level: A concentration typically one half the published, allowable limits (such as OSHA PEL or the ACGIH TLV) that triggers certain provisions defined by the applicable regulation. It must be implemented to further reduce exposures such as applying additional exposure controls, employee training, or medical monitoring.</p> <p>5.15 ACGIH: The American Conference of Governmental Industrial Hygienists (ACGIH) is a professional association of industrial hygienists and practitioners of related professions. ACGIH publishes guidelines known as Threshold Limit Values (TLVs) and Biological Exposure Indices (BEIs) for various chemical and physical agents found in the workplace.</p> <p>6.0 EHSS: NA</p> <p>7.0 PROCEDURE:</p> <p>7.1 One of the most important objectives of an industrial hygiene program is to accurately assess employee by identifying all potential contaminants that may be exposed to in the workplace.</p> <p>7.2 The Industrial Hygiene Exposure Assessment is a systematic approach for identifying potential exposure hazards associated with facility operations, including manufacturing, laboratory, maintenance, and other non-production activities.</p> <p>7.3 Each SYNGENE facility has to conduct an Industrial Hygiene Exposure Assessment of chemicals/physical agents used on site to assess employee exposure potentials.</p> <p>7.4 The Industrial Hygiene Exposure Assessment involves the Qualitative and/or Quantitative evaluation of environmental agents which may pose health hazard at the workplace.</p>			

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<p>7.5 The Industrial Hygiene Exposure Assessment strategy is made to facilitate better coordination between Site activities and occupational health resources for prevention and early detection of health hazards.</p>																																							
<p>7.6 In all instances the Industrial Hygienist & Line management share concurrent responsibility to identify and document existing and potential chemical, physical, and biological health hazards. Following is the classification of health hazards generally found in the industries:</p>																																							
<table border="1"> <thead> <tr> <th>Chemical</th> <th>Physical</th> <th>Biological</th> <th>Ergonomic</th> </tr> </thead> <tbody> <tr> <td>Gas</td> <td>Noise</td> <td>Bacteria</td> <td>Workstation Design</td> </tr> <tr> <td>Vapors</td> <td>Vibration</td> <td>Viruses</td> <td>Repetitive Motion</td> </tr> <tr> <td>Solids</td> <td>Temp. - Heat& Cold</td> <td>Fungi</td> <td>Manual Lifting</td> </tr> <tr> <td>Fibers</td> <td>Illumination</td> <td>Mold</td> <td>---</td> </tr> <tr> <td>Liquids</td> <td>Radiation</td> <td>---</td> <td>---</td> </tr> <tr> <td>Dusts</td> <td>---</td> <td>---</td> <td>---</td> </tr> <tr> <td>Mists</td> <td>---</td> <td>---</td> <td>---</td> </tr> <tr> <td>Fumes</td> <td>---</td> <td>---</td> <td>---</td> </tr> </tbody> </table>	Chemical	Physical	Biological	Ergonomic	Gas	Noise	Bacteria	Workstation Design	Vapors	Vibration	Viruses	Repetitive Motion	Solids	Temp. - Heat& Cold	Fungi	Manual Lifting	Fibers	Illumination	Mold	---	Liquids	Radiation	---	---	Dusts	---	---	---	Mists	---	---	---	Fumes	---	---	---			
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<p>7.7 Qualitative Exposure Assessment (Walk through survey): A qualitative assessment is an essential first step that helps to identify and recognize POTENTIAL personal exposure to workplace chemicals, physical and/or biological agents based on personal experience of the employees / contractors and professional judgement of EHSS personnel. The qualitative assessment will be performed by the Line management with the help of EHSS team/Industrial Hygienist. The assessment should include the following steps:</p>																																							
<p>7.7.1 A brief description of the location, purpose, or use of the facility.</p>																																							
<p>7.7.2 Identification of the routine activities performed in each facility or out-building/area.</p>																																							
<p>7.7.3 Identification of no of persons exposed frequency, modalities & duration of exposure by walk through survey and divide them into similar exposure groups.</p>																																							
<p>7.7.4 Identification of the potential health hazards associated with the exposures to – chemical, physical, biological and ergonomic factors.</p>																																							
<p>7.7.5 Identification of the need for confirming exposure monitoring</p>																																							
<p>7.7.6 Characterization of potential health risk level based on visual observation in the workplace and monitoring conducted.</p>																																							
<p>7.7.7 Identification of the controls (engineering, administrative, and PPE) required to mitigate or eliminate the potential for exposure to the hazard</p>																																							
<p>7.7.8 Refer FORM-EHSS-EHSS-0028(Annexure – 08) for Qualitative Exposure Assessment</p>																																							
<p>7.7.9 The qualitative exposure assessment covers following elements:</p>																																							
<p>7.7.9.1 Element 1: Basic Hazard Characterization</p>																																							

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<p>7.7.9.2 Element 2: Establish exposure potential / Similar Exposure Groups (SEGs). 7.7.9.3 Element 3: IH Improvement & monitoring plan.</p> <p>7.8 Quantitative Exposure Assessment:</p> <p>7.8.1 A quantitative assessment is an essential step for Evaluation of ACTUAL area / personal exposure to workplace chemicals, physical and/or biological agents using accredited numerical and mathematical analysis.</p> <p>7.8.2 Evaluation of identified parameters with the help of equipment and the risk of exposure parameters to verify the quantitative exposure assessment ratings and ensure personnel are adequately protected from potentially hazardous exposures.</p> <p>7.8.3 Refer FORM-EHSS-EHSS-0029(Annexure – 09) for Quantitative Exposure Assessment</p> <p>7.8.4 The quantitative exposure assessment covers the following elements:</p> <p>7.8.4.1 Element 4: Workplace Exposure Monitoring 7.8.4.2 Element 5: Analysis & Interpret results 7.8.4.3 Element 6: Prevention & Control 7.8.4.4 Element 7: End of the activity & periodic review</p> <p>7.9 Exposure Monitoring Sampling Plan:</p> <p>7.9.1 An IH sampling plan will be developed based on the results of the Qualitative Exposure assessment for each potential exposure, based on previous exposure monitoring results, if available & Industrial Hygienist’s recommendations. The plan will specify sufficient sampling such that, when completed, an accurate exposure determination can be made.</p> <p>7.9.2 Periodic sampling programs should be designed to represent TWA exposures and monitoring should be performed when changes or modifications are made to the process that could affect employee exposure potentials. Evaluation of the exposure potential should be conducted after process or operational changes have been completed.</p> <p>7.9.3 IH sample results will be interpreted by comparing the applicable published allowable exposure limit, like Threshold Limit Values (TLV) by ACGIH & Local applicable regulatory requirements (The Factories Act 1948).</p> <p>7.10 Monitoring Frequencies:</p> <p>7.10.1 Annual monitoring plan will be developed by EHSS team/Industrial Hygienist. Both full shifts (represents TLV-TWA) & task specific (represents TLV-STEL) shall be considered.</p> <p>7.10.2 Chemical Exposure Monitoring – Dust, Fumes, Gases & Vapours:</p> <p>7.10.2.1 Periodic exposure monitoring for identified chemicals should be performed annually (at a minimum), regardless of the documented exposure level. Other potentially hazardous chemicals identified by the EHSS team/industrial hygienist should also be monitored until the exposure is reduced below TLV. The monitoring will also be conducted as per FORM-</p>			

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<p>EHSS-EHSS-0021(Annexure-01) and when needed by any operating unit for any other purpose.</p> <p>7.10.2.2 Considering the large complex, Nominated champions/ employees should be trained from every operating unit for operating the equipment for various parameters. The same will conduct the exposure monitoring in their respective areas after the identification of locations in consultation with industrial hygienist.</p> <p>7.10.3 Physical Hazards Monitoring – Noise, Heat & Vibration (As Applicable):</p> <p>7.10.3.1 Periodic monitoring for identified high Noise, Heat and other physical hazards (except vibration), whichever applicable should be performed annually at a minimum regardless of the documented exposure level. The monitoring will also be conducted as and when needed by any operating unit for any other purpose including personal noise/heat measurement.</p> <p>7.10.3.2 Considering large complex, Nominated champions/ persons are to be trained from every operating unit for operating the equipment for various parameters. The same will conduct the noise, heat exposure and other applicable hazard monitoring in their respective areas after the identification of locations with the help of EHSS team/industrial hygienist as per FORM-EHSS-EHSS-0023, FORM-EHSS-EHSS-0025, FORM-EHSS-EHSS-0026 (Annexure-03, 05 and 06).</p> <p>7.10.4 Indoor Air Quality Monitoring:</p> <p>7.10.4.1 Periodic monitoring for Indoor Air Quality (IAQ) should be performed annually (at a minimum) regardless of the documented exposure level. The monitoring will also be conducted as and when needed by any operating unit for other purposes as per FORM-EHSS-EHSS-0027(Annexure-07).</p> <p>7.10.4.2 The IAQ monitoring will be covered inside the buildings/offices areas but not limited to. (HVAC, Air Condition Offices etc.)</p> <p>7.10.5 Illumination Monitoring:</p> <p>7.10.5.1 Periodic monitoring for Illumination should be performed annually (at a minimum) regardless of the documented exposure level. The monitoring will also be conducted as and when needed by any operating unit for other purposes as per FORM-EHSS-EHSS-0029(Annexure-09).</p> <p>7.10.5.2 Considering large complex, nominated departmental representative will conduct illumination monitoring in their respective areas.</p> <p>7.11 Sampling Rationale & Methodology:</p> <p>7.11.1 Air Samples for any task shall be – at least single or triplicate samples based on Industrial Hygienist judgement with a minimum of 1 blank or 10% of the total samples as blanks (whichever is greater).</p>			

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<p>7.11.2 Sample collection will be done by EHSS representative or trained personnel under the direction of an industrial hygienist.</p> <p>7.11.3 Sample collection and analysis will be performed using recognized methods, such as the OSHA & NIOSH Analytical Methods and IH laboratories like (First Preference – AIHA Lab & Second Preference – NABL Lab).</p> <p>7.11.4 All IH sample results will be retained on the site in an easily retrievable manner.</p> <p>7.12 Communication of Sampling Results:</p> <p>7.12.1 Sample results should be communicated to the following personnel:</p> <p>7.12.1.1 Head of the department</p> <p>7.12.1.2 The individual employee who was monitored.</p> <p>7.12.1.3 Reporting manager of the employee who was monitored.</p> <p>7.12.2 Monitoring results should be communicated within one week</p> <p>7.12.2.1 Communication of results should be written in standard Workplace/Personal Exposure Assessment format (Refer to FORM-EHSS-EHSS-0022(Annexure -02), Dust & Chemical sample record form etc.)</p> <p>7.12.2.2 Monitoring notification forms will be maintained at the site until such time as they may be permanently stored. These monitoring forms will be treated as confidential documents. Note: Noise, Heat, IAQ results should be communicated within 07 calendar days of survey in standard IH formats.</p> <p>7.13 Chain of Custodian: EHSS representative will maintain “chain of custody” requirements and document IH sample collection in accordance with applicable regulatory requirements.</p> <p>7.14 Employee Training:</p> <p>7.14.1 The employees should be trained to make them aware about the occupational health hazards and industrial hygiene program.</p> <p>7.14.2 Training should include employees all concerned employees and it shall be validated. Training record should be maintained in required format.</p> <p>7.15 Industrial hygiene equipment guidelines:</p> <p>7.15.1 General Calibration:</p> <p>7.15.1.1 Pre and post calibration of equipment are to be done limited to (Noise Dosimeter, Sound Level Meter, Air Sampling Pump & Heat Stress WBGT Meter, Personal Heat Stress Meter) before and after taking reading in the field.</p> <p>7.15.1.2 Comprehensive and accurate records are necessary to document the calibration of above industrial hygiene equipment.</p>			

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<p>7.16 Laboratory Calibration:</p> <p>7.16.1 Certain equipment must be calibrated periodically by a calibration laboratory, recommended calibration laboratories are those operated by equipment manufacturer (who is most familiar with the equipment), The Swan Environmental, or other accepted calibration laboratory.</p> <p>7.16.2 Examples of other accepted laboratories would be those recommended by the manufacturer or those with a demonstrated ability to calibrate a specific piece of equipment and a quality control program.</p> <p>7.16.3 The frequency of calibration for equipment's shall be once in a year by third party.</p> <p>7.16.4 Calibration record shall contain, as a minimum:</p> <p>7.16.4.1 Item description, including manufacture and model number;</p> <p>7.16.4.2 Item serial number;</p> <p>7.16.4.3 Date of calibration, when the next calibration is due.</p> <p>7.16.4.4 Third Party details including name and address.</p> <p>7.17 Other Industrial Hygiene Programs: Additional IH related programs have been briefly summarized below. The following program elements shall be implemented:</p> <p>7.18 Hearing Conservation: Employees and contractors exposed to high noise levels (i.e. > 85 dBA) are required to be offered a hearing conservation program. One part of this program is the exposure assessment of workers to measure their noise exposure. Based upon the assessment, periodic hearing tests and training may be required. The site requires hearing protection to be used in specific areas and for specific tasks. The contractor must make sure other tasks their workers perform do not also require hearing protection. Also certain tasks may generate extremely high noise levels (over 100dBA 8 hrs. avg.) which may require double protection (muffs over plugs).</p> <p>7.19 Control of Exposure to Heat:</p> <p>7.19.1 The primary objective is to prohibit or reduce heat exposure in the workplace.</p> <p>7.19.2 Activities involving heat must be evaluated by using Industrial Hygiene equipment (WBGT Meter / Personal Heat Stress Meter) and if it exceeds the occupational exposure limit then a written compliance program shall be developed.</p> <p>7.19.3 Engineering control must be the primary method used to minimize exposure and to prevent the heat into the work environment.</p> <p>7.19.4 Employees who work with, or are potentially exposed to, heat will be provided with documented use-specific training, including instruction on:</p> <p>7.19.4.1 Heat stress monitoring</p>			

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<p>7.19.4.2 Health hazard on heat stress</p> <p>7.19.4.3 Heat Stress disorders</p> <p>7.19.4.4 First aid on heat stress</p> <p>7.19.4.5 Control of heat stress</p> <p>7.20 Ventilation:</p> <p>7.20.1 LEV (Local exhaust ventilation) System: Local exhaust ventilation is required (as an engineering control) where feasible to maintain concentrations of hazardous and irritating air contaminants below their occupational exposure limit. Such systems must be evaluated by the Industrial Hygienist with the help of Line management before the start of the work effort to ensure proper application. Such systems must be use, inspected, and tested in accordance with manufacturer recommendations to ensure proper operation.</p> <p>7.20.2 General dilution ventilation system: It may be used to provide protection from low concentrations of low-hazard airborne contaminants. They must also be used and maintained in accordance with manufacturer’s recommendations.</p> <p>7.20.3 Ergonomic Program: The ergonomics strategy shall be documented and communicated to all personnel. At a minimum, it shall establish the goal of eliminating or reducing employees’ exposure to ergonomic hazards that could lead to occupational illnesses or injuries. Each location shall have a written program.</p> <p>7.20.4 IAQ Program: The IAQ Program shall be establishing the goal of reducing sick building syndrome and building related illness that could lead to occupational illness or injuries. Each location shall have a written program.</p> <p>7.20.5 It is the responsibility of each contractor to determine their own program</p> <p>8.0 REFERENCES: NA</p> <p>9.0 ANNEXURES:</p> <table border="1"> <tr> <td>FORM-EHSS-EHSS-0021</td> <td>Annexure – 01 Dust & chemical sample record form</td> </tr> <tr> <td>FORM-EHSS-EHSS-0022</td> <td>Annexure – 02 Dust & chemical sample reporting form</td> </tr> <tr> <td>FORM-EHSS-EHSS-0023</td> <td>Annexure – 03 Noise dosimetry record form</td> </tr> <tr> <td>FORM-EHSS-EHSS-0024</td> <td>Annexure – 04 Noise dosimetry reporting form</td> </tr> <tr> <td>FORM-EHSS-EHSS-0025</td> <td>Annexure – 05 Area noise monitoring form</td> </tr> <tr> <td>FORM-EHSS-EHSS-0026</td> <td>Annexure – 06 Area heat stress reporting form</td> </tr> <tr> <td>FORM-EHSS-EHSS-0027</td> <td>Annexure – 07 Indoor air quality reporting form</td> </tr> </table>				FORM-EHSS-EHSS-0021	Annexure – 01 Dust & chemical sample record form	FORM-EHSS-EHSS-0022	Annexure – 02 Dust & chemical sample reporting form	FORM-EHSS-EHSS-0023	Annexure – 03 Noise dosimetry record form	FORM-EHSS-EHSS-0024	Annexure – 04 Noise dosimetry reporting form	FORM-EHSS-EHSS-0025	Annexure – 05 Area noise monitoring form	FORM-EHSS-EHSS-0026	Annexure – 06 Area heat stress reporting form	FORM-EHSS-EHSS-0027	Annexure – 07 Indoor air quality reporting form
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FORM-EHSS-EHSS-0027	Annexure – 07 Indoor air quality reporting form																

Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability
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TITLE:INDUSTRIAL HYGIENE MANAGEMENT

Document Number: SOP-EHSS-EHSS-0004	Version no.: 2.0	Effective Date: 09-Mar-2023	Next Review Date: 08-Mar-2025
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FORM-EHSS-EHSS-0028	Annexure – 08 Qualitative risk assessment
FORM-EHSS-EHSS-0029	Annexure – 09 Quantitative risk assessment
FORM-EHSS-EHSS-0030	Annexure – 10 SOP Training Questionnaire
FORM-EHSS-EHSS-0031	Annexure – 11 Annual planner

10.0 REVISION HISTORY:

Version no.	Effective Date	Description of Change
2.0	09-Mar-2023	<u>Reference Change Control Number:</u> - EHSS/CCF/23/0004
1.0	04-Sep-2020	<u>Reference Change Control Number:</u> - EHSS/CCF/20/0009 Newly introduced SOP

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	Standard Operating Procedure	Department: Environmental Health Safety and Sustainability
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Title: LAB SAFETY

Document Number: SOP-EHSS-EHSS-0026	Version Number: 2.0	Effective Date: 16-Feb-2023
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Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Nidhi Cs/EHSS/ SYNGENE	11-Feb-2023 11:36:36 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Satish Birajdar/EHSS/ SYNGENE	13-Feb-2023 10:52:25 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	13-Feb-2023 15:40:29 (IST)

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Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability	
TITLE:LAB SAFETY			
Document Number: SOP-EHSS-EHSS-0026	Version no.: 2.0	Effective Date: 16-Feb-2023	Next Review Date: 15-Feb-2025
<p>1.0 OBJECTIVE: To have a documented procedure for laboratory safety.</p> <p>2.0 SCOPE: This Procedure is applicable to personnel working in the laboratory at Syngene International Limited.</p> <p>3.0 RESPONSIBILITY:</p> <p>3.1 EHSS Department: To train employees on laboratory safety.</p> <p>3.2 Personnel involved in Laboratory activities: To comply with the procedure.</p> <p>4.0 ABBREVIATION: EHSS : Environment, Health, Safety and Sustainability EPR : Emergency Preparedness and Response HOD : Head of the Department MCP : Manual Call Point SDS : Safety Data Sheet PPE : Personal Protective Equipment SOP : Standard Operating Procedure</p> <p>5.0 DEFINITION: NA</p> <p>6.0 EHSS: NA</p> <p>7.0 PROCEDURE:</p> <p>7.1 Personal and General Laboratory safety:</p> <p>7.1.1 Never eat, drink or smoke while working in the laboratory.</p> <p>7.1.2 Do not touch anything which is not completely familiar.</p> <p>7.1.3 If in case of not sure how to handle a particular situation, ask respective supervisor or HOD for advice.</p> <p>7.1.4 It is always better to ask questions oneself than to risk or damage the equipment.</p> <p>7.1.5 Read labels carefully.</p> <p>7.1.6 Do not use any equipment without proper training and approval by supervisor as a user.</p> <p>7.1.7 Wear appropriate PPE's (Safety shoes, Goggles, Lab coats/apron, Gloves, Respirators, Face shield, Helmet as applicable) when using any hazardous or toxic agent/ any equipment.</p> <p>7.1.8 When handling chemical substances, wear gloves, laboratory coats, shoes and safety shield or glasses. Shorts and sandals should not be worn in the lab at any time.</p>			

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<p>TITLE:LAB SAFETY</p>			
<p>Document Number: SOP-EHSS-EHSS-0026</p>	<p>Version no.: 2.0</p>	<p>Effective Date: 16-Feb-2023</p>	<p>Next Review Date: 15-Feb-2025</p>
<p>7.1.9 If you have long hair or loose clothes, make sure it is tied back or confined.</p> <p>7.1.10 Keep the work area clear of all materials except those needed for your work. Lab coats should not be taken to the workstation. It should be kept at the respective PPE cupboard or storage area.</p> <p>7.1.11 Clean up the working area before leaving.</p> <p>7.1.12 Wash hands before leaving the lab and before eating.</p> <p>7.1.13 Know the location of the fire extinguisher, eye wash station, Emergency shower, Spill kit, Manual call point and Fire Exit in the respective lab and know how to use.</p> <p>7.1.14 Notify supervisor or HOD immediately after any injury, fire or explosion or spill.</p> <p>7.1.15 Know the building evacuation procedures.</p> <p>7.1.16 During Emergency, shut off all the electrical equipment and stop all the activities as per shutdown procedure (Refer: SOP-EHSS-EHSS-0023, Equipment Emergency Shutdown) and follow EPR procedure (Refer SOP-EHSS-EHSS-0020, Emergency Preparedness and Response)</p> <p>7.2 Chemical safety:</p> <p>7.2.1 Treat every chemical as hazardous.</p> <p>7.2.2 Make sure that all chemicals are clearly and correctly labeled with the substance name, concentration, date, and name of the individual responsible.</p> <p>7.2.3 Never return chemicals to reagent bottles.</p> <p>7.2.4 Use volatile and flammable compounds only in a fume hood. Procedures that produce aerosols should be performed in a hood to prevent inhalation of hazardous material.</p> <p>7.2.5 Never allow a solvent to come in contact with skin. Always use gloves.</p> <p>7.2.6 Dispose of waste and broken glassware in proper containers.</p> <p>7.3 Additional Safety Guidelines:</p> <p>7.3.1 Awareness is the most fundamental rule of chemical safety.</p> <p>7.3.2 Read the SDS of the chemicals to be handled.</p> <p>7.3.3 Take time to understand the safety and health hazards of the chemicals in the workplace.</p> <p>7.3.4 Assume that unfamiliar chemicals are hazardous.</p> <p>7.3.5 Know appropriate procedures for emergencies, including the location and operation of all emergency equipment.</p> <p>7.3.6 When working with hazardous materials have a second person nearby or at minimum, maintain surveillance by telephone contact.</p> <p>7.3.7 Always order the least amount of chemical required.</p> <p>7.3.8 Use appropriate personal protective equipment at all times.</p> <p>7.3.9 Use hazardous chemicals in a chemical fume hood.</p>			

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<p>Document Number: SOP-EHSS-EHSS-0026</p>	<p>Version no.: 2.0</p>	<p>Effective Date: 16-Feb-2023</p>	<p>Next Review Date: 15-Feb-2025</p>
<p>7.3.10 Maintain equipment and inspect it regularly for proper function.</p> <p>7.3.11 Use guards and shields where possible.</p> <p>7.3.12 Use safety shields when there is a possibility for explosion or implosion.</p> <p>7.3.13 Store and handle chemicals in accordance with the guidelines contained in the Chemical Hygiene Plan and Chemical compatibility.</p> <p>7.3.14 Dispose the Hazardous waste as per SOP: SOP-EHSS-EHSS-0073, Waste Management.</p> <p>7.3.15 Do not pour chemical waste materials into the sink.</p> <p>7.3.16 Do not eat, drink, chew gum or apply cosmetics in the laboratory.</p> <p>7.3.17 Do not store food or beverages in the laboratory or in a chemical refrigerator.</p> <p>7.3.18 Never taste anything. Do not pipette through mouth. Use a mechanical pipette or aspirator.</p> <p>7.3.19 Do not use chipped or cracked glassware.</p> <p>7.3.20 Report all incidents and near miss (Refer: SOP-EHSS-EHSS-0055, Incident Reporting and Investigation).</p> <p>7.4 Housekeeping/Hygiene:</p> <p>7.4.1 Work areas should be kept clean and free from obstruction.</p> <p>7.4.2 Hands should be washed after every experiment, before touching any non-contaminated area or object, and before leaving the laboratory area.</p> <p>7.4.3 Access to exits, emergency exits, aisles and controls should never be blocked.</p> <p>7.4.4 Emergency exits should be kept unlocked from the inside.</p> <p>7.4.5 Stairways and hallways should not be used as storage areas.</p> <p>7.5 Chemical Storage and Handling:</p> <p>7.5.1 Many potential hazards are associated with the storage and handling of laboratory chemicals. These hazards may be minimized by understanding the properties of the chemicals and by developing procedures by which they may be handled safely. Simply storing chemicals alphabetically is not prudent. Flammable, corrosive, explosive, and peroxide forming agents require special precautions.</p> <p>7.5.2 Chemical handling: Use bottle carriers to transport chemicals. Close caps securely.</p> <p>7.5.3 Pour all chemicals carefully. Add acid to water, not water to acid.</p> <p>7.5.4 Chemical labels should be legible and easy to read. Shelves should be made of a chemically resistant material and should have a 2-inch lip or side rails.</p> <p>7.5.5 Incompatible chemicals: Incompatible chemicals should not be stored together. For each chemical, the hazardous nature must be considered individually and in relation to other chemicals in the area.</p> <p>7.5.6 Discard chemicals that are no longer needed or that have expired.</p>			

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Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability								
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Document Number: SOP-EHSS-EHSS-0026	Version no.: 2.0	Effective Date: 16-Feb-2023	Next Review Date: 15-Feb-2025							
<p>7.5.7 Fume hoods: In general, fume hoods should not be used for storage of chemicals, unless the chemicals are part of the experiment being conducted in the fume hood at that time.</p> <p>7.6 Emergency Response:</p> <p>7.6.1 It is each and every person’s responsibility to follow the instructions during an emergency (Refer: SOP-EHSS-EHSS-0020, Emergency Preparedness and Response).</p> <p>7.6.2 Emergency Response precautions:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 33%;">Spill</th> <th style="width: 33%;">Fire</th> <th style="width: 33%;">Chemical Exposure</th> </tr> </thead> <tbody> <tr> <td style="vertical-align: top;"> If there is any hazardous spill, Clean the spill, only: 1. If the spill is manageable 2. Spill kit has appropriate cleanup materials 3. If you are well trained. (Refer SOP: SOP-EHSS-EHSS-0029, Spill Control) 4. If failed to or not attempted to clean the spill, prevent the spread if possible, evacuate the area, close the lab door, and alert others or pull MCP. </td> <td style="vertical-align: top;"> Extinguish the fire, only 5. If it is small and contained 6. If the area has an appropriate fire extinguisher 7. If you are well trained. (Refer SOP: SOP-EHSS-EHSS-0005, Operation and maintenance of Fire extinguishers) 8. If failed to or not attempted to extinguish the fire, pull the nearest MCP and evacuate the building via the nearest exit. </td> <td style="vertical-align: top;"> 9. Splash to Skin or Eyes: Flush with water for at least 15 minutes using a safety shower or eye washer and seek immediate medical attention. 10. Ingestion: Seek medical attention immediately. 11. Inhalation: Stop emission if possible, alert others or pull MCP, get fresh air and seek immediate medical attention. (Refer to SOP-EHSS-EHSS-0017, Operation and maintenance of emergency eye washer and shower) </td> </tr> </tbody> </table>					Spill	Fire	Chemical Exposure	If there is any hazardous spill, Clean the spill, only: 1. If the spill is manageable 2. Spill kit has appropriate cleanup materials 3. If you are well trained. (Refer SOP: SOP-EHSS-EHSS-0029, Spill Control) 4. If failed to or not attempted to clean the spill, prevent the spread if possible, evacuate the area, close the lab door, and alert others or pull MCP.	Extinguish the fire, only 5. If it is small and contained 6. If the area has an appropriate fire extinguisher 7. If you are well trained. (Refer SOP: SOP-EHSS-EHSS-0005, Operation and maintenance of Fire extinguishers) 8. If failed to or not attempted to extinguish the fire, pull the nearest MCP and evacuate the building via the nearest exit.	9. Splash to Skin or Eyes: Flush with water for at least 15 minutes using a safety shower or eye washer and seek immediate medical attention. 10. Ingestion: Seek medical attention immediately. 11. Inhalation: Stop emission if possible, alert others or pull MCP, get fresh air and seek immediate medical attention. (Refer to SOP-EHSS-EHSS-0017, Operation and maintenance of emergency eye washer and shower)
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<p>7.7 Labeling and disposal of hazardous waste:</p> <p>7.7.1 Containers must be labeled legibly so that labels are clearly visible.</p> <p>7.7.2 Containers must be kept closed at all times, unless waste is being added or removed. Open-top funnels shall not be left in open containers.</p> <p>7.7.3 Condition: Containers must be in a good condition. There should not be severe rusting, dents or other conditions that could cause leaks, etc.</p> <p>7.7.4 Regulations: All hazardous wastes shall be accumulated and stored in properly managed containers on sufficiently impervious surfaces (free of cracks, gaps, etc.).</p> <p>7.7.5 Disposal: All waste container shall be transferred to waste collection point.</p>										

Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability										
TITLE:LAB SAFETY												
Document Number: SOP-EHSS-EHSS-0026	Version no.: 2.0	Effective Date: 16-Feb-2023	Next Review Date: 15-Feb-2025									
<p>7.8 Hazardous Waste Minimization:</p> <p>7.8.1 Process/equipment adjustment or modification</p> <p>7.8.2 Toxic material substitution</p> <p>7.8.3 Waste segregation and separation</p> <p>7.8.4 Recycling</p> <p>7.8.5 Where possible, microchemistry will reduce waste volume and has the added benefit of minimizing health and safety concerns. The exercise of prudence in ordering new chemicals will also ensure that excess chemical doesn't become subject to disposal as hazardous waste.</p> <p>8.0 REFERENCES: SOP-EHSS-EHSS-0055 SOP-EHSS-EHSS-0073 SOP-EHSS-EHSS-0020 SOP-EHSS-EHSS-0029 SOP-EHSS-EHSS-0017 SOP-EHSS-EHSS-0005 SOP-EHSS-EHSS-0023</p> <p>9.0 ANNEXURE: FORM-EHSS-EHSS-0163 : Annexure – 01 SOP Training Questionnaire</p> <p>10.0 REVISION HISTORY:</p> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:10%;">Version no.</th> <th style="width:20%;">Effective Date</th> <th style="width:70%;">Description of Change</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">2.0</td> <td style="text-align: center;">16-Feb-2023</td> <td><u>Reference Change Control Number: - EHSS/CCF/23/0004</u></td> </tr> <tr> <td style="text-align: center;">1.0</td> <td style="text-align: center;">17-Mar-2021</td> <td><u>Reference Change Control Number: - EHSS/CCF/20/0022</u></td> </tr> </tbody> </table>				Version no.	Effective Date	Description of Change	2.0	16-Feb-2023	<u>Reference Change Control Number: - EHSS/CCF/23/0004</u>	1.0	17-Mar-2021	<u>Reference Change Control Number: - EHSS/CCF/20/0022</u>
Version no.	Effective Date	Description of Change										
2.0	16-Feb-2023	<u>Reference Change Control Number: - EHSS/CCF/23/0004</u>										
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	Standard Operating Procedure	Department: Environmental Health Safety and Sustainability
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Title: PROCESS RISK ASSESSMENT

Document Number: SOP-EHSS-EHSS-0058	Version Number: 3.0	Effective Date: 25-May-2023
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Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Pooja Naik	17-May-2023 16:27:42 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Manivannan Arumugam/ EHSS/SYNGENE	19-May-2023 16:06:41 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	20-May-2023 15:23:32 (IST)

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	<p align="center">Standard Operating Procedure</p>	<p>DEPARTMENT: Environmental Health Safety and Sustainability</p>	
<p>TITLE:PROCESS RISK ASSESSMENT</p>			
<p>Document Number: SOP-EHSS-EHSS-0058</p>	<p>Version no.: 3.0</p>	<p>Effective Date: 25-May-2023</p>	<p>Next Review Date: 24-May-2025</p>
<p>1.0 OBJECTIVE:</p> <p>This document provides guidance for conducting a Process Risk Assessment (PRA) at Syngene International limited. A PRA is used to control significant hazards associated with hazardous chemicals, processes, and operations. PRA includes all the activities involved of in hazard identification & evaluation of risk at facilities throughout their life cycle to make certain that risks to employees, the public or the environment are consistently controlled within the organization’s risk tolerance</p> <p>This document provides mandatory requirements for identification of technical and managerial safety aspects by means of a systematic Process Risk Assessment.</p> <p>2.0 SCOPE:</p> <p>2.1 Process risk assessment (PRA) to be prepared, before the execution of any new process, operation, Ordering & Installation of new equipment, design stage, new facility setup, modification of existing procedures or processes, equipment, facility before commissioning, De-commissioning, Initial project risk assessment and revalidation.</p> <p>2.2 Operations as mandated by Management of Change.</p> <p>2.3 Process falls in high hazard category as per Laboratory Hazard analysis and scale of operations mentioned PSI guidelines.</p> <p>2.4 The assessment should reveal the significant necessary process-related hazards and enable their control through the identification of adequate safety measures.</p> <p>2.5 Project outsourcing guideline for chemical development.</p> <p>3.0 RESPONSIBILITY:</p> <p>3.1 OU/EF’s Head:</p> <p>3.1.1 Primary responsible to oversee and provide guidance in implementation of this procedure and to conduct audits on this procedure.</p> <p>3.1.2 Appointing PRA lead.</p> <p>3.2 Delivery Lead/Project Lead/TT Lead/MSAT Lead:</p> <p>3.2.1 Initiation of Process Risk Assessment</p> <p>3.2.2 Completion of Initial Project Risk Assessment</p> <p>3.2.3 Nominate the member to be part of PRA team.</p> <p>3.2.4 Coordinate with cross functional teams to provide necessary information demanded during the risk assessment. Refer FORM-EHSS-EHSS-0290 (Annexure – 03).</p> <p>3.2.5 Acceptance of Process Risk Assessment report.</p>			

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<p>3.3 PRA Lead:</p> <p>3.3.1 Overall responsible for driving the process risk assessment.</p> <p>3.3.2 Schedule PRA with approved team members.</p> <p>3.3.3 Discuss with the team members for assigning their roles.</p> <p>3.3.4 Organize the PRA discussion with a PRA team to conduct the study using methods of analysis consistent with the severity of the hazards and type of process.</p> <p>3.3.5 Ensure compilation of the PRA report along with the action items. PRA report shall be signed off by PRA lead followed by PRA team members.</p> <p>3.3.6 Submit the PRA report to Facility Manager.</p> <p>3.4 Facility Manager:</p> <p>3.4.1 Nominate the member to be part of PRA team.</p> <p>3.4.2 Accept the Process Risk Assessment report.</p> <p>3.4.3 Implementation of Process Risk Assessment recommendations.</p> <p>3.4.4 Follow-up & closure of the Process Risk Assessment recommendations.</p> <p>3.4.5 To conduct First Party Audit.</p> <p>3.5 EHSS:</p> <p>3.5.1 EHSS team member should be part of PRA team.</p> <p>3.5.2 To issue the RA number.</p> <p>3.5.3 Jointly with the PRA team lead to review the PRA team members.</p> <p>3.5.4 To conduct second party Audit.</p> <p>3.6 PRA team members:</p> <p>3.6.1 Conduct the PRA with the selected methodology.</p> <p>3.6.2 Identify the Hazards/Risk associated with the process/practices/step by brainstorming/selected PRA method and propose the recommendations.</p> <p>3.6.3 Process Risk Assessment report should be Signed off.</p> <p>3.6.4 PRA requires a team approach. Team members represent disciplines with specific knowledge of the hazard/installation/process and EHSS.</p> <p>3.6.5 PRA Team composition as mentioned below not limited.</p> <p>3.6.5.1 Technology transfer/MSAT/Project Lead.</p> <p>3.6.5.2 Engineering and Maintenance.</p> <p>3.6.5.3 Process Engineering.</p> <p>3.6.5.4 Area in charge including shop floor representative.</p> <p>3.6.5.5 EHSS</p> <p>3.6.5.6 Additional resources as deemed necessary, e.g. instrumentation, planning, Consultant etc.,</p>			

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<p>4.0 ABBREVIATION:</p> <p>AIR : Asset Integrity & Reliability EF : Enabling Function EHSS : Environment, Health, Safety & Sustainability HAZOP : Hazard & Operability study IPRA : Initial Project Risk Assessment JSA : Job safety Analysis MOC : Management of Change MSAT : Manufacturing Science and Technology OU : Operating Unit PRA : Process Risk Assessment PSSR : Pre-Startup Safety Review PSI : Process Safety Information PSM : Process Safety Management P&ID : Piping & Instrumentation Diagram TT : Technology transfer</p> <p>5.0 DEFINITION:</p> <p>5.1 Start-up:</p> <p>The point at which chemicals or energy is introduced into the system.</p> <p>5.2 PSI:</p> <p>5.2.1 Information pertaining to the hazards of the highly hazardous chemicals used in the process. 5.2.2 Information pertaining to the technology of the process. 5.2.3 Information pertaining to the equipment used in the process.</p> <p>5.3 Facility Manager:</p> <p>Any Employee from the department who has overall responsibility for operation, Maintenance and people management including safety for assigned area or facility i.e. lab Managers, production Manager etc.</p> <p>5.4 Batch Process:</p> <p>Batch process is a method of manufacturing where the products are made as specified groups or amounts, within a time frame. A batch can go through a series of steps in a manufacturing process to make the final desired product.</p>			

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<p>TITLE:PROCESS RISK ASSESSMENT</p>			
<p>Document Number: SOP-EHSS-EHSS-0058</p>	<p>Version no.: 3.0</p>	<p>Effective Date: 25-May-2023</p>	<p>Next Review Date: 24-May-2025</p>
<p>5.5 Continuous Process:</p> <p>Continuous Process is a flow production method used to manufacture, produce, transfer of chemical or process materials without interruption. Continuous production is called a continuous process or a continuous flow process because the materials, either dry bulk or fluids that are being processed are continuously in motion.</p> <p>6.0 EHSS:</p> <p>Follow site EHSS procedures.</p> <p>7.0 PROCEDURE:</p> <p>7.1 Initiate PRA:</p> <p>7.1.1 Process risk assessment (PRA) to be initiated for any new process, operation, new facility setup, modification of existing procedures or processes. Refer FORM-EHSS-EHSS-0288 (Annexure – 01).</p> <p>7.1.2 Segregation of the process under risk analysis into possible unit-operations or process steps and identify related nominal conditions.</p> <p>7.1.3 Selection of PRA lead and PRA team members for conducting the Process Risk Assessment</p> <p>7.1.4 Appoint the PRA team members in consultation with EHSS. Refer FORM-EHSS-EHSS-0289 (Annexure – 02).</p> <p>7.2 Methodology selection:</p> <p>7.2.1 PRAs shall use either the checklist or HAZOP technique as the primary hazard evaluation methodology refer FORM-EHSS-EHSS-0291 (Annexure-04).</p> <p>7.2.2 Multiple methodologies may be used to study different portions of the process at the sole discretion of the PRA team.</p> <p>7.2.3 Continuous process: Solvent transfer system, Solvent Recovery plant etc. follow HAZOP study. Refer FORM-EHSS-EHSS-0481 (Annexure-11 (a)).</p> <p>7.2.4 Conceptual Risk Assessment: Ordering of new Equipment, Modification of Equipment, Modification of Facility & Construction of new Facility.</p> <p>7.2.4.1 Ordering new Equipment / Modification of process equipment. Follow HAZOP study</p> <p>7.2.4.2 Modification of Facility & construction of new Facility. Follow Job Safety Analysis Method (Refer “Permit to Work Procedure” SOP-EHSS-EHSS-0007).</p> <p>7.2.5 Material movement: Follow Job safety analysis (stores, within facility and storage of raw material etc.)</p> <p>7.2.6 Batch Process: Follow Checklist Method (Deviation & Consequence Analysis). Refer FORM-EHSS-EHSS-0482 (Annexure-11 (b)).</p>			

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<p>7.3 Hazard Identification:</p> <p>7.3.1 Hazards in nominal conditions and conceivable deviations per unit-operation or process step must be identified. The identification must cover the following possible hazardous properties:</p> <p>7.3.1.1 Toxic (acute, chronic, aquatic toxicity)</p> <p>7.3.1.2 Fire, including generation of ignitable atmosphere</p> <p>7.3.1.3 Chemical reaction (primary, secondary)</p> <p>7.3.1.4 Pressure</p> <p>7.3.1.5 Electricity</p> <p>7.3.1.6 Moving parts</p> <p>7.3.1.7 Radiation</p> <p>7.3.1.8 Infectious / biohazardous agent, but not limited</p> <p>7.3.2 Information sources usually required are:</p> <p>7.3.2.1 Process/procedure description</p> <p>7.3.2.2 Process Safety Information</p> <p>7.3.2.3 Initial Project Risk Assessment</p> <p>7.3.2.4 Previous Process Risk Assessment documents</p> <p>7.3.2.5 Diagrams and plans (detail level according to design stage: P&IDs...)</p> <p>7.3.2.6 Transfer documents</p> <p>7.3.2.7 Former safety studies/safety reports</p> <p>7.3.2.8 History of past incidents and lessons learnt. but not limited</p> <p>7.3.2.9 Conceptual Risk Assessment (As Applicable).</p> <p>7.4 Risk Assessment:</p> <p>7.4.1 The deviations identified as relevant are occurring, possible consequences in terms of affecting employees, environment, assets, and image are balanced against their probability of occurrence by selecting the appropriate Process Risk Assessment methodologies.</p> <p>7.4.2 The risk has to be scored., by using the process risk assessment matrix is appended in the FORM-EHSS-EHSS-0300 (Annexure-06). The higher the risk is, the more reliable prevention, protection barriers are necessary.</p> <p>7.5 Risk Mitigation:</p> <p>7.5.1 If the identified risk is not found to be acceptable, it must be mitigated according to the following:</p> <p>7.5.1.1 Reduce the hazard (Reduce – Replace – Moderate).</p> <p>7.5.1.2 First try to improve by modifying materials (including hold-up), chemistry and process variables so that the hazard (Severity) is reduced.</p>			

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<p>7.5.2 Secondly reduce the probability of occurrence of the deviation identified with adequate prevention barriers, whose three generic types are existing:</p> <p>7.5.2.1 Structural provisions, acting without auxiliary energy (passive barriers)</p> <p>7.5.2.2 Measures, acting on demand, requiring change of energy input (active barriers)</p> <p>7.5.2.3 Measures executed by humans (organizational barriers).</p> <p>7.5.3 Generally passive barriers have the highest reliability; organizational barriers have a broad range of variation of reliability. Examples:</p> <p>7.5.3.1 Passive: Pressure resistant design, catch tanks, basins, and physical separation.</p> <p>7.5.3.2 Active: Pressure relief systems (pressure safety valves, rupture disks), explosion suppression, safeguarding with engineering controls.</p> <p>7.5.3.3 Organizational: Operating instruction, double check, training skills, ergonomic configuration means for error prevention.</p> <p>7.6 Risk Evaluation:</p> <p>7.6.1 The risk must be found acceptable when the proposed safety measures are considered sufficient to proceed. If not, the entire risk assessment to be revisit from the beginning.</p> <p>7.6.2 Refer FORM-EHSS-EHSS-0300 (Annexure – 06).</p> <p>7.7 Initial project risk assessment (New Project related to chemical Process):</p> <p>7.7.1 The new projects should undertake IPRA checklist by project lead with cross functional team and to decide on proposal acceptance / rejection based on the evaluation.</p> <p>7.7.2 Accepted IPRA shall be part of PSI & PRA.</p> <p>7.7.3 Refer FORM-EHSS-EHSS-0301 (Annexure-07).</p> <p>7.8 Outsourcing guideline for chemical development:</p> <p>7.8.1 The new project from chemical development planned for outsourcing due to feasibility constraint for executing the project inhouse or to delivery on time should follow the outsourcing guideline wherever applicable.</p> <p>7.8.2 Refer FORM-EHSS-EHSS-0303 (Annexure – 08).</p> <p>7.8.3 The outsourcing facility evaluation shall be done with as per the FORM-EHSS-EHSS-302 (Annexure-09).</p> <p>7.9 Documentation:</p> <p>7.9.1 The risk assessment shall be reported as per the FORM-EHSS-EHSS-0494 (Annexure – 13).</p> <p>7.9.2 Risk Assessment Number shall be done as “S/EHSS/RA/XX/YY”, where ‘XX’ indicates financial year and ‘YY’ indicates serial number starts from ‘01’. Risk Assessment Number shall be documented as per FORM-EHSS-EHSS-0495 (Annexure -14).</p>			

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<p>7.9.3 The resulting Process Risk Assessment safety measures and actions to be documented appropriately.</p> <p>7.9.4 PRA lead will compilation of the PRA report along with the action items. PRA report shall be signed off by PRA lead followed by PRA team members.</p> <p>7.9.5 Submit the PRA report and action items to Facility Manager & Delivery Lead/Project Lead/TT Lead/MSAT Lead.</p> <p>7.9.6 Facility Manager & Delivery Lead/Project Lead/TT Lead/MSAT Lead will accept the Process Risk Assessment report.</p> <p>7.9.7 Facility Manager should ensure implementation of Process Risk Assessment recommendations.</p> <p>7.9.8 Follow-up & closure of the Process Risk Assessment recommendations.</p> <p>7.9.9 Facility Manager should verify the closure of the Process Risk Assessment actions items compliance.</p> <p>7.9.10 Periodically review/revalidated the existing installations and processes.</p> <p>7.9.11 The PRA shall be valid for three years, only if there is no change in batch size, no change in equipment, no change in facility or no change in process/operation.</p> <p>7.9.12 If there is any change in batch size, change in facility, change in equipment, change in process/operation, or there are changes in statutory requirements, Separate PRA with new RA number shall be prepared to address the new risks from the changes.</p> <p>7.9.13 Project Lead is responsible for Laboratory PRA. Scientist is responsible to prepare the PRA report, in coordination with cross functional teams.</p> <p>7.9.14 The nature and depth of the review shall reflect the dynamics of change in the respective unit and the emerging issues (e.g. changed statutory requirements, consequences from incidents, programs resulting from audit findings, authoritative orders).</p> <p>7.10 Training:</p> <p>7.10.1 Awareness Training:</p> <p>7.10.1.1 PRA procedure training to be given to all applicable employees.</p> <p>7.10.2 Knowledge based training:</p> <p>7.10.1.2 Should undergo training on the overview of PSM elements.</p> <p>7.10.1.3 Training to be given to employees involved in the activity or process by PRA team before startup of the operations.</p> <p>7.10.1.4 PRA team to be provided with adequate training to ensure a high-quality analysis of the process hazards. Team training requirements shall include the following:</p> <p>7.10.1.5 Team members, including the team leader, must receive overview training in the PRA procedure and application of the hazard evaluation methodologies selected for the study.</p>			

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<p>7.10.1.6 Should undergo PSI training to understand the information required to assess the risk associated.</p> <p>7.10.1.7 Management of Change (MoC) and Asset Integrity and Reliability (AIR) training to follow the system and procedures involved during the implementation of recommendations.</p> <p>7.10.1.8 In-depth training in the selection and application of the hazard evaluation methodologies.</p> <p>8.0 REFERENCES: SOP-EHSS-EHSS-0007</p> <p>9.0 ANNEXURES:</p>			
FORM-EHSS-EHSS-0288	ANNEXURE – 01	Process Risk Assessment Process Workflow	
FORM-EHSS-EHSS-0289	ANNEXURE – 02	Process Risk Assessment Swim Lane Workflow	
FORM-EHSS-EHSS-0290	ANNEXURE – 03	Process Risk Assessment RACI Matrix	
FORM-EHSS-EHSS-0291	ANNEXURE – 04	Process Risk Assessment Methodology selection workflow.	
FORM-EHSS-EHSS-0300	ANNEXURE – 06	Process Risk Assessment Matrix	
FORM-EHSS-EHSS-0301	ANNEXURE – 07	Initial Project Risk Assessment Template	
FORM-EHSS-EHSS-0303	ANNEXURE – 08	Project Outsourcing Guideline For Chemical Development	
FORM-EHSS-EHSS-0302	ANNEXURE – 09	Project Outsourcing Facility Evaluation Checklist	
FORM-EHSS-EHSS-0304	ANNEXURE – 10	SOP Training Questionnaire	
FORM-EHSS-EHSS-0481	ANNEXURE – 11 (a)	Process Risk Assessment Methodology – HAZOP Method	
FORM-EHSS-EHSS-0482	ANNEXURE – 11 (b)	Process Risk Assessment Methodology – CHECK LIST Method	
FORM-EHSS-EHSS-0494	ANNEXURE – 13	Risk Assessment Report	
FORM-EHSS-EHSS-0495	ANNEXURE – 14	Risk Assessment Number Register	

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<p>10.0 REVISION HISTORY:</p>				
<p align="center">Version no.</p>	<p align="center">Effective Date</p>	<p align="center">Description of Change</p>		
<p align="center">3.0</p>	<p align="center">25-May-2023</p>	<p><u>Reference Change Control Number: - EHSS/CCF/23/0018</u></p> <ol style="list-style-type: none"> In section 3.5.2, To issue the RA number has been added. In section 7.9.1, The risk assessment shall be reported as per the FORM-EHSS-EHSS-0494 (Annexure – 13) has been added. In section 7.9.2, Risk Assessment shall be done as “S/EHSS/RA/XX/YY”, where ‘XX’ indicates financial year and ‘YY’ indicates serial number starts from ‘01’. Risk Assessment Number shall be documented as per FORM-EHSS-EHSS-0495 (Annexure -14) has been added. In section 7.9.11, The PRA shall be valid for three years has been added. 		
<p align="center">2.0</p>	<p align="center">24-Mar-2023</p>	<p><u>Reference Change Control Number: - EHSS/CCF/23/0009</u></p> <ol style="list-style-type: none"> In section 3.2.4, Coordinate with cross functional teams to provide necessary information demanded during the risk assessment. Refer FORM-EHSS-EHSS-290 (Annexure – 03) has been added. In section 7.8.3, The outsourcing facility evaluation shall be done with as per the FORM-EHSS-EHSS-302 (Annexure – 09) has been added. In section 7.9.1, The risk assessment shall be reported as per the FORM-EHSS-EHSS-0483 (Annexure – 12) has been added. In section 7.9.9, Periodically review/revalidated the existing installations and processes has been added. In section 7.9.10, The PRA shall be valid for two years, only if there is no change in batch size, no change in equipment, no change in facility or no change in process/operation has been added. In section 7.9.11, If there is any change in batch size, change in facility, change in equipment, change in process/operation, or there are changes in statutory requirements, Separate PRA with new RA number shall be prepared to address the new risks from the changes has been added. In section 7.9.12, Project Lead is responsible for Laboratory 		

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		<p>PRA. Scientist is responsible to prepare the PRA report, in coordination with cross functional teams has been added.</p>		
<p align="center">1.0</p>	<p align="center">16-Jul-2021</p>	<p><u>Reference Change Control Number: - EHSS/CCF/21/0013</u> The New Process Risk Assessment</p>		

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	Standard Operating Procedure	Department: Environmental Health Safety and Sustainability
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Title: PERMIT TO WORK SYSTEM

Document Number: SOP-EHSS-EHSS-0007	Version Number: 2.0	Effective Date: 09-May-2023
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Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Nidhi Cs/EHSS/ SYNGENE	27-Mar-2023 16:53:05 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Manivannan Arumugam/ EHSS/SYNGENE	28-Mar-2023 09:16:20 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	28-Mar-2023 12:36:01 (IST)

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<p>TITLE:PERMIT TO WORK SYSTEM</p>			
<p>Document Number: SOP-EHSS-EHSS-0007</p>	<p>Version no.: 2.0</p>	<p>Effective Date: 09-May-2023</p>	<p>Next Review Date: 08-May-2025</p>
<p>1.0 OBJECTIVE:</p> <p>The main purpose of a Permit-to-work system is to ensure that proper and specific consideration is given to all the hazards of a non-routine work activity for which SOP or work instruction are not available. It also ensures that all risks are assessed and controlled before work starts.</p> <p>This procedure describes requirements for obtaining a permit to undertake non-routine activities like breakdown maintenance, projects performed by Syngene employees, contactors, service providers in Syngene controlled area that involves hazards, potential danger and exposes personnel to risks. This ensure that the safe system of work (SSOW) is established.</p> <p>This procedure provides the basic understanding on:</p> <ul style="list-style-type: none"> • Conditions under which permit is required to carry out specific jobs • Conditions to comply • Standard permit formats <p>2.0 SCOPE:</p> <ul style="list-style-type: none"> • This procedure is applicable to Syngene International Limited/ Syngene controlled area for all onsite non-routine activities, which does not have any Standard Operating Procedure will be undertaken through Permit to work system. • Procedure is also applicable to offsite activities, which are under direct control of Syngene. <p>3.0 RESPONSIBILITY:</p> <p>3.1 Site EHSS Head:</p> <p>The site EHSS Head has the overall responsibility to ensure that the permit to work system is functioning and maintained in accordance with its objectives.</p> <p>3.2 OU and EF Responsibility:</p> <p>OU and EF are responsible to comply and ensure the requirements of the permit to work system are met. They are also responsible to ensure that required infrastructure, critical mass of trained personnel and adequate resources are made available for effective implementation and sustainability of PTW system. They are responsible for:</p> <ul style="list-style-type: none"> • Ensuring that all Permit Issuers & Permit Acceptors under their control are trained, validated and authorized. • Ensuring that competence of their authorized persons is reviewed at least on a three-yearly or as and when required basis & for informing the concerned departmental training coordinator of results. • Issuing permits in the areas demarcated. 			

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<ul style="list-style-type: none"> • Ensuring that a system for archiving permits for the period of at least 12 months is established in their work areas in consultation with EAM. Note that EAM is to maintain the archives. After a period of 12 months it can be discarded. • Ensuring that the list of Issuers / Acceptors is always maintained up to date as per FORM-EHSS-EHSS-0055(Annexure-15). • Issuer / acceptor must ensure the sequential order of the permit serial number before issuing permit. If any permit written and not carried out activity to be cancelled. • Any new addition of employee in permit authorization, Permit work training must be completed and EHSS will approve the authorization after assessing. • Issuer / acceptor should ensure the availability of JSA before authorizing the permit. If same JSA is applicable for extended works a duplicate copy of JSA shall be enclosed with the new permits. • Ensuring that the list of issuers and authorizers of HV (high voltage) Permit is to be displayed in all electrical HV MCC rooms. (As per FORM-EHSS-EHSS-0055(Annexure-15)). <p>3.3 Issuer of Permit (Area Owner): Only level 6 and above to nominate as an issuer of permit. Also, those who are trained and authorized by EHSS can work as an issuer of the permit regardless of the level.</p> <p>Area owner, as an issuer of the permit, will ensure that area is cleared, decontaminated, and is made safe for work execution. During execution, if any deviation or safety non-compliance is observed, the area owner must stop the work and inform the executor.</p> <p>Some of the specific responsibilities of area owners are:</p> <ul style="list-style-type: none"> • To personally inspect the area and to carry out/witness tests as required under the concerned permit. For example, it is the responsibility of an issuer of the permit for confined space entry to ensure that a safe atmosphere is present throughout the entry through periodic measurement of oxygen level. • To discuss face-to-face with the acceptor prior to handing-over the PTW. • To check the work area on completion of work, especially for housekeeping restoring machine guarding and electrical earthing. • To ensure that supporting permits are issued • To ensure that all work is carried out within the scope detailed in the permit • To ensure that all signatories have signed the permit in the relevant sections in Chronological order. • Not to issue permit if found that previous work permit are not closed by permit stakeholders. 			

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<p>3.4 Acceptor:</p> <ul style="list-style-type: none"> • High risk activity permit Acceptor will be of one level down of Issuers and direct reporting to level 6 designated issuers. All other employees who are not reporting to Issuers directly are authorized for accepting only General work permit. • Acceptors ensure that all required permits with test certificates as needed are in place. • To ensure that permit is unambiguous and written clearly so that intents of the permits are clearly understood. • To discuss and understand permit conditions with Issuer. If the situation warrants, challenge the conditions laid down, which are not possible to comply • To ensure that a site visit and face-to-face discussion takes place with the Issuer prior to accepting a work permit. • To ensure that equipment /area clearance is obtained from respective area owner. • To coordinate and prepare JSA before work starts. • To initiate the relevant permits depending on nature of works and hazards. • To identify and define hazards associated with the work and to ensure that proper precautions are taken along with area owner. • To ensure that experienced supervisor and trained workers are employed on the job. • To ensure that permit conditions are followed if it is self-executed. If second party is carrying out the work, it is to be ensured that all involved are informed about permit requirements, hazards and mitigating measures. • To ensure that the nature and extent of work doesn't differ from the agreed scope as mentioned in the permit. • To monitor the work periodically so as to ensure safe work practices • To suspend or cancel the permits if non-compliance is observed or during emergencies in consultation with Issuer • To close the permit after ensuring that all signatures are available, and area is cleared for restoration of operations. If activity is completed and permit not closed at 1800 hrs then further permit must not be obtained. • Contractor Employees shall produce Fitness Certificate from the MBBS qualified medical practitioner. • Acceptor must complete the Permit to Work Training and is responsible for implementing the safety control measures as mentioned in JSA (Refer FORM-EHSS-EHSS-0052(Annexure-12)) at site. <p>3.5 Doer (Performing Team): All individuals (contractors / In-house team) carrying out activities requiring permit have the following responsibilities:</p>			

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<ul style="list-style-type: none"> • Job supervisors should ensure that, they do not start the work or any job requiring a work permit until valid permit and JSA as applicable is issued. • Contractors/Vendors/Service providers/Syngene employees as a doer, are required to counter-sign the permit to acknowledge the acceptance of permit conditions prior to commencement of work. • All contract vendors should complete the Contract safety management training as per the task from KIOSK training system and passport must be attained for all workmen, supervisor and their team member. The training must be completed before the start of work. • Follow all the precautions and safety measures stipulated in the permits and strictly comply with the requirements and procedures of the permit-to-work system. • Get advice immediately from Acceptor/EHSS, if they are in doubt or if any circumstances or change of conditions are likely to make the work area unsafe. • Escalate the matter if in their opinion, the safe conditions for work are not fully established. • Respond quickly to the emergency as needed. <p>3.6 EHSS:</p> <ul style="list-style-type: none"> • To maintain the procedure in line with the site practices. • To maintain the authorization lists using relevant formats. • To prepare permit to work thematic audit schedules, conduct audits and to collate and issue audit reports to management for necessary action. • To assess the competence of permit issuer, acceptor and authorized personnel after their training and to arrange for the retention of authorization certificate in their training file. • Respective OU/area EHSS member to visit the work location and review the JSA, critical permit requirements and preparations, jointly with Acceptor except for general work permit. Critical permit requirements to be reviewed are given in the respective permit format. • Provide work clearance upon satisfactory safety compliance of permit to work requirements and site conditions. • EHSS members are authorized to cancel the permit in the case of deviation from procedure or violation of any permit condition during work executions. <p>3.7 Fire watch:</p> <p>Fire watch is a dedicated mandatory resource for the hot work. Requirement of fire watch for drilling activities in non-operational area should be reviewed and decided on need basis by Acceptor of permit & EHSS. Fire watch duties are:</p>			

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<ul style="list-style-type: none"> • Inspecting the hot work area before any hot work is conducted. • Confirming that proper fire-fighting equipment is readily available. • Confirming that all conditions of the permit are maintained throughout the hot work. • Stopping the work, if conditions are unsafe and notifying the permit Issuer and/or Acceptor. • Know how to initiate the emergency alarm, location of the safety equipment & assembly points. <p>3.7.1 Continuously monitor the area throughout the work and</p> <ul style="list-style-type: none"> • At least 30 minutes continuous monitoring after completion of work • Intermittently further for 2.5 hours (with frequency of visit 30 minutes or on need basis) after completion of work. • Fire watch must not be involved in any other activities. • Fire watch must be aware of operating fire extinguishers. <p>3.8 Standby Watch / Person(s):</p> <p>The standby person is a mandatory requirement for confined space and need based for other works like work at height. The Standby Person's sole duty is safety of the task performer(s) working inside the confined space. Under no circumstances the Standby Person(s) leave their place while task performers are inside the confined space or working at height. Stand by person must be trained for his duties.</p> <ul style="list-style-type: none"> • Must fully understand the Emergency Rescue Plan in place and know how to operate the rescue equipment so that initial rescue can begin once the alarm is raised. • Will communicate with ERT Leader via intercom or over the phone with the Control Room. • Continuously monitors and maintains accurate count of all personnel in the confined space and maintains the entry logbook. • Is knowledgeable of the area and recognizes potential hazards in the confined space. • Maintain effective and continuous communication with all personnel by stationing himself within hearing distance outside the confined space. • Orders evacuation immediately, if he observes violation of permit condition, detects behavioral effects of exposure, or detects a hazard inside or in the vicinity of the confined space. • Supports rescue and other emergency services that may need assistance to escape from the confined space work. • Keeps unauthorized personnel out of the confined space or height work as the case may be. • Ensures that necessary standby equipment or emergency equipment are available. 			

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<ul style="list-style-type: none"> • Ensures that conditions of the permit are always maintained. • For height work, stand by watch can be demanded by the EHSS depending upon the specific requirement. <p><i>NOTE: A standby watch must not enter the confined space for rescue.</i></p> <p>4.0 ABBREVIATION:</p> <p>OU : Operating Unit CSEWP : Confined Space Entry Work Permit EAM : Engineering and Maintenance EF : Enabling Function EHSS : Environment Health Safety Sustainability ELCB : Earth leakage circuit breaker EX WP : Excavation Work Permit GEN : General GWP : General Work Permit HWP : Hot Work Permit LEL : Lower Explosive Limit LOTOTO : Lock Out Tag Out Try Out NA : Not Applicable SME : Subject Matter Expert WP : Work Permit JSA : Job Safety Analysis KIOSK : A small, free-standing physical structure that displays information or provides a service.</p> <p>5.0 DEFINITION:</p> <p>5.1 Acceptor: Any Syngene employee, who is responsible and authorized to raise the work permit and monitor work execution. Acceptor will be of one level down of issuer and direct reporting to level 6 designated issuers. All other down the line of Issuer are authorized for accepting only General work permit.</p> <p>5.2 Area Owner/Issuer: One who has control of the respective area and activities (Lab In-charge, Team Lead & Group Lead). Only level 6 and above to work as Issuer.</p> <p>5.3 Authorization: Grant of authority to a Syngene employee, contractor or employee of contractor by EHSS department (after due training and approval process) for issue or acceptance of a specified type of work permit.</p>			

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<p>5.4 Contractor or Vendor Supervisor: An employee of an approved contractor at site, who is authorized and has knowledge about the work and Syngene safety systems for monitoring and ensuring that the work is done by his employees safely.</p> <p>5.5 Certified Electrician: Person having a qualification (Diploma and above) or license issued by the Licensing Authority.</p> <p>5.6 Confined Space: Confined space has one or more of the following attributes:</p> <ul style="list-style-type: none"> • The space is not intended for continuous occupancy. • Limited access or egress. • The space can contain known or potentially hazardous substances and/or atmosphere. Confined space can include chamber, tank, container, silo, pit, trench, pipe, sewer, chimney vent, well or other similar space in which, by virtue of its enclosed nature there is risk of oxygen deficiency or presence of toxic and flammable gas or excessive heat or cold. <p>5.7 Dead Voltage: At Zero voltage and disconnected from any live system.</p> <p>5.8 Earthed: Means connected to the general mass of earth in such a manner to ensure an immediate discharge of electrical energy without danger; and means when applied to cables, switchgear and other equipment that efficiently connected to earth.</p> <p>5.9 Electrical Emergencies: Where normal electrical operating conditions cease to exist and/or where switching off the feeder is needed immediately due to any abnormal condition.</p> <p>5.10 Electrical Engineer: A person, who has the diploma or graduate degree in electrical engineering and has adequate experience to carrying out HT & LT installation and maintenance of equipment. Only certified electrical engineer can give area clearance for the electrical permit. (Note: Only electrical engineer with class I license should work as HV Officer or Electrical Distribution Engineer. He is authorized by Head-Engineering on behalf of site manager & the authorization is maintained. He is responsible for the overall operation and maintenance of the Electrical Distribution System).</p> <p>5.11 Electrical Field Checks: A system of checks carried out by isolation personnel to ensure that the correct (isolated) plant/equipment is being worked on.</p> <p>5.12 Electrical Work: Any work in high tension, transformer yard, power control center, motor control center & electrical distribution panels. Working on energized equipment is considered as electrical work and this requires permit.</p> <p>5.13 Excavation Work: Excavation means removal of earth or digging manually below a level of 300 mm typically. In addition, any excavation where there is a possibility of utilities lines regardless of depth is to be considered as excavation requiring permit. Removal of earth by mechanical means require excavation permit irrespective of depth.</p>			

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<p>5.14 Fire Impairment Permit: Maintenance, modification or by-pass of fire system like hydrant system, sprinkler, fire suppression system, fire alarm system, gas detection, public address system. Impairment of the process related controls are outside scope of permit system.</p> <p>5.15 General work permit: General work permit is a basic permit which defines further work permit requirements, if any. Standalone general work permit to be used for non-routine activities.</p> <p>5.16 Hot Work: An activity or operation of an equipment/instrument or a job which can create source of ignition for a fuel, which could be present in vicinity of the work area or could be moved/flown through an abnormal event, e.g. loss of containment of a flammable gas or liquid while the activity/job/operation is going on. Activities which can create sparks or involves naked flames are brazing, soldering, welding, cutting, drilling and chipping. Hammering to be considered as hot work in process area.</p> <p>Note: Drilling, chipping and hammering in office area / non processing area to be considered as general work.</p> <p>5.17 Ignition Hazard: Anything that can give rise to a temporary source of ignition, e.g. sparks or flame (including hammers and chisels) and heat sources. This type of hazard has high potential especially in areas where flammable and combustible materials are stored or processed</p> <p>5.18 Isolated: Any equipment disconnected and separated from every source energy in such a way that the disconnection and separation is secure.</p> <p>5.19 Isolation: The act of separating plant and equipment from every source of energy (chemical, thermal (utilities & services), mechanical, radiation, pressure (stored), vibration & noise, electrical and process hazards in such a way that the separation is secure.</p> <p>5.20 Isolation Point/s: A point or points used to remove/control the potential stored energy or source of energy from plant to make the plant safe to work on (e.g. switch, plug, de-contacter, valve, clamp, restraint or locking point)</p> <p>5.21 Job Safety Analysis: The JSA (Refer FORM-EHSS-EHSS-0052(Annexure-12)) is a document in which task is divided into various sub-tasks. For each sub-task, hazards are identified and mitigating measures together with the responsibility for the implementations are defined.</p> <p>JSA is a mandatory requirement for all Permits except general work permit. In case of General work permit if the activity involves the following points then JSA must be taken.</p> <ul style="list-style-type: none"> • Shifting of materials which involves weight greater than 25 kgs • Materials shifting from one floor to another floor (irrespective of its weight) • Lifting and shifting of material on scaffolding. 			

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<ul style="list-style-type: none"> • For executing any activity if there is narrow space and less space. <p>If routine activity is not performed for period of three month or more, then also JSA is required to be performed regardless of availability of SOP or work instruction.</p> <p>5.22 Lifting & Lowering of loads: Lifting and lowering of loads by mechanical means such as crane, hydra, using multi cranes, chain pulley block, tower crane and such other equipment. Use Crane Inspection checklist – FORM-EHSS-EHSS-0054(Annexure-14) for ensuring defect free cranes at site.</p> <p>5.23 LOTOTO (Lock out Tag Out Try Out): Isolation of all forms of energy (electrical, mechanical, hydraulic, static & pneumatic etc.) and trying out to ensure that correct sources are isolated.</p> <p>5.24 Line Break Clearance: Working on pipelines with hazardous material or high temperature, or high pressure.</p> <p>5.25 Non-Routine Activity: Work normally requiring initiation of work orders or call log such as maintenance work on equipment, installation or modification of equipment/facility, painting, repairs of machinery and equipment for which the written document for carrying out the activity in a safe manner is not available.</p> <p>5.26 Out of Service Tag: Identification tag used to identify plant that must not be operated, as doing so may cause further damage to equipment or pose a safety hazard if operated.</p> <p>5.27 Permit Acceptor Lock: A lock that is placed on an isolation point by permit acceptor</p> <p>5.28 Permit issuer lock (Master Lock): A lock that is placed on an isolation point by issuer or by an authorized person on behalf of issuer.</p> <p>5.29 Permit-to-work System: A formal written system used to control certain types of work, which are identified as non-routine work, which are potentially hazardous. It is also a means of communication among site personnel to ensure that all necessary safety precautions are taken before commencing such work. Routine works such as daily maintenance, taking readings etc. are exempted from permit to work system</p> <p>5.30 Repeater Panel: A panel installed for each zone/area which indicates/replicates the details of emergency.</p> <p>5.31 Routine Activity: Day to day activities or activities which are performed periodically, and which are expected to have procedure/SOP, work instructions/checklist.</p> <p>5.32 Standby Watch:</p> <ul style="list-style-type: none"> • Dedicated individual, who continuously monitors the work and maintains the communication with personnel carrying out the work. A standby watch for the confined space must maintain the entry and exit movement of the entrant in the register. • Standby watch is mandatory for confined space and when demanded by EHSS for height work. 			

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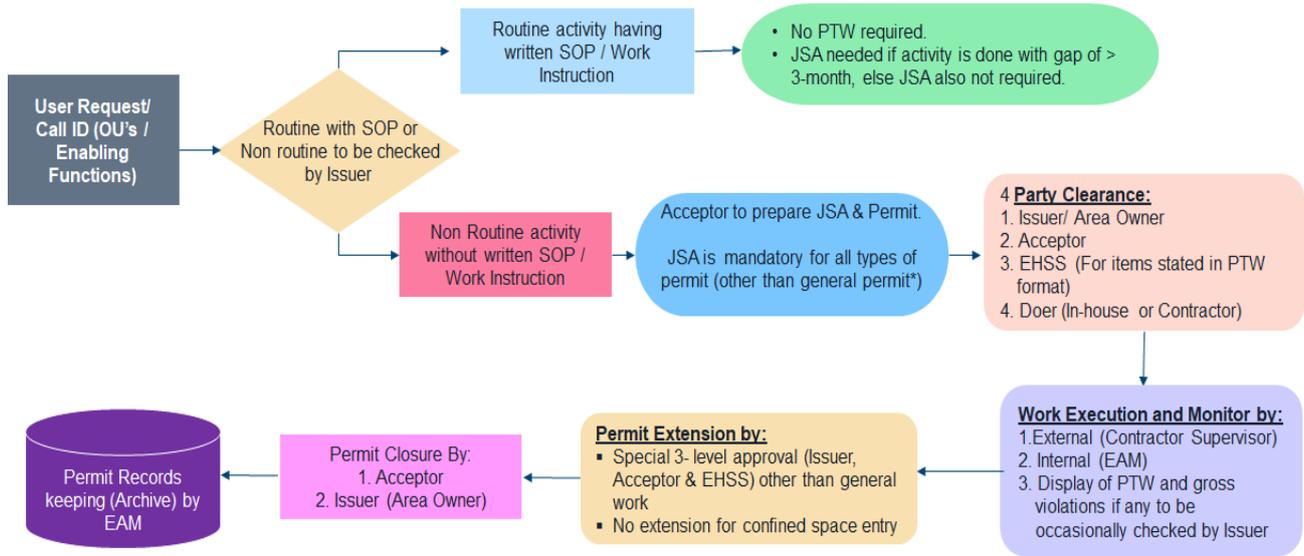
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<p>5.33 Toolbox Talk: Briefing to the performing team about the nature of activity and its associated hazards, risk and its mitigation plan.</p> <p>5.34 Work at Height:</p> <ul style="list-style-type: none"> • Any work performed at the height of 1.8 meter and above from the ground level. • Non-availability of permanent structure/working platform and where there is a possibility of fall injury. • Ladder beyond 1.8 meter and above (6 feet) height considered as work at height. <p>6.0 EHSS:</p> <p>6.1 Safety precautions: The Control measures mentioned in permit to work and JSA must be ensured at site. If any control measures mentioned in Permit to work and JSA is not observed at site, then the activity must be stopped.</p> <p>7.0 PROCEDURE: The different types of work permits adopted in Syngene are:</p> <ul style="list-style-type: none"> • General Work Permit - FORM-EHSS-EHSS-0042(Annexure-02) • Height Work Permit - FORM-EHSS-EHSS-0043(Annexure-03) • Hot Work Permit - FORM-EHSS-EHSS-0044(Annexure-04) • Confined Space Entry Permit - FORM-EHSS-EHSS-0045(Annexure-05) • Electrical Work Permit - FORM-EHSS-EHSS-0046(Annexure-06) • Excavation Permit - FORM-EHSS-EHSS-0047(Annexure-07) • Line Break Permit - FORM-EHSS-EHSS-0048(Annexure-08) • Lock Out Tag Out Try Out Permit - FORM-EHSS-EHSS-0049(Annexure-09) • Lifting & Lowering of Load Permit - FORM-EHSS-EHSS-0050(Annexure-10) • Fire System Impairment Permit - FORM-EHSS-EHSS-0051(Annexure-11) <p>7.1 Procedure for work permit issuance: These permits will follow the general principles as set-out below. This diagram is given reproduced again as FORM-EHSS-EHSS-0041(Annexure-01).</p>			

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- 7.1.1 All permits must be completed in duplicate, in pen, on the form specified with first copy to be displayed at the location of job by permit acceptor & second copy is to be kept in a rack/file/board or a suitable means & place to identify permits for the area with adequate segregation into sub areas for large buildings such as manufacturing plants at the designated place in the control room/office. The detailed color coding can be referenced through FORM-EHSS-EHSS-0058(Annexure-18) Permit Color Coding.
- 7.1.2 For large areas, such a manufacturing plant the permit issuer shall hand over a permit to section/area operator to ensure that the operator is made aware of the work going on the area. The section operator shall then keep the permit copy into designated area.
- 7.1.3 In case of a site emergency, all permits shall stand cancelled. On resuming normal operation new permits are issued. Person declaring “all clear” to revalidate permit by signing. EAM to help them in this process.
- 7.1.4 In case a PTW is to be extended over three days or yet to be renewed, the acceptor shall ensure that the first copy of the permit is returned to permit issuer. The permit issuer shall ensure that both copies of such permits are kept separately in a rack/file/designated area typically labeled as “permits for renewal”. No copy shall remain at job location or with acceptor, if the work under the permit is not in progress.
- 7.1.5 The Issuer and or the Acceptor must visit the workplace at the periods agreed between them during the validity of the work permit. This is to ensure that environmental and work area conditions have not changed, and that conditions/stipulations of the work permit are being complied with. In some cases, if recorded on the permit and by agreement during the

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<p>handover, the visiting and monitoring of the workplace can be delegated to other personnel; for example, plant operator, who has adequate knowledge of the workplace & is aware of the job.</p> <p>7.1.6 The acceptor is accountable, and doer is responsible to ensure that the work is done safely and in line with the provisions laid down in the permit.</p> <p>7.1.7 No live testing of the job shall be taken up prior to closure & return of permit. Any issues found with the work done after reinstatement & testing of the work done shall undergo any form of correction under a fresh permit.</p> <p>7.1.8 If a permit becomes invalid (end of time limit prescribed at the time of issuing or latest renewal of the permit) for any reason, then work must stop. Personnel will vacate the work area and the permit will be withdrawn. Withdrawal can be for the following reasons:</p> <ul style="list-style-type: none"> • Where changes in the conditions of the environment have been detected during a routine monitoring check by an Issuer / Acceptor in the area where work is being done. • Where the equipment used/ required is different from that stated on the permit. • The addition of any other hazard likely to affect the safety of the workplace. <p>In the above cases, any person, who notices the changed conditions or alarms, can withdraw the permit and return it to either the Acceptor or to the Issuer who signed the permit having recorded on the permit the reasons for withdrawal. The Issuer then must ensure that the withdrawal is publicized so that everyone knows that permission granted is no longer in force. In these circumstances, the withdrawal will be a subject of an investigation so that an investigation can be carried out and documented.</p> <p>7.1.9 The sequence of activities for work permit issue shall be followed as per flow chart given in FORM-EHSS-EHSS-0041(Annexure-01).</p> <p>7.1.10 Area Owner (Issuer) shall raise a request and communicate to EAM(Acceptor) about the job to be carried out. Issuer will also ensure that the process and area related safety aspects are taken care off.</p> <p>7.1.11 Acceptor shall raise the respective work permit form and fill all the required information permit form and give it to area owner.</p> <p>7.1.12 Area Owner and Acceptor shall ensure that the PTW requirements are complied as specified and both to sign the permit.</p> <p>7.1.13 Acceptor shall seek EHSS department review and guidance for critical items as mentioned in the respective permit form and sign off. EHSS sign is not required for general work permit.</p> <p>7.1.14 Doer (contractor or in-house) signs on the permit as an acknowledgment that he has understood and accepted scope of work and safety requirement. This whole process ensures the 4-party confirmation as follows:</p> <ul style="list-style-type: none"> • I party: Issuer (Area owner) to provide area clearance • II party: Acceptor (EAM) to assess hazards and control measures 			

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- III party: EHSS, final review for approval for critical items
- IV party: Doer (contractor or Syngene employee) to understand the requirements and acknowledge.

7.1.15 At the beginning of work, the “Toolbox talk” to be given and recorded in FORM-EHSS-EHSS-0484(ANNEXURE-19). If the work is not started within two hours of the issue of permit the permit shall be considered as invalid work permit. The work should be commenced only after re-assessment by team.

7.1.16 The area owner and if required EHSS, to visit periodically the work site during the validity of the work permit. This is to ensure that environmental and work area conditions have not changed, and that conditions/stipulations of the work permit are being complied with.

7.1.17 Bump test shall be carried for portable gas detector before using of gas detectors in confined space. The purpose of the bump test is to ensure the portable gas detectors are in working condition.

7.1.18 Gas level monitoring method: Gas shall be monitored at 3 levels (Bottom, middle and top of the confined space) and the critical value (least/higher value of different parameters) will be considered and recorded in PTW form FORM-EHSS-EHS-0045(Annexure-05).

7.1.19 The validity of permit is from 0900 hrs to 1800 hrs and the permit may be extended on need basis up to 2200 hrs in a day. If same work continues with same set of issuer and acceptor, then same permit can be extended two more days after revalidation.

7.1.20 Permit extension should be obtained from all stakeholders on or before 1600 Hrs.

7.1.21 Not all permits can be extended as specified in below gives the details of whether extension is allowed or not.

Permit type	Time Extension	Day Extension
General work permit	Yes	Yes
Hot work permit	Yes	No
Confined Space permit	No	No
Other types of Permit (electrical, line break, excavation and lifting /lowering of loads	Yes	Yes

7.1.22 Confined space permits will not be issued on Non – working days/weekend.

7.1.23 No permit shall be issued on National Holidays. (Republic Day, May Day, Independence Day, Gandhi Jayanthi and Kannada Rajyothsava). For weekend and other non-working days, EHSS, EAM & Issuer is necessary to be present on the weekend during the work and sign the permit and be present during execution. It is the responsibility of Acceptor in such a scenario to understand and maintain the same conditions.

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<p>7.1.24 Under normal circumstances, permits are non-transferrable. In the event of change of Acceptor or a performing team, the permit can be transferred to another Acceptor & performing team provided a visit to the workplace has been done and person taking over responsibility has clearly understood the job. The person taking over must counter sign in the general work permit.</p> <p>7.1.25 EHSS shall also recommend the additional Safety control measures, if required and all parties (Area Owner/EAM/Vendor) shall follow this strictly.</p> <p>7.1.26 On completion of the specific work for which the permit is issued, permit Acceptor shall visit the location of job and ensure that, the work been completed as per requirements expected by the permit area owner that is Issuer.</p> <p>7.1.27 All the work permits need to be closed on daily basis expect permits having day extension option.</p> <p>7.1.28 The shift handing over should be done properly and both handing over and taking over person should align and sign the permit at the work spot.</p> <p>7.1.29 If any road clearance is required for crane movement/road excavation work at Biocon park, prior written permission (through mail or proper means) from Biocon Admin department is mandatory.</p> <p>7.2 Special approval:</p> <p>7.2.1 Special approval for hot work permit extension for process area should be taken from OU Section in-charge, EAM section in-charge & EHSS SPOC.</p> <p>7.2.2 Hot work permit is not necessary for the designated temporary or permanent workshop subject to EHSS & EAM Head review and approval of the designated area.</p> <p>7.2.3 Any deviation from the procedure to be approved by Operation Unit Head and EHSS head.</p> <p>7.3 Authorized Signatory:</p> <p>7.3.1 Only trained and designated on-site Syngene Team Members are authorized to apply and approve work permits.</p> <p>7.3.2 Contractors are required to counter-sign the permit prior to commencement of work. This is to acknowledge that they have understood and accepted permit conditions and requirements.</p> <p>7.4 Display of Permit:</p> <p>7.4.1 There will be two copies in book, one copy will be issued to Acceptor for display and other copy will be in permit book for reference.</p> <p>7.4.2 One copy of permit to be displayed near work location.</p> <p>7.5 Permit Suspension and Cancellation:</p> <p>7.5.1 A work permit will be automatically suspended if there is an Emergency Alarm, resulting into the activation of site emergency response team. Work can only be resumed upon clearance given by the permit approving authority. Person declaring “all clear” is to sign on permit as a</p>		

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<p>revalidation with suitable noting. For this Acceptor (EAM) to support. However, if the safety conditions established have changed due to the emergency, the work permit should be treated as null and void and a fresh one should be re-issued if work is to be resumed after the emergency is called off.</p> <p>7.5.2 Anyone, who spots a hazardous condition or a life-threatening situation developing around the work site has the responsibility to suspend or stop the work and alert the permit Acceptor or the EHSS.</p> <p>7.5.3 During adverse whether condition, the permit shall be suspended.</p> <p>7.5.4 Non-Compliance to PTW standards: The person observing the non-compliance shall take immediate steps to reduce the immediate risks to persons, plant and/or equipment. The person shall then stop the work, if required, in a safe manner & cease the permit. Consequence management initiation should be carried out.</p> <p>7.6 Summary of important requirements of work permits: Important requirements of work permits are summarized in FORM-EHSS-EHSS-0053(Annexure -13).</p> <p>7.7 Training:</p> <p>7.7.1 Training must be provided initially and periodically on need basis for all employees involved in the permit process.</p> <p>7.7.2 Awareness training should be provided for all stakeholders after identifying needs. Target audience for awareness training to be identified by OU, EF and I&P work stream.</p> <p>7.7.3 The specific training or on the job training required for stand-by and fire watch members must be provided.</p> <p>7.7.4 Approval mechanism for authorizing employees to issue/accept the PTW will be through post training assessment and those who get less than 80% of the mark need to reappear for the training and assessment. Those who qualified are authorized to issue / accept the permit.</p> <p>7.7.5 If there is a failure to comply with permit requirements, EHSS authorized person can cancel the authorization of the Acceptor and/or Issuer. In such a case, its mandatory for those, whose authorization is canceled, to undergo the training and re-assessment.</p> <p>7.8 Record Keeping:</p> <p>7.8.1 All loose copies of work permit to be kept in the file for 12 months by Acceptor (EAM).</p> <p>7.8.2 Permit book to be maintained by EAM. After finishing the book, it should be returned to EHSS department for maintaining further as per the internal requirement.</p> <p>7.8.3 EHSS & EAM shall maintain excel sheet to track the issued permits (Work Permit Register - Refer FORM-EHSS-EHSS-0056(Annexure -16)).</p> <p>7.8.4 List of authorizers will be maintained in FORM-EHSS-EHSS-0055(Annexure-15).</p>			

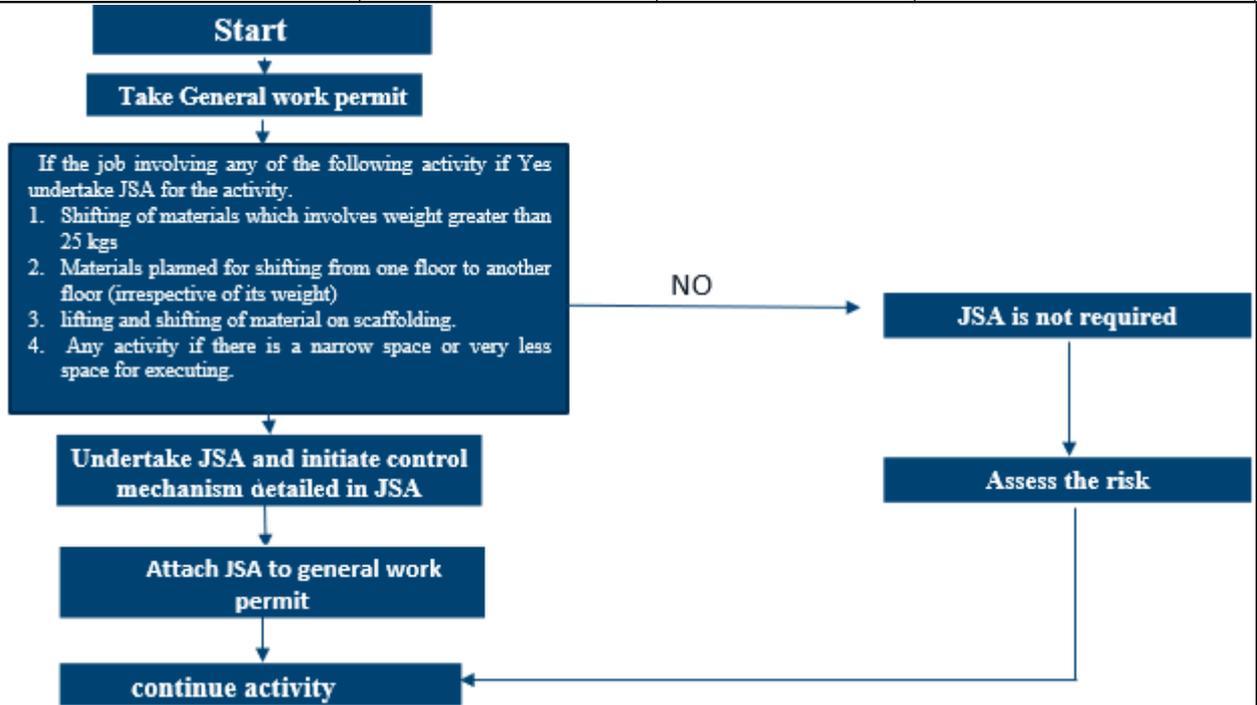
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<p>7.9 Deviation Process: 7.9.1 Deviations if any, with respect to this procedure can be granted by Head EHSS or his/her authorized representative after thorough risk assessment and risk mitigation plan is put in place by concerned parties.</p> <p>7.10 Review of Procedure and Audits: 7.10.1 Procedure should be reviewed on need basis or once in two years whichever is earlier. System audit should be carried out by EHSS with support from OU & EF team at least once in two years.</p> <p>7.11 JSA Procedure: Job safety analysis must be prepared by Syngene executor in coordinating with user/Issuer and the JSA must be approved from EHSS before start of the job. JSA shall be prepared as following: -</p> <ol style="list-style-type: none"> a. The person leading the work is responsible for preparing JSA. b. Person doing the work for single person tasks. c. Person supervising the work for team tasks. d. Person in charge of designing new work or equipment. e. For JSA preparation, must involve group of experienced workers by completing the analysis through discussion. f. In case of any changes in activity/procedure/process JSA should be reviewed by EAM JSA Team leader/Area owner/executor/EHSS. g. In General work permit the following flow shall be done 			

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7.11.1 The basic 8 steps for JSA Process are: -

- Step 1: Select the job/task.
- Step 2: List out steps of the job/task.
- Step 3: Identify the hazards and assess the risks.
- Step 4: Develop control measures.
- Step 5: Review the control measures on site and approve the JSA as defined in JSA Template of FORM-EHSS-EHSS-0052(Annexure-12).
- Step 6: Implement control measures of JSA and PTW requirement.
- Step 7: Communicate, conduct training, and implement the JSA.
- Step 8: Monitor and maintain control measures.

Step 1: Select the job/task. When writing the description of the works, clearly define the activities for which the JSA applies. Complex jobs, or jobs that last several weeks, it's often more effective to break the job analysis into specific work packs each with an individual JSA.

When selecting a job to be analyzed, consider the following:

- The scope of the work.
- When and where is the job performed
- Who must do it and how often?
- The activities involved and how are they done

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<ul style="list-style-type: none"> What equipment, tools and procedures are needed to perform the job safely Which are the permit requirement <p>Step 2: <u>List out the steps of the job/task.</u> Examine a specific job by breaking it down into a series of steps of the job/task. This will enable to discover potential hazards which task team may encounter. Be sure to list all the steps needed to perform the job. Some steps may not be performed each time, i.e. setting up the work area, however, if that step is generally part of the job, it should be listed. Associated pre and post activities also needs to be incorporated in JSA.</p> <p>Step 3: <u>Identify the hazards and assess the risks.</u> A hazard is a potential danger. The purpose of the Job Safety Analysis is to identify all hazards, both those produced by the environment or conditions and those connected with the work activities. Compiling an accurate and complete list of potential hazards will allow you to develop the recommended controls to ensure that work proceeds safely.</p> <p>Step 4: <u>Develop control measures.</u> Hierarchy of Control is to Reduce the LIKELIHOOD and SEVERITY of harm occurring by adding prevention controls. The Hierarchy of controls must be followed as following.</p> <ul style="list-style-type: none"> Elimination Substitution Engineering controls Administrative controls PPE controls. <p>Step 5: <u>Review the control measures on site and approve the JSA as defined in JSA Template of FORM-EHSS-EHSS-0052(ANNEXURE-12).</u> The Person in Charge (executor)of the work is responsible for reviewing control measures on site and implement all aspect and adherence to the JSA. Executor must ensure that the JSA is approved as per JSA Template of FORM-EHSS-EHSS-0052(Annexure-12) and activities must be started only after approval.</p> <p>Step 6: <u>Implement control measures of JSA and PTW requirement.</u> All the control measures mentioned in JSA must be implemented at site and must not be any deviations and uncertainty in understanding the control measures. Control measures which are practically difficult to adopt at site must not be mentioned in JSA. Doer must need to follow the implemented control measures.</p>			

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<p>Step 7: <u>Communicate, conduct training, and implement the JSA.</u> Make sure that the JSAs are easy to read and understand. Conduct training for the team involved in executing the job. Communicate the JSA to all personnel associated with the task and have the documents available onsite.</p> <p>Step 8: <u>Monitor the work and maintain control measures</u> During the work an appropriate level of supervision must be provided to ensure that the control measures are maintained. Whenever a variation from the JSA occurs, for example a new task, change of risk, unexpected event; the variation must be updated /revised the JSA. For revising JSA need to start from step 1 to 8 and JSA must be approved by the EAM JSA Team Leader and EHSS person before the execution.</p> <p>7.11.2 Generic Control Measures to be adopted in JSA can be referred from High-Risk procedure (SOP-EHSS-EHSS-0067).</p> <p>7.11.3 The below table will only give you the basic control measures, so based upon the criticality of task performed additional control measures must be incorporated.</p>			

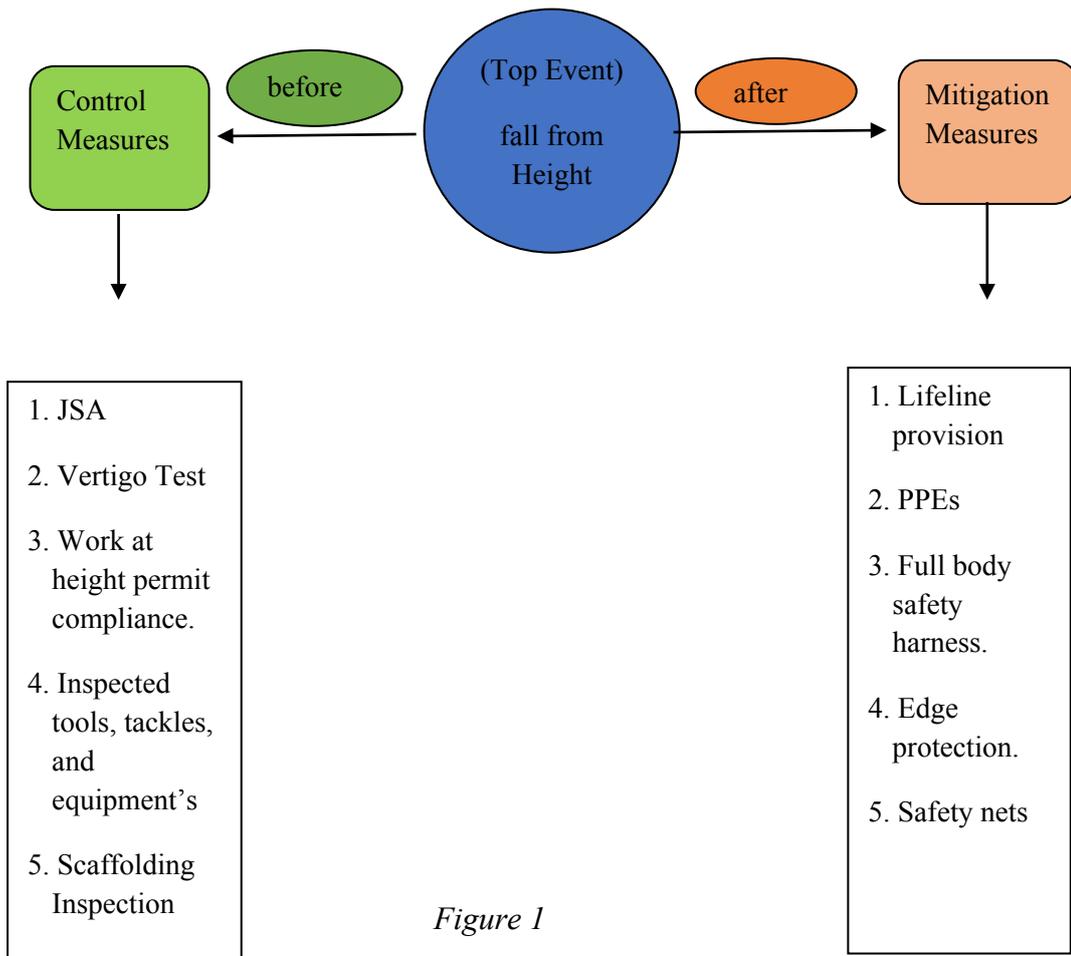
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Below Figure 1 shows control and mitigation measures of an event.



7.11.4 Validity of JSA: The validity of JSA for a Task at given location is only till the completion of task and the maximum time during which the JSA for a task can be used must be up to 6 months or any changes in activity. The JSA for construction of new facility and construction project must be revised every 6 months and approved by EAM/EHSS.

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<p>8.0 REFERENCES: SOP-EHSS-EHSS-0067</p>			
<p>9.0 ANNEXURES:</p>			
FORM-EHSS-EHSS-0041	Annexure - 01 Work Permit Process Flow		
FORM-EHSS-EHSS-0042	Annexure - 02 General Work Permit		
FORM-EHSS-EHSS-0043	Annexure - 03 Height Work Permit		
FORM-EHSS-EHSS-0044	Annexure - 04 Hot Work Permit		
FORM-EHSS-EHSS-0045	Annexure - 05 Confined Space Work Permit		
FORM-EHSS-EHSS-0046	Annexure - 06 Electrical Work Permit		
FORM-EHSS-EHSS-0047	Annexure - 07 Excavation Work Permit		
FORM-EHSS-EHSS-0048	Annexure - 08 Line Break Work Permit		
FORM-EHSS-EHSS-0049	Annexure - 09 LOTOTO (Lock Out Tag Out Try Out) permit		
FORM-EHSS-EHSS-0050	Annexure - 10 Lifting and Lowering of Load Permit		
FORM-EHSS-EHSS-0051	Annexure - 11 Fire System Impairment Permit		
FORM-EHSS-EHSS-0052	Annexure - 12 JSA (Job Safety Analysis) Template		
FORM-EHSS-EHSS-0053	Annexure - 13 Summary of Permit to Work System Important Requirements & Authorized Signatories		
FORM-EHSS-EHSS-0054	Annexure - 14 Crane Inspection Checklist		
FORM-EHSS-EHSS-0055	Annexure - 15 Criteria for Authorizing Personnel as Issuer and Acceptor		
FORM-EHSS-EHSS-0056	Annexure - 16 Work Permit Register		
FORM-EHSS-EHSS-0057	Annexure - 17 SOP Training Questionnaire		
FORM-EHSS-EHSS-0058	Annexure - 18 Permit Color Coding		
FORM-EHSS-EHSS-0484	Annexure - 19 Tool Box Talk Format		

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<p>10.0 REVISION HISTORY:</p>			
<p align="center">Version no.</p>	<p align="center">Effective Date</p>	<p align="center">Description of Change</p>	
<p align="center">2.0</p>	<p align="center">09-May-2023</p>	<p><u>Reference Change Control Number: - EHSS/CCF/23/0007</u></p> <ul style="list-style-type: none"> • Under section 3.2, Ensuring that the list of Issuers / Acceptors is always maintained up to date as per FORM-EHSS-EHSS-0055(Annexure-15) has been included. • In section 3.4, High risk activity permit Acceptor will be of one level down of Issuers and direct reporting to level 6 designated issuers. All other employees who are not reporting to Issuers directly are authorized for accepting only General work permit has been included. • In section 5.1, Acceptor will be of one level down of issuer and direct reporting to level 6 designated issuers. All other down the line of Issuer are authorized for accepting only General work permit has been added. • In point 7.1.15, At the beginning of work, the “Toolbox talk” to be given and recorded in FORM-EHSS-EHSS-0484(ANNEXXURE-19) has been captured. • In point 7.1.23, No permit shall be issued on National Holidays. (Republic Day, May Day, Independence Day, Gandhi Jayanthi and Kannada Rajyothsava). For weekend and other non-working days, EHSS, EAM & Issuer is necessary to be present on the weekend during the work and sign the permit and be present during execution. It is the responsibility of Acceptor in such a scenario to understand and maintain the same conditions has been included. • In point 7.8.4 List of authorizers will be maintained in ANNEXXURE-15 has been added. • In section 7.11, JSA procedure has been added. • In point 7.11.2 Generic Control Measures to be adopted in JSA can be referred from High-Risk procedure SOP-EHSS-EHSS-0067 has been captured. • In point 7.11.4, Validity of JSA has been included. • Tool Box Talk Format FORM-EHSS-EHSS-0484(Annexure – 19) has been added. 	

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		<ul style="list-style-type: none"> • General work permit - FORM-EHSS-EHSS-0042(Annexure-02) has been revised • Height work permit - FORM-EHSS-EHSS-0043(Annexure-03) has been revised • Hot work permit - FORM-EHSS-EHSS-0044(Annexure-04) has been revised. • Confined space work permit - FORM-EHSS-EHSS-0045(Annexure-05) has been revised. • Electrical work permit FORM-EHSS-EHSS-0046(Annexure-06) has been revised. • Excavation work permit - FORM-EHSS-EHSS-0047(Annexure-07) has been revised. • Line break work permit - FORM-EHSS-EHSS-0048(Annexure-08) has been revised. • LOTOTO permit - FORM-EHSS-EHSS-0049(Annexure-09) has been revised. • Lifting and lowering of load permit - FORM-EHSS-EHSS-0050(Annexure-10) has been revised. • Fire system impairment permit - FORM-EHSS-EHSS-0051(Annexure-11) has been revised. • JSA Template - FORM-EHSS-EHSS-0052(Annexure-12) has been revised. • Crane Inspection checklist – FORM-EHSS-EHSS-0054(Annexure-14) has been revised. • Criteria for authorizing personnel as issuer and acceptor – FORM-EHSS-EHSS-0055(Annexure-15) has been revised. 	
<p>1.0</p>	<p>03-Nov-2020</p>	<p><u>Reference Change Control Number: - EHSS/CCF/20/0015</u></p> <ol style="list-style-type: none"> 1. As a part of conversion from paper based to electronic document management system, this SOP is being revised 2. To include point regarding Bump test in 6.1.17 3. To include point regarding gas level monitoring method in 6.1.18 	

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Syngene	Guideline	Department: Environmental Health Safety and Sustainability
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Title: GUIDELINE FOR RESPIRATORY PROTECTION

Document Number: GUI-EHSS-EHSS-0005	Version Number: 2.0	Effective Date: 08-Feb-2023
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Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Nidhi Cs/EHSS/ SYNGENE	18-Jan-2023 21:35:00 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Manivannan Arumugam/ EHSS/SYNGENE	19-Jan-2023 09:26:04 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	19-Jan-2023 11:57:10 (IST)

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TITLE: GUIDELINE FOR RESPIRATORY PROTECTION

Document Number: GUI-EHSS-EHSS-0005	Version number: 2.0	Effective Date : 08-Feb-2023	Next Review Date: 07-Feb-2025
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1.0 OBJECTIVE:

It is the policy of Syngene International Limited to eliminate potential inhalation exposures to hazardous materials whenever possible. In cases where the elimination of an inhalation hazard is not possible, appropriate engineering controls shall be used when available. Respirators shall be used as the principal means of control only in situations where neither hazard elimination, nor engineering controls are feasible.

The purpose of this Respiratory Protection Guideline is to includes the requirements of the Occupational Safety and Health Administration (OSHA) Standard for Respiratory Protection [29 CFR 1910.134]. These requirements include medical evaluations, employee training and fit-testing, and procedures for selection, use, and care of respirators.

2.0 SCOPE:

2.1 The requirements of the Respiratory Protection Guideline apply to all Syngene personnel required to wear a respirator. A respirator is considered required if;

2.1.1 A hazard assessment indicates that there exists an inhalation hazard that requires respiratory protection, or

2.1.2 A job description or a risk assessment requires the employee to don a respirator.

3.0 RESPONSIBILITY:

3.1 Management:

3.1.1 Provides the resources, expertise and assistance to Facility.

3.1.2 Staff necessary to support the implementation of this guideline.

3.1.3 Ensures that related business unit or staff function.

3.1.4 Documents are aligned with this guideline.

3.1.5 Ensures periodic assessments are conducted to verify that related activities are in compliance with this guideline.

3.2 EHSS:

3.2.1 Identify proper selection of respirator.

3.2.2 Support respiratory protection guideline and ensure compliance.

3.2.3 Maintain documentation of employee respirator training, fit testing and medical approval.

3.2.4 Conduct annual fit testing and training of authorized respirator users.

3.2.5 Conduct ongoing work area surveillance and monitoring of employee exposure to potentially hazardous materials.

3.2.6 Provides guidance to assist in implementation of this guideline.

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<p>3.2.7 Audits compliance with this guideline.</p> <p>3.2.8 Review and revise guideline as needed after discussion with respective safety committees and stakeholders.</p> <p>3.3 User Departments- Line management (Reporting Manager):</p> <p>3.3.1 Ensure that employees complete required training regarding this guideline and that it is properly documented.</p> <p>3.3.2 Ensure employees wear appropriate respiratory protection where applicable and are in compliance with this guideline.</p> <p>3.3.3 Ensure employees have been medically cleared to wear a respirator</p> <p>3.3.4 Ensure respirators are used in accordance with instructions and training, and that employees who fail to use respirators properly are retrained.</p> <p>3.3.5 Ensure that each employee under his or her supervision using a respirator has received appropriate training and an annual medical evaluation.</p> <p>3.3.6 Comply with this guideline and report non-compliance to EHSS and functional SLT.</p> <p>3.4 Medical Evaluation (Occupational health Centre):</p> <p>3.4.1 Schedule and conduct initial and periodic evaluations (i.e. blood pressure, pulmonary function test, etc.) for respirator users to determine if individuals are capable of using respirator.</p> <p>3.4.2 Administer and review OSHA Respirator Medical Evaluation Form.</p> <p>3.4.3 Provide EHSS with notification that employee has been medically approved/not approved to wear a respirator.</p> <p>3.4.4 Comply with this guideline and report violations to the management.</p> <p>3.5 Respirator User:</p> <p>3.5.1 Maintain compliance with Respiratory Protection Program.</p> <p>3.5.2 Attend annual respirator training and fit-testing.</p> <p>3.5.3 Wear respirator when and where required, in the manner in which they were trained and in accordance with this procedure.</p> <p>3.5.4 Report respiratory failures to manager and EHSS immediately.</p> <p>4.0 ABBREVIATION:</p> <p>OSHA : Occupational Safety and Health Administration</p> <p>SLT : Syngene Leadership Team</p>			

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EHSS	:	Environment Health Safety and Sustainability
APF	:	Assigned protection factor
SARs	:	Supplied-air respirators
SCBA	:	Self-contained breathing apparatus
ESLI	:	End-of-service-life indicator
QLFT	:	Qualitative fit test
QNFT	:	Quantitative fit test
HEPA	:	High efficiency particulate air
IDLH	:	Immediately dangerous to life or health
OEL	:	Occupational exposure limit
TLVs	:	Threshold Limit Values
TWA	:	Time Weighted Average
STEL	:	Short-Term Exposure Limit
MUC	:	Maximum use concentration
PLHCP	:	Physician or other licensed health care professional
PAPR	:	Powered air-purifying respirator
APFs	:	Assigned Protection Factors
MMAD	:	Mass Median Aerodynamic Diameters
SDS	:	Safety data sheet
NIOSH	:	National Institute for Occupational Safety and Health
ECG	:	Electrocardiogram

5.0 DEFINITION:

5.1 Respirator: - A respirator is a device that protects a person from inhaling dangerous substances, such as chemicals and infectious particles. Respirators are among the most important pieces of protective equipment for working in hazardous environments. Selecting the right respirator requires an assessment of all the workplace operations, processes or environments that may create a respiratory hazard. The identity of the hazard and its airborne concentrations need to be determined before choosing a respirator. This assessment should be

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done by experienced safety personnel or by an industrial hygienist. There are several different types of respirators, as described below.

5.1.1 **Air-purifying respirator** means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

5.1.2 **Assigned protection factor (APF)** means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by this section.

5.1.3 **Atmosphere-supplying respirator** means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

5.1.4 **Canister or cartridge** means a container with a filter, sorbent, or catalyst, or combination of these items, which removes specific contaminants from the air passed through the container.

5.1.5 **Demand respirator** means an atmosphere-supplying respirator that admits breathing air to the face piece only when a negative pressure is created inside the face piece by inhalation.

5.1.6 **Emergency situation** means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an uncontrolled significant release of an airborne contaminant.

5.1.7 **Employee exposure** means exposure to a concentration of an airborne contaminant that would occur if the employee were not using respiratory protection.

5.1.8 **End-of-service-life indicator (ESLI)** means a system that warns the respirator user of the approach of the end of adequate respiratory protection, for example, that the sorbent is approaching saturation or is no longer effective.

5.1.9 **Escape-only respirator** means a respirator intended to be used only for emergency exit.

5.1.10 **Filter or air purifying element** means a component used in respirators to remove solid or liquid aerosols from the inspired air.

5.1.11 **Filtering facepiece (dust mask)** means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium.

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<p>5.1.12 Fit factor means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.</p> <p>5.1.13 Fit test means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual. (See also Qualitative fit test QLFT and Quantitative fit test QNFT.)</p> <p>5.1.14 Helmet means a rigid respiratory inlet covering that also provides head protection against impact and penetration.</p> <p>5.1.15 High efficiency particulate air (HEPA) filter means a filter that is at least 99.97% efficient in removing monodisperse particles of 0.3 micrometers in diameter. The equivalent NIOSH 42 CFR 84 particulate filters are the N100, R100, and P100 filters.</p> <p>5.1.16 Hood means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.</p> <p>5.1.17 Immediately dangerous to life or health (IDLH) means an atmosphere that poses an immediate threat to life, would cause irreversible adverse health effects, or would impair an individual's ability to escape from a dangerous atmosphere.</p> <p>5.2 OEL Occupational Exposure Limit: In general, the occupational exposure limit (OEL) represents the maximum airborne concentration of a toxic substance to which a worker can be exposed over a period of time without suffering any harmful consequences. The occupational exposure limits listed are 2019 ACGIH Threshold Limit Values (TLVs), unless otherwise stated. From ACGIH®, 2019 TLVs® and BEIs® Book. Copyright 2019. Reprinted with permission. The concentrations are expressed in ppm — parts per million (parts of contaminant per million parts of air) — unless specifically stated as mg/m3 (milligrams of contaminant per cubic meter of air) or some other unit.</p> <p>5.3 TWA Time Weighted Average Exposure Limits are for a normal eight (8) hour workday and a forty (40) hour work-week.</p> <p>5.4 STEL Short-Term Exposure Limit is a 15-minute time weighted average exposure which should not be exceeded at any time during a workday.</p> <p>5.5 Ceiling (C) Exposure Limits refer to concentrations that should not be exceeded during any part of the working exposure.</p>			

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<p>5.6 Interior structural firefighting means the physical activity of fire suppression, rescue or both, inside of buildings or enclosed structures which are involved in a fire situation beyond the incipient stage. (See 29 CFR 1910.155)</p> <p>5.7 Loose-fitting face piece means a respiratory inlet covering that is designed to form a partial seal with the face.</p> <p>5.8 Maximum use concentration (MUC) means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator and is determined by the assigned protection factor of the respirator or class of respirators and the exposure limit of the hazardous substance. The MUC can be determined mathematically by multiplying the assigned protection factor specified for a respirator by the required OSHA permissible exposure limit, short-term exposure limit, or ceiling limit. When no OSHA exposure limit is available for a hazardous substance, an employer must determine an MUC on the basis of relevant available information and informed professional judgment.</p> <p>5.9 Negative pressure respirator (tight fitting) means a respirator in which the air pressure inside the face piece is negative during inhalation with respect to the ambient air pressure outside the respirator.</p> <p>5.10 Oxygen deficient atmosphere means an atmosphere with an oxygen content below 19.5% by volume.</p> <p>5.11 Physician or other licensed health care professional (PLHCP) means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide.</p> <p>5.12 Positive pressure respirator means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.</p> <p>5.13 Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.</p> <p>5.14 Pressure demand respirator means a positive pressure atmosphere-supplying respirator that admits breathing air to the face piece when the positive pressure is reduced inside the face piece by inhalation.</p>			

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5.15 Fit test: A fit test is used to determine an adequate match between the face piece of a respirator and the face of the wearer. Ideally this should be done before the respirator is first issued and then at regular intervals.

5.16 Qualitative fit test (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

5.17 Quantitative fit test (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

5.18 Respiratory inlet covering means that portion of a respirator that forms the protective barrier between the user's respiratory tract and an air-purifying device or breathing air source, or both. It may be a facepiece, helmet, hood, suit, or a mouthpiece respirator with nose clamp.

5.19 Self-contained breathing apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

5.20 Service life means the period of time that a respirator, filter or sorbent, or other respiratory equipment provides adequate protection to the wearer.

5.21 Supplied-air respirator (SAR) or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

This section means this respiratory protection standard.

Tight-fitting facepiece means a respiratory inlet covering that forms a complete seal with the face.

User seal check means an action conducted by the respirator user to determine if the respirator is properly seated to the face.

- **How do respirators work?**
Respirators work by either filtering particles from the air, chemically cleaning (purifying) the air, or supplying clean air from an outside source.

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6.0 EHSS: NA

7.0 PROCEDURE:

TYPES OF RESPIRATORY PROTECTION EQUIPMENT:

- 7.1 Particulate /Dust respirators**
- 7.2 Chemical Cartridge/Gas Mask Respirator**
- 7.3 Powered Air-Purifying Respirator (PAPR)**
- 7.4 Self-Contained Breathing Apparatus (SCBA)**
- 7.5 Supplied Air Respirator (SAR)**

7.1 Particulate /Dust Respirators:

Particulate respirators are the simplest, least expensive, and least protective of the respirator types available. These respirators only protect against particles (e.g., dust). They do not protect against chemicals, gases, or vapors, and are intended only for low hazard levels.

Particulate respirators are "air purifying respirators" because they clean particles out of the air as you breathe.

Particulate respirators:

- a) Filter out dusts, fumes and mists.
- b) Are usually disposable dust masks or respirators with disposable filters.
- c) must be replaced when they become discolored, damaged, or clogged.
- d) Examples: filtering face piece or elastomeric respirator.



7.2 Chemical Cartridge/Gas Mask Respirator:

Gas masks are also known as "air-purifying respirators" because they filter or clean chemical gases out of the air as you breathe. This respirator includes a face piece or mask, and a cartridge or canister. Straps secure the face piece to the head. The cartridge may also have a filter to remove particles.

Gas masks are effective only if used with the correct cartridge or filter (these terms are often used interchangeably) for a particular biological or chemical substance. Selecting the proper filter can be a complicated process. There are cartridges available that protect against more than one hazard, but there is no "all-in-one" cartridge that protects against all substances. It is



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important to know what hazards you will face in order to be certain you are choosing the right filters/cartridges.

Use 5N11 filter with retainer (3M 501) along with the cartridge while handling solid chemicals / products.

Chemical Cartridge/Gas Mask respirator:

- a) Uses replaceable chemical cartridges or canisters to remove the contaminant.
- b) Are color-coded to help you select the right one.
- c) May require more than one cartridge to protect against multiple hazards.

7.3 Powered Air-Purifying Respirator(PAPR): Powered air-purifying respirators use a fan to draw air through the filter to the user. They are easier to breathe through; however, they need a fully charged battery to work properly. They use the same type of filters/cartridges as other air-purifying respirators. It is important to know what the hazard is, and how much of it is in the air, in order to select the proper filters/cartridges.



7.4 Self-Contained Breathing Apparatus (SCBA) is the respirator commonly used by firefighters and confined space entry where there is oxygen Deficiency or other toxic gas beyond the permissible limit or where the chemical cartridge mask will not protect from the toxics. These use their own air tank to supply clean air, so you don't need to worry about filters. They also protect against higher concentrations of dangerous chemicals. However, they are very heavy (30 pounds or more), and require very special training on how to use and to maintain them. Also, the air tanks typically last a forty-five minutes or less depending upon their rating and your breathing rate (how hard you are breathing). Provide clean air from a portable air tank when the air around you is simply too dangerous to breathe. All of these respirators (except for the "dust masks" or filtering face pieces) are available in either half-mask or full-face pieces.



7.5 Supplied Air Respirator: The respirator commonly used by firefighters and confined space entry where there is oxygen Deficiency or other toxic gas beyond the permissible limit or where the chemical cartridge mask will not protect from the toxics and due to limitation in

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time for use of SCBA, this use fresh air pumps the form outside clear air to the employee’s respirator mask. Required to check before use the leakage and filter cartridges,
Limitation - It is danger to use if it kept near to toxic substances and gas emission point, must be ensure the placing and continues electrical supply to avoid stopping of the pump. There is no storage available in case of power failure.

Additional optional features are available for respirators:

Various features are available to help the user to customize respirators to overcome the issue they encounter. For example, nose cups reduce lens fogging with full face-piece respirators and lens covers protect the lens from paint, minor chemical splash and scratches. Spectacle kits are needed when using prescription corrective lenses. The frame mounts into full-face masks, and the prescription lenses are made by the users' optometrist. This allows the wearer to maintain a proper fit and still wear prescription lenses.

Cautions or limitations when using respirators:

Each type of respirator can come in several varieties, each with its own set of cautions, limitations, and restrictions of use. Tight fitting respirators require fit testing to ensure an adequate fit to the face and cannot be used with facial hair. Certain escape respirators use a nose clip and mouthpiece, which is clenched between your teeth, similar to a snorkel. Some respirators prevent the user from talking while others have speaking diaphragms or electronic communication devices. Every respirator contaminated with hazardous chemicals should be cleaned and decontaminated or disposed of properly.

All respirators require training in order to be properly used. Sometimes you can practice using your own respirator. Some escape respirators come in a package that must remain sealed until use, so you need to be trained using a special “practice” version. Training is extremely important in regard to the storage, maintenance, use, and disposal of the respirator. This information is provided by the supplier of the respirator (i.e., seller, distributor, or manufacturer). If you do not use a respirator correctly, it is very likely that it will not adequately protect you and may even hurt you.

The color coding for gas mask chemical cartridges/canisters:

All cartridges are assigned a color designating the type of contaminant they filter:

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CONTAMINANT	COLOR CODING ON CARTRIDGE/CANISTER	
Acid gases		White
Hydrocyanic acid gas		White with 1/2 inch green stripe completely around the canister near the bottom.
Chlorine gas		White with 1/2 inch yellow stripe completely around the canister near the bottom.
Organic vapors		Black
Ammonia gas		Green
Acid gases and ammonia gas		Green with 1/2 inch white stripe completely around the canister near the bottom.
Carbon monoxide		Blue
Acid gases & organic vapors		Yellow
Hydrocyanic acid gas and chloropicrin vapor		Yellow with 1/2 inch blue stripe completely around the canister near the bottom.
Acid gases, organic vapors, and ammonia gases		Brown
Radioactive materials, except tritium & noble gases		Purple (magenta)
Pesticides		Organic vapor canister plus a particulate filter
Multi-Contaminant and CBRN agent		Olive
Any particulates - P100		Purple
Any particulates - P95, P99, R95, R99, R100		Orange
Any particulates free of oil - N95, N99, or N100		Teal

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Assigned Protection Factors (APFs):

Employers must use the assigned protection factors listed in Table 1 to select a respirator that meets or exceeds the required level of employee protection. When using a combination respirator (e.g., airline respirators with an air-purifying filter), employers must ensure that the assigned protection factor is appropriate to the mode of operation in which the respirator is being used.

TABLE 1 - ASSIGNED PROTECTION FACTORS

Type of respirator	Quarter mask	Half mask	Full facepiece	Helmet/hood	Loose-fitting facepiece
1. Air-Purifying Respirator	5	10	50
2. Powered Air-Purifying Respirator (PAPR)	50	1,000	25/1,000	25
3. Supplied-Air Respirator (SAR) or Airline Respirator					
• Demand mode	10	50
• Continuous flow mode	50	1,000	25/1,000	25
• Pressure-demand or other positive-pressure mode	50	1,000
4. Self-Contained Breathing Apparatus (SCBA)					
• Demand mode	10	50	50
• Pressure-demand or other positive-pressure mode (e.g., open/closed circuit)	10,000	10,000

For contaminants consisting primarily of particles with Mass Median Aerodynamic Diameters (MMAD) of at least 2 micrometers, an air-purifying respirator equipped with any filter certified for particulates by NIOSH.

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TABLE 2 – OXYGEN PERCENTAGE W.R.T ALTITUDE

Altitude (ft.)	Oxygen deficient Atmospheres (% O ₂) for which the employer atmosphere-may rely on supplying respirators
Less than 3,001	16.0-19.5
3,001-4,000	16.4-19.5
4,001-5,000	17.1-19.5
5,001-6,000	17.8-19.5
6,001-7,000	18.5-19.5
7,001-8,000 ¹	19.3-19.5.

Above 8,000 feet the exception does not apply. Oxygen-enriched breathing air must be supplied above 14,000 feet.

7.6 Respirator Selection:

Respiratory protective devices will be selected by the EHSS department using the following criteria:

- 7.6.1 Effectiveness of the device against the substance of concern.
- 7.6.2 Estimated maximum concentration of the substance in the work area with consideration to relevant permissible exposure limits.
- 7.6.3 Physical characteristics, functional capabilities and limitations of the respiratory protective device.
- 7.6.4 Nature of the work.
- 7.6.5 Length of time the protection is needed.
- 7.6.6 Comfort fit and worker acceptance.

7.7 When selecting any respirator in general:

- 7.7.1 Select and provide respirators based on respiratory hazard(s) to which a worker is exposed and workplace and user factors that affect respirator performance and reliability. The product SDS will usually provide direction in respirator selection.
- 7.7.2 Select a NIOSH-certified (National Institute for Occupational Safety and Health) respirator.
- 7.7.3 Identify and evaluate the respiratory hazard(s) in the workplace, including a reasonable estimate of employee exposures to respiratory hazard(s) and an identification of the contaminant's chemical state and physical form. Consider the atmosphere to be immediately

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dangerous to life or health (IDLH) if you cannot identify or reasonably estimate employee exposure.

7.7.4 Select respirators from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user.

7.8 When selecting respirators for IDLH atmospheres:
Provide these respirators:

7.8.1 A full facepiece pressure demand self-contained breathing apparatus (SCBA) certified by NIOSH for a minimum service life of thirty minutes, or.

7.8.2 A combination full facepiece pressure demand supplied-air respirator Self-contained breathing apparatus (SAR) with auxiliary self-contained air supply.

7.8.3 Provide respirators NIOSH-certified for escape from the atmosphere in which they will be used when they are used only for escape from IDLH atmospheres. We consider all oxygen-deficient atmospheres to be IDLH.

7.9 When selecting respirators for atmospheres that are not IDLH:
We provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA/Local regulatory requirements, under routine and reasonably foreseeable emergency situations.

For protection against gases and vapors, provide:

7.9.1 An atmosphere-supplying respirator, or

7.9.2 An air-purifying respirator.

7.10 If I have the right cartridges/filters for a certain hazard, and my mask fits, will they always protect me against that hazard?
No. Gas masks and respirators reduce exposure to the hazard, but if the exposure is such that it goes beyond what the filter is capable of handling (either because the amount of toxic gas or particles is more than what the filter is designed to handle, or because the exposure lasts longer than what the filter is designed to handle), the filter may not be effective in providing required protection. Also, there may be a small amount of leakage even if the fit of the respirator has been tested. If so, and if there is a large amount of a toxic chemical in the outside air, even that small leakage can be dangerous.

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7.11 Respirator Characteristics, Capabilities, and Limitations:

A respirator may not be able to help protect against all of the contaminants present in a particular work environment. Specific limitations are stated on the approval labels and are included with User Instructions. These must be carefully reviewed for each respirator before use. General precautionary information is given below. Refer to respirator packaging and User Instructions for specific information.

7.12 Face piece Seal / Routine Fit Checking:

- 7.12.1 Prior to the fit testing, a positive and/or negative pressure fit check should be conducted with all tight-fitting respirators to determine if the respirator is properly sealed to the face of the user.
- 7.12.2 Any hindrance with the seal of the tight-fitting positive or negative pressure respirator shall not be accepted. This includes but not limited to facial hair such as growth of beard, or sideburns / locks, head coverings, eye glass temples, absence of dentures, or skull cap that projects under the face piece seal.
- 7.12.3 Respiratory Fit Test Report shall be as per the FORM-EHSS-EHSS-0328(ANNEXURE – 03).

7.13 Respirator Training:

- 7.13.1 Selecting the proper respirator for a given hazard is important, but equally important is using the device correctly. Proper usage can be ensured by training the respiratory program administrator and user in the selection, use and maintenance of respirators.
- 7.13.2 The administrator who oversees the requirement, issuance and proper usage of respirators in the company should have a comprehensive knowledge of respirators and respiratory protection practices. The training must include:
 - Nature, extent and health effects of airborne contaminants in the workplace.
 - Principles and criteria for selecting respirators.
 - Fitting and issuance of respirators.
 - Organization’s respiratory protection program.
 - Regulatory requirements concerning respirator usage.
 - Limitations of respirator use in the situation used.
 - Probable time over which it will provide protection.
 - Necessity for proper handling, maintenance, and cleaning of the equipment.

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<p>7.13.3 How to use the respirator effectively in emergency situations, including situations in which the respirator malfunctions?</p> <p>7.13.4 How to inspect, put on and remove, use and check the seals of the respirator?</p> <p>7.13.5 How to recognize medical signs and symptoms that may limit or prevent effective use of respirators?</p> <p>7.13.6 What the change out schedule is for cartridges as applicable?</p> <p>7.13.7 Utmost importance of this training should be given to the user with easily understood explanations about the need and reasons for using a respirator. This is to motivate the user to accept the fact that protection is necessary and to instill the desire to wear and maintain a respiratory properly.</p> <p>7.13.8 Retraining shall be administered annually and when the following situations occur.</p> <p>7.13.9 Changes in the workplace or the type of respirator render previous training obsolete.</p> <p>7.13.10 Inadequacies in the employee’s knowledge or use of respirator indicate that the employee has not retained the requisite understanding or skill, or</p> <p>7.13.11 Any other situation arises in which retraining appears necessary to ensure safe respirator use.</p> <p>7.13.12 Respirator training shall be documented in an appropriate system. Documentation will include date of training session, names of the personnel trained, and name of the instructor, course outline or agenda, and the types and models of respirator for which the individual has been trained.</p> <p>7.14 Medical Evaluation: Medical evaluation shall be performed as mentioned in FORM-EHSS-EHSS-0327(ANNEXURE – 02).</p> <p>7.15 Physiological Considerations:</p> <p>7.15.1 Carrying heavy respirators, for example SCBA and other equipment in addition to a heavy workload may impose stress on the cardiopulmonary system. Intense ambient heat (for example during firefighting) could be an additional stress on the heart. Persons with severe lung disease may experience difficulty with breathing against the additional resistance of a respirator.</p> <p>7.15.2 Full-face respirators especially with full body protection may give rise to feelings of anxiety and isolation in some people, making it difficult for them to perform their work satisfactorily.</p>			

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<p>7.16 Types of Medical Evaluations:</p> <p>7.16.1 A medical history and at least a limited physical examination by a physician are recommended.</p> <p>7.16.2 In particular, the cardiopulmonary system should be evaluated.</p> <p>7.16.3 The medical history can detect most problems that might require further evaluation.</p> <p>7.16.4 The physical examination can confirm any findings from the medical history and also detect certain medical conditions (for example hypertension) that may be symptomatic. A previous history of respirator usage should also be elicited.</p> <p>7.16.5 Chest X-ray, spirometry and exercise stress tests with ECG monitoring may be considered in persons using SCBA, when extremely stressful work conditions are expected or when indicated by the history and physical examination.</p> <p>7.16.6 The respirator user should be observed during a trial period to evaluate any potential anxiety or claustrophobic reactions during the use of the respirator during training.</p> <p>7.17 Frequency:</p> <p>7.17.1 The examination should be carried out prior to the issue of respirators and periodically. The periodic examinations (Consisting of the clinical examination) may be conducted once every three years. For employees above 45 years of age who are carrying out strenuous work with SCBA, annual examinations are recommended.</p> <p>7.18 Medical Conditions That May Limit Respirator Usage:</p> <p>7.18.1 Impaired workers would be able to work safely while wearing respirators if they could control their own workplace, including having sufficient time to rest. Some of the medical conditions are:</p> <ul style="list-style-type: none"> • Moderate to severe pulmonary disease. • Angina pectoris, significant arrhythmias, recent myocardial infarction or Symptomatic or uncontrolled hypertension. • Claustrophobia/anxiety reaction and • History of spontaneous pneumothorax <p>7.19 Respiratory Fit Testing:</p> <p>Refer FORM-EHSS-EHSS-0270(Annexure – 01) for a detailed procedure on Respirator fit test.</p>				

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7.20 Maintenance of Respirators:

7.20.1 Respirators shall be stored and maintained as per manufacturer’s instructions.

7.20.2 Cartridge to be removed from the face piece immediate after the usage. The cartridges should be stored in a Zip lock air tight cover to avoid chemical expose to cartridges.

7.20.3 All respirators shall be inspected before use. Do not use damaged respirator.

7.20.4 Worn out or deteriorated parts must be replaced prior to use of the respirator.

7.20.5 Single use respirators are to be disposed of when they become wet, soiled or when added breathing resistance is detected by the wearer. As a minimum single use respirator are to be replaced at least daily.

7.20.6 Cartridge type filters to be replaced based on the contaminant level in the atmosphere. Or If the person feels the smell of the contaminant while wearing the respirator, the same has to be replaced immediately. The sealed cartridge expiry date is mentioned in the packing to be checked before use and Name and Date of opening to be written on the side of the cartridge for track.

7.21 Cleaning of Respirators:

7.21.1 Respirators issued shall be cleaned periodically and after each use. Users who maintain their own respirators should be trained in cleaning procedures. The following procedure shall be used for cleaning and disinfecting respirators:

7.21.1.1 Re-usable respirators must be cleaned and sanitized on a periodic basis.

7.21.1.2 Respirators issued for exclusively personal use of an employee shall be cleaned and sanitized after each use by the wearer.

7.21.1.3 Respirators issued to more than one employee shall be cleaned and disinfected before being worn by different individuals.

7.21.1.4 Respirators maintained for emergency use shall be cleaned and disinfected after each use.

7.21.1.5 Replacement cartridges and filters can be obtained from OU operation team for R &D and Stores in charge for Production facility.

7.21.1.6 The following procedure is recommended for cleaning and disinfecting respirator where applicable.

- Remove and discard all used filters, cartridges, or canisters.
- Wash the face piece using warm water and mild detergent or with a cleaner or disinfectant solution recommended by the manufacturer. A hand brush may be used to remove dirt. Do not use solvents that could deteriorate rubber and other parts.

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- Clean other respirator parts as recommended by the manufacturer.
- Inspect the face piece, valves, head straps, and other parts to verify proper working condition.
- Reassemble the respirator and replace any damaged or worn parts.
- Store the respirator in a clean, dry plastic bag or other suitable container after each cleaning and disinfection.

7.22 Procedures for Cleaning Respirators:

- 7.22.1 Dispose of cartridges and pre-filters when you smell or taste contaminants, or if your eyes, nose, or throat become irritated (they cannot be cleaned). They must also be replaced if they show any sign of damage.
- 7.22.2 Disassemble the respirator, following the manufacturer's instructions.
- 7.22.3 Inspect the parts and replace damaged or worn parts.
- 7.22.4 Wash hands before and after cleaning.
- 7.22.5 Clean the inhalation and exhalation valves in a mild soap solution. Don't damage or distort the valves during cleaning.
- 7.22.6 Remove filters, cartridges, or canisters. Disassemble facepiece by removing speaking diaphragms, demand and pressure- demand valve assemblies, hoses, or any components recommended by the manufacturer. Discard or repair any defective parts.
- 7.22.7 Wash components in warm (43°C maximum) water with a mild detergent or with a cleaner recommended by the manufacturer. A stiff bristle (not wire) brush may be used to facilitate the removal of dirt.
- 7.22.8 Rinse components thoroughly in clean, warm (43°C maximum), preferably running water drain.
- 7.22.9 When the cleaner used does not contain a disinfecting agent, respirator components should be immersed for two minutes in one of the following:
 - Hypochlorite solution (50 ppm of chlorine) made by adding approximately one milli liter of laundry bleach to one liter of water at 43°C ; or,
 - Aqueous solution of iodine (50 ppm iodine) made by adding approximately
 - 0.8 milliliter of tincture of iodine (6-8 grams ammonium and/or potassium iodide/100 cc of 45% alcohol) to one liter of water at 43°C; or,
 - Other commercially available cleansers of equivalent disinfectant quality when used as directed, if their use is recommended or approved by the respirator manufacturer.
 - Air dry the parts that have been cleaned. They must be completely dry before they can be reassembled.

Syngene	Guideline	DEPARTMENT: Environmental Health Safety and Sustainability
	Guideline	

TITLE: GUIDELINE FOR RESPIRATORY PROTECTION

Document Number: GUI-EHSS-EHSS-0005	Version number: 2.0	Effective Date : 08-Feb-2023	Next Review Date: 07-Feb-2025
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- After reassembling, check seals and gaskets for tightness and leaks.

7.23 Respirator Storage:

7.23.1 Employees are responsible for proper storage of their respirators.

7.23.2 Clean respirators should be stored in nonporous, sturdy, airtight containers (like a "Ziploc" plastic bag). To avoid collecting dust, the respirator should be put away as soon as it is dry.

7.23.3 Respirator face pieces and valves should be stored in a manner that does not distort the shape. Keep the respirator in a cool, dry cabinet specifically designated for storage.

7.23.4 Respirators must be stored so that the face piece and exhalation valves will rest in a normal position and not be deformed.

7.23.5 Emergency respirators shall be:

- Kept accessible to work area.
- Stored in accordance with any applicable manufacturer instructions.
- Respirators are to be immediately repaired by a qualified individual, or discarded and replaced when they are no longer in proper original working condition.

7.24 Inspection:

7.24.1 Employees are responsible for inspecting their respirators.

7.24.2 All respiratory protective equipment should be inspected:

- Prior to every use, and
- During and after cleaning.

7.25 General Use Instructions:

7.25.1 Failure to follow all instructions and limitations on the use of these respirators and/or failure to wear them properly during all times of exposure can reduce respirator effectiveness and may result in sickness or death.

7.25.2 Many of the contaminants that can be dangerous to a person's health include ones that are so small they cannot be seen or smelled at dangerous levels.

7.25.3 Before use of any respirator, the wearer must first be trained by the Department Manager in proper respirator use in accordance with applicable safety and health standards. The OSHA Respiratory Protection Standard (29 CFR 1910.134(f)(1)) requires that the wearer of any tight-fitting respirator be fit tested.

Syngene	Guideline			DEPARTMENT: Environmental Health Safety and Sustainability
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TITLE: GUIDELINE FOR RESPIRATORY PROTECTION				
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<p>7.25.4 Leave the contaminated area immediately if dizziness or other distress occurs, if the respirator becomes damaged or breathing becomes difficult, if contaminants can be smelled or tasted, or if irritation occurs.</p> <p>7.25.5 Review the Following Points</p> <ul style="list-style-type: none"> • Clean respirators after each use. • Cartridges and prefilters should be disposed after they are "used up" and cannot be cleaned. • After cleaning, store respirators in a cool, dry place. <p>If the filter cartridges are outdated, have been open to the air or are damaged, you may not be protected. Cartridges that contain charcoal or other chemicals for filtering the air should be kept in air-tight packages until use. If cartridges are open or not packed in air-tight packaging, they should not be used. Even cartridges in original packaging have expiration dates that should be checked before purchase and use.</p> <p>The service life (i.e. how long it will last) of any gas and vapour cartridge filter is affected by many factors – some being: concentration and identity of contaminants, breathing rates, humidity levels, ventilation, temperature, carbon exposure time etc.</p> <p>Replace both the Gas & Vapour Cartridge Filters:</p> <ul style="list-style-type: none"> • When the expiry date stamped on the sealed packet has elapsed. • Once opened, maximum use time is 6 months (even if not used). The carbon will absorb contaminants from the general environment. • When contaminant can be detected by smell or taste. • Or in accordance with your department established Filter Change Schedule based on the exposure assessment and report from 3M Service Life software. Please use the below link to connect 3M Service Life Software. <p>https://sls.3m.com/</p>				

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<p>8.0 REFERENCES:</p> <p>OSHA: 29CFR 1910.134</p> <p>3M guidelines.</p> <p>9.0 ANNEXURES:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 35%;">FORM-EHSS-EHSS-0270</td> <td>ANNEXURE – 01 Respiratory Fit Test</td> </tr> <tr> <td>FORM-EHSS-EHSS-0327</td> <td>ANNEXURE – 02 Medical Evaluation Form</td> </tr> <tr> <td>FORM-EHSS-EHSS-0328</td> <td>ANNEXURE – 03 Respiratory Fit Test Report</td> </tr> <tr> <td>FORM-EHSS-EHSS-0440</td> <td>ANNEXURE – 04 SOP Training Questionnaire</td> </tr> </table> <p>10.0 REVISION HISTORY:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">Version</th> <th style="width: 15%;">Effective Date</th> <th>Description of Change</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">2.0</td> <td style="text-align: center;">08-Feb-2023</td> <td> <p><u>Reference Change Control Number: EHSS/CCF/22/0036</u></p> <p>1. In section 5.15, Fit test has been included.</p> <p>2. In section 7.25, points related to General use instructions has been updated.</p> </td> </tr> <tr> <td style="text-align: center;">1.0</td> <td style="text-align: center;">01-Jul-2021</td> <td> <p><u>Reference Change Control Number: EHSS/CCF/21/0017</u></p> </td> </tr> </tbody> </table>				FORM-EHSS-EHSS-0270	ANNEXURE – 01 Respiratory Fit Test	FORM-EHSS-EHSS-0327	ANNEXURE – 02 Medical Evaluation Form	FORM-EHSS-EHSS-0328	ANNEXURE – 03 Respiratory Fit Test Report	FORM-EHSS-EHSS-0440	ANNEXURE – 04 SOP Training Questionnaire	Version	Effective Date	Description of Change	2.0	08-Feb-2023	<p><u>Reference Change Control Number: EHSS/CCF/22/0036</u></p> <p>1. In section 5.15, Fit test has been included.</p> <p>2. In section 7.25, points related to General use instructions has been updated.</p>	1.0	01-Jul-2021	<p><u>Reference Change Control Number: EHSS/CCF/21/0017</u></p>
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	Standard Operating Procedure	Department: Environmental Health Safety and Sustainability
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Title: SAFETY COMMITTEE

Document Number: SOP-EHSS-EHSS-0054	Version Number: 2.0	Effective Date: 23-May-2023
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Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Nidhi Cs/EHSS/ SYNGENE	08-May-2023 16:19:25 (IST)
Technical Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Jayaseelan Arivalagan/ EHSS/SYNGENE	11-May-2023 12:30:28 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	16-May-2023 11:10:51 (IST)

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Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability	
TITLE:SAFETY COMMITTEE			
Document Number: SOP-EHSS-EHSS-0054	Version no.: 2.0	Effective Date: 23-May-2023	Next Review Date: 22-May-2025
<p>1.0 OBJECTIVE: To have a documented procedure for constitution and functions of the Safety Committee.</p> <p>2.0 SCOPE: The procedure is applicable to Syngene International Limited.</p> <p>3.0 RESPONSIBILITY:</p> <p>3.1 Environment, Health, Safety and Sustainability department:</p> <p>3.1.1 Organizing safety committee</p> <p>3.1.2 Review of EHSS Activities</p> <p>3.1.3 Discuss about safety issues, Corrective and Preventive Action and improvement plans.</p> <p>3.2 Safety Committee:</p> <p>3.2.1 To discuss the safety issues, Corrective and Preventive Action and improvement plans.</p> <p>4.0 ABBREVIATION:</p> <p>CAPA : Corrective and Preventive Action</p> <p>EHSS : Environment, Health, Safety and Sustainability</p> <p>KFR : Karnataka Factories Rules</p> <p>SOP : Standard Operating Procedure</p> <p>5.0 DEFINITION: NA</p> <p>6.0 EHSS: NA</p> <p>7.0 PROCEDURE:</p> <p>7.1 Constitution of safety committee shall be as per KFR (Karnataka Factories Rules) -1969, Rule No. 88 C.</p> <p>7.2 Tenure of Safety committee shall be for two years and conducted once in three months as per annual planner i.e. FORM-EHSS-EHSS-0276(Annexure-03).</p> <p>7.3 It comprises of,</p> <p>7.3.1 Chairman: One of the Level 6 and above employee of Syngene</p> <p>7.3.2 Vice -Chairman: Head – EHSS</p> <p>7.3.3 Secretary: Manager – EHSS</p> <p>7.3.4 Heads / Department In charge</p> <p>7.3.5 Medical officer</p> <p>7.3.6 Members from each department</p> <p>7.3.7 Safety Officer</p> <p>7.3.8 Member from Legal Department</p> <p>7.3.9 Member from Purchase and Supply Chain Department</p>			

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	<p align="center">Standard Operating Procedure</p>	<p>DEPARTMENT: Environmental Health Safety and Sustainability</p>	
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<p>Document Number: SOP-EHSS-EHSS-0054</p>	<p>Version no.: 2.0</p>	<p>Effective Date: 23-May-2023</p>	<p>Next Review Date: 22-May-2025</p>
<p>7.3.10 Members from HR</p> <p>7.3.11 Contract Workmen</p> <p>7.4 Two members shall be selected from each department of level – 7 and below.</p> <p>7.5 Selected safety committee members shall be approved by Chairman. Refer: FORM-EHSS-EHSS-0278(Annexure-05).</p> <p>7.6 EHSS department shall arrange for the meeting, informed by mail to all safety committee members.</p> <p>7.7 Attendance shall be taken as per the FORM-EHSS-EHSS-0274(Annexure-01).</p> <p>7.8 Safety committee meeting shall mainly focus on following:</p> <p>7.8.1 Review of incidents</p> <p>7.8.2 Review of Process hazard analysis</p> <p>7.8.3 Effectiveness of EHSS training</p> <p>7.8.4 Review of EHSS inspections and audits</p> <p>7.8.5 Unsafe conditions and acts</p> <p>7.8.6 Review of Safety Inspection</p> <p>7.8.7 Environmental Abnormalities</p> <p>7.8.8 Environment/Safety Day celebration</p> <p>7.8.9 EHSS SOP requirement</p> <p>7.8.10 Safe suggestions for improvement of safety culture</p> <p>7.8.11 The agenda of the meeting shall cover discussion on completed points, previous meeting pending points and new safety concerns.</p> <p>7.9 For the points discussed during the meeting, the CAPA with target date shall be decided by respective department’s safety committee members.</p> <p>7.10 Status of pending points, new concerns raised, responsibility and target dates shall be recorded as Minutes of Meeting. Refer: FORM-EHSS-EHSS-0275(Annexure-02).</p> <p>7.11 In next meeting, the previous meeting points shall be discussed. All completed points shall be discussed and updated. New safety issues shall also be discussed and the same is captured as minutes as per FORM-EHSS-EHSS-0275(Annexure-02).</p> <p>7.12 As per Karnataka Factories Rules, 1969, Rule No 88 C (5), responsibilities of Safety committee members are,</p> <p>7.12.1 Assisting and co-operating with management in achieving the aims and objectives outlined in EHSS policy of the organization.</p> <p>7.12.2 Dealing with all matters concerning health, safety and environment and to arrive at practicable solutions to problems encountered.</p> <p>7.12.3 Creating EHSS awareness amongst all employees.</p> <p>7.12.4 Undertaking educational, training and promotional activities.</p> <p>7.12.5 Discussing on various aspects as mentioned in point 7.8 and implementation of the recommendations made in the reports.</p>			

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<p>7.12.6 Carrying out EHSS surveys and identifying the causes of incidents.</p> <p>7.12.7 Looking into any complaint made on the likelihood of an imminent danger to the safety and health of the employee and suggesting corrective and preventive measures.</p> <p>7.12.8 Reviewing the implementation of the recommendations made by the committee.</p> <p>8.0 REFERENCES: KFR (Karnataka Factories Rules) -1969, Rule No. 88 C.</p> <p>9.0 ANNEXURES:</p> <table border="1"> <tr> <td>FORM-EHSS-EHSS-0274</td> <td>Annexure – 01 Attendance record for Safety Committee</td> </tr> <tr> <td>FORM-EHSS-EHSS-0275</td> <td>Annexure – 02 Minutes of safety committee meeting</td> </tr> <tr> <td>FORM-EHSS-EHSS-0276</td> <td>Annexure – 03 Annual planner</td> </tr> <tr> <td>FORM-EHSS-EHSS-0277</td> <td>Annexure – 04 SOP Training Questionnaire</td> </tr> <tr> <td>FORM-EHSS-EHSS-0278</td> <td>Annexure – 05 List of Safety committee members</td> </tr> </table> <p>10.0 REVISION HISTORY:</p> <table border="1"> <thead> <tr> <th>Version no.</th> <th>Effective Date</th> <th>Description of Change</th> </tr> </thead> <tbody> <tr> <td>2.0</td> <td>23-May-2023</td> <td><u>Reference Change Control Number: - EHSS/CCF/23/0004</u></td> </tr> <tr> <td>1.0</td> <td>01-Oct-2021</td> <td><u>Reference Change Control Number: - EHSS/CCF/21/0012</u></td> </tr> </tbody> </table>				FORM-EHSS-EHSS-0274	Annexure – 01 Attendance record for Safety Committee	FORM-EHSS-EHSS-0275	Annexure – 02 Minutes of safety committee meeting	FORM-EHSS-EHSS-0276	Annexure – 03 Annual planner	FORM-EHSS-EHSS-0277	Annexure – 04 SOP Training Questionnaire	FORM-EHSS-EHSS-0278	Annexure – 05 List of Safety committee members	Version no.	Effective Date	Description of Change	2.0	23-May-2023	<u>Reference Change Control Number: - EHSS/CCF/23/0004</u>	1.0	01-Oct-2021	<u>Reference Change Control Number: - EHSS/CCF/21/0012</u>
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Syngene	Standard Operating Procedure	Department: Environmental Health Safety and Sustainability
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Title: SELECTION OF PERSONAL PROTECTIVE EQUIPMENT

Document Number: SOP-EHSS-EHSS-0046	Version Number: 3.0	Effective Date: 22-May-2023
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Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Nidhi Cs/EHSS/ SYNGENE	07-Mar-2023 16:51:31 (IST)
Department Review	Environment Health Safety Sustainability	Satish Birajdar/EHSS/ SYNGENE	16-Mar-2023 16:17:05 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	16-Mar-2023 16:32:19 (IST)

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	<p align="center">Standard Operating Procedure</p>	<p>DEPARTMENT: Environmental Health Safety and Sustainability</p>	
<p>TITLE:SELECTION OF PERSONAL PROTECTIVE EQUIPMENT</p>			
<p>Document Number: SOP-EHSS-EHSS-0046</p>	<p>Version no.: 3.0</p>	<p>Effective Date: 22-May-2023</p>	<p>Next Review Date: 21-May-2025</p>
<p>1.0 OBJECTIVE: To have a documented procedure for selection of Personal Protective Equipment.</p> <p>2.0 SCOPE:</p> <ul style="list-style-type: none"> • This procedure is applicable to Syngene International Limited. • This procedure applicable to all departments where “Personal Protective Equipment” are practiced and maintained. <p>3.0 RESPONSIBILITY:</p> <p>3.1 EHSSS Department:</p> <p>3.1.1 To advise and recommend Personal Protective Equipment based on activities to the users.</p> <p>3.1.2 To ensure the Personal Protective Equipment compliance.</p> <p>3.2 User Department:</p> <p>3.2.1 To follow Personal Protective Equipment as per EHSS recommendation.</p> <p>3.2.2 To procure appropriate Personal Protective Equipment based on the activity.</p> <p>4.0 ABBREVIATION:</p> <p>EHSS : Environment, Health, Safety and Sustainability PPE : Personal Protective Equipment SCBA : Self Contained Breathing Apparatus</p> <p>5.0 DEFINITION:</p> <p>5.1 PPE: PPEs are specialized clothing or equipment worn for protection against health and safety hazards. Personal protective equipment is designed to protect many parts of the body, i.e., eyes, head, face, hands, feet, and ears etc.</p> <p>6.0 EHSS: NA</p> <p>7.0 PROCEDURE: Types of protection required:</p> <p>7.1 Hearing protection</p> <p>7.2 Head protection</p> <p>7.3 Eye protection</p> <p>7.4 Foot protection</p> <p>7.5 Hand and arm protection</p> <p>7.6 Respiratory protection</p> <p>7.7 Body protection</p> <p>7.8 Guidelines for the selection of PPEs are given in FORM-EHSS-EHSS-0244(Annexure-01).</p>			

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	<p align="center">Standard Operating Procedure</p>	<p>DEPARTMENT: Environmental Health Safety and Sustainability</p>	
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<p>Document Number: SOP-EHSS-EHSS-0046</p>	<p>Version no.: 3.0</p>	<p>Effective Date: 22-May-2023</p>	<p>Next Review Date: 21-May-2025</p>
<p>7.1 Hearing Protection: Hearing protection requires when the person expose to the noise of 85 decibels or greater than for an 8-hour period of time.</p> <p>7.1.1 Foam Earplugs 7.1.2 Earmuffs</p> <p>7.1.1 Foam Earplugs: To insert foam earplugs properly:</p> <ul style="list-style-type: none"> • Reach around the back of your head, and gently pull your ear back and up. • Roll the plug into a small diameter • Insert the plug well into the ear canal • Hold the plug-in place for a few seconds while it expands and forms a good seal <p>7.1.2 Earmuffs: When using earmuffs:</p> <ul style="list-style-type: none"> • Make sure that the earmuffs fit snugly around your ears. • Consider using earplugs if you wear glasses, earrings, or have facial hair that would prevent the earmuffs from forming a good seal around your ears. Once inserted, wait a few seconds to make sure the plug is securely fitted into your ear. Hold the plug-in place for a few seconds while it expands and forms a good seal. <p>7.2 Head protection:</p> <p>7.2.1 Hard hats protect against electrical shock, falling objects, spills and splashes.</p> <p>7.2.2 A hemispherical mass of 5 kg is allowed to fall from a height of 1 m. A suspension system inside the hat that acts as a shock absorber. Some hats serve as an insulator against electrical shocks. Shields your scalp, face, neck, and shoulders against splashes, spills, and drips. These helmets are for general service. They are used mainly in mining, building construction, and manufacturing.</p> <p>7.2.3 Wearing of Helmet: 7.2.3.1 Adjust the suspension inside hard hat so that the hat sits comfortably, but securely on head.</p>			



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<p>Document Number: SOP-EHSS-EHSS-0046</p>	<p>Version no.: 3.0</p>	<p>Effective Date: 22-May-2023</p>	<p>Next Review Date: 21-May-2025</p>
<p>7.2.3.2 Never paint, scratch or drill "air holes" in hat. Never use metal tape on your helmet because it can conduct electricity.</p> <p>7.2.3.3 Never carry personal belongings such as lighters, or pens with hard hat</p> <p>7.3 Eye and Face protection: Eye and face protection requires when the person expose to Chemical splash, dust and toxic gases.</p> <p>7.3.1 Safety glasses</p> <p>7.3.2 Splash Goggles</p> <p>7.3.3 Face Shield</p> <p>7.3.4 Welding helmets</p> <p>7.3.1 Safety glasses: Safety glasses widely used type of eye protection. It is much stronger and more resistant to impact and heat than regular glasses. In addition, most safety glasses are equipped with side shields that give protection from hazards hitting sides.</p> <p>7.3.2 Splash Goggles:</p> <ul style="list-style-type: none"> • Splash Goggles are stronger than safety glasses • It's used for higher impact protection, greater particle protection, chemical splashes, and welding light protection • It's used for splash or high dust protection should have indirect venting • Splash Goggles with direct venting (a mesh of small holes around the sides) tend to fog less, but should not be used with liquid or fine dust hazards <p>7.3.3 Face shield: Face shields offer full face protection and are often used around operations which expose to molten metal, chemical splashes, or flying particles. Many face shields can be used while wearing a hard hat.</p> <p>7.3.4 Welding Helmets: Welding helmets provide both face and eye protection. Welding helmets use special absorptive lenses that filter the intense light and radiant energy that is produced during</p>			



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<p>welding operations. As with face shields, safety glasses or goggles should be worn when using a welding helmet.</p> <p>7.3.5 Wearing of Eye and face protection glasses and shield:</p> <ul style="list-style-type: none"> • Select and use the right kind of protection for the job you are going to be performing. • Select goggles/face shield and check for fit. • Inspect before use. Look for holes and cracks. • Avoid borrowing gloves. Store in a clean, cool, dry area. <p>7.4 Foot protection:</p> <p>7.4.1 Steel footwear:</p> <ul style="list-style-type: none"> • Steel toe footwear protects your toes from falling objects and from being crushed. <div data-bbox="1187 893 1417 1122" data-label="Image"> </div> <p>7.4.2 Nitrile footwear:</p> <ul style="list-style-type: none"> • Nitrile footwear resists animal fats, oils, and chemicals. <div data-bbox="1187 1198 1417 1426" data-label="Image"> </div> <p>7.4.3 Wearing of Footwear:</p> <ul style="list-style-type: none"> • Select and use the right kind of footwear for the job you are going to be performing. • Avoid footwear made of leather or cloth if you work around acids or caustics. These chemicals quickly eat through the leather or cloth and can injure your feet. • Select footwear that fit. • Inspect footwear before use. Look for holes and cracks that might leak. • After working with chemicals, hose it footwear with water to rinse away any chemicals or dirt before removing footwear. • Avoid borrowing footwear. Store footwear in a clean, cool, dry area. 			

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Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability
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TITLE:SELECTION OF PERSONAL PROTECTIVE EQUIPMENT

Document Number: SOP-EHSS-EHSS-0046	Version no.: 3.0	Effective Date: 22-May-2023	Next Review Date: 21-May-2025
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7.5 Hand and arm protection:

7.5.1 Gloves:

There are many types of gloves that are designed to protect hands.

				
Nitrile glove afford excellent protection from a wide range of chemicals for splash or intermittent contact.	Heat resistant gloves protect your hands from heat and flames.	Leather gloves shield your hands from rough surfaces.	Vinyl and neoprene gloves protect your hands against toxic chemicals.	Rubber gloves protect you when working around electricity.

7.5.2 Wearing and Using Gloves:

- 7.5.2.1 Select and use the right kind of glove for the job you are going to be performing.
- 7.5.2.2 Select gloves that fit.
- 7.5.2.3 Some gloves may be chemical specified and have a life expectancy.
- 7.5.2.4 Discard them after the recommended time has expired.
- 7.5.2.5 Remove any rings, watches, or bracelets that might cut or tear your gloves.
- 7.5.2.6 Wash your hands before and after wearing gloves.
- 7.5.2.7 Inspect gloves before use them. Look for holes and cracks that might leak.
- 7.5.2.8 After working with chemicals, hold your gloved hands under running water to rinse away any chemicals or dirt before removing the gloves.
- 7.5.2.9 Wash cotton gloves as needed.
- 7.5.2.10 Store gloves right side out in a clean, cool, dry area.

7.6 Respiratory protection:

7.6.1 Half face respiratory protection:

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(a) Inspection before Use:

It is required to inspect the following before respiratory use:

- Cracks in the faceplate
- Cracks or holes in the breathing tube or airlines;
- Worn or frayed straps
- Worn or damaged fittings;
- Dirty or improperly seated valves.



(b) Donning the respirator:

- With one hand, hold the respirator to your face.
- While holding the respirator in place, slip the head harness over our head.
- Adjust and tighten the head harness straps until the respirator fits snugly to your face. The best way to tighten a respirator is to tighten the straps from the bottom up. If you find anything wrong with respirator, do not use it. Have it repaired or replaced immediately.



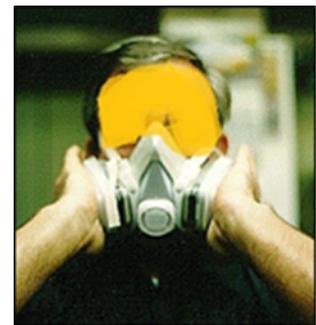
(c) Fit testing the respirator:

Because you want an airtight seal between your face and the respirator, you will need to fit test the respirator each time you wear it to make sure no contaminant gets inside the face piece and into your lungs.

Positive Pressure Test:

Begin by closing the respirator's exhalation valve by covering it with your hand, then breathe out slowly. The face piece will bulge out slightly. Hold your breath

for about 10 seconds. If during this time no air leaks from around the face piece, it is good fit. If you do not have a good fit, readjust the head harness straps, and repeat the pressure test.



(d) Fit testing the respirator:

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Another way to test the seal formed by your respirator around your face is to perform a negative pressure test.

Negative pressure Test:
Begin by closing the respirator's inhalation valves with your hands, then breathe in slowly. The face piece will collapse slightly. Hold your breath for about 10 seconds. And if during this time no air leaks in from around the face piece, it is good fit. If you do not have a good fit, readjust the head harness straps, and repeat the pressure test.



7.6.2 Full face respiratory protection:

- Protect respiratory tract from airborne infectious agents. This respirator does not supply oxygen when used in air-purifying mode.
- Do not use in atmospheres containing less than 19.5% oxygen.
- Do not use with beards or other facial hair or other conditions that prevent a good seal between the face and the face seal of the respirator.



(a) Inspection before Use

It is required to inspect the following before respiratory use:

- Cracks in the faceplate
- Cracks or holes in the breathing tube or airlines;
- Worn or frayed straps
- Worn or damaged fittings;
- Dirty or improperly seated valves.

(b) Donning the respirator:

- With one hand, hold the respirator to your face.
- While holding the respirator in place, slip the head harness over our head.
- Adjust and tighten the head harness straps until the respirator fits snugly to your face. The best way to tighten a respirator is to tighten the straps from the bottom up. If you find anything wrong with respirator, do not use it. Have it repaired or replaced immediately.

(c) Fit testing the respirator:

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Because you want an airtight seal between your face and the respirator, you will need to fit test the respirator each time you wear it to make sure no contaminant gets inside the face piece and into your lungs.

- **Positive Pressure Test:**

Begin by closing the respirator's exhalation valve by covering it with your hand, then breathe out slowly. The face piece will bulge out slightly. Hold your breath for about 10 seconds. If during this time no air leaks from around the face piece, it is good fit. If you do not have a good fit, readjust the head harness straps, and repeat the pressure test.

(d) Fit testing the respirator:

Another way to test the seal formed by your respirator around your face is to perform a negative pressure test.

- **Negative Pressure Test:**

Begin by closing the respirator's inhalation valves with your hands, then breathe in slowly. The face piece will collapse slightly. Hold your breath for about 10 seconds. And if during this time no air leaks in from around the face piece, it is good fit. If you do not have a good fit, readjust the head harness straps, and repeat the pressure test.

7.6.3 Self-Contained Breathing Apparatus:

- It helps to protect from Heat, Smoke, Toxic gases (poisonous & Superheated) and Oxygen deficiency locations (<19.5%). For operation of SCBA Refer SOP No: SOP-EHSS-EHSS-0028



7.6.4 Powered Air Purifying Respirator:

- Helps reduce respiratory exposure to airborne particles such as dust, mist, Biological and radiological aerosols.



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<p>7.7 Body protection:</p> <p>7.7.1 Full body suit: Providing outstanding protection, the coverall shields you from many hazardous materials, nonhazardous light liquid splash and skin irritants. It is an ideal disposable clean up suit for a variety of dirty jobs.</p> <div style="text-align: right;">  </div> <p>7.7.2 PVC Suit: Providing protection against hazardous chemical.</p> <div style="text-align: right;">  </div> <p>7.7.3 Aluminized fire suit: Providing protection against the heat splash.</p> <div style="text-align: right;">  </div> <p>8.0 REFERENCES: SOP-EHSS-EHSS-0028</p> <p>9.0 ANNEXURES:</p> <table border="1" data-bbox="225 1751 1434 1973"> <tr> <td data-bbox="225 1751 758 1861">FORM-EHSS-EHSS-0244</td> <td data-bbox="758 1751 1434 1861">Annexure – 01 Guidelines for the selection of PPEs</td> </tr> <tr> <td data-bbox="225 1861 758 1973">FORM-EHSS-EHSS-0245</td> <td data-bbox="758 1861 1434 1973">Annexure – 03 SOP Training Questionnaire</td> </tr> </table>				FORM-EHSS-EHSS-0244	Annexure – 01 Guidelines for the selection of PPEs	FORM-EHSS-EHSS-0245	Annexure – 03 SOP Training Questionnaire
FORM-EHSS-EHSS-0244	Annexure – 01 Guidelines for the selection of PPEs						
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<p>10.0 REVISION HISTORY:</p>			
<p align="center">Version no.</p>	<p align="center">Effective Date</p>	<p align="center">Description of Change</p>	
<p align="center">3.0</p>	<p align="center">22-May-2023</p>	<p><u>Reference Change Control Number: - EHSS/CCF/23/0004</u></p>	
<p align="center">2.0</p>	<p align="center">01-Apr-2022</p>	<p><u>Reference Change Control Number: - EHSS/CCF/22/0009</u> Under section 6.9.2 (d) Negative Pressure test has been included</p>	
<p align="center">1.0</p>	<p align="center">25-Aug-2021</p>	<p><u>Reference Change Control Number: - EHSS/CCF/21/0012</u></p>	

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Title: OPERATION AND MAINTENANCE OF SPILL CONTROL KIT

Document Number:
SOP-EHSS-EHSS-0029

Version Number:
3.0

Effective Date:
01-Mar-2023

Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Pooja Naik	25-Feb-2023 11:18:13 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Satish Birajdar/EHSS/ SYNGENE	27-Feb-2023 10:40:15 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	28-Feb-2023 09:40:25 (IST)

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	<p align="center">Standard Operating Procedure</p>	<p>DEPARTMENT: Environmental Health Safety and Sustainability</p>	
<p>TITLE: OPERATION AND MAINTENANCE OF SPILL CONTROL KIT</p>			
<p>Document Number: SOP-EHSS-EHSS-0029</p>	<p>Version no.: 3.0</p>	<p>Effective Date: 01-Mar-2023</p>	<p>Next Review Date: 28-Feb-2025</p>
<p>1.0 OBJECTIVE: To have a documented procedure for operation and maintenance of Spill control kit.</p> <p>2.0 SCOPE: This Procedure is applicable for the operation and maintenance of Spill control kit at Syngene International Limited, Bangalore and Hyderabad.</p> <p>3.0 RESPONSIBILITY:</p> <p>3.1 EHSS Department:</p> <p>3.1.1 To inspect Spill Kit once in a month and fill the FORM-EHSS-EHSS-0188 (Annexure – 02). 3.1.2 Disposal of used spilled kit contents 3.1.3 Investigate Spill Incident (if any). 3.1.4 Follow up the spill incident CAPA (if any).</p> <p>3.2 OU Representatives (From Respective Operation Unit):</p> <p>3.2.1 To monitor the Spill Kit regularly. 3.2.2 To report the Spill incident to EHSS Department (via SynZero). 3.2.3 To be a part of Spill Incident investigation team. 3.2.4 To instruct the personnel on handling of Spill Kit during emergency.</p> <p>3.3 Respective Department:</p> <p>3.3.1 To control the spill using spill control kit. 3.3.2 To attend training on handling of Spill Control. 3.3.3 To report the spill incident to respective EHSS representative or Incident Controller/ERT.</p> <p>4.0 ABBREVIATION:</p> <p>BRD : Biology Research Development CAPA : Corrective and Preventive Action ERT : Emergency response team SPOC : Single Point of contact EHSS : Environment, Health, Safety and Sustainability EPR : Emergency Preparedness and Response FDC : Formulation Development Centre HOD : Head of the Department IC : Incident Controller MCP : Manual Call Point</p>			

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<p>SDS : Safety Data Sheet OSEP : Onsite Emergency Plan PPE : Personal Protective Equipment SOP : Standard Operating Procedure SCBA : Self Contained Breathing Apparatus BC : Building Controller TICO : Test Items Control Office</p>			
<p>5.0 DEFINITION: NA</p>			
<p>6.0 EHSS: NA</p>			
<p>7.0 PROCEDURE:</p>			
<p>7.1 Spill Kit is kept in all Emergency safety cupboard (Refer: SOP-EHSS-EHSS-0028, Operation and maintenance of Emergency Safety Cupboards), and the strategic location mentioned as per FORM-EHSS-EHSS-0186 (Annexure – 01) Spill kit index with location and code number. This annexure is prepared by respective EHSS team/OU SPOC.</p>			
<p>7.2 Once the spill is observed, Spill Kit shall be collected from the nearest area or emergency cupboard installed and neutralizing agent (if required) based on the nature of the spill. In case if the spill is not controlled, immediately declare the emergency as per emergency response procedure. (Refer SOP: SOP-EHSS-EHSS-0020, Emergency preparedness and response).</p>			
<p>7.3 While handling the hazardous spill, use most appropriate PPE's like SCBA, chemical suit, acid/ alkali proof hand gloves/ Nitrile gloves, Butyl rubber gloves, face shield, safety goggles, gum boots or even respiratory masks with suitable cartridges</p>			
<p>7.4 Once the spill is controlled using Sorbent pad/Boom collect in a double polythene bag and secure with the plastic cable ties. Dispose it as per applicable disposal procedure. (Refer SOP-EHSS-EHSS-0073, Waste Management).</p>			
<p>7.5 Report the incident of spill to EHSS department through online portal/SynZero (Via Syngconnect).</p>			
<p>7.6 Once in a month, as per the FORM-EHSS-EHSS-0194 (Annexure – 03) Annual Planner for the Spill Kit, the items of the Spill Kit shall be inspected and recorded in the FORM-EHSS-EHSS-0188 (Annexure – 02) Inspection Report of Spill control Kit, by OU representatives of the individual area and will be checked by EHSS team/OU SPOC.</p>			
<p>7.7 Biomaterials emergency response for small volume spills (0.1 L- 50 L):</p>			
<p>7.7.1 Clear warning signs (caution tape and caution boards) must be put up to other personnel's to keep clear from the contaminated area until decontamination is completed.</p>			
<p>7.7.2 For liquid spills, spreading of the liquid must be prevented primarily or in the first place.</p>			

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<p>7.7.3 A spill kit absorbent pad and boom must be used to surround the liquid to prevent the spreading (Use boom for large volume spillage only).</p> <p>7.7.4 The contaminated surface must be disinfected with 1% bleach/sodium hypochlorite for 30mins.</p> <p>7.7.5 After wiping with the bleach/sodium hypochlorite, the surface must be disinfected with 70% ethanol.</p> <p>7.7.6 Along with the second pair of gloves, all wiping towels must be discarded in the biohazard bin (yellow biohazard bags).</p> <p>7.7.7 After completion, hands should be thoroughly washed with soap for at least for 20 seconds.</p> <p>7.7.8 If the containment comes in bodily contact with the personnel, then the person should seek help immediately with the first aider. All contaminated clothing must be removed, and the person must rinse oneself thoroughly under the emergency shower. For minor contamination, the affected area must be thoroughly washed with soap in the sink. The waste generated from the spill considered as bio-waste and appropriately handled as per procedures. (Refer SOP-EHSS-EHSS-0073, Waste Management).</p> <p>7.7.9 Any employee exposures should be reported to OHC for further evaluation and treatments.</p> <p>7.8 All incidents to be reported through online portal/SynZero (Via Syngconnect).</p>			

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7.9 Contents of Biological Spill Control Kit:

<p align="center">Biological spill kit contents</p>		
<p align="center">Available in the spill kit</p>		
<p align="center">1</p>	<p align="center">Absorbent pad</p>	
<p align="center">2</p>	<p align="center">Absorbent Booms</p>	
<p align="center">3</p>	<p align="center">Yellow disposable bag (Biohazard)</p>	
<p align="center">4</p>	<p align="center">Goggles</p>	
<p align="center">5</p>	<p align="center">Mask</p>	<p align="center">  or  </p>

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6	Nitrile gloves	
Other required materials (Not provided in the spill kit)		
1	1% Bleach/Sodium hypochlorite*	
2	70% Ethanol*	
3	Hydrogen peroxide **	
4	Glutaraldehyde **	

Note:

**** Additionally, these disinfectants are used in Viral testing facility**

*** Required for cleanup procedure but not provided in the spill kit (Users should maintain the stock and freshly dilute as and when required)**

7.10 Biomaterials emergency response for large volume spills:

- 7.10.1 Clear warning signs (caution tape and caution boards) must be put up to other personnel's to keep clear from the contaminated area until decontamination is completed.
- 7.10.2 Once the spill is observed, spill kit shall be collected from the nearest area / emergency cupboard installed and neutralizing agent (if required) based on the nature of spill. Spill kit is kept in all emergency cupboard/near laboratories.
- 7.10.3 In case if the spill is not controlled, immediately declare the emergency as per emergency response procedure (Refer SOP: SOP-EHSS-EHSS-0020, Emergency preparedness and response).
- 7.10.4 While handling the spill, use most appropriate PPE's like Self Contained Breathing Apparatus (SCBA), chemical suit, acid / alkali proof hand gloves, face shield, safety goggles, gum boots or even respiratory mask with suitable cartridges.
- 7.10.5 Once the spill is controlled using sorbent pad/ boom, collect in a double polythene bag and secure with the plastic ties. Dispose it as per applicable disposable procedure (Refer SOP-EHSS-EHSS-0073, Waste management).
- 7.10.6 Report the incident of spill to EHSS department through online portal/SynZero (Via Syngconnect).
- 7.10.7 Once in a month, as per the FORM-EHSS-EHSS-0194 (Annexure – 03) Annual Planner for the Spill Kit, the items of the Spill Kit shall be inspected and recorded in the FORM-EHSS-EHSS-0188 (Annexure – 02) Inspection Report of Spill Control Kit, by OU representatives of the individual area and will be checked by EHSS building representative or OU EHSS SPOC.

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7.11 Contents of Chemical Spill control Kit:

Chemical Spill control kit content	
Available in the Kit	
1	Absorbent pads 
2	Absorbent Booms 
3	Disposable bag (Biohazard)
4	Plastic Scoop
5	Cleaning wiper
6	Gloves: PVC, Nitrile, Neoprene, Butyl Rubber, Cut resistant gloves, (Each One pair)
7	Tychem or Tyvek suit
8	Splash Goggles
9	Full face mask with Multi gas cartridge

7.12 Chemical emergency response for small volume spills:

- 7.12.1 Clear warning signs (caution tape and caution boards) must be put up to other personnel's to keep clear from the contaminated area until decontamination is completed.
- 7.12.2 For liquid spills, spreading of the liquid must be prevented primarily or in the first place.
- 7.12.3 Along with the second pair of gloves, all wiping towels must be discarded appropriately as per applicable disposable procedure (Refer SOP-EHSS-EHSS-0073, Waste Management).
- 7.12.4 After completion, hands should be thoroughly washed with soap for at least for 20 seconds.
- 7.12.5 If the chemicals comes in bodily contact with the personnel, then the person should seek help immediately with the first aider. All contaminated clothing must be removed, and the person must rinse oneself thoroughly under the emergency shower. For minor contamination, the affected area must be thoroughly washed with soap in the sink. The waste generated from the spill cleaning should be discarded appropriately as per applicable disposable procedure (Refer SOP-EHSS-EHSS-0073, Waste Management).
- 7.12.6 Any employee exposures should be reported to OHC for evaluation and treatments.
- 7.12.7 All incidents to be reported through online portal/SynZero (Via Syngconnect).

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<p>7.13 Chemical emergency response for large volume spills:</p> <p>7.13.1 Clear warning signs (caution tape and caution boards) must be put up to other personnel's to keep clear from the contaminated area until decontamination is completed.</p> <p>7.13.2 Once the spill is observed, spill kit shall be collected from the nearest area / emergency cupboard installed and neutralizing agent (if required) based on the nature of spill. Spill kit is kept in all emergency cupboard.</p> <p>7.13.3 In case if the spill is not controlled, immediately declare the emergency as per emergency response procedure (Refer SOP: SOP-EHSS-EHSS-0020, Emergency preparedness and response).</p> <p>7.13.4 While handling the spill, use most appropriate PPE's like Self Contained Breathing Apparatus (SCBA), chemical suit, acid / alkali proof hand gloves, face shield, safety goggles, gum boots or even respiratory mask with suitable cartridges.</p> <p>7.13.5 Once the spill is controlled using sorbent pad/ boom, collect in a double polythene bag and secure with the plastic ties. Dispose it as per applicable disposable procedure (Refer SOP-EHSS-EHSS-0073, Waste Management).</p> <p>7.13.6 Report the incident of spill to EHSS department through online portal/SynZero (Via Syngconnect).</p> <p>7.13.7 Once in a month, as per the FORM-EHSS-EHSS-0194 (Annexure – 03) Annual Planner for the Spill Kit, the items of the Spill Kit shall be inspected and recorded in the FORM-EHSS-EHSS-0188 (Annexure – 02) Inspection Report of Spill Control Kit, by OU representatives of the individual area and will be checked by EHSS building representative or OU EHSS SPOC.</p> <p>7.14 Spill Emergency Mitigation Procedure:</p> <p>7.14.1 Once incipient stage of spill is observed, the observer(s) should inform Incident Controller immediately about the spill and pull the MCP for evacuation</p> <p>7.14.2 IC instructs one trained personnel from the respective department to protect themselves with personal protective equipment (SCBA and Tychem / Tyvek suit) and barricade the area of spill.</p> <p>7.14.3 Incident controller (IC) protects himself and also instructs others of the respective area to wear PPE's such as SCBA /full face mask/chemical suit/acid / alkali proof hand gloves, Nitrile gloves, Butyl rubber gloves/face shield/safety goggles/gum boots/even respiratory masks with suitable cartridges (depending on the nature of spilled material) to make an initial inspection of the spill.</p> <p>7.14.4 Identify the source of the spill and mitigation to be initiated at the source as per IC</p> <p>7.14.5 IC instructs personnel from the department to fetch “Spill Kit” from the nearest installation, identify the chemical that has been spilled, fetch specific SDS and use the procedure as described in the same to contain the spill.</p>			

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- 7.14.6 In parallel IC instructs other department personnel to follow emergency shutdown procedure (Refer SOP-EHSS-EHSS-0023, Equipment Emergency Shutdown), except any critical processes in progress (if required) and instructs them to protect with personal protective equipment to contain the spill.
- 7.14.7 Further IC instructs (if required) one person to break nearest MCP & dial internal emergency telephone number “4001” for seeking support from Site ERT members (If required).

		EMERGENCY CONTACT NUMBERS	
Site Emergency Response Team (SERT)	4001 / 080-66334001		
Ambulance	1009		
Aerial Ladder Platform (ALP)	3003 / 080-68913003		
Shift EHSS Team-1	09606067556		
Shift EHSS Team-2	09606067559		
Occupational Health Center (OHC)	3761 / 080-68913761		
Security Main Gate	3791 / 080-68913791		
Security Material Gate	3795 / 080-68913795 & 96		
Vijayashree Hospital	080-67338888		

- 7.14.8 IC shall deploy department personnel with Spill kit to mitigate the situation. If required, even neighboring department ERT personnel shall get ready with PPE to collect sorbents (depending on the nature of the material that has spilled) to arrest and contain the spill.
- 7.14.9 In case the situation goes out of control, IC will initiate emergency response procedure or even “OSEP” to mitigate the spill.
- 7.14.10 Once the spill is controlled & contained, dispose the used sorbents or booms by following specified disposal procedure (Refer SOP-EHSS-EHSS-0073, Waste Management) applicable to that chemical.
- 7.14.11 Do not dispose these used chemical booms in dustbins or waste containers.

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Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability													
TITLE: OPERATION AND MAINTENANCE OF SPILL CONTROL KIT															
Document Number: SOP-EHSS-EHSS-0029	Version no.: 3.0	Effective Date: 01-Mar-2023	Next Review Date: 28-Feb-2025												
<p>7.14.12 On investigation, the users will arrange to replenish the spill kit with exhausted items based on consultation with EHSS.</p> <p>7.14.13 In case affected department fails to report the spill incident and EHSS checks during their safety rounds/checks and finds out the usage of spill kits without incident log and appropriate investigation shall be taken for the usage of spill kit.</p> <p>7.14.14 It is the responsibility of respective departments HOD to deploy and ensure their own identified personnel to attend EHSS training sessions with respect to mitigation of spills/such emergencies, PPE, SCBA, EPR, Mock drills or any other related topic and prepare his team to be ready for such emergencies.</p> <p>7.15 Maintenance:</p> <p>7.15.1 Spill kit shall be installed in specific locations listed which shall be updated in the format: FORM-EHSS-EHSS-0186 (Annexure – 01) Spill kit index with location and code number.</p> <p>7.15.2 It shall be inspected once in a month as per annual planner FORM-EHSS-EHSS-0194 (Annexure – 03) and same will be recorded in FORM-EHSS-EHSS-0188 (Annexure – 02) Inspection Report of Spill Control Kit, by OU representatives of the individual area and will be checked by EHSS building representative.</p> <p>7.15.3 OU representatives will check/inspect the spill kit monthly once and sign the annexure and continuously monitor the spill kit.</p> <p>7.15.4 EHSS team will check/inspect the spill kit monthly once and sign the annexure during the archival after reviewing the spill related incident and refilling requirements.</p> <p>8.0 REFERENCES: SOP-EHSS-EHSS-0020 SOP-EHSS-EHSS-0023 SOP-EHSS-EHSS-0028 SOP-EHSS-EHSS-0073</p> <p>9.0 ANNEXURES:</p> <table border="1"> <tr> <td>FORM-EHSS-EHSS-0186</td> <td>Annexure - 01</td> <td>Spill kit index with location and code number</td> </tr> <tr> <td>FORM-EHSS-EHSS-0188</td> <td>Annexure – 02</td> <td>Inspection report of Spill Control Kit</td> </tr> <tr> <td>FORM-EHSS-EHSS-0194</td> <td>Annexure – 03</td> <td>Annual planner</td> </tr> <tr> <td>FORM-EHSS-EHSS-0196</td> <td>Annexure – 04</td> <td>SOP Training Questionnaire</td> </tr> </table>				FORM-EHSS-EHSS-0186	Annexure - 01	Spill kit index with location and code number	FORM-EHSS-EHSS-0188	Annexure – 02	Inspection report of Spill Control Kit	FORM-EHSS-EHSS-0194	Annexure – 03	Annual planner	FORM-EHSS-EHSS-0196	Annexure – 04	SOP Training Questionnaire
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Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability
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TITLE: OPERATION AND MAINTENANCE OF SPILL CONTROL KIT

Document Number: SOP-EHSS-EHSS-0029	Version no.: 3.0	Effective Date: 01-Mar-2023	Next Review Date: 28-Feb-2025
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10.0 REVISION HISTORY:

Version no.	Effective Date	Description of Change
3.0	01-Mar-2023	<p><u>Reference Change Control Number:</u> - EHSS/CCF/22/0006</p> <ol style="list-style-type: none"> In point 7.9 ** Additionally, these disinfectants are used in Viral testing facility * Required for cleanup procedure but not provided in the spill kit (Users should maintain the stock and freshly dilute as and when required) has been included. In point 7.15.4 EHSS team will check/inspect the spill kit monthly once and sign the annexure during the archival after reviewing the spill related incident and refilling requirements has been included.
2.0	01-Mar-202302- Aug-2021	<u>Reference Change Control Number:</u> - EHSS/CCF/21/0015
1.0	01-Apr-2021	<u>Reference Change Control Number:</u> - EHSS/CCF/20/0022

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Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability	
TITLE:PROCEDURE FOR CYANIDE MANAGEMENT			
Document Number: SOP-EHSS-EHSS-0060	Version no.: 1.3	Effective Date:	Next Review Date:
<p>1.0 OBJECTIVE: To describe the system & procedure to be followed for procurement, safe transportation and temporary storage & handling for cyanide-based compounds and to identify appropriate safety precautions during its operation within all premises of Syngene.</p> <p>2.0 SCOPE: This procedure covers the safety aspects that need to be considered during procurement, transportation, storage & handling for cyanides between various user points and the main store.</p> <p>3.0 RESPONSIBILITY:</p> <p>3.1 Department Head: Department Heads are responsible for the following:</p> <p>3.1.1 Line managers/ Heads of respective departments shall be responsible during handling of cyanides.</p> <p>3.1.2 Ensure that the chemists in their Departments are trained on this Procedure.</p> <p>3.1.3 Any discrepancy is observed in this Procedure shall be handled by initiating a change control as per Change control SOP (SOP-EHSS-EHSS-0025) or any deviation as per Deviation control SOP (SOP-EHSS-EHSS-0010).</p> <p>3.1.4 Ensure that any unsafe incidents pertaining to cyanides are reported in the Incident management portal at Syngconnect, investigated and suitable CAPA measures are taken.</p> <p>3.2 Chemists: Chemists are responsible for the following:</p> <p>3.2.1 Chemists must ensure that all necessary PPEs like disposable apron, hand gloves, mask and approved secondary containers are used to transport Cyanides from main store to user location.</p> <p>3.2.2 Chemists must complete all assigned training relating to this Procedure like, spill control and emergency evacuation procedures as required before any cyanide issuance and transfer.</p> <p>3.2.3 Any unsafe incident pertaining to cyanides must be reported in the Incident management portal at Syngconnect.</p> <p>3.2.4 Ensure Cyanide Caution Display board is displayed in bench fume hood area/ Reactor area.</p> <p>3.2.5 Ensure no other incompatible reaction is performed in the lab clusters/manufacturing area during cyanide reaction.</p> <p>3.2.6 Before starting the cyanide reaction, Inform to the First Aiders and other lab chemists about reaction details</p> <p>3.2.7 Aware of Occupational Health center operation. Incase of emergency contact 1009 for ambulance & 3761 for OHC.</p>			

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Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability	
TITLE:PROCEDURE FOR CYANIDE MANAGEMENT			
Document Number: SOP-EHSS-EHSS-0060	Version no.: 1.3	Effective Date:	Next Review Date:
<p>3.3 EAM: EAM are responsible for the following:</p> <p>3.3.1 Check the hood maintenance schedule, suction velocity of the hood and also possible maintenance schedule for the shutdown hoods.</p> <p>3.4 EHSS: EHSS personnel are responsible for the following:</p> <p>3.4.1 Only personnel trained on the chemical properties of cyanide, should be involved in the transportation, handling, spill control, emergency evacuation and disposal.</p> <p>3.4.2 Imparting training to users/employees with the properties of the cyanide compounds being used, have proper training and education in the handling and disposal of such material, and to know-how the emergency notification procedures, prior to performing operations involving cyanide compounds. Training on handling of Cyanide shall be conducted once in a year to the users through LMS.</p> <p>3.4.3 Ensure that no other chemicals are transported along with cyanides.</p> <p>3.4.4 Ensure compliance to statutory requirements.</p> <p>3.5 Strategic Sourcing: SS team personnel are responsible for the following:</p> <p>3.5.1 Based on the indent, the materials shall be issued to the user department by stores personnel.</p> <p>3.5.2 Procurement Manager to ensure centralized procurement and receipt of Cyanides at only main store approved by the statutory authority.</p> <p>3.5.3 Stores personnel shall update the cyanide issuance register in the presence of User department (Operation team).</p> <p>3.5.4 Stores personnel must ensure appropriate delegation of authority in their absence and other stakeholders must be kept informed.</p> <p>3.5.5 Stock ledger to be maintained as per FORM-EHSS-EHSS-0343 (Annexure – 03 Cyanide Stock ledger).</p> <p>4.0 ABBREVIATION:</p> <p>EHSS : Environment, Health, Safety and Sustainability ERT : Emergency Response Team HDPE : High Density Polyethylene SS : Strategic Sourcing PR : Purchase Request CPR : Cardiopulmonary Resuscitation ppm : parts per million PPE : Personal Protective Equipment</p>			

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Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability	
TITLE:PROCEDURE FOR CYANIDE MANAGEMENT			
Document Number: SOP-EHSS-EHSS-0060	Version no.: 1.3	Effective Date:	Next Review Date:
<p>OHC : Occupational Health Center LMS : Learning Management System EAM : Engineering and Maintenance CAPA : Correction and Preventive action</p> <p>5.0 DEFINITION: NA</p> <p>6.0 EHSS:</p> <p>6.1 Precaution before process:</p> <p>6.1.1 Personnel should wear appropriate PPE (Refer PPE section 7.2.1) and follow good EHSS practices in order to reduce the potential exposure/injury during the process.</p> <p>6.1.2 Cyanide reactions to be performed only with Fume hood connected to the wet scrubber.</p> <p>6.1.3 Ensure the Cyanide Antidote kit is available in the respective floor where Cyanide reaction is undergoing.</p> <p>6.1.4 Display the warning board “CYANIDE REACTION IS IN PROGRESS” in the fume hoods where cyanide reaction is planned.</p> <p>6.1.5 Inorganic cyanide chemical reactions shall not be carried out during weekends and public holidays.</p> <p>6.1.6 Before starting cyanide experiment, a “lab buddy” should be informed. It shouldn’t be handled by a single scientist at any point of time. Consuming food or drink is strictly prohibited in the working area.</p> <p>6.1.7 Whomsoever handles cyanide should discard apron, head cap, hand gloves, mask after completion of their work in the lab/manufacturing/dispensing area and take shower (need basis) before leaving the department and sign in the batch register.</p> <p>6.1.8 The discarded gowning shall be collected in HDPE container and sent for incineration.</p> <p>6.2 Precaution during process:</p> <p>6.2.1 Risk assessment shall be done for all reactions involving Cyanide by respective line managers and EHSS Representatives.</p> <p>6.2.2 During acidification of cyanide compounds, hydrogen cyanide gas shall be generated. This step of the experiment would require a lab buddy, to be available in the lab.</p> <p>6.2.3 During quenching, if any power failure occurs sash door shall be closed and the same shall be informed to all personnel’s immediately (Lab people) for evacuation purpose.</p> <p>6.2.4 Use an appropriately sized 3 neck flask/reactor for all cyanide reactions. Consider the possibility of heat or gas evolution when choosing the size of the reaction flask. Check all glass ware for cracks, chips, or any manufacturing defects, before taking into the process. Do not use any glassware which is not suitable to use. (E.g. cracks or chipped glassware).</p>			

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Document Number: SOP-EHSS-EHSS-0060	Version no.: 1.3	Effective Date:	Next Review Date:
<p>6.2.5 The reaction vessel must be properly secured, and some type of containment vessel shall be placed below the reaction vessel as a precautionary measure in order to prevent spillage out of the hood.</p> <p>6.2.6 Use a mechanical stirrer if any precipitate form, which can inhibit the spinning of a magnetic stirring bar.</p> <p>7.0 PROCEDURE:</p> <p>7.1 Training requirements:</p> <p>The employee's immediate supervisor is responsible for ensuring the employee has been properly trained. Training shall include:</p> <p>7.1.1 Proper reaction set-ups.</p> <p>7.1.2 Extra caution when acidification is required.</p> <p>7.1.3 Procedures to follow in case of unforeseen adverse events.</p> <p>7.1.4 Additional steps and precaution for reactions greater than 100 m mole.</p> <p>7.1.5 Quenching method.</p> <p>7.2 Personal Protective Equipment (PPE) requirements:</p> <p>7.2.1 Wearing two pairs of disposable gloves with the cuff overlapping the disposable lab coat sleeve to avoid skin contact.</p> <p>7.2.2 If dimethyl sulfoxide is used as a solvent for cyanide compounds, it is strongly recommended that a double layer of surgical-style gloves is worn with the inner glove made of neoprene and the outer glove made of nitrile. Neoprene is superior to both latex and nitrile rubber with regards to protecting the skin from dimethyl sulfoxide.</p> <p>7.2.3 Supplied Air-line mask or any other masks recommended by EHSS.</p> <p>7.2.4 Goggles with side cover to be used during work up reaction.</p> <p>7.3 Statutory Requirements: For handling cyanides following statutory bodies approval are mandatory and they are listed below:</p> <ul style="list-style-type: none"> • Approval from Drug Controller Department • Approval from Fire & Emergency Services • Approval from local Police • Approval from village Panchayat • Final approval from District Magistrate/Deputy Commissioner 			

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Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability	
TITLE:PROCEDURE FOR CYANIDE MANAGEMENT			
Document Number: SOP-EHSS-EHSS-0060	Version no.: 1.3	Effective Date:	Next Review Date:
<p>7.4 Procurement & Storage:</p> <p>7.4.1 User:</p> <p>7.4.1.1 User shall raise the PR and his/her line Manager shall approve the same. The administrative control includes User indent, User Approval, Stores Approval and EHSS approval.</p> <p>7.4.1.2 The cyanide will be issued only from the stores during the specified timings from 1000 hours to 1030 hours (10:00 AM to 10:30 AM) in the morning and 1500 to 1530 hours (03:00 PM to 03:30 PM) in the afternoon.</p> <p>7.4.1.3 The scientist shall be accompanied by the lab manager/team lead for collection of cyanide from stores, weighing, dispensing and return back to their respective departments.</p> <p>7.4.1.4 After complete consummation of received cyanide, new bottle of cyanide can be transferred from Main store to day store in presence of User and their manager.</p> <p>7.4.2 Stores:</p> <p>Cyanide needs to be stored in a dedicated room with lock and key. There should be double locking system. Storage shall have 2 keys, one with Stores, second with Production or user (Discovery operation team, Head-Production). They shall handover to their deputies during their absence.</p> <p>7.4.2.1 Administrative controls, such as, issue and authorization shall be followed.</p> <p>7.4.2.2 Cyanide containers must be labelled with appropriate hazard labels and identification label of contents (Cyanide) and day store location.</p> <p>7.4.2.3 Gross and net weight of individual bottles must be recorded before issuance.</p> <p>7.4.2.4 The usage/consumption register shall be maintained and monitored on monthly basis (reconciliation).</p> <p>7.4.2.5 Procurement of all kind of cyanides should be done in smaller pack sizes based on the market availability.</p> <p>7.4.2.6 Cyanides shall be issued to all day store FORM-EHSS-EHSS-0341 Day store details (Annexure-02) and remaining quantity to be stored in main store.</p> <p>7.4.2.7 During the issuance of cyanides from main stores to day store, user shall be accompanied by their Manager/designee. All individuals involved in transfer of cyanides should wear appropriate PPE's (refer sec: 7.2).</p> <p>7.5 Operation of Scrubbers during process:</p> <p>7.5.1 Appreciable discharge of highly toxic gases should be passed through a scrubbing system before venting to outside. The objective is to trap any hydrogen cyanide gas which is being generated by slowly bubbling it through a caustic or bleach solution as a</p>			

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<p>means of converting it to an inorganic cyanide salt, such as sodium cyanide, potassium cyanide, etc. This should then be disposed of in an appropriately labeled container.</p> <p>7.5.2 Consider the quenching volume while deciding the volume of the reaction flask/reactor.</p> <p>7.5.3 During acidification process, ensure portable gas detectors is placed in the scrubber area.</p> <p>7.5.4 Supervisors must inspect the setup prior to starting the reaction.</p> <p>7.5.4.1 A reaction employing cyanide may be run over night, however, the setup and work up of the reaction must take place during the core working hours. Any reaction involving cyanide that is run outside the core operating hours (8.30 am - 4:00 pm) must be setup (during core hours) in a hood with the hood sash lowered. Ensure the "CYANIDE REACTION IN PROGRESS" sign is posted on the doors of the lab.</p> <p>7.5.4.2 Inform the night shift working chemist about the process, procedure and precaution through Overnight Reaction Monitoring System.</p> <p>7.5.4.3 Detoxification of equipment and area: This needs to be addressed in detail separately for Lab and plant as this is extremely important. We have elaborated the waste disposal (SOP No: SOP-EHSS-EHSS-0073, Waste Management) but the equipment detoxification and cleaning are also important.</p> <p>7.5.4.4 Scientist/User: To ensure portable Cyanide gas detector is in place inside the fume hood/manufacturing area.</p> <p>7.6 First Aid measures in case of Emergency:</p> <p>7.6.1 Contact Maintenance, EHSS and all the designated First Aiders in the immediate lab area prior to beginning the procedure.</p> <p>7.6.2 Designated First Aiders are current, active members of the Emergency Response Team who have been certified in CPR and First Aid.</p> <p>7.6.3 Designated Medical Responders are trained specifically in responding to medical emergencies involving cyanide compounds including the use of oxygen and amyl nitrite. Their names, locations and phone extensions shall be posted on the required cyanide signage.</p> <p>7.6.4 Cyanide Antidote Kits are placed in designated areas where cyanide handling is done, for ease in use in case of emergency.</p> <p>7.6.5 The contents of Antidote Kits are 10ml ampoules of Sodium nitrite (2 Nos), 50ml Vial of Sodium Thiosulphate (1 No), Injection Kit (1 No), Amyl Nitrite Inhalant (12 durules).</p> <p>7.6.6 In case of an emergency notify to OHC by dialing 1009 immediately followed by the designated medical responders identified on the cyanide signage. Carry the antidote kit along with victim to OHC.</p>			

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TITLE:PROCEDURE FOR CYANIDE MANAGEMENT											
Document Number: SOP-EHSS-EHSS-0060	Version no.: 1.3	Effective Date:	Next Review Date:								
<p>7.7 Waste Disposal:</p> <p>7.7.1 Upon completion of the operation, dispose of dry cyanide waste in an appropriate type and sized container with the Hazardous Waste label affixed and duly filled as cyanide waste.</p> <p>7.7.2 In case of any contamination remove all PPE's like disposable lab coat, safety glasses, or other articles put in an appropriate type and sized container with the Hazardous Waste label affixed and duly filled as cyanide waste.</p> <p>7.7.3 Segregate cyanide waste from other lab waste regardless of the scale of the reaction.</p> <p>7.7.4 Upon completion of the experiment, add bleach (Sodium hypochlorite) to the liquid cyanide waste.</p> <p>7.7.5 Transfer the cyanide liquid waste in an appropriate container.</p> <p>7.7.6 Affix the Hazardous Waste label to the container and list the chemical contents as soon as you begin adding to the container. This container is always to be kept closed and stored within secondary containment.</p> <p>7.7.7 Analyze the spent Cyanide solution for traces of cyanide. Acceptable limit of 0.2 ppm, prior to the disposal need to be established.</p> <p>7.7.8 The cyanide waste should be removed from the lab as soon as the reaction/cleanup is completed.</p> <p>7.7.9 Dry cyanide waste is to be disposed of in an appropriate sized container. Affix the Hazardous Waste label as soon as you start filling it and describe the contents as "Cyanide Waste".</p> <p>7.7.10 Inform designated cyanide disposal team in the site.</p> <p>8.0 REFERENCES: SOP-EHSS-EHSS-0073 SOP-EHSS-EHSS-0025 SOP-EHSS-EHSS-0010</p> <p>9.0 ANNEXURES:</p> <table border="1" data-bbox="240 1615 1326 1912"> <tr> <td data-bbox="240 1615 652 1700">FORM-EHSS-EHSS-0340</td> <td data-bbox="652 1615 1326 1700">Annexure – 01 Format for Location of Cyanide Antidote Kit</td> </tr> <tr> <td data-bbox="240 1700 652 1771">FORM-EHSS-EHSS-0341</td> <td data-bbox="652 1700 1326 1771">Annexure – 02 Day Store Details</td> </tr> <tr> <td data-bbox="240 1771 652 1843">FORM-EHSS-EHSS-0343</td> <td data-bbox="652 1771 1326 1843">Annexure – 03 Cyanide stock ledger</td> </tr> <tr> <td data-bbox="240 1843 652 1912">FORM-EHSS-EHSS-0342</td> <td data-bbox="652 1843 1326 1912">Annexure – 04 SOP Training Questionnaire</td> </tr> </table>				FORM-EHSS-EHSS-0340	Annexure – 01 Format for Location of Cyanide Antidote Kit	FORM-EHSS-EHSS-0341	Annexure – 02 Day Store Details	FORM-EHSS-EHSS-0343	Annexure – 03 Cyanide stock ledger	FORM-EHSS-EHSS-0342	Annexure – 04 SOP Training Questionnaire
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Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability
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TITLE:PROCEDURE FOR CYANIDE MANAGEMENT

Document Number: SOP-EHSS-EHSS-0060	Version no.: 1.3	Effective Date:	Next Review Date:
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10.0 REVISION HISTORY:

Version no.	Effective Date	Description of Change
1.3		<u>Reference Change Control Number: - EHSS/CCF/23/0004</u>
1.0	20-Sep-2021	<u>Reference Change Control Number: - EHSS/CCF/21/0007</u> 1. Merged OCP-EHSS-EHSS-0001 ‘Procurement, transportation and temporary storage of cyanide chemicals within premises’ with this SOP 2. Updated responsibility section 3.0 – Responsibility of Department head, EAM, EHSS,SS and Chemist 3. Revised section 7.4 – Procurement and storage (User, Store, Precaution before process, Operation of Scrubbers during process, Precaution during Process, First Aid measures in case of Emergency 4. Introduced new annexure Cyanide stock ledger

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Syngene	Standard Operating Procedure	Department: Environmental Health Safety and Sustainability
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Title: HANDLING OF PYROPHORIC CHEMICALS FOR LABORATORIES

Document Number: SOP-EHSS-EHSS-0018	Version Number: 2.0	Effective Date: 16-Feb-2023
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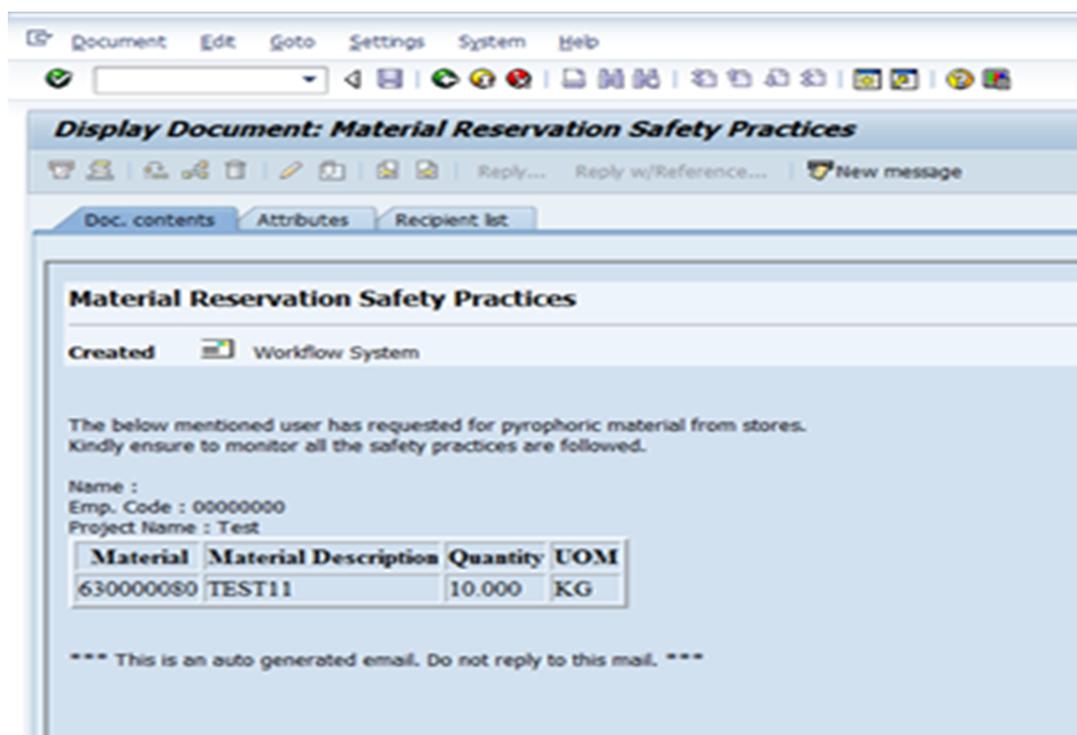
Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Nidhi Cs/EHSS/ SYNGENE	11-Feb-2023 11:21:15 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Satish Birajdar/EHSS/ SYNGENE	13-Feb-2023 10:57:33 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	13-Feb-2023 15:50:57 (IST)

Declaration - **Document Electronically Signed** This document is Valid for 24 hrs. from 02-Jun-2023 09:05:06

Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability	
TITLE: HANDLING OF PYROPHORIC CHEMICALS FOR LABORATORIES			
Document Number: SOP-EHSS-EHSS-0018	Version no.: 2.0	Effective Date: 16-Feb-2023	Next Review Date: 15-Feb-2025
<p>1.0 OBJECTIVE: To have a documented procedure for handling pyrophoric chemicals across Syngene. This procedure includes:</p> <ol style="list-style-type: none"> Classification of pyrophoric chemicals Procurement and inventory management Issuance, storage and handling of pyrophoric chemicals in labs Quenching Emergency spill procedures Disposal Training <p>2.0 SCOPE: This procedure is applicable to all Syngene laboratory, Stores and Supply chain staff handling pyrophoric chemicals.</p> <p>3.0 RESPONSIBILITY:</p> <p>3.1 Operations team: To order and maintain the inventory of pyrophoric chemicals for the respective OU's.</p> <p>3.2 Strategic sourcing team:</p> <ol style="list-style-type: none"> 3.2.1 Ensure just in time concept for prompt delivery of pyrophoric chemicals as per the schedule shared by operations team. 3.2.2 Supervision and training of the contract employees for the transportation of pyrophoric chemicals from main stores to floor stores. <p>3.3 Stores team:</p> <ol style="list-style-type: none"> 3.3.1 Responsible for the overall issuance, track and return of the pyrophoric chemicals from stores to lab and vice versa. 3.3.2 Ensure chemicals are returned in proper condition using approved secondary container within specified time limits and stored as per the chemical compatibility, zone classification with relevant SAP entry. 3.3.3 Conduct a physical check to ensure there is no leak/ damage to the containers. 3.3.4 Ensure pyrophoric chemicals are labelled properly with date of opening and shelf life period. 3.3.5 Initiate for disposal post shelf life period. In case of any particle formation/color change, the material to be sent for disposal irrespective of the shelf life as per the SOP. 3.3.6 Issue pyrophoric chemicals only after receiving the trigger mail (example presented below). 			

Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability	
TITLE:HANDLING OF PYROPHORIC CHEMICALS FOR LABORATORIES			
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3.4 Lab scientist:

- 3.4.1 Ensure that pyrophoric materials are handled safely with all precautions as mentioned in the procedure (Section 7.0).
- 3.4.2 Lab hazard analysis template to be filled as per EHSS guideline for Laboratory Hazard Analysis Risk Assessment
- 3.4.3 Conduct a physical check for any particle formation or color change in the liquid pyrophoric compounds before use
- 3.4.4 Ensure sealing of chemical bottles with parafilm before returning to stores.
- 3.4.5 In case of any particle formation/color change the chemical to be sent for disposal in coordination with the stores staff, as per procedure mentioned in Section 7.8.

3.5 Team leader and lab manager:

- 3.5.1 Ensure team members follow the procedure (Section 7.0) while handling pyrophoric chemicals.
- 3.5.2 Email communication to be shared to lab manager before performing the reaction.
- 3.5.3 Team leader should accompany the scientist while handling pyrophoric chemicals.

Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability	
TITLE:HANDLING OF PYROPHORIC CHEMICALS FOR LABORATORIES			
Document Number: SOP-EHSS-EHSS-0018	Version no.: 2.0	Effective Date: 16-Feb-2023	Next Review Date: 15-Feb-2025
<p>3.5.4 Share the monthly procurement forecast to the operations team for placing purchase order</p> <p>Note: In case of any unpredicted changes like change in project plan/ change in synthetic route/project on hold/reagent no longer required, prior communication to be sent to stores and operations team.</p> <p>3.6 Section Head:</p> <p>3.6.1 Reviewing the process whenever the pyrophoric chemicals are handled by their team in larger quantities (> 1 mol) and as per the reaction guidelines.</p> <p>3.7 EHSS Team:</p> <p>3.7.1 Training and verification of implemented procedure.</p> <p>4.0 ABBREVIATION:</p> <p>EHSS : Environment, Health, Safety and Sustainability SDS : Safety Data Sheet SS : Strategic sourcing SOP : Standard Operating Procedure TL : Team Leader GHS : Globally Harmonized System OU : Operating unit SAP : Systems Applications and Products in Data Processing AoR : Area of Responsibility PR : Purchase Requisition WBS : Work Breakdown Structure °C : Centigrade °F : Fahrenheit M : Mole mL : Milli-litre SS : Stainless Steel TL : Team Leader HCl : Hydrochloric Acid ERT : Emergency Response Team LMS : Learning Management System DIBAL-H : Diisobutyl Aluminium Hydride 9-BBN : 9-borabicyclo[3.3.1]nonane GRN : Goods Receipt Note</p>			

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5.0 DEFINITION:

5.1 Pyrophoric (Air Reactive)



Pyrophoric materials are chemicals that readily ignite when exposed to air at a temperature of 130°F (54.4°C) or below. Pyrophoric can react with water violently or with atmospheric moisture.

6.0 EHSS: NA

7.0 PROCEDURE:

7.1 Classification of Pyrophoric chemicals:

Type	Category	Examples	Remarks
Pyrophoric liquids	Organolithiums	<i>n</i> -butyl lithium, <i>sec</i> -butyl lithium, methyl lithium, phenyl lithium, lithium hexamethyldisilazide, etc.	Pyrophoric effect would increase in order of <i>n</i> -butyl lithium < <i>sec</i> -butyl lithium < <i>t</i> -butyl lithium*.
	Grignard Reagents	RMgX (R = alkyl, aryl X = halogen)	Includes aryl magnesium halides too
	Alkali metal amides	Sodamide, Potassium amide Sodium hexamethyldisilazide, potassium hexamethyldisilazide	Many of the Pyrophoric liquids listed are available as neat reagents or dissolved in a highly flammable solvent like Tetrahydrofuran, hexane, diethyl ether, etc.
	Alkyl Zinc Reagents	Diethyl Zinc	
	Metal hydrides (solutions)	Lithium aluminium hydride, DIBAL-H, Super hydride, etc.	

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	Organo aluminiums	Trimethyl aluminium (2.0M solution in Toluene), Diethyl aluminium chloride	
	Boranes	9-BBN (0.5M solution in THF), Borane-tetrahydrofuran complex; Borane-Dimethyl Sulfide complex	
Pyrophoric solids	Metal hydrides (solids)	Lithium hydride, Sodium hydride, Potassium hydride, Lithium aluminium hydride, Lithium borohydride, L-Selectride etc.	Pyrophoric solids must be transferred under inert atmosphere.
	Non-metal hydrides	Diethyl arsine, diethyl phosphine, etc	Reactions involving hydrogen gas to be performed only in hydrogenation lab.
	Group I (Alkali) metals	Lithium, potassium, sodium	
	Hydrogenation catalysts	Palladium on Carbon, Raney Nickel, Palladium hydroxide, Rhodium on Carbon, Platinum on carbon	
*Additional administrative control and detailed risk assessment to be performed while handling <i>t</i> -butyl lithium even for smaller volumes required for the usage of <i>t</i> -butyl Lithium			
<i>Note: The above table is a classification of common pyrophoric chemicals being used. For any chemical, the SDS should be referred to check on its pyrophoric properties.</i>			
7.2 Procurement and inventory management of pyrophoric chemicals:			
7.2.1 Project specific ordering is NOT allowed and strategic sourcing team should cancel the order if requisition is raised from technical team			
7.2.2 Requirement of pyrophoric chemicals will be shared by the scientists/AoR from respective section heads of the lab (biweekly/monthly)			
7.2.3 Operations team to collate the data shared by the scientists and raise an open PR in general WBS based on the quantity available in SAP			
7.2.4 The order will be split into smaller volume bottles (100 mL/ 250 mL/ 500 mL) or larger volumes as appropriate.			

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<p>7.2.5 Staggered delivery will be planned based on consumption.</p> <p>7.2.6 If there is any change in project planning or change in synthetic route or project kept on hold or any reagent is no longer required by the project team, scientists to communicate to stores team and operations team.</p> <p>7.2.7 Pyrophoric with long lead time should be maintained in stock by the vendor as per communication from strategic sourcing team.</p> <p>7.2.8 Stores team to share the physical stock of pyrophoric materials every 2 weeks with operations team through email.</p> <p>7.2.9 Information on low stock to be sent by stores team to operations personnel.</p> <p>7.2.10 Physical stock to be verified and checked by stores personnel every month to ensure inventory is maintained properly.</p> <p>Note 1: While ordering pyrophoric chemicals, safe alternate options can be considered:</p> <ul style="list-style-type: none"> • Options like t-butyl lithium in heptane, although still pyrophoric it is much safer to handle than the traditional pentane formulation because heptane has a much higher flash point (-1 °C) than pentane (- 49 °C). • Options like preferring hexyl lithium over butyl lithium <table border="1"> <thead> <tr> <th></th> <th>Butyl lithium</th> <th>Hexyl lithium</th> </tr> </thead> <tbody> <tr> <td>Reactivity</td> <td>Similarly reactive</td> <td>Similarly reactive</td> </tr> <tr> <td>Strength/Molar solution</td> <td>1.5 M to 10 M solution in hexane</td> <td>2.5 M solution in hexane</td> </tr> <tr> <td>Pyrophoricity</td> <td>Pyrophoric at 15% weight in conc.</td> <td>Non-pyrophoric even at conc. up to 85% weight</td> </tr> <tr> <td>By-product</td> <td>In de-protonation reaction, butane is liberated</td> <td>In de-protonation reaction, hexane is liberated</td> </tr> <tr> <td>Risk</td> <td>High</td> <td>Low</td> </tr> <tr> <td>Safety</td> <td>Not safe, as boiling point of liberated butane is -0.5 °C</td> <td>Highly safe, as boiling point of liberated hexane is 68°C. Hexane is easier to contain rather than butane</td> </tr> <tr> <td>CAS No.</td> <td>109-72-8 (2 M solution)</td> <td>21369-64-2 (2.3 M solution)</td> </tr> <tr> <td>Price in INR (Aldrich)</td> <td>6,238.00 (100 mL bottle)</td> <td>6,316.00 (100 mL bottle)</td> </tr> </tbody> </table> <p>Note 2: If any new chemicals to be introduced in pyrophoric chemicals list, Scientists/Line manager need to perform change management through Lab Hazard Analysis by selecting “New technology” and attaching the relevant SDS files for reference.</p>					Butyl lithium	Hexyl lithium	Reactivity	Similarly reactive	Similarly reactive	Strength/Molar solution	1.5 M to 10 M solution in hexane	2.5 M solution in hexane	Pyrophoricity	Pyrophoric at 15% weight in conc.	Non-pyrophoric even at conc. up to 85% weight	By-product	In de-protonation reaction, butane is liberated	In de-protonation reaction, hexane is liberated	Risk	High	Low	Safety	Not safe, as boiling point of liberated butane is -0.5 °C	Highly safe, as boiling point of liberated hexane is 68°C . Hexane is easier to contain rather than butane	CAS No.	109-72-8 (2 M solution)	21369-64-2 (2.3 M solution)	Price in INR (Aldrich)	6,238.00 (100 mL bottle)	6,316.00 (100 mL bottle)
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<p>7.3 Issuance of Pyrophoric Chemicals:</p> <p>7.3.1 Reservation will be raised by the scientists in the respective project WBS specifying the quantity of the pyrophoric material required.</p> <p>7.3.2 All pyrophoric materials will be issued and should be returned on below specific timings ONLY.</p> <ul style="list-style-type: none"> • 1st shift: 0630 hrs to 1230 hrs • 2nd shift: 1430 hrs to 2030 hrs • General shift: 0900 hrs to 1600 hrs <p>7.3.3 The chemical requested will be handed over by the stores staff and updated in SAP.</p> <p>7.3.4 Scientists will use the requested amount and return the remaining quantity to the store staff.</p> <p>7.3.5 Date of opening and shelf life period should be entered on the bottle label by stores staff before handing over the chemical to scientist.</p> <p>7.3.6 After usage, pyrophoric material should be handed over to the store staff within specified duration in the respective shift. If not returned in time, an email should be sent by the stores staff to the receptive team lead for further action.</p> <p>7.3.7 Stores staff should physically verify the integrity of bottle.</p> <p>7.3.8 Stock available should be verified. Low stock should be informed to operations personnel.</p> <p>7.4 Storage of pyrophoric chemicals (general guidelines):</p> <p>7.4.1 Store as per recommended temperature mentioned in SDS with chemical resistant secondary containers and chemical compatibility. Ensure hazardous label as per GHS is affixed on the pyrophoric chemicals.</p> <p>7.4.2 The Sure/Seal™ packaging system provides a convenient method for storing and dispensing air sensitive reagents.</p> <p>7.4.3 Pyrophoric chemicals must be used and stored away from all other flammable and combustible materials such as paper, bench liners and solvents.</p> <p>7.4.4 Ensure that enough protective solvent, oil, kerosene or inert gas remains in the container while metal pyrophoric are stored, Scientists to check physically whether the metals are immersed in the protective solvent.</p> <p>7.4.5 All the pyrophoric chemicals need to be returned to stores immediately after use (within the same shift) with proper sealing along with secondary container. Stores personnel to maintain a register for reconciliation of pyrophoric chemicals.</p> <p>7.4.6 Dispensing/transfer of pyrophoric chemicals inside stores is prohibited.</p> <p>7.4.7 All pyrophoric chemicals must have date of opening entered in the bottle label before its use</p> <p>Shelf life period:</p> <ul style="list-style-type: none"> • Shelf life period of liquid pyrophoric: 6 months (from date of GRN) 			

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- Shelf life period of solid pyrophoric: 6 months (from date of GRN)

7.5 Handling of pyrophoric chemicals in the labs:

Refer Safety Data Sheets (SDS) of the relevant pyrophoric reagent on the usage, quenching before handling.

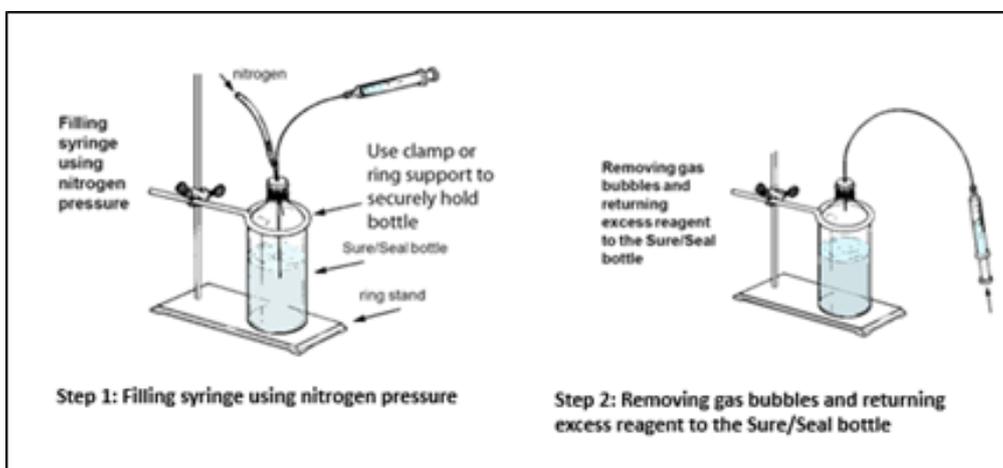
7.5.1 Dispensing of pyrophoric Solids:

Required to weigh using secondary container in the fume hood/column hood and dispense under inert gas atmosphere.

7.5.2 Dispensing of pyrophoric Liquids:

By using proper needle and syringe techniques or cannula/specially designed Teflon braided with SS hose pipes, these reagents can be handled safely in the laboratory fume hood under inert gas atmosphere.

7.5.2.1 Syringe Transfer: (Preferable for small volumes <25 mL)



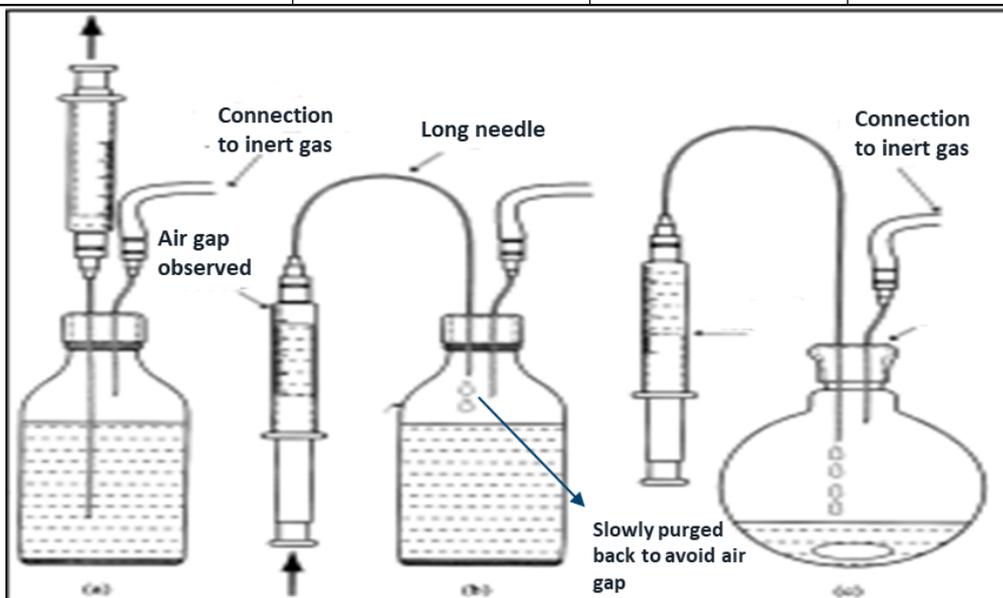
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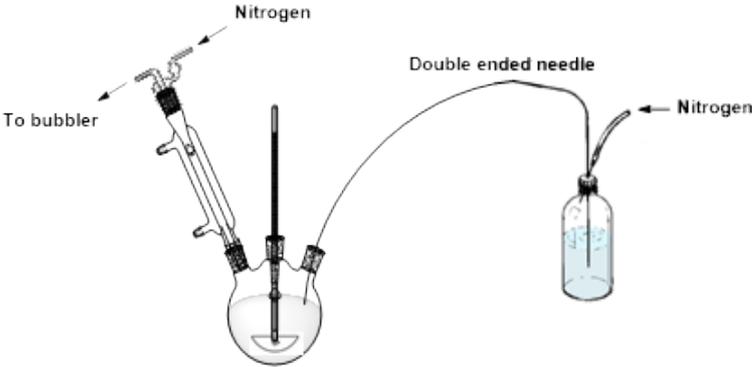
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- 7.5.2.1.1 Smaller volumes (<25 mL) of pyrophoric chemicals can be transferred using syringe with the use of a long needle.
- 7.5.2.1.2 A syringe should only be filled to about half of its capacity.
- 7.5.2.1.3 Volumes beyond its maximum capacity (2/3rd) are unsafe and hence not recommended.
- 7.5.2.1.4 Glass syringes with Teflon-tipped plungers (gas tight) syringes are best, but simple glass syringes are more prone to cause gas bubbles.
- 7.5.2.1.5 Disposable plastic syringes with needle-lock mechanism (Luer-Lock) to prevent separation of needle and syringe should be used for handling pyrophoric chemicals.
- 7.5.2.1.6 Excess drawn pyrophoric chemical during dispensing should not be transferred back to the original container.
- 7.5.2.1.7 Small amounts of impurities introduced into the container may cause a fire or explosion. Please refer the quenching section for disposing the excess reagent.

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<p>7.5.2.2 Double-Tipped Needle (Cannula) Transfer - Preferable for volume >25 mL:</p>  <p>7.5.2.2.1 For larger quantities (> 25 ml) of the reagent, use double-tipped needle/cannula (16, 18, or 20 gauge) to transfer the reagent directly to the reaction flask/reactor or to the pre-calibrated/graduated measuring cylinder/flask.</p> <p>Note: Addition funnel should be avoided for transferring pyrophoric reagents. It is recommended to use a nitrogen bladder to control the positive pressure/flow.</p> <p>7.5.3 General Precautions and guidelines:</p> <p>7.5.3.1 Scientists should consult Team leader or Section head before start of any pyrophoric reaction. Section Head should be aware of all the pyrophoric reaction planned in the lab (>1 M).</p> <p>7.5.3.2 In the absence of the direct reporting team leader, another team leader in the same group can supervise pyrophoric reactions being performed by a scientist.</p> <p>7.5.3.3 Use the buddy system. DO NOT work alone or during late hours when there are few members around to help in the lab.</p> <p>7.5.3.4 Pyrophoric reactions should not be performed on holidays.</p> <p>7.5.3.5 Before start of any pyrophoric reaction, check the condition of round bottom flask, addition funnel, syringe, cannula, condenser, connecting tube, chilled water circulation and nitrogen flow for any abnormalities.</p> <p>7.5.3.6 Many pyrophoric chemicals release noxious or flammable gases and should be handled in a laboratory fume hood with the sash down at the safe working height.</p> <p>7.5.3.7 Keep the fume hoods clean and ensure it is free from any combustible sources and clutter.</p> <p>7.5.3.8 When more than one reaction is performed in the same hood, reaction/chemical compatibility must be ensured by scientist.</p> <p>7.5.3.9 Ensure that the class D Type Fire extinguisher/sand bucket/ is available within 1 meter distance of the fume hood before start-up of any pyrophoric reaction. Also to ensure that fire</p>			

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<p>blanket and spill kit is available inside the lab premises. Fume hood should display the 'pyrophoric reaction caution board'.</p> <p>7.5.3.10 Do not use extinguishers containing or developing water or Carbon dioxide.</p> <p>7.5.3.11 Chemical Splash goggles or safety glasses must be worn while working with pyrophoric chemicals.</p> <p>7.5.3.12 A face shield and/or portable shield is required when there is a risk of explosion, splash hazard or exothermic reaction.</p> <p>7.5.3.13 Nitrile gloves should be used.</p> <p>7.5.3.14 Flame retardant lab coats are mandatory while handling pyrophoric materials (> 1mol).</p> <p>7.5.3.15 Scientists should be aware of location of eyewash/ shower, fire extinguishers, fire alarm pulls, and emergency exits.</p> <p>7.5.3.16 Pyrophoric reaction should be quenched before the end of each shift (1 hour before the end of shift just to make sure that there is enough time for quenching to bring the reaction mass to a safe hold point). The scientist or team lead should ensure that syringe, cannula and needles to be quenched immediately after each addition of pyrophoric chemicals.</p> <p>7.5.3.17 In case of prolonged reaction time (overnight), the details should be shared to the TL's and Lab Manager. With prior approval only, overnight pyrophoric reactions are allowed. If the reaction is not completed within the shift, reaction maintenance can be continued in the presence of scientist with approval from Lab manger and Section head. Addition and dispensing of pyrophoric chemicals are NOT allowed after shift timings.</p> <p>7.5.3.18 The cooling bath used for maintaining the lower temperatures while performing the pyrophoric reaction should be removed. The solvent used for preparing the cooling bath should be removed once the ambient temperature (~25 °C) is achieved.</p> <p>Note: Preferably isopropanol can be used for the cooling bath to reduce the bath temperature.</p> <p>7.6 Quenching of pyrophoric materials</p> <p>7.6.1 Quenching of Syringes/needles/cannula:</p> <p>7.6.1.1 Syringes/needles/cannula should be quenched immediately after use.</p> <p>7.6.1.2 Quenching media should be checked, studied and discussed with team leaders for all the pyrophoric chemicals or reactions.</p> <p>7.6.1.3 Quenching media should be made ready in the fume hood before the addition of pyrophoric chemicals.</p> <p>7.6.1.4 Group leader/Team leader should accompany the chemist while performing/quenching the reaction using pyrophoric chemicals.</p> <p>7.6.1.5 After the transfer of a pyrophoric reagent is complete, the syringe should be immediately washed at least three times with the solvent in which the reagent was dissolved.</p>			

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<p>7.6.1.6 If the syringe was used to transfer alkyl lithium's or other pyrophoric reagents, it should be washed successively with dilute HCl, water followed by methanol.</p> <p>7.6.2 Quenching of excess reagent (pyrophoric liquid) withdrawn:</p> <p>7.6.2.1 Excess reagent should NOT be transferred back to reagent bottle.</p> <p>7.6.2.2 The excess reagent should be transferred to a round bottom flask with a septum under inert atmosphere and diluted with adequate amount of less hazardous solvent as per LHA recommendation.</p> <p>7.6.2.3 Under inert atmosphere, the round bottom flask should be cooled and quenched by the slow addition of appropriate quenching agent like ammonium chloride or 1.5 N HCl solution or Isopropanol followed by methanol and water to ensure that there are no reactive materials left.</p> <p>7.6.2.4 The quenched mass to be disposed in a safe way to ensure no active reagent is available in quenched mass and raw material/empty bottles should be sent to quenching station by raising request through waste management module.</p> <p>7.6.2.5 Group leader/Team leader should accompany the chemist while performing/quenching the reaction using pyrophoric chemicals.</p> <p>7.6.3 Quenching of the reagent present in the reaction flask/Reactor:</p> <p>7.6.3.1 If for any reason, the second reagent could not be added after the addition of the pyrophoric reagent to the reaction flask, then the excess reagent must be quenched as per the standard procedure that is followed to quench the reagent.</p> <p>7.6.3.2 Group leader/Team leader should accompany the chemist while performing/quenching the reaction using pyrophoric chemicals.</p> <p>7.6.4 Quenching of excess pyrophoric solid reagents:</p> <p>7.6.4.1 Transfer the materials to an appropriate reaction flask for hydrolysis and/or neutralization under inert atmosphere.</p> <p>7.6.4.2 Dilute the substance with an unreactive solvent such as hexane or tetrahydrofuran under lower temperature to make sure all solid material is sufficiently wetted and suspended in the unreactive solvent, this need to be discussed well in advance with team leader before doing any such exercise</p> <p>7.6.4.3 Slowly add ammonium chloride solution or 1.5 N HCl solution to ensure that there are no reactive materials left to ensure completion.</p> <p>7.6.4.4 Upon completion, add methanol as a more reactive quenching agent to ensure completion.</p> <p>7.6.4.5 Finally add water drop wise under cooling to make sure there are no pockets of reactive materials.</p> <p>7.6.4.6 After quenching of excess reactive materials, dispose safely in aqueous waste.</p>			

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<p>7.6.4.7 Group leader/Team leader should accompany the chemist while performing/quenching the reaction using pyrophoric chemicals.</p> <p>Note: To quench chemical bottles, request should be raised in waste management module and should be moved to quenching station post approval from EHSS.</p> <p>7.7 Emergency spill procedures:</p> <p>7.7.1 DO NOT use water to attempt to extinguish a pyrophoric material fire as it can enhance the combustion of some pyrophoric materials, e.g. metal compounds.</p> <p>7.7.2 DO NOT use combustible materials (paper towels) to clean up a spill, as these may increase the risk of igniting the pyrophoric compound.</p> <p>7.7.3 Use spill kit or fire blanket (in case of any fire).</p> <p>7.7.4 If anyone is exposed to fire, wash the person's body with copious amounts of water</p> <p>7.7.5 If the situation is uncontrollable, call site ERT to take required action</p> <p>7.8 Disposal of pyrophoric chemicals:</p> <p>7.8.1 A container with any residue of pyrophoric materials should never be left open to the atmosphere.</p> <p>7.8.2 Scientists should avoid quenching unwanted reactive chemicals (e.g. an old bottle of butyl lithium or sodium hydride etc.).</p> <p>7.8.3 Raise the request through the waste management module to remove/quench the unwanted reactive materials and empty bottles/containers.</p> <p>7.8.4 Post approval, handover the chemical bottles to EHSS team for quenching.</p> <p>7.8.5 All materials (disposable gloves, wipers, bench paper, used sorbents, etc.) that are contaminated with pyrophoric chemicals should be disposed as hazardous waste after proper quenching.</p> <p>7.9 Training:</p> <p>7.9.1 Classroom/online training:</p> <p>7.9.1.1 LMS training for this SOP will be assigned by EHSS and operations team for all relevant employees once a year.</p> <p>7.9.1.2 Any employee who has a necessity to perform or supervise a pyrophoric reaction or issuing pyrophoric chemicals should undergo this SOP training.</p> <p>7.9.1.3 In addition to this SOP, Scientists should have completed the required EHSS training mentioned below.</p> <p>Lab safety – SOP-EHSS-EHSS-0026, Hazardous material management – SOP-EHSS-EHSS-0009 Selection of personal protective equipment- SOP-EHSS-EHSS-0046</p>			

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<p align="center">Emergency preparedness and response procedure – SOP-EHSS-EHSS-0020</p> <p>7.9.2 On the Job training:</p> <p>7.9.2.1 On the job training will be organized by operations team. Training will be provided by Team leaders/Group leaders.</p> <p>7.9.2.2 On the job training is for new employees and any other employees on need basis.</p> <p>7.9.2.3 New employees (including campus hires/trainees), who have less than six months’ experience in chemical laboratories performing pyrophoric reactions, should perform pyrophoric reactions ONLY under strict supervision of the team leader/group leader.</p> <p>7.9.2.4 New employees who have more than six months’ experience in chemical laboratories performing pyrophoric reactions, should demonstrate one reaction in the presence of team leader/group leader after on the job training.</p> <p>8.0 REFERENCES: SOP-EHSS-EHSS-0026 SOP-EHSS-EHSS-0009 SOP-EHSS-EHSS-0046 SOP-EHSS-EHSS-0020</p> <p>9.0 ANNEXURES:</p> <table border="1"> <tr> <td>FORM-EHSS-EHSS-0179</td> <td>Annexure – 01 Template for list of commonly used pyrophoric chemicals used in Syngene along with its storage temperature condition</td> </tr> <tr> <td>FORM-EHSS-EHSS-0180</td> <td>Annexure – 02 SOP Training Questionnaire</td> </tr> </table> <p>10.0 REVISION HISTORY:</p> <table border="1"> <thead> <tr> <th>Version no.</th> <th>Effective Date</th> <th>Description of Change</th> </tr> </thead> <tbody> <tr> <td>2.0</td> <td>16-Feb-2023</td> <td><u>Reference Change Control Number: - EHSS/CCF/23/0004</u></td> </tr> <tr> <td>1.0</td> <td>22-Mar-2021</td> <td><u>Reference Change Control Number: - EHSS/CCF/20/0018</u></td> </tr> </tbody> </table>				FORM-EHSS-EHSS-0179	Annexure – 01 Template for list of commonly used pyrophoric chemicals used in Syngene along with its storage temperature condition	FORM-EHSS-EHSS-0180	Annexure – 02 SOP Training Questionnaire	Version no.	Effective Date	Description of Change	2.0	16-Feb-2023	<u>Reference Change Control Number: - EHSS/CCF/23/0004</u>	1.0	22-Mar-2021	<u>Reference Change Control Number: - EHSS/CCF/20/0018</u>
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Title: WASTE MANAGEMENT

Document Number: SOP-EHSS-EHSS-0073	Version Number: 1.0	Effective Date: 03-Jan-2023
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Signature Manifestation

Responsibility	Department	Signed By	Date
Author	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Pooja Naik	17-Dec-2022 13:37:11 (IST)
Department Review	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Sunil Kumar/EHSS/ SYNGENE	19-Dec-2022 13:07:57 (IST)
HOD Approval	ENVIRONMENT HEALTH SAFETY SUSTAINABILITY	Rajendra Patil/EHSS/ SYNGENE	28-Dec-2022 10:11:13 (IST)

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TITLE: WASTE MANAGEMENT

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1.0 OBJECTIVE:

This standard sets minimum requirements to protect environment (soil, water, air) by managing wastes generated (solid, liquid & gaseous) at Syngene International Limited, in line with Indian Regulatory Framework.

2.0 SCOPE:

This standard is applicable for generation, segregation, minimization, reuse/recycle, collection, handling, storage, transportation, treatment and disposal of solid and liquid from all operations within the offices, laboratories and manufacturing locations across Syngene Biocon Park, Syngene Hyderabad, Syngene Mangalore sites of Syngene International Limited.

3.0 RESPONSIBILITY:

Activities	User department personnel	EHSS
Development of procedures	C, I	R, A
Implementation of procedure	R, A	C
Proper segregation, packing and labeling of the wastes	R, A	C
Safe disposal of waste	R	A
Environment aspect impact register	C, R	A
EHSS legal compliance	I, R	A
To treat and dispose of waste sustainably	R	A
Audit for compliance	I, R	A
Operation and maintenance of site-specific intermediate waste collection points and waste yard	R, A	C
External vendor evaluation (FORM-EHSS-EHSS-0415, Annexure – 06, Vendor evaluation checklist)	I	R, A

Here **R** - Responsible **A** - Accountable **C** - Consult **I** – Inform

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<p>4.0 ABBREVIATION:</p> <p>AERB : Atomic energy regulatory board BMW : Biomedical waste CBWTF : Common Biomedical waste treatment facility CO₂ : Carbon dioxide CPCB : Central Pollution Control Board CPU : Central Processing Unit DG : Diesel generator EAM : Engineering and Maintenance EHSS : Environment, Health, Safety and Sustainability ETP : Effluent Treatment Plant FRP : Fiber reinforced plastic HDPE : High Density Polyethylene HTDS : High Total Dissolved Solids HWM : Hazardous waste management SPCB : State Pollution Control Board LDPE : Low Density Polyethylene LTDS : Low Total Dissolved Solids LED : Light-Emitting Diode MEE : Multiple Effect Evaporator MS : Mild Steel MSEZ : Mangalore Special Economic Zone PDCA : Plan Do Check Act PPE : Personal Protective Equipment PVC : Poly vinyl chloride RSO : Radiation Safety Officer R&D : Research and Development STP : Sewage Treatment Plant TREM Card : Transport Emergency Card TSDF : Treatment Storage Disposal Facility TDS : Total dissolved solids AIDS : Acquired Immune Deficiency Syndrome</p> <p>5.0 DEFINITION:</p> <p>5.1 Battery waste: New or refurbished cell and/or Battery and/or their component, including accumulator, which is any source of electrical energy generated by direct conversion of chemical energy and includes disposable primary and/or secondary battery.</p>			

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<p>5.2 Biodegradable wastes: Any organic material that can be degraded by micro-organism into simpler stable compounds.</p> <p>5.3 Biomedical waste: Any waste, which is generated during diagnosis, treatment or immunization of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps.</p> <p>5.4 Collection: means collection and transport of waste from place of generation to the place of segregation/sorting/storage of wastes for further treatment or disposal.</p> <p>5.5 Disposal: The final activity after options of reuse, recycling, recovery, utilization including co-processing have been exhausted, and includes physico-chemical treatment, biological treatment, incineration or deposition in secured landfill.</p> <p>5.6 E-waste: Electrical and electronic equipment, whole or in part discarded as waste by the consumer or bulk consumer as well as rejects from manufacturing, refurbishment and repair processes.</p> <p>5.7 Generation: Waste generation includes all materials discarded, whether they are later recycled or disposed in a landfill.</p> <p>5.8 Hazardous Waste: Any waste which by reason of characteristics such as physical, chemical, biological, reactive, toxic, flammable, explosive or corrosive, causes danger or is likely to cause danger to health or environment, whether alone or in contact with other wastes or substances.</p> <p>5.9 Occupier: Person who has ultimate control over affairs of the company.</p> <p>5.10 Plastic waste: Any plastic discarded after use or after their intended use is over.</p> <p>5.11 Recovery: Any operation or activity wherein specific materials are recovered.</p> <p>5.12 Recycling: The process of transforming segregated non-biodegradable solid waste into new material or product or as raw material for producing new products which may or may not be like the original product.</p> <p>5.13 Reuse: Use of hazardous or non-hazardous waste for the purpose of its original use or other use.</p> <p>5.14 Segregation: Sorting and separate storage of various components of wastes namely biodegradable wastes, non-biodegradable wastes including recyclable waste, non-recyclable combustible waste, sanitary waste and non-recyclable inert waste, hazardous wastes and construction and demolition wastes.</p> <p>5.15 Storage: Storing any hazardous or non-hazardous waste for a temporary period, at the end of which such waste is processed or disposed of.</p> <p>5.16 Transportation: Conveyance of wastes (hazardous or non-hazardous), either treated, partly treated or untreated from a location to another location in an environmentally sound manner through specially designed and covered transport system to prevent foul odor, littering and unsightly conditions.</p> <p>5.17 User department: Department, division, branch or section of procuring and disposing entity</p>			

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<p>5.18 Waste: Materials that are not products or by-products, for which generator has no further use for the purposes of production, transformation or consumption.</p> <p>5.19 Waste Generator: Any person, or site, whose act or process produces waste.</p> <p>6.0 EHSS:</p> <p>6.1 Precautionary measures for Handling of liquid and solid waste:</p> <p>6.1.1 Provide necessary/appropriate storage containers/bins/tanks with required labelling, secondary containments (if applicable), color coded of bins (if applicable).</p> <p>6.1.2 User department is responsible for operation and maintenance of site-specific intermediate waste collection points and waste yard.</p> <p>6.1.3 Use appropriate PPEs as required for handling of waste.</p>			

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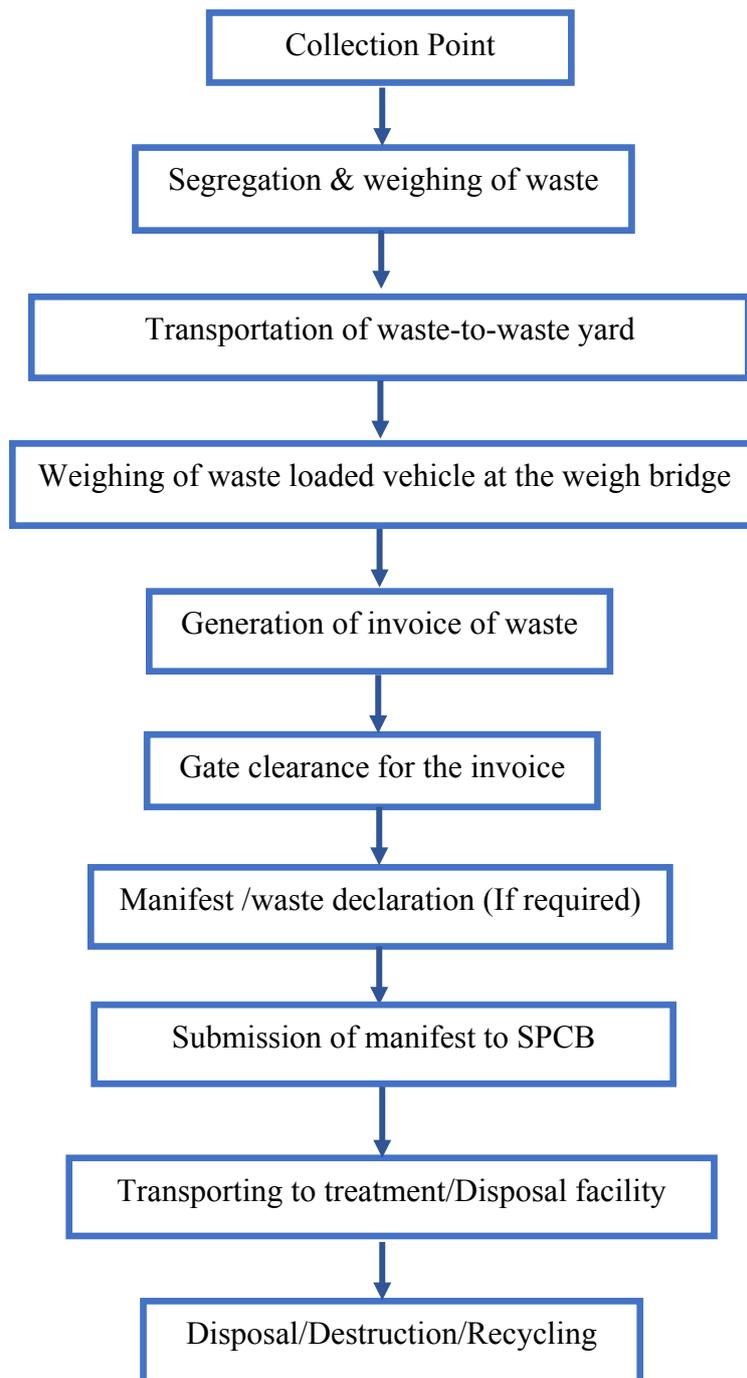
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7.0 PROCEDURE:

Overview of waste management

Figure-1: Flow chart for waste disposal process



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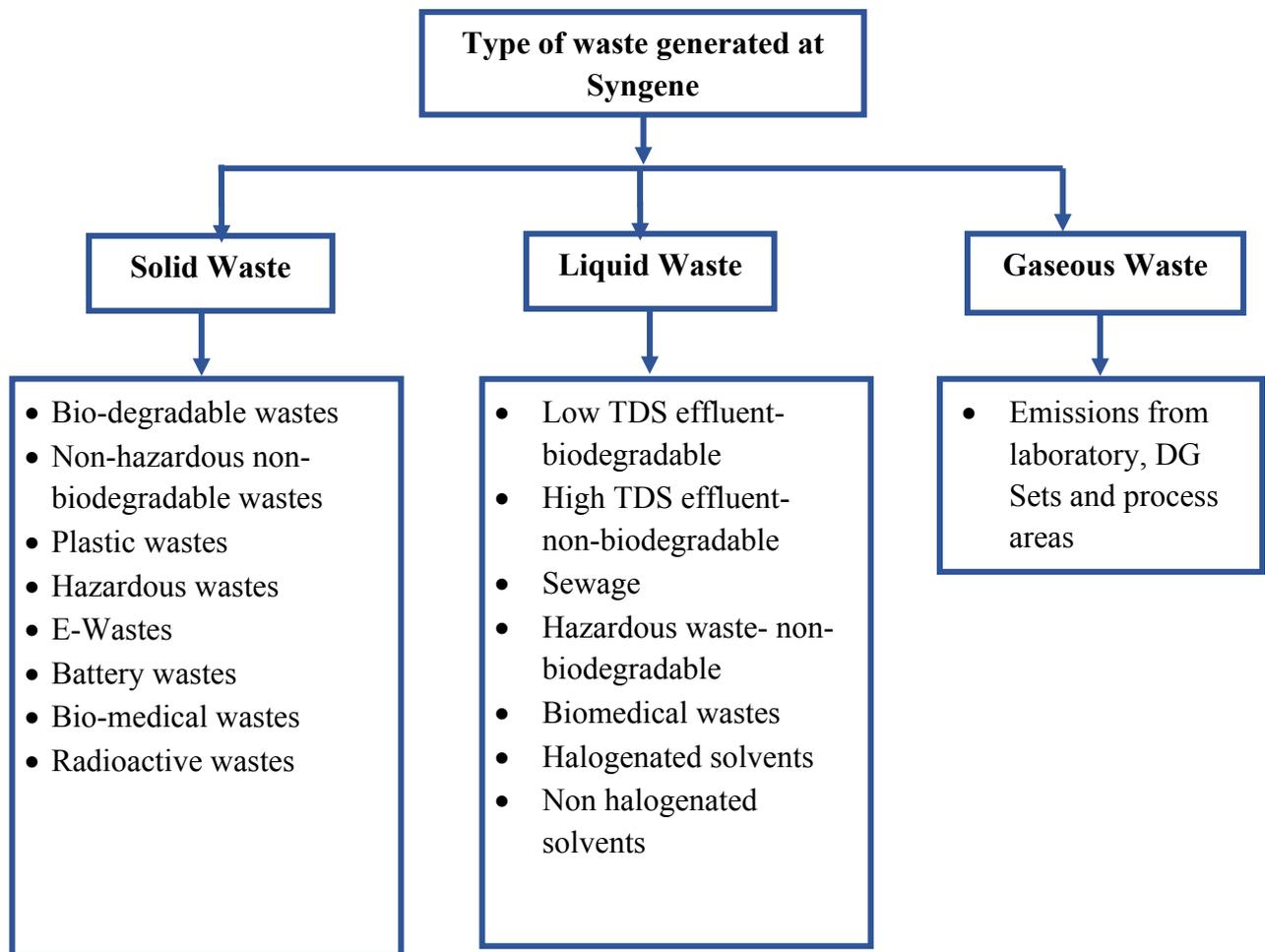
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7.1 Types of waste generation at Syngene:

The following flow diagram depicts types of wastes generated at Syngene

Figure-2: Schematic Diagram showing types of waste generated at Syngene



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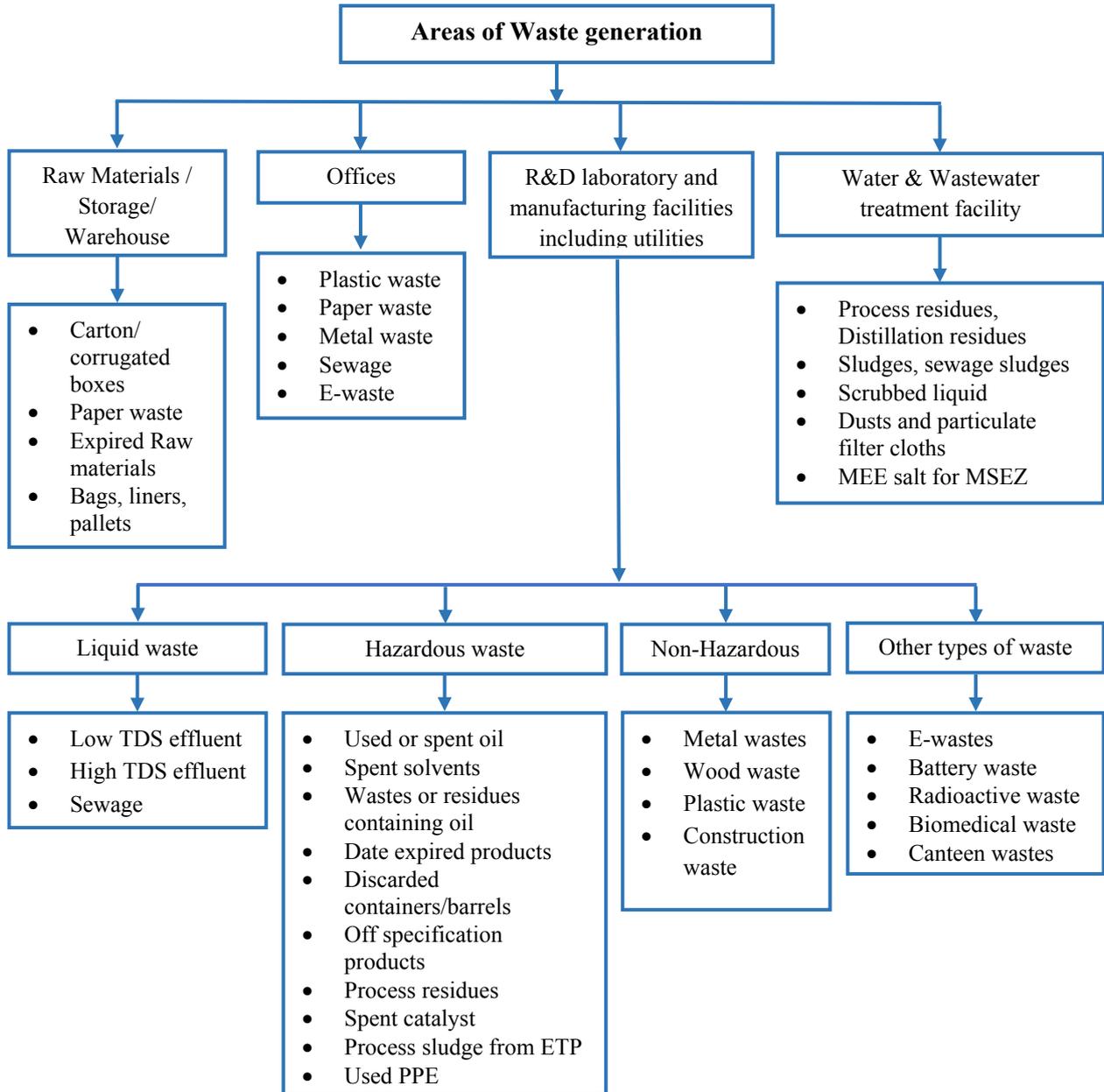
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7.2 Areas of waste generation at Syngene:

The following are the areas of waste generation at Syngene

Figure-3 Areas of waste generation and types of waste generated



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Table-1 Collection, Storage, Treatment and Disposal of waste generated			
CATEGORY NUMBER	WASTE DESCRIPTION	COLLECTED IN	DISPOSAL METHOD
LIQUID WASTE			
-	Low TDS effluent	Local collection pits	Follow as per the Consent for operation conditions
-	High TDS organic & inorganic effluent	Local collection pits	Follow as per the Consent for operation conditions
-	Sewage effluent	Local collection pits	Follow as per the Consent for operation conditions
HAZARDOUS WASTE			
20.3/36.1	Distillation residues/process residue and waste	LDPE/HDPE bags	Authorized incinerator/ Co-processing in Cement kiln
20.2/28.6	Spent solvents	Tankers/ Drums	SPCB authorized recycler
28.5	Date-expired products	HDPE containers	Authorized incinerator
28.3/36.2	Spent carbon	LDPE/HDPE bags	Authorized TSDF/ Authorized incinerator/ Co-processing in Cement kiln
5.2	Wastes or residues containing oil, oil-soaked cotton waste	MS/PVC Drums	CPCB & SPCB Authorized incinerator/ Co-processing in Cement kiln
5.1	Used oil	MS/PVC Drums	Authorized recycler
33.1	Discarded containers used for barrels (MS drums /HDPE/barrels/carboys)	-	Containers shall be cleaned with appropriate reagent/water, shred and disposed to Authorized recycler
28.4	Off specification products	LDPE/HDPE bags	Authorized incinerator
28.1	Process residues and waste	Biodegradable bags	Authorized incinerator
28.2	Spent catalyst	HDPE Bags	Authorized recycler or incinerator or Co-processing in Cement kiln
20.4	Process sludge from Effluent collection tank	HDPE containers	Authorized incinerator
35.3	Chemical sludge from Wastewater treatment	LDPE/HDPE bags	Authorized TSDF/ Co-processing in Cement kiln

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37.3	Concentration or evaporation residues (MEE salts)	LDPE/HDPE bags	Authorized TSDF/ Co-processing in Cement kiln	
-	Used PPE's	Biodegradable bags	Authorized incinerator	
-	Contaminated Tissue paper,	Biodegradable bags	Authorized incinerator	
-	Discarded liner (Contaminated PP bags, Contaminated cloth)	LDPE/HDPE bags	Authorized incinerator	
-	Used Silica	LDPE/HDPE bags	Authorized TSDF/ Co-processing in Cement kiln	
-	Contaminated Spill control materials	Biodegradable bags	Authorized incinerator	
-	Other incinerable waste	Biodegradable bags	Authorized incinerator	
ELECTRONIC WASTE				
-	Electrical and Electronic waste	Packed in puncture proof boxes	Authorized E waste recycler	
BATTERY WASTE				
-	Used or discarded batteries	Carton/ corrugated boxes	Authorized battery waste recycler	
NON-HAZARDOUS WASTE				
-	Plastic waste	Biodegradable bags	Authorized recycler	
-	Paper waste	Biodegradable bags	Authorized recycler	
-	Used Tissue paper waste	Biodegradable bags	Authorized incinerator	
-	Insulation Waste, Glass wool	Biodegradable bags	Authorized recycler, Authorized incinerator	
-	Metal waste	-	Authorized recycler	
-	Wooden waste	-	Authorized recycler	
-	Canteen waste	Biodegradable bags	Composting	
-	Garden waste	Biodegradable bags	Composting	
-	Date expired consumables	-	Authorized recycler	
-	Thermocol, Foam, FRP material	-	Authorized recycler/ Authorized incinerator	
-	Used carton/ corrugated boxes	-	Authorized recycler	
-	Construction and Demolition waste	-	Land filling	

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	Used Bottle, Glass waste	Carton/ corrugated boxes	Authorized recycler		
	Biological sludge	-	Authorized incinerator		
BIO-MEDICAL WASTE					
Yellow	(a) Human Anatomical Waste (Human tissues, organs, body parts)	Yellow colored non-chlorinated plastic bags	Incineration at CBWTF		
Yellow	(b) Animal Anatomical Waste (Experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses), Pest control waste	Yellow colored non-chlorinated plastic bags	Incineration at CBWTF		
Yellow	(c) Soiled waste (Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components), Contaminated Spill control materials	Yellow colored non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial		
Yellow	(d) Expired or discarded Medicines (Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.	Yellow colored non-chlorinated plastic bags or containers	All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.		
Yellow	(e) Chemical Waste (Chemical used in production of biological and used or discarded disinfectants)	Yellow colored non-chlorinated plastic bags or containers.	Incineration at CBWTF		
Yellow	(f) Chemical Liquid Waste	Separate collection	After resource recovery,		

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	(Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, silver X-ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, housekeeping and disinfecting activities etc.	system leading to effluent treatment system	the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms given in Schedule-III. Treated in ETP	
Yellow	(g) Discarded linen, mattresses, beddings contaminated with blood or body fluid.	Yellow colored non-chlorinated plastic bags	Incineration at CBWTF	
Yellow	(h) Microbiology Biotechnology and other clinical laboratory waste (Blood bags, Laboratory cultures, stocks or specimens of micro-organisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial laboratories, production of biological, residual toxins, dishes and devices used for cultures.	Autoclave safe plastic bags or containers/ non-chlorinated yellow plastic bags or suitable packing material	Pre-treat to sterilize with non-chlorinated chemicals on-site as per National AIDS Control Organization or World Health Organization guidelines thereafter for incineration.	
Red	Contaminated waste (Recyclable) (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and fixed needle	Red colored non-chlorinated plastic bags or containers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for	

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	syringes) and vacutainers with their needles cut) and gloves.			energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
White	Waste sharps including Metals (contaminated needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Puncture proof, leak proof, tamper proof containers		Autoclaving or dry heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete, combination of shredding cum autoclaving, and sent for final disposal to iron foundries or sanitary landfill or designated concrete waste sharp pit.
Blue	(a) Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes. (b) Metallic Body Implants	Puncture proof and leak proof boxes or containers with blue colored marking		Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.
RADIOACTIVE WASTE				
	Radioactive waste	Packed as per AERB guidelines/ Procedure		1. Liquid waste shall be diluted and disposed to ETP. 2. Solid waste shall be collected in appropriate container. 3. Stored in AERB approved In-house Radioactive pit.

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<p>7.3 Steps to follow for In-House segregation/ treatment/ documentation of waste within the premises:</p> <p>7.3.1 Waste generator shall segregate, label, pack waste in leak proof condition and transfer waste to building waste collection point. Improper waste segregation will not be accepted at waste collection point.</p> <p>7.3.2 The quantity of different types of waste generated shall be weighed using a calibrated weighing balance kept in waste collection point and same shall be recorded in waste declaration slips.</p> <p>7.3.3 Waste declaration slips FORM-EHSS-EHSS-0412(Annexure – 03) Hazardous waste declaration slip, FORM-EHSS-EHSS-0413(Annexure – 04) Non-Hazardous waste declaration slip, FORM-EHSS-EHSS-0414 (Annexure – 05) Biomedical waste declaration slip, FORM-EHSS-EHSS-0416(Annexure – 07) Electronic waste declaration slip, shall be issued from EHSS department and same shall be recorded in FORM-EHSS-EHSS-0410(Annexure – 01) Waste disposal records issue log.</p> <p>7.3.4 The waste generator shall submit waste declaration slips declaring type and quantity of waste to EHSS department representative on the same day when waste is transferred to waste collection point.</p> <p>7.3.5 If waste declaration slip is not submitted, then waste will not be removed/ received from waste collection point.</p> <p>7.3.6 For non-regular wastes, respective waste generating department shall share list of non-regular wastes through email to EHSS representatives.</p> <p>7.3.7 The chemical wastes which can be quenched inside premises shall be separated from other chemicals and shall be handed over to quenching station by concerned department representatives for necessary disposal and other chemicals shall be handed over to waste yard for final disposal.</p> <p>7.3.8 All external vendors shall be evaluated for handling and disposal of waste and an audit report shall be filed in EHSS Department as per FORM-EHSS-EHSS-0415(Annexure-06) Vendor evaluation checklist.</p> <p>7.3.9 A TREM card FORM-EHSS-EHSS-0411(Annexure-02) shall be issued to external vendor describing safety procedures to be followed during emergency.</p> <p>7.3.10 A destruction certificate for disposed waste shall be provided as per FORM-EHSS-EHSS-0417 (Annexure – 08) Destruction certificate to waste generators based on requirement.</p> <p>7.3.11 The effluent generated from Quenching activity will be transferred for further treatment at MEE plant.</p> <p>7.3.12 The waste which cannot be quenched shall be sent for appropriate disposal.</p>			

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Table-2 Steps to be followed for segregation and destruction of waste		
Steps to be followed for segregation		
S. No	Type of Waste	Segregation process
1	Confidential document, Record, Labels, paper waste	<ol style="list-style-type: none"> 1. Shredding by user Department and hand over to waste collection point/ waste yard 2. Tissue paper waste shall be packed separately (tissue paper waste shall not be mixed with canteen waste)
2	Expired raw materials, expired chemicals, media preparation, failed batches, testing samples, rejected samples and left-over product samples	Collected as per compatibility in leak proof condition, handed over to waste collection point/ waste yard, stored in secured manner
3	Resins (contaminated)	Collected in leak proof condition, handed over to waste collection point/ waste yard, stored in secured manner
4	Empty bottle waste, discarded containers, drums	<ol style="list-style-type: none"> 1. To be rinsed properly with water/ suitable reagent, packed in the carton/ corrugated box, stored in waste collection point after removing Syngene label 2. Broken glass bottles to be packed properly in carton box or Carton/ corrugated drum and stored in waste collection point <p>Note: Glass bottles and plastic bottles are not to be mixed in one bag</p> <ol style="list-style-type: none"> 3. All types of containers and drums shall be decontaminated appropriately and stored in waste collection point
5	Canteen/ Waste	<ol style="list-style-type: none"> 1. Canteen cups, stirrers to be packed separately in biodegradable bags 2. Mixed food waste shall be packed separately in two biodegradable bags to avoid leakage 3. Waste from canteen shall be segregated and stored in drums
6	Used PPE waste	All used PPEs except shoe cover shall be packed separately as it needs to be incinerated. Shoe cover shall be packed separately
7	Thermocol Waste	<ol style="list-style-type: none"> 1. Small thermocol box shall be cut into pieces and tied together

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		2. Big thermocol box are not easy to cut and can be sent to waste collection point as it is
8	Carton/ corrugated box	Should be folded properly and if possible, can be tied together or adjusted properly in the waste collection point.
9	Process Residues, Distillation Residues, Off Specification Products	To be packed in double layered covers and sent to waste collection point to avoid spillage.

7.4 Monitoring:

- 7.4.1 Sites shall monitor effectiveness of implementation of waste management plan by adopting periodic workplace inspections.
- 7.4.2 Monitoring mechanisms to ensure that waste generated at the facility do not impact the environment adversely.

8.0 REFERENCES:

- 8.1 Environmental Protection Act, 1986
- 8.2 The Air (Prevention and Control of Pollution) Act 1981
- 8.3 The Water (Prevention and Control of Pollution) Act, 1974
- 8.4 The Solid Waste Management Rules, 2016
- 8.5 Plastic Waste Management Rules, 2016
- 8.6 Bio-Medical Waste Management Rules, 2016
- 8.7 Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016
- 8.8 E-Waste (Management) Rules, 2016
- 8.9 Batteries (Management and Handling) Rules, 2001
- 8.10 Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards: Updated Version, 2011
- 8.11 Information Required for the Selection and Performance Evaluation of Wet Scrubbers: Journal of the Air Pollution Control Association, 2012
- 8.12 Monitoring by Control Technique - Wet Scrubber for Gaseous Control: United States Environmental Protection Agency.

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Syngene	Standard Operating Procedure	DEPARTMENT: Environmental Health Safety and Sustainability
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TITLE:WASTE MANAGEMENT

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9.0 ANNEXURES:

FORM-EHSS-EHSS-0410	Annexure - 01 Waste disposal records issuance log
FORM-EHSS-EHSS-0411	Annexure - 02 TREM card details
FORM-EHSS-EHSS-0412	Annexure - 03 Hazardous Waste declaration slip
FORM-EHSS-EHSS-0413	Annexure - 04 Non-Hazardous Waste declaration slip
FORM-EHSS-EHSS-0414	Annexure - 05 Biomedical Waste declaration slip
FORM-EHSS-EHSS-0415	Annexure - 06 Vendor evaluation checklist
FORM-EHSS-EHSS-0416	Annexure - 07 Electronic waste generation details
FORM-EHSS-EHSS-0417	Annexure - 08 Destruction Certificate
FORM-EHSS-EHSS-0418	Annexure - 09 Regulatory framework in India
FORM-EHSS-EHSS-0419	Annexure - 10 SOP Training Questionnaire

10.0 REVISION HISTORY:

Version no.	Effective Date	Description of Change
1.0	03-Jan-2023	<u>Reference Change Control Number: EHSS/CCF/22/0031</u> Newly introduced procedure

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