PI:					
LS-1	**American Society of Microbiology GLPS Large Scale**	**N/A**	**Conform**	**Non-Conform**	**Comments**
	A. Standard Microbiological Practices BSL-LS1				
	1. Individuals wash their hands after handling viable material.				
	2. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not allowed in the work area.				
	3. Mouth pipetting is prohibited.				
	4. Work surfaces are capable of being cleaned and disinfected.				
	5. An insect and rodent control program is in effect.				
	B. Special Practices				
	1. Institutions that engage in large scale work should have a health and safety program for their employees.				
	2. Written instructions and training are provided for personnel who work at GLSP conditions.				
	3. Processing, sampling, transfer, handling, etc. of viable organisms are done in a manner that minimizes employee exposure and the generation of aerosols.				
	4. Discharges of viable organisms are disposed of in accordance with applicable local, state, and federal requirements.				
	5. The facility should have an emergency response plan which includes the handling of spills.				
	C. Safety Equipment				
	1. Protective clothing, e.g. uniforms, laboratory coats, etc., is provided to minimize the soiling of personal clothing.				
	2. Safety glasses are worn in the facility. Face shields and/or goggles and face masks are provided for procedures that may involve splashing or spraying of viable organisms.				
	D. Facilities				
	1. Sinks, eyewash stations, and safety showers are provided in the work area.				
LS-2	***AMS BSL2-LS***				
	A. Standard Microbiological Practices				
	1. Access to the work area may be restricted at the discretion of the project manager when work is ongoing.				
	2. Persons wash / clean their hands after they handle viable organisms, after removing gloves, and on leaving the work area.				
	3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work area.				
	4. Food is stored outside of the work area in cabinets or refrigerators designated and used for this purpose only.				
	5. Mouth pipetting is prohibited. Only mechanical pipetting devices are used.				
	6. Work surfaces are decontaminated on a routine basis and after any spill of viable organisms.				
	7. Procedures are performed carefully in a manner which minimizes aerosol generation.				
	8. All discharges of the viable organisms are disposed of in accordancewith applicable local, state and federal regulations..				
	9. An insect and rodent control program is in effect.				

	B. Special Practices				
	1. Institutions that engage in large scale work have a health and safety program for their employees.				
	2. Written procedures and training in basic microbiological practices are provided and documented.				
	3. Medical evaluation, surveillance and treatment are provided where indicated; e.g. determine functional status or competency of employees' immune system when working with opportunistic pathogens, etc.				
	4. Spills and accidents which result in overt exposure to viable organisms are reported to the facility supervisor/manager Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.				
	5. Emergency plans shall include methods and procedures for handling spills and employee exposures.				
	6. Cultures of viable organisms are handled in a closed system or other primary containment equipment, e.g. biological safety cabinet, which is designed to reduce the potential for the escape of viable organisms.				
	7. Sample collection and material addition to a closed system, and transfer of culture materials from one closed system to another are conducted in a manner which minimizes employee exposure, the release of viable material and the generation of aerosols.				
	8. Culture fluids may be removed from a closed system or other primary containment system in a manner which minimizes employee exposure, the release of viable material and the generation of aerosols.				
	9. Exhaust gases removed from a closed system or other primary containment system minimize the release of viable organisms to the environment by the use of appropriate filters or procedures.				
	10. A closed system or other primary containment equipment that has contained viable organisms shall not be opened for maintenance or other purposes until it has been decontaminated.				
	C. Safety Equipment				
	1. Protective clothing; e.g. uniforms, laboratory coats, etc., is provided to prevent the contamination or soiling of personal clothing.				
	2. Safety glasses must be worn. Protective face protection consisting of a face shield, or goggles and face mask is worn for procedures that may involve splashing or spraying of viable organisms.				
	3. Gloves are worn if the skin on the hands is broken, irritated, or otherwise not intact.				
	D. Facilities				
	1. Each work area contains a sink for handwashing, an eyewash station, and an emergency shower. The sink is located near the exit of the work area.				
	2. The work area has a door which can be closed when large scale work is ongoing.				
	3. The work area is designed to be easily cleaned.				
	4. Floors are able to be cleaned and disinfected in case of spills of viable organisms. Rugs are not allowed.				
	5. Work surfaces are impervious to water and resistant to acids, alkali, organic solvents, and moderate heat.				
	6. Furniture in the work area is sturdy and placed so that all areas are accessible for cleaning.				
	7. If the work area has windows that open, they are fitted with fly screens.				

	8. Facilities are designed to prevent the release of large volumes of viable organisms directly to sewer; e.g. floor drains are capped or raised, fitted with liquid tight gaskets to prevent release of untreated organisms to sewer.				
	A. Standard Microbiological Practices				
	1. Access to the work area is restricted to personnel who meet the entry requirements.				
	2. Persons wash their hands after they handle viable organisms, after removing gloves and before leaving the work area.				
	3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the facility.				
	4. Food is stored outside of the facility in cabinets or refrigerators designated and used for this purpose only.				
	5. Mouth pipetting is prohibited. Only mechanical pipetting devices are used.				
	6. Work surfaces are decontaminated on a routine basis and after any spill of viable organisms.				
	7. Procedures are performed carefully in a manner which minimizes aerosol generation.				
	8. All contaminated wastes are decontaminated by an approved method prior to disposal in accordance with local, state, and federal regulations. Wastes that need to be transported to a different area or facility are closed and placed in a durable, leakproof container for transfer. Material to be transferred off site for decontamination is packaged and labeled in accordance with the applicable regulations.				
	9. All discharges of viable organisms are inactivated by a validated process, i.e. one that has been demonstrated to be effective using the organism in question, or with an indicator organism which is known to be more resistant to the physical or chemical methods used; e.g. Bacillus stearothermophilus for steam heat.				
	10. An insect and rodent control program is in effect.				
	B. Special Practices				
	1. Institutions that engage in large scale work have a health and safety program for their employees.				
	2. Doors to the work area are kept closed when work is ongoing.				
	3. Access to the work area is restricted to personnel whose presence is required and who meet entry requirements, i.e., immunization, if any. Individuals who can not take / do not respond to the vaccine, who cannot take the recommended prophylaxis in the event of an exposure incident, who are at increased risk of infection, or for whom infection may prove unusually hazardous, are not allowed in the work area until their situation has been reviewed by appropriate medical personnel. The individuals are informed of the potential risks and sign an acknowledgement / consent form, or similar vehicle, which indicates that they understand and accept the potential risk.				
	4. Written procedures and policies for handling infectious organisms are provided.				
	5. Personnel are able to demonstrate proficiency in standard microbiological practices and procedures, handling of human pathogens at a Biosafety Level 2. This can consist of previous experience and /or training. Training in the hazards associated with the organisms involved, and the practices and operations specific to the large scale work area are provided and documented.				
	6. Appropriate immunizations, medical evaluation surveillance, and treatment are provided where indicated; e.g., immunization, survey of immune status, etc.				
	7. A hazard warning sign, incorporating the universal biohazard symbol, identifying the infectious agents, listing the name and telephone numbers of the persons knowledgeable about and responsible for the work area, along with any special entry requirements for entering the work area, is posted at the entry to the work area.				

	8. When appropriate, baseline serum samples or other surveillance samples are collected and stored for all personnel working in or supporting the work area.				
	9. A biosafety manual is available which details required safety practices and procedures, spill clean-up, handling of accidents, and other appropriate safety information.				
	10. The use of sharps is avoided. If required, additional safety devices or personal protective equipment are used to prevent accidental exposure. Plasticware is substituted for glassware whenever possible. If glassware is used, it is coated or shielded to minimize the potential for breakage.				
	11. Viable organisms are placed in a container that prevents leakage during collection, handling, processing , and transport.				
	12. Viable organisms are handled in a closed system or other primary containment equipment which prevents their release into the environment.				
	13. Sample collection and material addition to a closed system, and transfer of culture materials from one closed system to another are conducted in a manner which prevents employee exposure and the release of material from the closed system.				
	14. Culture fluids shall not be removed from a closed system (except as allowed in #13) unless the viable organisms have been inactivated by a validated procedure, or the organism itself is the desired product.				
	15. Exhaust gases removed from a closed system or other primary containment system are filtered or otherwise treated to prevent the release of viable organisms to the environment.				
	16. A closed system that has contained viable organisms will not be opened for maintenance or other purposes unless it has been decontaminated.				
	17. Rotating seals and other mechanical devices directly associated with a closed system used for the propagation of viable organisms are designed to prevent leakage or are fully enclosed in ventilated housings that are are exhausted through filters or otherwise treated to prevent the release of viable organisms to the environment				
	18. Closed systems used for the propagation of viable organisms and other primary containment equipment are tested for the integrity of the containment features prior to use, and following any changes/modifications to the system that could affect the containment characteristics of the equipment. These systems are equipped with a sensing device which monitors the integrity of the containment while in use. Containment equipment for which the integrity cannot be verified or monitored during use, are enclosed in ventilated housings that are exhausted through filters or otherwise treated to prevent the release of viable organisms.				
	19. Closed systems that are used for propagation of viable organisms or other primary containment equipment are permanently identified. This identifier is used on all records regarding validation, testing, operation, and maintenance.				
	20. Contaminated equipment and work surfaces are decontaminated with a suitable disinfectant on a routine basis, after spill cleanup, etc. Contaminated equipment is decontaminated prior to servicing or transport. Absorbent toweling / coverings can be used on work surfaces to collect droplets and minimize aerosols and are discarded after use.				
	21. Individuals seek medical attention immediately after an exposure incident. Spills and accidents that result in overt exposure to infectious materials are immediately reported to the facility supervisor / manager and the BSO. Appropriate medical treatment, medical evaluation, and surveillance are provided, and written records maintained.				
	22. Emergency procedures includes provisions for decontamination and clean-up of all spills/releases of viable material, including proper use of personnel protective equipment..				
	23. Animals not involved in the work being performed, are not permitted in the work area.				
	C. Safety Equipment				
	1. Protective clothing, e.g.. lab coats, protective coveralls, etc., is worn to prevent contamination of personal clothing. If the organism can be transmitted through the skin, the protective clothing should be waterproof with a solid-front, e.g.. wrap-around , or back- or side-tie coats. Protective clothing is removed when leaving the work area.				

	2. Protective eyewear is worn at all times in the work area. Protective face protection, i.e., face shield or goggles and face mask / respirator are worn for any procedures that may involve splashing or spraying. Respirators are worn if the agents involved are respiratory transmissible.				
	3. Impervious gloves are worn at all times in the work area when work is ongoing. Double gloving and/or the use of latex gloves is considered if personnel are working over extended periods of time, or with processes that may require direct contact with the infectious material. Gloves are discarded upon leaving the work area.				
	4. The selection of a respirator / face mask is made based on the transmissibility of the agent. If the agent is transmitted through the respiratory route, a respirator with a filtration efficiency capable of protecting the individual from the organism is used, e.g., HEPA for viruses, N95s for Mycobacteria tuberculosis, etc. If the agent is transmitted through mucous membrane contact, a face mask which prevents droplet penetration, e.g., plastic molded, is preferred. Personnel are trained in the use of respirators / face masks for procedures that may involve aerosol generation, and for emergency situations that involve the release of viable organisms in the work area.				
	5. Biological safety cabinets or other ventilated containment devices are used to contain processes of viable organisms if removed from a closed system.				
	6. Only centrifuge units with sealed rotor heads or safety cups that can be opened in a biological safety cabinet are used; or the centrifuge is placed in a containment device.				
	D. Facilities				
	1. Each facility contains a sink for handwashing, an eyewash station, and an emergency shower. The sink is foot, elbow, automatic, etc., or otherwise not hand operated, and located near the door of each room in the work area.				
	2. The work area has a door which can be closed when large scale work is ongoing.				
	3. The work area is designed to be easily cleaned and disinfected. Furniture and stationary equipment are sealed to the floor or raised to allow for cleaning and disinfection of the facility.				
	4. Floors, walls, and ceilings are made of materials that allow for cleaning and disinfection of all surfaces. Light fixtures are covered with a cleanable surface.				
	5. Work surfaces are impervious to water and resistant to acids, alkali, organic solvents, and moderate heat.				
	6. Windows to the facility are kept closed and sealed while work is ongoing.				
	7. General laboratory-type work areas are designed to have a minimum of 6 air changes per hour. For large scale facilities, the number of air changes per hour will depend on the size of the area, the chemicals and agents handled, the procedures and equipment utilized, and the microbial / particulate requirements for the area.				
	8. The ventilation in the work area is designed to maximize the air exchange in the area,, i.e., the supply and exhaust are placed at opposite ends of the room, ceiling supply with low level exhaust, etc.				
	9. The work areas in the facility where the infectious organisms are handled is at negative pressure to the surrounding areas.				
	10. Provisions are made to contain large spills of viable organisms within the facility until appropriately decontaminated. This can be accomplished by placing the equipment in a diked area, or sloping or lowering the floors in those areas to allow for sufficient capacity to contain the viable material and disinfectant.				
	11. Drainage from the facility is designed to prevent the release of large volumes of viable material directly to sewer, e.g., floor drains is capped, raised, or fitted with liquid tight gaskets to prevent release of untreated organisms to sewer.				