

**Environmental Health Risk Management Plan (EHRMP)**

**Enzene Biosciences Limited**

**Proposal entitled:** Large Scale production of high quality full length spike Protein and/or it's Sub-Domains Of Sars-Cov2 to be used for diagnostic purpose

**1. Institutional Arrangements**

(i) Brief description of the proposed activity				
Large scale production of high quality full length Spike protein and/or it's sub-domains of SARS-CoV2 to be used for diagnostic purpose.				
(ii) List of environment related regulatory clearances required for the activity. Consents from SPCB				
<b>Institutional Arrangement</b>				
Area of Risk	Yes	No	Details	Proposed Plan
1. Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Yes		Santosh Ghule- EHS Manager	Any further staff recruitment, if required, will be done in the future.
2. Does the EHS staff handle the following?				
Occupational Health and Safety	yes		PPE's like Lab Coat, Masks, Chemical resistance Gloves, Safety glasses, Fully enclosed footwear, Ear Muff, Heat	Regular trainings are being conducted to the working personnel.
Waste Management	yes		Resistance Gloves, Cryo Apron, Cryo Gloves are provided.	
List of consents and regulatory clearances	Yes		SOP FOR WASTE DISPOSAL - ENZ/CRA/SOP/008.03	
Record keeping of accidents and procedures	yes		available.	
EHS trainings for staff	yes		Consent to operate form MPCB, Hazardous waste disposal membership.	
			Accident, incident reporting	

				procedure is in place and record available.  EHS training conducted on fire fighting, usage of PPEs, handling of waste, Spillage Handling and Spill Kit, Laboratory safety and waste handling.	
	Environment Management Framework compliance for Innovate in India Project	yes		Compliance manager software is in place for Environment and safety compliance.	
3.	Is there a reporting structure in place regarding EHS issues?	Yes		Accident, incident reporting system is in place. Safety inspection rounds being conducted. Internal safety audit conducted periodically.	The present reporting system will be followed.
4.	Are regular EHS trainings provided to staff?	yes		EHS training conducted on fire fighting, usage of PPEs, handling of waste, spill control.	The trainings, which are given will be continued in the future.
5.	Institutional Bio-Safety Committee (IBSC)	Yes		We have committee in place as per RCGM guidelines.	We will ensure that the committee meets regularly and discusses key issues.
6.	Ethics Committee (EC)		No	Not applicable	
<b>General Occupational Health and Safety</b>					
	<b>Area of Risk</b>	<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	Yes		Incident reporting format (ENZ/General/F1;00) is in place and training imparted to concern personnel. Other emergencies like Chemical spill, Fire hazard, Heat hazard covered in on site emergency plan.	SOP for spillage control shall be prepared and implemented.
8.	Are the following in place?				
	Chemical spill kits	Yes		Spill kits available at labs.	
	Eye wash	Yes		Eye wash bottles available at labs.	
	Shower stations		No		

	First Aid Kit	Yes		Eye wash bottles provided in place of showers.	
	Fire Extinguishers	Yes		6 Nos of first aid kits available and maintained on monthly basic.	
	Register of accidents and injuries		No	30 nos of fire fire extinguishers available with ABC Type, CO2 Type, clean agent and servicing done on quarterly basic.	Register for accident and injuries reporting will be maintained.

9.	Are proper signage and storage system in place?	Yes		Emergency exit signage's available.	MSDS of hazardous chemicals will be displayed at relevant places.
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes		Material safety data sheets maintained in file.	
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical Places.	Yes		Emergency contact numbers displayed.  Signage's displayed in labs, storage area.	
	Signage across the facility (labs, storage, hazardous areas, etc.)	Yes		Flammable materials stored separately and secured.	
	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		Fire alarm system is in place including fire alarm panel – 1 no, Smoke detectors – 93 nos, Manual call points – 5 nos, hooter – 5 nos available and maintained.	The existing systems will ensure safety of our facility.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	Yes		Air emission for DG set monitored periodically for MOEF approved laboratory. Safety valve, pressure gauzes available on autoclaves. At Enzene we do not use any VOC and pathogens/vectors.	Periodic monitoring will be continued.
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Mock drill conducted in march 2019 and march 2020 on fire scenario. Frequency of mock drill : Once in year.	The next mock drill will be conducted on chemical spillage scenario at the earliest.
13.	Are staff provided with OHS training?	Yes		EHS training conducted on fire fighting, usage of	Training will be

			PPEs, handling of waste, Spillage Handling and Spill Kit, Laboratory safety and waste handling.	imparted on material safety data sheets and on chemical handling to the concerned personnel.		
<b>Biomedical Waste (BMW)</b>						
	<b>Area of Risk</b>	<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>	
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Yes		Disposable pipettes, syringes, Cell culture vials, Cell culture (pipettes, pipette tips, tubes etc) petri plates, gloves, falcon or microcentrifuge tubes, tissue culture flasks, Polymerized gels (Agarose/ SDS-PAGE), Cell culture pellets, Sharps, needles are disposed in respective colour coded bags.	Compliance to the biomedical waste management rules, 2016 will be followed.	
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes		Training provided to biomedical waste handling personnel.	It will be a regular process throughout the project.	
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?		No		The current authorization is valid upto 31/03/2021. During renewal of this consent to operate a combine consent will be taken.	
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		Yellow	Yes	This will be done as per Bio-Medical Waste Management (Amendment) Rules, 2018
				Red	Yes	
				White	-	
				Blue	-	
18.	Is the bar code system for the segregated waste in place?	Yes		Bar coding system is in place and followed.	Bar coding will be regularly updated as per policy guidelines.	

19.	Is the biomedical waste being sent to an <b>authorized</b> common BMW facility?	Yes		Name and address of CBMWF: <b>Passco Environmental Solutions Pvt. Ltd.</b> Distance from facility: <b>1 Km</b> Frequency: <b>Alternate day</b> Mode of transport: <b>Authorized vehicle</b> Who transports: <b>Passco Environmental Solutions Pvt. Ltd.</b>	The vendor's contract shall be renewed on time to ensure this practice is being followed.
20.	Does the grantee have an in-house BMW treatment facility?		No	All liquid biological wastes including the cell culture media are treated with Sodium hypochlorite solution and then treated in ETP.	Biomedical waste generated in facility sending to CBMWF: Passco Environmental Solutions Pvt. Ltd. This facility is located around 1 km from our facility.
	Is the treatment facility own (individual)?		No		
	Is the treatment facility a shared facility in an industrial park?		No		
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?		No	All liquid biological wastes including the cell culture media are treated with Sodium hypochlorite solution and then treated in ETP.	Solid biomedical waste will be autoclaved.
22.	Is the liquid waste checked for active cells before sending to treatment plant?		No	The cell culture waste is treated with a strong bleach hence no live cells will survive.	Using strong bleach to kill live cells will be done regularly.
23.	Are necessary waste pre-treatment equipment in place?		No	List of equipment (autoclaves, shredders, incinerators, etc.):	Will ensure necessary equipments are in place as and when required.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?		No		
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes		We are not using chlorinated plastic gloves and bags.	Since we are not use chlorinated plastic gloves and bags there is no harm to environment and

					health.
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Training is being imparted to personnel.	

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 Medical examination carried out in February 2020 for those handling of biomedical waste.	We plan to continue the same.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		Biomedical waste disposal record maintained.	This practice would be followed and checked periodically.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		No	Not submitted so far	After approval of combined consent to operate, annual returns will be submitted.

#### 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		Following are the list of hazardous waste 1. Used oil 2. ETP sludge 3. Expired materials, 4. Date expired chemicals 5. Spent solvents.	The collection, treatment and disposal of these hazardous waste generated will comply with the Hazardous Waste Rules 2016.
30.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes		Training imparted to handling personnes.	Refresher training will be imparted.
31.	Does the grantee have authorization from SPCB for hazardous waste?		No		During renewal of the existing consent to operate, hazardous waste categories will be included. Existing consent valid upto 31/03/2021.

32.	Is there a secure location for storage of HW with proper signage?	Yes		Hazardous waste like ETP sludge stored near ETP area, Spent solvent stored in labs at designated areas.	Hazardous waste is being sent for disposal regularly to the common hazardous waste treatment, storage and disposal facility.
	Are hazardous waste stored for more than 90 days in the grantee's premises?		No		
33.	Is the hazardous being send to an <b>authorized</b> disposal facility or user?	Yes		Name and address of facility: <b>Maharashtra Enviro power limited</b>	The contract renewal will be done as and when required.
	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 i.e. form 10 maintained.	Will continue to maintain the register with frequent review and updates.

**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		E-waste being sent for disposal to authorized party.  List of E- waste are following :  Cartridge Desktop Keyboard Laptop Monitor Motherboard Mouse Printer/Scanner Telephone Wifi(Huawei)	Disposal will be done as per e-waste requirement. All items will be sent to the authorized recycler for proper disposal

36.	Has the grantee obtained SPCB authorization on e-waste?		No	E-waste authorization not taken.	During renewal of existing consent to operate, combine consent will be taken. Existing consent to operate is valid upto 31/03/2021.
37.	Does the grantee channelize the e-waste to <b>authorized</b> recycling or disposal facility?	Yes		Name and address of disposal facility/ recycler: <b>E-waste Global</b>	E-waste generated will be sent to authorized party for recycling.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	Not applicable, we are not producer.	
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?	Yes		We are not using hazardous substances.	
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	Considering the size of our company and the equipment, this waste is not significant.	
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	Yes		Records available.	
42.	Does the grantee submit annual reports on e-waste to SPCB?		No	Not applicable	
43.	Is there accident reporting and records in place?		No	Till no accident happened.	Will ensure a register is being maintained recording any such incidents in future.
44.	Are PPEs available to staff?	Yes		Safety goggle, hand gloves, mask available.	Use of PPE's for staff will be made mandatory. Ensure regular and sufficient provision under the project.
45.	Is the grantee involved in manufacture of batteries?		No	Not involved in manufacturing of batteries.	
46.	Does the grantee generate battery waste?	Yes		Battery waste	



				generated and sending to recycler.	
47.	Does the grantee deposit the battery waste to <b>registered</b> recycler/dealer/manufacturer/reconditioner/collecton center?	Yes		battery waste sending to Shakti Metal Industries.	
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		No	Not involved in manufacturing of batteries.	

**Community Health and Safety and risk mitigation**

		Yes	No	Details	Proposed Plan
49.	Safety Transportation Management System (for transport Of hazardous material)	Yes		Hazardous waste being sent to through authorized vehicle.	Will follow the same for the project activities.
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		On site emergency plan is in place.	The local community health workers and community leaders will be informed about any issues that can affect the community. The Emergency Preparedness plan will be executed as per the SOP in place.

**Other**

	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		NO	Not using any radioactive material.	We do not have any plan to use radioactive material in the near future
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		NO	Not using any radioactive material.	We do not have any plan to use radioactive material in the near future
	Are radioactive warning signs in place?		No	Not using any radioactive material.	We do not have any plan to use radioactive material in the near future hence not required to put signage
52.	Is the lab/room air regularly checked for microbial contamination?	Yes		Microbial contamination being monitored periodically.	Routine monitoring

53.	Are there any odor control measures in place?	Yes	PPEs being used during handling of chemicals.	Periodic cleaning will be done
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes	Preventive maintenance being carried out regularly.	Periodic maintenance will be done.
55.	Does the grantee use DG set > 15 KVA?	Yes	320 KVA	Periodic maintenance will be done.
	Does the grantee have consent for DG > 15 KVA?	Yes	Consent to operate is in place.	
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	Yes	Air emission from DG set monitored quarterly through MOEF approved laboratory.	
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	Solid waste being sending to disposal to authorized party.	Will be following the instruction of solid waste management 2016.
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes	ETP plant is in place for treatment of effluent. Chemicals, solvents being send to authorized party for disposal.	Periodic checks will be done and the treatment plant shall be maintained.
	Are there sludge management and cut off drains in place for wastewater?	Yes	ETP sludge being send to authorized party. Separate drains available for water waste water.	These will be periodically checked and maintained to ensure their proper functioning.
58.	Are necessary provisions for noise cancellation in place?	Yes	Acoustic enclosure provided to DG set. Ear plug provided to working personnel.	Will keep reviewing the noise generated and cap them according to the existing cancellation provisions.
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?	No	No cultivable land or water bodies in nearby area.	Since, no water bodies or cultivable land nearby, no environmental risk.
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	No	Fire vehicle entry route available at site.	The site is on main road hence there is access to fire vehicles.
<b>COVID Precautions &amp; Guidelines Implementation</b>				
61	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?	No	No live SARS-CoV2 virus is been handled in the facility	No SARS-CoV2 virus related work is undertaken in the premises. However, will ensure that proper

				measures are taken as per the guidelines in future.
62	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	Yes	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed.	SOP for preventive measures in place will be followed throughout the Project.

**Notwithstanding the above other risk (relevant to the project activities) that will be identified in the course shall be addressed as per standard mitigation monitoring parameters and manner of records keeping shall be in accordance to the recommendations of the project monitoring committee on subject experts engaged by BIRAC.**