Centre for Advance Protein Studies CAPS

Syngene International Ltd.

Environmental and Health Risk Management Plan

1. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Use of solvents	Emission to air	Fume hood with local exhaust with scrubbing system and Operational control procedures
Water Pollution and Waste water treatment	Usage of biological cultures, and laboratory chemicals	Release to water	Impervious work surfaces and, Operational control procedures to handle biomedical waste in place.
Chemical waste	Usage of laboratory chemicals	Waste Management including disposal of waste	Usage of Secondary containment e.g. chemical fume hood ; established Operational control procedures for Hand gloves - chemical resistant- and Ensuring PPEs, Proper disposal of hazardous waste materials according to SOP: S/EHSS/SOP/004.
Biological Waste	Usage of biological cultures, organisms, cells, cell lines, viral vectors	Waste Management including disposal of waste	Usage of Secondary containment e.g. Biosafety cabinet; established Operational control procedures for Hand gloves - chemical resistant- and Ensuring PPEs, vaccination when essential. Proper

			disposal of hazardous waste materials according to SOP: S/EHSS/SOP/004.
Heavy metals	N.A.	N.A.	N.A.
Radiation Waste	N.A.	N.A.	N.A.
Destruction/alteration of surrounding ecosystem	N.A.	N.A.	N.A.
others	N.A.	N.A.	N.A.

2. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Autoclave operation	High temperature, burn injury	Standard operating procedures Hand gloves - heat resistant, Administrative controls: hands on training to personnel's
Chemical hazards, including fire and explosions	Handling of test compounds and laboratory chemicals-solvents	loss of containment/ spills	Usage of Secondary containment e.g. chemical fume hood ; established Operational control procedures for Hand gloves - chemical resistant- and Ensuring PPEs. SOP in place to mitigate the risk;(Ref: S/EHSS/SOP/010) (Ref: S/EHSS/SOP/043) (Ref: S/EHSS/SOP/017)
		Fire hazard	Fire detection and warning systems are being in place; Fire

			EGRESS routes labels in place, Firefighting equipment; Fire extinguishers in place, recommended PPE in place.
Pathogenic and biological hazards	Aerosolization, Splash/ Splatter.	loss of containment/ spills Health hazard	Usage of Secondary containment e.g. Biosafety cabinet; established Operational control procedures
Radiological hazards	N.A.	N.A.	N.A.
Noise	Sonicator operation	Hearing impairment	Dedicated Acoustic enclosure, hazard communication Sign boards/posters/visual signs Ear muff/plug, and regular workplace monitoring: S/EHSS/SOP/043
Process safety	N.A.	N.A.	N.A.
others	N.A.	N.A.	N.A.

3. Community Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Safety Transportation Management System (for transport of hazardous material)	Safe Handling and transportation of Hazardous materials	environment and personnel safety	Usage of Secondary containment; established Operational control procedures ; Ensuring PPEs, Hazardous material management: S/EHSS/SOP/004 and 048.
Emergency preparedness and participation of local authorities and potentially affected communities	Lab emergencies: Fire and loss of containment	Personnel safety	All type of emergency identified and SOP and Onsite emergency plan and (Trained personal) in place to mitigate the same Operational procedures in place S/EHSS/SOP/010
In case your organization already has **EHS guideline**, please summarise the same. If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion**.**			

Governance model

Areas	Monitoring Parameters
Procurement Policy	Standard Operating Procedure (SOP) is in place and following the same for procuring Raw materials, Engineering and Capex items.
Vendor Evaluation and Supply Chain Management	Performing vendor evaluation as per the SOP on Vendor Selection, Evaluation and Performance measure
Manpower Recruitment Policy	Syngene has a well-defined policy for Recruitment / onboarding. The policy does cover the process / guidelines / decision making powers on hiring
Subcontract and Outsourcing model	Based on the business requirements, analysing Buy Vs. outsourcing and subcontracting model. Also studying the feasibilities such as process technology, capacity and capabilities and commercial viability of the subcontracting and outsourcing model and proceeding further.
Internal Monitoring Mechanism	Monitoring and reviewing the performance and improvements on monthly basis.
For Oversight by NBM-BIRAC 1. **Implementation Governance model** – Checks on fund utilization Syngene will create a No-Lien account and maintain financial transparency, we will apportion general consumable expenditure-CAPS and syngene usage **- Checks on Technical side** Syngene will create an oversight committee having both BIRAC and syngene representatives Syngene's technical team will work with the clients functional leads to deliver on the projects goals	BIRAC monitoring committee to have the authority to review the costing charged to identified segment (Researchers, academia, SMEs, Start-ups) Online requests on the website for services Fixed cost apportioned for all projects undertaken by the facility

CAPS functional leads will supervise the work and address the issues Syngene PM team will coordinate the project progress periodically and update the clients Syngene will implement a -Online tracking system for monitoring efficient resource utilization. Syngene will ensure to align CAPS policies with its corporate quality policies on data integrity **2. Sustainability and Differential Costing Model** Syngene-CAPS client categories will include a) International b) Indian non-BIRAC c) BIRAC. We will apply premium costing to our International category clients to subsidize BIRAC category clients The charges for BIRAC category clients will be ≤25% of our standard rates for international clients International clients and large domestic clients will be charged full cost components Syngene will recover own costs and a profit margin on Syngene cost only, from its international client pool. All remaining revenue will be maintained as corpus fund and will be used for eventual replacement of equipment at the end of life **3. Trainings** (to be provided to identified segment – Researchers, academia, start-ups, SMEs) *CAPS will conduct recurring training-cum-workshop sessions*	

half-yearly. Each training session will both theory based sessions followed by hands-on training covering various analytical modules including ***HPLC:*** *SEC, IEX, RPLC, HIC;* ***Capillary electrophoresis:*** *CE-SDS, IEF, Glycan, etc.;* ***LC-MS:*** *Intact, Peptide mapping, Light and Heavy chain, N-Terminal, etc.,* ***Functional assays*** *(Biacore), FACS, ELISA, etc.)****.*** *The trainings will be provided by in-house scientists as well as external invited scientists.* *In addition, we will make our facility available for organizations that want to conduct the analysis of their samples to also get trained on using the instruments and analyzing the data, allowing them to run their own samples (under supervision of CAPS scientists*	