

Environmental and Health Risk Management Plan (EHRMP)

Yaathum Biotech Private Limited

Proposal entitled: Development and validation of a real-time RT-PCR test for detection of SARS-CoV-2 virus for COVID-19 diagnosis

i) Brief description of the proposed activity: Development and validation of a real-time RT-PCR test for detection of SARS-CoV-2 virus for COVID-19 diagnosis

ii) List of environments related regulatory clearances required for the activity.
IITM Bio incubator obtained all the required environment authorisations

		Yes	No	Details	Proposed Plan
Institutional Arrangement					
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Yes		The concerned staff in the IITM Bioincubator. Handles the EHS Issues	We will follow the EHS guidelines of the IITM Bio-incubator.
2.	Does the EHS staff handle the following?			The concerned EHS staff in the IITM Bioincubator Handles these.	Regular training and maintaining the records and waste management is handled by the IITMBI. We will comply to Environment Management Framework compliance for Innovate in India Project
	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			
3.	Is there a reporting structure in place regarding EHS issues?	Yes		EHS issues will be taken care by the IITM Bioincubator.	We will address any issues raised by IITMBI.
4.	Are regular EHS trainings provided to staff?	Yes		Training will be provided by the IITM Bioincubator.	We will participate in trainings that may be conducted for the incubatees.
5.	Institutional Bio-Safety Committee (IBSC)	Yes		IITM Bio-incubator follows the institute (IITM) IBSC committee/guidelines.	We will comply to the guidelines of IITMBI.
6.	Ethics Committee (EC)	Yes		IITM Bio-incubator	We will comply to the

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				follows the institute (IITM) bioethics committee norms	ethics guidelines of IITMBI
General Occupational Health and Safety					
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	Yes		Standard Operating Procedures are in place. SOPs are reviewed on regular basis. Training on SOPs is conducted on regular basis. Radioactive material is not used in any process.	1. Standard Operating Procedures are in place and are reviewed on regular basis. 2. Training on SOPs are conducted on regular basis. 3. Training evaluation procedure is in place. 4. e-DMS is in place for the SOPs documentations.
8.	Are the following in place?			All are located at strategic locations for easy accessibility	Register will be maintained for ensuring provisions of such requisites.
	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?			All details are printed on a sheet with visible fonts size and placed located at strategic locations for easy accessibility and readability	Facilities will be upgraded with the activities increased.
	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/shutoff systems, overflow preventors, etc. in place and regularly maintained?	yes		Systems in place.	Facilities will be maintained and upgraded with the activities increased by the IITM Bio-incubator
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	Yes		Monitoring will be conducted by the IITM Bio-incubator	Preventive measures with all precautions will be put in place as and when required during the project.

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12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		mock drills are conducted by the IITM Research Park	
13.	Are staff provided with OHS training?	Yes		training is provided by the IITM Research Park	All the staff will be provided with trainings including newly joined staff.
Biomedical Waste (BMW)					
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Yes		BMW managed by IITMBI outsourced vendor GJ Multiclave. Waste generated: i)Microbiological waste ii)PCR plates and tubes and chemicals in PCR mixes; gels iii)Sharps	Biomedical waste will be sent to PCB authorized third party
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes			staff will be trained on biomedical waste policies.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes		Given to the incubation facility as a whole.	Necessary Authorizations will be taken if required with timely renewals.
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		BMW managed by outsourcing vendor GJ Multiclave Different colour bins for waste segregation in place: Yellow Blue Red	Will follow Biomedical waste management rules
18.	Is the bar code system for the segregated waste in place?	Yes		System is in place	Will follow the bar code system
19.	Is the biomedical waste being sent to an authorized common BMW facility?	Yes		GJ Multiclave facility (PCB authorized)	Biomedical waste will be sent to PCB authorized facility
20.	Does the grantee have an in-house BMW treatment facility?		No		
	Is the treatment facility own (individual)?		No		

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	Is the treatment facility a shared facility in an industrial park?	Yes		GJ Multiclave facility – outsourcing partner of IITMBI.	
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		Necessary pre treatments done before discarding by the company employees	Specific SOPs in place will be followed for colour-coded segregation of waste as per guidelines. Compliance calendar shall be maintained.
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes		Liquid waste is checked for active cells before disposal.	Will monitor this during the Project and if needed will propose a plan of treating the same as per BWM Regulations.
23.	Are necessary waste pre-treatment equipment in place?	Yes		Autoclaves	SOP is in place for operation and maintenance of the equipments for pretreatment.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes			
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes			Will use only non-chlorinated bags
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Provided once in 6 months	Training will be provided to the staff handling biomedical waste as per the existing frequency mentioned.
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		Outsourced by IITM Bioincubator	This practice will be checked periodically and compliance will be ensured.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		Handled by the IITM Bioincubator.	This practice will be followed and updated with constant review.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Yes		Handled by the IITM Bioincubator.	Will ensure that this compliance is done regularly within the timelines.
Hazardous Waste (HW)					
29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?		No	no hazardous waste generated	If Hazardous waste generated it will disposed as per CPCB rules
30.	Is there trained staff in the facility to identify and handle hazardous waste?		No	no hazardous waste generated	

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31.	Does the grantee have authorization from SPCB for hazardous waste?		No	no hazardous waste generated	
32.	Is there a secure location for storage of HW with proper signage?		No	no hazardous waste generated	
	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?		No	no hazardous waste generated	
	Is the disposal facility in house?		No		
	Is the disposal facility external/outourced?		No		
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?		No	no hazardous waste generated	
E-Waste and Batteries					
35.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?		No	no e-waste/batteries generated)	
36.	Has the grantee obtained SPCB authorization on e-waste?		No		Company will obtain the authorization from SPCB as and when the need arises.
37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?		No	no e-waste is generated	
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	no e-waste is generated	
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		No	no e-waste is generated	
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	no e-waste is generated	
41	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		No	no e-waste is generated	

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42.	Does the grantee submit annual reports on e-waste to SPCB?		No	no e-waste is generated	
43	Is there accident reporting and records in place?		No	no e-waste is generated	
44	Are PPEs available to staff?		No		The stock status of PPE will be regularly monitored and procurement will be done in time to avoid any situation of stock out as and when needed.
45	Is the grantee involved in manufacture of batteries?		No	no battery waste is generated	
46	Does the grantee generate battery waste?		No	no battery waste is generated	
47	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/collection center?		No	no battery waste is generated	
48	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		No	no battery waste is generated	
Community Health and Safety and risk mitigation					
49	Safety Transportation Management System (for transport Of hazardous material)	Yes		Handled by IITM Bio-incubator's outsourcing partner GJ Multiclave	It will be ensured through GJ Multiclave
50	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		Emergency plan and systems is in place and managed by the IITMBI and IITM research park includes Fire detection systems and emergency kits	It will be reviewed/monitored by the research park. Mock drills conducted by research park.
Others					
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc.)?		No	No radioactivity will be used for this project.	

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	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	No radioactivity will be used for this project.	
	Are radioactive warning signs in place?		No	No radioactivity will be used for this project.	
52.	Is the lab/room air regularly checked for microbial contamination?	Yes			1. SOPs are in place for the monitoring and reviewed on regular basis. 2. Records are maintained and handled by the IITM Bioincubator
53.	Are there any odor control measures in place?		No		Periodic checks will be done
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes		fume hoods are provided in the lab	Filters of fume hoods are changed on regular basis. The hood is maintained and handled by the IITM Bioincubator
55.	Does the grantee use DG set > 15 KVA?		No	Within a common facility at the IITM research park.	Regular monitoring of emissions will be done by RP.
	Does the grantee have consent for DG > 15 KVA?		No		
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	Yes		Consents with the research park and regular monitoring will be done by RP.	
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		Proper disposal of solid and plastic waste is carried out by IITM Bioincubator	It will be ensured that segregation rules are followed. This will be maintained and monitored.
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)		No	Waste water treatment is managed by IITM bioincubator and Research park. Effluent Treatment plant installed in Research park. STP of 360 KLD capacity	These will be periodically checked and maintained to ensure their proper functioning.
	Are there sludge management and cut off drains in place for wastewater?		No		Maintained by IITM Research Park These will be periodically

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					checked and maintained to ensure their proper functioning.
58.	Are necessary provisions for noise cancellation in place?		No		Preventive measures will be taken for reducing noise levels if generated
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No		
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes			Fire vehicles routes are provided and managed by IITM Research Park
COVID Precautions & Guidelines Implementation					
61	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?	Yes		Waste with potential COVID-19 risks such as used gloves, used masks and other PPE materials are treated as BMW handled and processed as by GJ multiclave (SPCB authorised)	Any COVID-19 waste generated will be processed/handled by outsourcing partner GJ Multiclave (SPCB authorised).
62	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	Yes		Health protocol for COVID-19 control being followed such as social distancing; wearing mask and gloves inside the facility; placing thermal scanners and sanitizers at the entry of the buildings; frequent handwash; sanitizing the workplace; minimising the no. of employees working inside the facility/site; conducting meetings online mostly;	It will be ensured that the COVID-19 protocol issued by GoI for workplace is being strictly adhered to and any updates will be implemented.

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.