Establishment of a state of the art facility for design and fabrication of medical devices and equipment with in house quality control system for cultivating a local production hub of medical grade technology and solution industry in north India.

Indian Institute of Technology Kanpur

Environmental and Health Risk Management Plan

1. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Minimal Risk. Fine (PM 2.5) metallic dust due activities such as grinding, milling and polishing.	There is very little potential impact in the air quality due to the usage of the equipment to be used in the facility. Metal dust may lead to respiratory problems.	We (IIT-Kanpur) will follow the norms prescribed in the **Air Prevention and Control of Pollution Act (1981) amended in 1987.** To improve the air quality, we will install HEPA filters for maintaining the air quality inside the facility. Regular air quality monitoring will be done for PM2.5 and PM10 particles.
Water Pollution and Waste water treatment	Minimal Risk. Routine use of water as in any facility (cleaning, washrooms etc.).	The facility will not emit any water pollutant as a process by product, as this will be a prototyping facility for making indigenous medical devices.	Water supply and waste water management are handled by the institution (IIT-Kanpur) and not specific to lab. Compliance under the provisions of the **Water Pollution Act in 1974** to prevent the pollution of water by industrial waste will be undertaken.
Chemical waste (including signage, storage and SOP for spillage)	Minimal Risk. Chemicals (such as plastics, organic polymers, oils etc.) and organic solvents will be used in a limited manner.	If in any circumstances, chemical waste management is required, we will follow the **Hazardous process industry under the Factories Act, 1948.**	**The Environment (Protection) Act, 1986 and the Rules framed there** will be applied for the concerned facility for handling hazardous chemicals and the above aspects are covered including responsibilities assigned to the Chief Inspector of facility and

			other concerned authorities. Hazardous chemicals covered under the Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 made under the Act will be followed in the facility.
Biological Waste	Minimal Risk. The facility will not undertake handling of any biological material for service.	Any biomedical waste is generated due to in-house testing will be treated as per regulations.	In case of any incidence of managing biological waste in the facility, **Bio-medical Waste (Management & Handling) Rules, 1998** rules will apply to all persons in the facility who generate, collect, receive, store, transport, treat, dispose, or handle bio medical waste in any form while working 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.	High financial burden. Environmental destruction due to improper waste disposal.	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	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 4i lab will be augmented for a full-fledged prototyping facility for MedTech devices as only refurbishment will be done.	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	Not applicable as we are not undertaking any civil construction work under this project.	Not applicable as we are not undertaking any civil construction work under this project.	Not applicable as we are not undertaking any civil construction work under this project.

2. 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.	Disaster Management Act, 2005 for industrial management will be followed. Centralized air conditioning will be installed. Personal protective equipment will be provided to users as required.
Chemical hazards, including fire and explosions	Minimal Risk. Primary source will be flammable material used in prototyping, which will be very minimal.	Destruction of material and property, health deterioration, loss of life and limb.	The Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, 1996 will be followed in the facility. Flammable chemicals will be labeled, segregated and stored appropriately. Fire extinguishers will be available in the facility. Personal protective

			equipment will be provided to users as required.
Pathogenic and biological hazards	Not applicable as the facility will not handle any biological material.	Not applicable as the facility will not handle any biological material.	Not applicable as the facility will not handle any biological material.
Radiological hazards	Moderate Risk of Ionization Radiation caused by use of Class 4 laser equipment for cutting and welding. May produce laser-generated air contaminants and hazardous plasma radiation. No other sources (such as radioactive elements/ compounds) will be used.	Laser radiation with wavelengths less than 0.4 μm and greater than 1.4 μm are largely absorbed by the cornea and lens, leading to the development of cataracts or burn injuries.	Proper demarcation of area and indicators to warn users when lasers are in use. Personal protective equipment will be provided to users as required.
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.	The implementation of any measure that will reduce noise being generated, and/or will reduce the noise transmission through the air or through the structure of the workplace will be undertaken. Approach for noise hazard control in the work environment, is to eliminate or reduce the hazard at its source of generation, either by direct action on the source or by its confinement. ISO 11690 rules will be followed. Acoustic environment will be created. The noise levels in the facility shall not exceed the ambient air quality standards in respect of noise as specified in the Schedule. The institute shall be responsible for the

			enforcement of noise pollution control measures and the due compliance of the ambient air quality standards in respect of noise. Proper personal protective equipment (such as earmuffs) will be provided to users of noise-generating machinery.
Process safety	Moderate Risk. The proposed facility comes under guidelines of Hazardous process industry. Therefore, there is moderate 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:	Incorporating Section 7A of Factories Act, 1948 relating to General Duties of Occupier: Absolute liability of the occupier for ensuring the safety, health and welfare of the workers, with specific provision for maintenance of facility and systems of work in the facility. ISO 13485:2016 guidelines will be implemented at the facility.

3. 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 there will be no hazardous material produced in the facility or needed to be transported.	Not applicable as there will be no hazardous material produced in the facility or needed to be transported.	Not applicable as there will be no hazardous material produced in the facility or needed to be transported.
Emergency preparedness and participation of local authorities and potentially affected communities	Moderate Risk. The hazards to which a community is exposed and the vulnerabilities are least for this project.	Since the facility is relatively small and does not contain highly flammable material, potential impact of any accident or calamity is very limited.	The risk is modified by the level of the local preparedness of the institute by undertaking: 1. Mock trials 2. Safety workshop 3. Fire extinguishers drills. Emergency contact numbers will be listed in the facility. Emergency exit signs will be

			displayed appropriately in the facility. Fire extinguishers will be placed.
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**.**			

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