

Environmental Health Risk Management Plan (EHRMP)

1. Institutional Arrangements

(i) Brief description of the activity Protein characterization using mass spectrometer and other specialized techniques to offer the service for clients (startup companies , research institutes and international clients).					
(ii) List of environment related regulatory clearances required for the activity.					
Syngene International Limited (Biocon park)					
Existing Environmental consents					
1	Water & Air consent	No : A-303115	30.06.2021		
2	Hazardous waste authorization	No:309364	30.06.2021		
3	Plastic waste authorization under Brand Owners	No: PCB/WMC/2359/PLS/2017/H753	23.11.2021		
4	Bio medical waste authorizations	KSPCB/RO-Anekal/Addendum-BMW Authorization/Syngene/2019-20/541	Lifetime validity		
Institutional Arrangement					
Area of Risk		Yes	No	Details	Proposed Plan
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Yes		EHSS team consist of 30 full time staffs to manage EHSS operations.	NA
2.	Does the EHS staff handle the following?			Any other: All the related documents can be reviewed during onsite.	NA
	Occupational Health and Safety	Yes			
	Waste Management	Yes			
	List of consents and regulatory clearances	Yes			
	Record keeping of accidents and procedures	Yes			
	EHS trainings for staff	Yes			
	Environment Management Framework compliance for Innovate in India Project	Yes		Environmental management system (EMS -ISO 14001:2018) is in place.	
3.	Is there a reporting structure in place regarding EHS issues?	Yes		Online Incident reporting system available which can be accessed by all the employees to report any EHSS issues.	

4.	Are regular EHS trainings provided to staff?	Yes		Frequency: Monthly As per inhouse procedure (S/EHSS/SOP/026 Planning & organizing EHSS training programs)	-
5.	Institutional Bio-Safety Committee (IBSC)	Yes		As per DBT guidelines Syngene has IBSC for reviewing biological materials and projects.	-
6.	Ethics Committee (EC)	Yes		IRB, ICH-GCP and ICMR guidelines for clinical subject, research projects are followed.	-

General Occupational Health and Safety

	Area of Risk	Yes	No	Details	Proposed Plan
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	Yes		I) Incident reporting & investigation S/EHSS/SOP/015. II) Onsite emergency plan is available which is approved by Directorate of factories. III) Emergency response procedure (S/EHSS/SOP/005) is available . IV) Lab safety procedure (S/EHSS/SOP/017) is available.	-
8.	Are the following in place?			Required Emergency gadgets are available at facility and periodic monitoring is carried out as per internal procedure.	-
	Chemical spill kits	Yes			
	Eye wash	Yes			
	Shower stations	Yes			
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
	Register of accidents and injuries	Yes			

9.	Are proper signage and storage system in place?	Yes		I) Proper signages are in place as per IS standards . II) All safety data sheets available for all the chemicals in use. We are also using Chemwatch software SDS management. III) Emergency numbers are displayed as per Emergency response procedure (S/EHSS/SOP/005). IV) All the flammable materials are stored in flame proof cabinets ensuring compatibility.	-
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes			
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical Places	Yes			
	Signage across the facility (labs, storage, hazardous areas, etc.)	Yes			
	Are flammable materials appropriately stored to prevent fire hazards?	Yes			
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?	Yes		List: Below list of SOP's are available to ensure the healthiness of fire protection systems. I) SOP-029 Fire suppression system II) SOP-05 Fire extinguisher operation and maintenance. III) SOP-60 Safety and maintenance control of fire hydrant overhead system IV) SOP-07 Fire alarm service procedure	-
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	Yes		Engineering controls like fume hood , scrubbers , and bio safety cabinets are in place. Work place monitoring is carried out as per (S/EHSS/SOP/062) Industrial hygiene management procedure.	-
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency (type wise): Mock drills are conducted every month in accordance with the identified scenarios in Onsite emergency plan.	-
13.	Are staff provided with OHS training?	Yes		All employees are trained on OHS as per Standard Operating Procedures – (S/EHSS/SOP/026) Planning and organizing EHSS Trainings.	-
Biomedical Waste (BMW)					
	Area of Risk	Yes	No	Details	Proposed Plan
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Yes		List of bio medical waste: i) Human Anatomical Waste ii) Animal anatomical waste iii) Expired discarded medicines,. iv) Microbiology Biotechnology and other clinical laboratory waste	-

				and etc.,									
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes		Employees handling bio medical wastes are trained on bio medical waste management as per(S/EHSS/SOP/004 – handling of solid and liquid waste) procedure.	-								
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes		Bio medical waste authorization in place (KSPCB/RO-Anekal/Addendum-BMW Authorization/Syngene/2019-20/541)	-								
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	yes		<table border="1"> <tr> <td>Yellow</td> <td>Yes</td> </tr> <tr> <td>Red</td> <td>Yes</td> </tr> <tr> <td>White</td> <td>Yes</td> </tr> <tr> <td>Blue</td> <td>Yes</td> </tr> </table>	Yellow	Yes	Red	Yes	White	Yes	Blue	Yes	-
Yellow	Yes												
Red	Yes												
White	Yes												
Blue	Yes												
18.	Is the bar code system for the segregated waste in place?	Yes		Bar code system is followed as per bio medical waste management rules.	-								
19.	Is the biomedical waste being sent to an authorized common BMW facility?	Yes		<p>Name and address of CBMWF: M/s. Maridi Eco Industries Pvt Ltd No 1/37& 1/38. Gabbadikaval Village 35th Mile stone, Kanakapura Road Bangalore-112.</p> <p>Distance from facility: 30KM</p> <p>Frequency and Mode of transport: Daily basis through dedicated transport vehicle.</p> <p>Who transports? M/s. Maridi Eco Industries Pvt Ltd</p>									
20.	Does the grantee have an in-house BMW treatment facility?		No	Reason: NA	NA								
	Is the treatment facility own (individual)?		No	Authorization: NA									
	Is the treatment facility a shared facility in an industrial park?		No	Distance of nearest CBWM from facility: NA Types of treatment: NA									

21.	Are lab waste, microbiological waste and chemical liquid waste pre-treated before storing and sending to treatment facilities according to guidelines prescribed in BWM, 2016 regulations?	Yes	Types of treatment: Autoclaves and chemical treatment (10% Hypochlorite solution as per BMW rules 2016) decontamination procedures	-
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes	Liquid wastes are decontaminated before sending to treatment plant (Autoclaves and chemical treatment -10% Hypochlorite solution as per BMW rules 2016)	-
23.	Are necessary waste pre-treatment equipment in place?	Yes	List of equipment Autoclaves & Bio kill systems	-
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes	Details of waste pre-treatment: Autoclave method and 10% Hypochlorite solution as per BMW rules 2016	
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes	All chlorinated plastic gloves and bags phased out and non-Chlorinated bags are used across the site.	-
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes	Frequency: Monthly refreshers Trainer: EHSS Officer	-
26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	Yes	Frequency of medical examination: Yearly Hepatitis B and Tetanus are given to all employees who handles bio medical waste.	-
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes	Maintained	-
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Yes	Annual report is submitted to state pollution control board as per prescribed timelines.	-

Hazardous Waste (HW)					
	Area of Risk	Yes	No	Details	Proposed Plan
29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	Yes		List of hazardous waste produced in the facility : Spent solvents, process residue wastes, Process sludge , spent carbon ,Off spec products, Date expired products, used spent oil, spent catalyst.	-
30.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes		Trained staffs are engaged in the activity .	-
31.	Does the grantee have authorization from SPCB for hazardous waste?	Yes		Hazardous waste Authorization in place valid upto 30.06.2021.	-
32.	Is there a secure location for storage of HW with proper signage?	Yes		Dedicated Hazardous waste storage yard is available for safe storage of hazardous waste . Hazardous wastes (Liquid & Solid) are collected in dedicated leakproof containers & segregation done based on compatibility & as per hazardous waste categorization.(Hazardous waste handling rule 2016) and disposed with in 90 days of generation.	-
	Are hazardous waste stored for more than 90 days in the grantee's premises?		No		
33.	Is the hazardous being send to an authorized disposal facility or user?	Yes		Name and address of facility: E Nano Incintech (Hazardous waste incineration) Plot No.342/B,2nd phase ,2nd sector ,harohalli industrial area,Kanagapura, ramnagara district.	-
	Is the disposal facility in house?		No		
	Is the disposal facility external/outsourced?	Yes			
34.	Is a register maintained on production and treatment, and a manifest system followed for transport of hazardous waste from the grantee to treatment facility?	Yes	-	Manifest system followed a per hazardous waste handling rules 2016.	-
E-Waste and Batteries					
	Area of Risk	Yes	No	Details	Proposed Plan
35.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?	Yes		Generated E-wastes such as Personal computers,	-

				Electrical, printers cartridges & electronic equipments.	
36.	Has the grantee obtained SPCB authorization on e-waste?		No	Not applicable since we are not bulk consumers as per e-waste management rule.	-
37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	Yes		Name and address of disposal facility/ recycler: E-Parisaraa pvt ltd., 30 – P3, Karnataka Industrial Area Development Board, Dabaspeta Industrial Area, Bangalore Rural District, Pin:, Karnataka 562111	-
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		NO	We are not the manufacturer of electrical or electronic equipment.	
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		No	NA	-
40.	Does the grantee provide detailed information on the constituents of the equipment and their components/spares and declaration of conformation to Reduction in Hazardous Substances in the product user documentation?		No	NA	-
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	Yes		Records are maintained	-
42.	Does the grantee submit annual reports on e-waste to SPCB?	Yes		Submitted on annually as per prescribed timelines.	-
43.	Is there accident reporting and records in place?	Yes		Incident reporting & investigation S/EHSS/SOP/015.	-

44.	Are PPEs available to staff?	Yes		All Required PPE's are made available for the staffs.	-
45.	Is the grantee involved in manufacture of batteries?		No	NA	NA
46.	Does the grantee generate battery waste?	Yes		Batteries from UPS are returned to suppliers	-
47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/re-conditioner/collection center?	Yes		Name and address of battery waste receiving entity: M/s. Sri ponni industries, No.24, 4th Phase, Bommasandra Industrial Area, Bangalore – 560099.	-
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?	Yes		Handed over to authorised vendor only	-
Community Health and Safety and risk mitigation					
		Yes	No	Details	Proposed Plan
49.	Safety Transportation Management System (for transport Of hazardous material)	Yes		Complying to hazardous waste management and transboundary rules 2016	-
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		Emergency preparedness plan in place to mitigate the potential hazardous situations.	-

Other

	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?	Yes		-	-
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?	Yes		Proper storage and disposal systems in place.	-
	Are radioactive warning signs in place?	Yes		Appropriate warning signages are provided.	-
52.	Is the lab/room air regularly checked for microbial contamination?	Yes		-	-
53	Are there any odor control measures in place?	Yes		Fume hoods, scrubbers are in place.	-
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes		As per preventive maintenance schedule they are regularly checked and maintained.	-
55.	Does the grantee use DG set > 15 KVA?	Yes		All the utilities are provided by biocon SEZ developer and	-
	Does the grantee have consent for DG > 15 KVA?	Yes		maintaining mechanism in accordance with Air act is available for all the emission sources.	-
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	Yes			-
56.	Does the grantee have proper disposal process for solid and plastic waste in compliance to Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016?	Yes		Describe: all types of wastes are segregated as per the Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016	-
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		Types of wastewater: Effluent & Sewage Treatment of wastewater: Treated in ETP (ZLD) & STP maintained by Biocon limited. Chemical management in wastewater treatment plants: chemicals are used as per the characteristic of effluent in the treatment process.	-

	Are there sludge management and cut off drains in place for wastewater?	Yes		Effluent collection tank sludge is sent to TSDf facility for disposal.	-
58.	Are necessary provisions for noise cancellation in place?	Yes		Describe: Acoustic enclosures provided for all the noise emitting equipments and periodic noise monitoring in place.	-
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No	Describe: NA Distance from premises: NA	-
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		Fire tender movement road is available around the building	-