

**"MedTech Rapid Prototyping Facility for Microfluidic Medical Devices"
Centre for Cellular and Molecular Platforms (C-CAMP),**

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	We have already constituted a institutional bio-safety committee. The staff and users who would require biosafety clearance for their projects submit their projects to the committee and they are reviewed on a routine basis. The projects need to be cleared by the IBSC before they are allowed to be initiated.	The project approvals of the bio-safety committee will be monitored by the facility advisory committee and the minutes as well as data on the projects will be recorded and archived.
EHS Team	The campus instrumentation and medical teams are trained in the emergency response and in environment and health safety assessment and work synergistically in case of any incidences or emergencies.	Emergency preparedness drills are conducted on a routine basis. All incidences and accidents on campus are recorded and assessed by the management committee.
Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.	All waste discarded will be properly labelled, and quantity and specification recorded. The records will be archived and analysed for methods of reducing waste and to ensure compliance with the prevailing pollution control norms.	The records will be maintained and monitored routinely by the facility advisory committee.
SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc.	<ul style="list-style-type: none"> • All contractors undertaking works at CCAMP are to be briefed prior to commencement of work to collect and dispose off waste/ debris etc at designated places where bins are provided. • However, for small quantity of debris, weekly debris clearance will be organized by respective agencies undertaking work for which a separate item will be created in SOQ of each contract and will be operated as “per trip basis”. 	The records will be monitored routinely by the facility advisory committee.

	<ul style="list-style-type: none">• Debris are to be segregated at designated point and disposed off suitably. Debris are not to be accumulated and left in the campus. Final bill clearance should be subject to disposal of all waste by the contractor.• Useful items or any reusable material are to be segregated and stored properly at designated points or storage area.• Contractors are not leave any leftover materials in the campus on completion of works.• All Engineers are required to take surprise rounds of work sites and ensure proper and prompt disposal of waste/ debris etc. Specific instructions to be recorded in the site register.• A suitable clause has to be incorporated in all contracts for the contractor to comply with waste disposal procedure and the same need to be linked up to the stage payments.• All unused /unserviceable items are to be handed over to store section periodically for disposal in normal course as per procedure in vogue.• All section in charges holding stores are also required to follow proper waste disposal procedure and avoid cramping up of store space with unwanted materials.• “Repair, Reuse and Recycle” norms are to be followed strictly to reduce environmental damage due to dumping of waste materials and reduction of wastage.• The site order book must be maintained for each work in which respective engineer will record instructions relating to day-to-day work and signed by both Engineer and Contractor. This will also cover waste handling/disposal aspect.• Engineers who record the work done by contractor will be directly responsible for strict compliance of above guidelines and to levy penalty to the offending party as per contract terms.• Packing materials (wooden/ cardboard/ plastic) are not to be left on the	
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	<p>corridors/ side of the pathways. They are to be handed over to stores-section for proper disposal.</p> <ul style="list-style-type: none"> Personnel attending works in the lab area are to be specifically instructed to collect/ remove debris generated in the process of work and maintain cleanliness of lab area. 	
General Safety and Storage	<p>All items will be stored appropriately in as small quantities as feasible. The chemicals will be stored in closed cabinets, acid cabinets, corrosive cabinets, and flammables cabinets as applicable. The total volume of flammables will be kept under the appropriate volume for the facility.</p> <p>Sharps, tools and other physical hazards will be stored in lockable storage with appropriate warnings.</p> <p>Electrical grounding and safety will be routinely tested by the electrical team.</p> <p>Other general lab safety procedures will also be followed.</p>	The storage and general safety will be monitored routinely by the facility in charge and the facility advisory committee.

2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	The proposal will have use of chemicals which release fumes. Fine particulate matter due to plastic/ metal grinding, milling and polishing may be generated.	Minimal risk. Particulate matter may impact quality of air	All chemical fume exhausts will be routed through scrubbers, filters and fume hoods as appropriate. Regular air quality monitoring will be done.
Water Pollution and Waste water treatment	Acids and chemicals will be used in the facility.	These chemicals if untreated are hazardous and will contaminate water	All water waste will be treated appropriately in our in-campus water treatment plant before discard.
Chemical waste (including signage, storage and SOP for spillage)	Acids and chemicals will be used in the facility.	These chemicals if untreated are hazardous.	All chemical waste will be segregated and discarded through appropriate chemical waste discard companies. Pollution control board permission already enclosed in the proposal.

Biological Waste	Not applicable as biological material will not be used in the facility.	Not applicable as biological material will not be used in the facility.	Not applicable as biological material will not be used in the facility.
Heavy metals	Minimal Risk. There is least possibility of the risk of contamination of heavy metals in the environment near and inside the facility. Only possible sources include the metals and alloys used for fabrication of prototypes (such as Titanium for implants and lead for soldering). Other minimal risk material includes wires, metal shavings etc.	There can be an adverse effect on human health due to the presence of these heavy metal in the environment.	As the facility is primarily for development of medical devices, high-toxicity heavy metals and other non-biocompatible material will not be used. Lead-free solder will be used for electronic devices. Proper regulatory measures will be undertaken if at all there will be any incidence of heavy metal contamination, related to the handling and disposal.
Electronic Waste	Minimal Risk. Iterative designs of prototypes, PCBs, electronic chips, accessories, spares of equipment, metallic wires etc.	Project implementation will not create any adverse electronic waste.	Software-based designs will be undertaken to minimize financial losses. Electronic waste generated will be disposed according to existing laws
Radiation Waste	Not applicable as project implementation will not create any radiological waste.	Not applicable as project implementation will not create any radiological waste.	Not applicable as project implementation will not create any radiological waste.
Destruction/alteration of surrounding ecosystem	Not applicable as no new structures are being constructed.	Not applicable as no new structures are being constructed. Project implementation will not lead to any adverse destruction/alteration of surrounding ecosystem.	Not applicable as no new structures are being constructed. Project implementation will not lead to any adverse destruction/alteration of surrounding ecosystem.
Construction and Demolition waste	Construction waste from refurbishing and cleanroom construction.	The wastes could have hazardous chemical ingredients and pollutants.	The wastes will be discarded appropriately through waste processing companies.

3. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Moderate Risk. Primary sources will be welding equipment, lasers etc. Other than these, heavy usage of some particular equipment for longer duration may generate substantial heating.	Burns and physical injuries due to heat and sparks.	Personal protective equipment will be provided to users and engineering solutions from the equipment providers will be used.
Chemical hazards, including fire and explosions	Hazardous chemicals and flammables used as part of fabrication	Fire, explosions and chemical burns	Personal protective equipment will be provided to users and engineering solutions from the equipment vendors will be used. Flammable and acids safety cabinets will be procured and used for storage. Eye wash and safety shower will be provided in an accessible place.
Pathogenic and biological hazards	Not applicable as biological material will not be used in the facility.	Not applicable as biological material will not be used in the facility.	Not applicable as biological material will not be used in the facility.
Radiological hazards	Not applicable as radioactive material will not be used in the facility.	Not applicable as radioactive material will not be used in the facility.	Not applicable as radioactive material will not be used in the facility.
Noise	High Risk. Use of heavy machinery for metal prototyping, activities such as grinding, milling, polishing of metals and plastics.	Continuous high decibel noise can lead to hearing impairment and deterioration of health.	Personal protective equipment, headsets and noise damping insulation will be used to protect the facility personnel, users and visitors. Damping and enclosure solutions from the equipment manufacturers will be used where available.
Process safety	Pinch hazards, abrasion hazards, fumes, entanglement hazards, slips, trips and falls hazards, etc	Damage to personnel	Personal protective equipment and engineering solutions from the equipment manufacturers will be used.

4. Community Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Safety Transportation Management System (for transport of hazardous material)	Not applicable as we do not plan to transport hazardous materials. Hazardous material transport into the facility will be handled by the suppliers and waste disposal will be handled by the waste disposal vendors/companies.	Not applicable as we do not plan to transport hazardous materials. Hazardous material transport into the facility will be handled by the suppliers and waste disposal will be handled by the waste disposal vendors/companies.	Not applicable as we do not plan to transport hazardous materials. Hazardous material transport into the facility will be handled by the suppliers and waste disposal will be handled by the waste disposal vendors/companies.
Emergency preparedness and participation of local authorities and potentially affected communities	Accidents, spillages, etc	Human harm, release of wastes	CCAMP policy on emergency preparedness will be utilized. We already have an in-campus clinic, and an emergency ambulance as well as a front desk available around the clock. In case of accidents, the personnel can be transported immediately to nearby hospitals with the front desk coordinating with the local authorities as needed.
<p>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.</p> <p>Each individual, at C-CAMP, needs to go through and pass a lab safety course that is organized by the campus to enter the lab area. Depending on the kind of work to be done at C-CAMP (e.g. office work), he/she can take a basic course. Individuals working inside the lab need to strictly follow the lab safety rules. While working in the lab, everyone needs to wear proper clothes, lab coats, gloves and closed toe shoes.</p> <p>We have a lab safety manual for more details.</p> <p>NO infectious or clinical samples are allowed inside C-CAMP without special permission from C-CAMP management.</p> <p>Depending on the projects, IBSC meetings are arranged by C-CAMP.</p> <p>Every six months there is a refresher safety program conducted by C-CAMP lab manager for the staff and incubatees.</p>			

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.