

Environmental Health Risk Management Plan (EHRMP)

ICAR-National Institute of High Security Animal Diseases (NIHSAD)

Proposal entitled: Development and validation of LFA POCT kits for SARS COV-2 Antigen detection

(i) Brief description of the proposed activity Development and validation of LFA POCT kits for SARS-COV-2 Antigen detection.				
(ii) List of environment related regulatory clearances required for the activity. Consent from pollution control board is available.				
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	-	ICAR-NIHSAD has a well-known BSL3+ containment facility to handle high risk animal pathogens.	The safety officer will ensure that EHS issues are addressed properly. The concerned staff will be trained on the Environment Health and Safety (EHS) and will comply with the norms and requirements of the Pollution Control Committee.
2. Does the EHS staff handle the following?			Institute has a dedicated and trained Biosafety staff to deal with any emergency situations.	The trained staff will ensure EHS of highest standards.
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	-	The waste disposal is done by as per the guidelines of state pollution control board. On daily basis, all the waste generated out of research is submitted to authorized biomedical	

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				waste collection agency.	
3.	Is there a reporting structure in place regarding EHS issues?	Yes	-	Describe: Yes, Biosafety Unit, NIHSAD Comprising One Biosafety Officer, Assistant Biosafety officers and Biosafety engineers.	The reporting structures is in place and shall be updated and maintained.
4.	Are regular EHS trainings provided to staff?	Yes	-	All the staff deals with waste has been trained for collection, and disposal of waste.	The well trained staff will ensure that EHS issues are addressed properly. The trainings will continue.
5.	Institutional Bio-Safety Committee (IBSC)	Yes	-	IBSC approval received in Oct-2020	Existing procedures, process and regulatory compliance will be extended and followed as per statutory requirement and internally established processes.
6.	Ethics Committee (EC)	Yes	-	IAEC is in place	Project will begin only after getting approval from Ethics Committee (EC).Periodic review and meeting wil be scheduled.
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		Institution biosafety and biosecurity guidelines are strictly followed for	SOPs outlined in the Biosafety Manual of the

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				working in BSL-3 containment facility of ICAR-NIHSAD. SP are well in place for each criteria.	Institute will be followed.
8.	Are the following in place?			ICAR- NIHSAD usually works with high risk pathogen therefore each parameter is strictly taken care to deal with any accident. All the occupational safety equipment mentioned are available	The EHS lab in-charge describes the procedure for correct usage of all these emergency services during the periodic EHS classes. Registers for recording accidents and injuries will be maintained by the lab team.
	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		Any accident reported is immediately reported to Biosafety Unit and action is taken accordingly to deal with situations.	The reporting of accidents to Biosafety unit will be continued.
	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: All the rooms and corridors are equipped with Smoke detector, fire alarm system and fire extinguisher and water Hydrant.	Will ensure proper functioning of warning systems in place.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	Yes		Air Handling Units (AHU) which maintains the air supply and exhaust into the laboratory and animal containment area.	The SOP will be followed.

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				The HEPA filters and Fine filters at the exhaust and supply ensure biosafety. The air-handling system of the facility is comprised of 23 air-handling units (AHUs) with 97 HEPA filters fitted in 92 filter housings. The Air conditioning system is amalgamated with the AHU to ensure controlled temperature environment	
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency (type wise): once in every 6 months.	We proposed to have mock drills/ training to handle other types of accidents also other than fire safety as per schedule. Every 6 months.
13.	Are staff provided with OHS training?	Yes		Yes, In compliance to ISO-9001:2015 and NABL accreditation every staff has been trained for OHS training.	Temporary Staff/ visitor joining the lab will have training at the time of joining duty.
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		a list of biomedical waste produced in the facility: Laboratory animal waste, cultures, embryonated eggs, animal clinical samples, research materials, media.	The proposed plan is to dispose any kind of biomedical waste as per the BWM Rules, 2016 .
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes			Will ensure that this is followed regularly throughout the project.

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16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes		Consent No. AW-50401 dated 02.09.2019 from Madhya Pradesh Pollution control Board	Timely renewals and proper approvals in future will be taken.	
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		Yellow	YES	Bio-medical waste segregation will be performed as per the colour-code schedule I of the 2016 BMW rules.
				Red	YES	
				White	YES	
				Blue	YES	
18.	Is the bar code system for the segregated waste in place?	Yes		It is being provided by CBWTF contracted by the Institute for BMW disposal as per PCB norms	Yes, the implemented system will be followed.	
19.	Is the biomedical waste being sent to an authorized common BMW facility?	Yes		Name and address of CBMWF: M/s. BMW solutions, 6, Thana Road, Shahajahanabad, Bhopal - 462001 Distance from facility: 11 km Frequency and Mode of transport: Daily except on Sundays in the Completely sealed vehicle authorized for BMW transport. Who transports : CBWTF (M/s. BMW solutions)		
20.	Does the grantee have an in-house BMW treatment facility?		No		As per MP PCB directions a CBWTF has been appointed	
	Is the treatment facility own (individual)?	-	-			

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	Is the treatment facility a shared facility in an industrial park?	-	-		for treatment of BMW generated by the Institute.
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: The Waste is segregated in different colour coded bags that are placed in specific colour coded bins. Before the waste is taken out from the laboratory all the waste is autoclaved at minimum of 121° C for 30 minutes in two barrier autoclaves and the sterile waste is then picked up by the PCB authorized CBWTF for its further treatment and disposal. The basement floor has the effluent treatment plant (ETP) wherein all the liquid waste from the laboratory and solids/semisolids from the animal containment are decontaminated by heat sterilization.	
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes			All the liquid waste discarded will be treated as per the current mechanism in place.
23.	Are necessary waste pre-treatment equipment in place?	Yes		List of equipment (autoclaves, shredders, incinerators, etc.):	Pre-Treatment will be done by decontamination by our staff regularly.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes		Details of waste pre-treatment: Annexure A at the end of the form	
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes			Only nonchlorinated bags and gloves are being used for BMW

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					disposal and handling.
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Frequency: Training to the concerned is provided every 3 months or whenever new personnel are entrusted with the task of handling and pretreatment of BMW. The training is provided by the Designated Biosafety personnel of the institute.	Regular training will be given to all the personnel and all the stakeholders will be trained to handle BMW.
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: Annual	This practice will be checked periodically and ensure compliance.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes			Maintained both at the institute level and at the level of CBWTF for Biomedical Waste.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	-Yes		Annual Reports are being submitted to SPCB as per BMW 2016 guidelines	Will ensure that this compliance is done regularly within the 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?		No		If any hazardous waste is generated as per rules it will be handled and disposed.
30.	Is there trained staff in the facility to identify and handle hazardous waste?		No		As and when required a staff will be trained to treat and handle the hazardous wastes.
31.	Does the grantee have authorization from SPCB for hazardous waste?		No		Necessary Authorizations will be taken if required.

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32.	Is there a secure location for storage of HW with proper signage?		No		We will arrange proper storage facilities when required
	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		
	Is the disposal facility in house?		No		
	Is the disposal facility external/outsourced?		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		We will maintain the register when required

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?		No	No substantial electrical waste is generated in the lab	Procedures will be followed as per guidelines.
36.	Has the grantee obtained SPCB authorization on e-waste?		No	No substantial electrical waste is generated in the lab	Necessary Authorizations will be taken if required.
37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?		No	No substantial electrical waste is generated in the lab	As and when the need arises proper system will be put in place during the project.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	No substantial electrical waste is generated in the lab	
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 substantial electrical waste is generated in the lab	
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 substantial electrical waste is generated in the lab	

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41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		No	No substantial electrical waste is generated in the lab	
42.	Does the grantee submit annual reports on e-waste to SPCB?		No	No substantial electrical waste is generated in the lab	
43.	Is there accident reporting and records in place?		No	No substantial electrical waste is generated in the lab	
44.	Are PPEs available to staff?	Yes			The stock status of PPE will be regularly monitored and procurement will be done in time to avoid any situation of stock out.
45.	Is the grantee involved in manufacture of batteries?		No	No substantial electrical waste is generated in the lab	
46.	Does the grantee generate battery waste?		No	No substantial electrical waste is generated in the lab	
47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/ collection center?		No	No substantial electrical waste is generated in the lab	
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		No	No substantial electrical waste is generated in the lab	

Community Health and Safety and risk mitigation

		Yes	No	Details	Proposed Plan
49.	Safety Transportation Management System (for transport Of hazardous material)	Yes	-	Authorized CBWTF vehicles	Authorized CBWTF vehicles will be continuously pressed for safety transportation.
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes	-		The local community health workers and community leaders will be informed about any issues that can affect the

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					community. The Emergency Preparedness plan will be executed as per the SOP in place.
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Other

	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		No	We do not use any radioactive materials	Will ensure to take proper measures and steps if required in future throughout the Project.
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	We do not use any radioactive materials hence not applicable.	
	Are radioactive warning signs in place?		No	We do not use any radioactive materials hence not applicable.	
52.	Is the lab/room air regularly checked for microbial contamination?	Yes	-	Air sampling is regularly done. The laboratory has dedicated HEPA filter installed Air Handling system.	Cleaning will be regularly done.
53	Are there any odor control measures in place?	Yes		The designated air exchange precludes any odor emission inside the laboratory premises	Cleaning and maintain records regularly.
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes		The filter efficiency of the containment equipment are checked routinely as per the laid out SOP for the purpose.	Outward air flow in the cabinets is monitored by anemometers regularly.
55.	Does the grantee use DG set > 15 KVA?	Yes			Regular inspections will be conducted by the local electricity officials, PCB officials and the authorized Boiler inspectors. Periodic maintenance will be done.
	Does the grantee have consent for DG > 15 KVA?	Yes			
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	Yes			

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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		All the solid waste is pretreated by autoclaving and handed over to the authorized municipal bodies as per the Solid waste management and plastic waste rules.	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		Types of wastewater: Laboratory effluent The basement floor has the effluent treatment plant (ETP) wherein all the liquid waste from the laboratory and solids/ semisolids from the animal containment are decontaminated by heat sterilization followed by digestion in the effluent treatment plant	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	-		These will be periodically checked and maintained to ensure their proper functioning.
58.	Are necessary provisions for noise cancellation in place?	Yes	-	Sound mufflers in the generator	Utilization ear buds /ear muffs during the project to mitigate this risk in future.
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?	-	No	Distance from premises: >500 m	
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		Carpeted open roads are available right upto the laboratory premises for access to fire vehicles. Water hydrants are available at designated places for the purpose, which serves the safety purpose.	Fire vehicles will be accessed in our existing premises.

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COVID Precautions & Guidelines Implementation					
61	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?	Yes		All the specified guidelines for handling the COVID wastes are being followed. All the records regarding the generation, pretreatment and disposal are being followed and being entered in the specific COVID APP designed and mandated for the purpose.	Will ensure that proper measures are taken as per the guidelines issued by the Government of India 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		Specific SOP applicable for the institute based on the ICMR/GOI guidelines have been prepared and is being followed scrupulously.	SOP for preventive measures in place will be followed.

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.

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Annexure A

Details of treatment equipment (number, type & capacity of each unit)

	No. of Units	Capacity of each unit
Autoclaves	15 of varying capacities including four barrier autoclaves, six effluent sterilizers and one animal digester	Effluent sterilizers – 150 litres Animal digester- 300 litres Barrier autoclaves- 810 litres Others ranging for 150 to 300litres
Microwave	3	12 litres, each
Shredder	4	20/hr
Needle tip cutter or destroyer	4	20/hr
Sharps encapsulation or concrete pit	1	Approx. 48 cft.
Deep burial pits	1	1000 kg
Chemical disinfection	3	1000 cft Fumigation chambers