

Establishment of Med Tech Design and Rapid Prototyping Facility Yenepoya

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	IBSC exists in the University. We also have NABH accreditation.	Approvals will be taken from the IBSC as per the projects that come to the facility.
EHS Team	Environmental Officer is employed by the organization. Dept. of studies for environmental sciences conducts annual audits of every department on campus.	Compliance to annual audits for environmental compliance
Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.	All documentary records are stored for referrals. We have MoU with the state-identified waste management unit for safe disposal of biomedical waste.	Records will be maintained for all waste disposed.
SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc.	SOPs available as part of environmental audit compliance and NABH accreditation.	SOPs will be maintained and updated as per work and/ or audit findings.
General Safety and Storage	Storage areas for hazardous chemicals are properly marked. Fire fighting equipment are available and fire exits properly marked at all places.	Compliance with internal audit findings.

2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Minimal Risk. Fumes from the laser cutter and PCB soldering. Use of volatile solvents. Fine (PM 2.5) metallic dust due activities such as metal grinding, milling and polishing.	Respiratory disorders due to inhalation. However, quantities of air pollutants will be very low.	No direct release of potential pollutants into the environment. Using fume hood and treating using the exhaust

Water Pollution and Waste water treatment	Minimal Risk. Waste water from post-processing of prototypes. Routine use of water as in any facility (cleaning, washrooms etc.).	Contamination of soil and water table, skin infections upon contact with untreated waste water.	Connecting the waste water line to the dedicated collection and storage tanks and disposal as per the standard reclamation methods and waste water treatment methods.
Chemical waste (including signage, storage and SOP for spillage)	Moderate Risk. Using solvents will create chemical waste. Chemicals (such as plastics, organic polymers, oils etc.) and organic solvents will be used in a limited manner.	Organic solvents may lead to contamination of air, water and soil causing a large number of health problems upon exposure.	Chemical fume hoods will be used for handling liquid chemicals. Storage areas will be clearly demarcated. SOPs for spillage will be in place. We have a contract with Ramky Enviro Engineers Limited for handling of chemical wastes.
Biological Waste	Moderate Risk. Cell culture and tissue culture laboratory waste.	Release of biological toxins into the atmosphere, contamination of environment and the biosphere, release of mutant drug-resistant genes into the environment.	All biological waste from the facility will be autoclaved and then treated appropriately before discard. Contract agency will be on-board to handle biological waste from the facility.
Heavy metals	Minimal Risk. Use of metal 3D printers (such as Titanium) for design and fabrication of implants and other rapid prototyping work (wastage from sheet cutters, millers 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, other electronic consumables etc.	Environmental destruction due to improper waste disposal.	Software-based designs will be undertaken to minimize 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	Minimal Risk. No civil construction activities will be undertaken as part of the proposal.	There will no destruction or alteration of the surrounding ecosystem as the existing lab will be augmented for a full-fledged prototyping facility for MedTech devices.	All waste generated at the facility will be treated as per regulation and not discarded as is which may harm the environment.
Construction and Demolition Waste	Minimal Risk. No civil construction activities will be undertaken as part of the proposal Only refurbishment will be done.	Possible destruction of surrounding ecosystem.	All waste generated at the site will be treated as per local regulations.

3. Occupational Health and Safety and Risk Mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Moderate Risk. Heat generated from the CNC, soldering and metal work might cause health hazards.	Burns and physical injuries due to heat and sparks.	Using appropriate protective gear and good lab design and instrument placement.
Chemical hazards, including fire and explosions	Minimal Risk. Fire and health hazards due to risk of fire from laser cutter and operation of other instruments	Destruction of material and property, health deterioration, loss of life and limb.	Building fire and evacuation plan, installing fire alarms and smoke detectors, and use of fire extinguishers. Emergency exits will be properly marked. Proper protective gear will be used when working with chemicals.

Pathogenic and biological hazards	Minimal Risk. Project implementation will not create any adverse pathogenic and biological hazards. Biological material used will be for research and laboratory use.	Not applicable as the facility will not handle any pathogenic material.	Project implementation will not create any adverse pathogenic and biological hazards.
Radiological hazards	Minimal Risk. Using UV and laser might create health hazards. Radioactive material will not be used.	Laser radiation of certain wavelengths are absorbed by the cornea and lens, leading to the development of cataracts or burn injuries. Skin burns are also possible.	Using protective gear and appropriate filters on equipment. Proper demarcation of areas and use of indicators when lasers are in use. Personal protective equipment will be provided.
Noise	Minimal Risk. Noise generated from the CNC machines and other instruments might create noise pollution.	Continuous high decibel noise can lead to hearing impairment and deterioration of health.	Placing the noisy instruments in the sound-proof rooms and providing noise isolation gear for the employees and users
Process safety	Minimal Risk. Industrial processes will be used in the facility, leading to process-specific risk.	The facility can cause (i) material impairment to the health of the persons engaged in or connected therewith, or (ii) result in the pollution of the general environment.	Establishing SOPs for safe use of the instruments and implementing good lab design and practices. Following guidelines.

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)	Moderate Risk. 3D printed biological material is subject to risk management during transportation.	Potential exposure to individuals and contamination of environment, compromise integrity of the material itself.	Use of leak proof and temperature-controlled containers for shipment, proper and detailed documentation along with shipment, mention of material description and process of handling in case of accidents/ spillage/ exposure.
Emergency preparedness	Moderate Risk.	Since the facility is relatively small and	The risk is modified by the level of the local

<p>and participation of local authorities and potentially affected communities</p>	<p>These are similar to process risk associated with operation of the facility.</p>	<p>does not contain highly flammable material, potential impact of any accident or calamity is very limited.</p>	<p>preparedness of the institute by undertaking:</p> <ol style="list-style-type: none"> 1. Mock trials 2. Safety workshop 3. Fire extinguishers drills. <p>Emergency contact numbers will be listed in the facility. Emergency exit signs will be displayed appropriately in the facility. Fire extinguishers will be placed.</p>
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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.