Laboratory Biosafety (Level 2) Inspection Report

Central Michigan University

Mt. Pleasant, MI 48859

Lab Director:	Inspected By:	
Lab Location (Bldg/Rm Nos.):	Department:	Inspection Type: ☐Initial ☐Annual ☐3 yr Renewal
Lab Safety Officer:	Biosafety Officer:	Inspection Date:

List of Agents that will be Used/Stored in Lab (Check all applicable agent categories and list agents by category):

☐Recombinant DNA:
☐Bacterial:
☐Viral:
☐Fungal:
☐Parasitic:
☐Toxin:
☐Prion:
☐Other

☐**Biosafety Level 2 (BSL-2):** Suitable for working with pathogenic agents that pose a moderate risk to lab personnel or the environment. Lab access is restricted when work is in progress. Extreme precautions are taken regarding the use of sharps. Procedures that may generate infectious aerosols or splashes are performed in a biosafety cabinet or physical containment equipment. Lab personnel are trained to handle pathogens.

BSL	AGENTS	PRACTICES	SAFETY EQUIPMENT	FACILITIES
2	Associated with human disease. Hazard = percutaneous injury, ingestion, mucous membrane exposure.	BSL-1 practices plus: ●Limited access ●Biohazard warning signs ●"Sharps" precautions ●Biosafety manual defining any needed waste decontamination or medical surveillance policies	**Primary Barriers:** Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; **PPE:** Lab coats, gloves, face protection as needed	BSL-1 plus: ●Autoclave available

INSPECTION CHECKLIST			
Verbal Inspection		**Yes**	**No**
1.1.	Lab access limited/restricted when experiments or work with cultures/specimens or organisms containing rDNA molecules are in progress		
1.2.	Minimum requirements to enter/work in lab are established and enforced.		
1.3.	Personnel at risk of acquiring infections or for whom infections may have serious consequences are denied access to lab		
1.4.	All personnel are advised of potential hazards prior to entering/working in lab		
1.5.	Lab personnel have read and follow biosafety procedures/practices		
1.6.	All employees have attended orientation training.		
1.7.	Lab personnel are trained on the potential hazards, precautions to prevent exposures, & exposure evaluation procedures		
1.10.	Lab personnel receive annual refresher training and/or additional training as necessary		
1.11.	All lab employees' have attended chemical hygiene or hazard communication training.		
1.12.	All employees have been provided with training on how to read an MSDS.		
1.13.	Lab personnel are appropriately immunized against or tested for the agents being used (e.g., HBV vaccinations, Tb skin test)		
1.14.	Baseline and periodic serum samples are collected/stored as required		
1.15.	Lab personnel wash hands after handling viable materials and materials involving organisms containing rDNA, removing gloves, or leaving lab		
1.16.	Gloves are worn if skin on hands is broken or has rash		
1.16.	Gloves are worn if hands are at risk of contacting infectious materials or materials containing rDNA molecules, infected animals, or contaminated surfaces/equipment.		
1.18.	Gloves are not worn outside lab or when touching "clean' surfaces (*e.g.,* telephones, keyboards, elevator buttons, *etc*.)		
1.19.	Gloves are disposed of when overtly contaminated, work w/infectious materials is completed, or integrity is compromised.		
1.20.	Disposable gloves are not reused.		
1.21.	No eating, drinking, smoking, handling contact lenses, applying cosmetics, or storing human food in lab		
1.22.	Mechanical pipetting devices are used (*i.e.,* no mouth pipetting)		
1.23.	Sharps handling policies/practices in place		
1.24.	Plastic ware is substituted for glassware whenever possible		
1.25.	Broken glassware is only handled by mechanical means		
1.26.	Sharps containers are decontaminated (e.g., autoclaved or appropriate chemical treatment) prior to disposal or reprocessing		
1.27.	Needle/syringe use is kept to absolute minimum		
1.28.	Only needle-locking syringes or syringes w/ permanently affixed needles are used for injection/aspiration of infectious materials or fluids containing organisms that contain rDNA molecules		
1.29.	Syringes that "re-sheath" the needle or needleless systems are used when appropriate		
1.30.	Disposable needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated prior to disposal		
1.31.	Contact lens users wear safety glasses, goggles or face shields		
1.32.	Procedures minimize splashes/aerosols		
1.33.	Goggles or face shield used when performing procedures that pose a splash risk outside of a BSC		
1.34.	Work surfaces are decontaminated at least daily and/or at completion of work w/ effective disinfectant		
1.35.	Work surfaces are decontaminated after any spill/splash of viable material w/ effective disinfectant		
1.36.	Lab equipment is decontaminated on routine basis w/ effective disinfectant and prior to sending it for repair/maintenance, or packaging it for shipment		
1.37.	Method for decontaminating lab waste is available in building (*i.e.,* autoclave, incinerator, *etc*.)		
1.37.	Materials decontaminated outside of lab are transported in durable, leak-proof, closed containers (plastic bags transported in tray or pan with a leakproof bottom)		
1.39.	All cultures/stocks/regulated wastes are decontaminated by approved method (*e.g*., autoclaving) before disposal		
1.40.	Cultures, tissues, specimens, or infectious wastes are kept in covered, leak-proof containers during collection, handling, processing, storage, transport or shipment.		
1.41.	Protective laboratory clothing such as lab coats, solid-front/wrap-around gowns, scrub suits, or coveralls are worn (this protective clothing must be removed before exiting the laboratory and left in the laboratory)		
1.42.	Protective clothing is changed when overtly contaminated		
1.43.	Protective clothing is either discarded appropriately in the lab or laundered on-site		
1.44.	Soiled/used lab clothing is autoclaved before laundering		
1.45.	Spills/accidents are immediately reported to the lab director (If the spills and/or accidents result in overt exposure to organisms containing rDNA molecules they must be immediately reported to the IBC and NIH/OBA)		
1.46.	Animals not involved in work are not allowed in lab		
1.47.	Plants not related to work are not allowed in lab		
1.48.	Insect/rodent control program in effect		
1.49.	All biohazards have been classified into the appropriate biosafety levels.		
1.50	There is a documented risk assessment indicating the risk the identified hazards represent.		
1.51.	There are appropriate controls in place to minimize/eliminate the risks.		
1.52.	MSDS's are available for any biohazards used in the lab.		
1.53.	The biohazard spill/decontamination training is adequately documented.		
1.54.	There are written procedures in place for offsite transportation of biohazards.		
1.55.	Lab personnel are trained in the opening of packages containing biohazards.		
1.56.	Written procedures are in place for handling leaking or damaged packages containing biohazards.		
1.57.	The lab personnel working with human materials have been offered the Hepatitis B vaccine.		
1.58.	The lab maintains a needlestick injury log that contains the type of device involved, and where and how the incident happened.		
Verbal Inspection		**Yes**	**No**

1.1.1.	Class II BSC or equivalent are used for procedures that have potential to create aerosols or splashes		
1.1.2.	Class II BSC or equivalent are used for work w/ high concentrations or large volumes of infectious agent		
Verbal Inspection		**Yes**	**No**
1.2.1.	Lab doors kept closed when experiments in progress		
1.2.2.	Written policy/procedure on who can enter lab		
1.2.3.	Minors not allowed in lab		
1.2.4.	Lab personnel are periodically tested for agent being worked with and/or periodic serum specimens are banked		
1.2.5.	Employees have been provided with task specific training by the lab supervisor.		
1.2.6.	Lab personnel have demonstrated proficiency for all procedures they will perform before working with BSL-3 agents		
1.2.7.	Spills of infectious materials are decontaminated by professional staff or personnel trained/equipped to handle concentrated infectious material.		
1.2.8.	All open work with infectious materials is performed in a BSC or equivalent		
1.2.9.	Lab has a written emergency/accident response plan which includes reporting accidents, exposures, employee absenteeism		
1.2.10.	Accidental exposures are documented (i.e., medical evaluations, plan for follow-up medical surveillance, treatment)		
1.2.11.	Respirators and face protection are used when in rooms containing infected animals.		
1.2.12.	Class II or III BSC are used for all manipulations of infectious materials, necropsies of infected animals, harvesting tissue/fluids from infected animals/embryonated eggs, etc.		
1.2.13.	Biological materials transported outside of laboratory is to be placed in a primary non-breakable, leak-proof, sealed containers and then enclosed in a non-breakable, sealed secondary container. These materials are to remain under the control of an FBI cleared person.		
1.2.14.	Lab HVAC system provides 100% make-up air, 100% ducted exhaust, and maintains lab at a negative relative air pressure.		
1.2.15.	Outside exhaust is dispersed away from occupied areas and building air intakes, or is HEPA filtered.		
1.2.16.	Lab equipped w/ visual device that allows lab personnel to verify that lab is negative at lab entry		
1.2.17.	HVAC system is designed to prevent the lab from being positively pressurized.		
1.2.18.	Lab equipped with audible HVAC failure alarms		
1.2.19.	Safety glasses with permanently affixed side-shields or HEPA respirators with face shield are required to be worn.		
1.2.20.	Autoclave test strips or biological indicators are included in every load (to demonstrate attaining 121°C to verify decontamination).		
1.2.21.	Autoclave records are maintained.		
1.2.22.	HEPA respirators are used for biohazard spill clean-up and decontamination.		
Visual Inspection		**Yes**	**No**
2.1.	Labs are located away from public areas.		
2.2.	Labs have doors for access control		
2.3.	Labs where “select agents” are used or stored have lockable doors (See 42 CFR 72.6).		
2.4.	Lab has adequate lighting		
2.5..	Biohazard signage posted at all lab entrances when infectious agents are present (should display PI name/phone)		
2.6.	Posted biohazard signage includes biosafety level, required immunizations, required PPSE, and required lab exit procedures		
2.7.	Lab designed to be easily cleaned (e.g., no carpets/rugs, spaces between cabinets/equipment/furniture are accessible, etc.)		
2.8.	Bench tops are impervious to water and resistant to heat, organic solvents, acids, alkalis, and disinfectants.		
2.9.	Lab furniture/equipment is suitable for intended use/loads.		
2.10.	No fabric upholstered/covered furniture or chairs		
2.11.	Lab has a sink for hand washing		
2.12.	Lab Director has prepared biosafety procedures into lab SOPs		
2.13.	Lab coats, gowns, or uniforms are removed and left in lab before leaving for non-lab areas		
2.14.	BSC are tested and certified at least annually		
2.15.	BSC not located near doors or windows that can be opened		
2.16.	Sharps containers are labeled, conveniently located, and puncture resistant		
2.17.	Nondisposable sharps containers are hard-walled and leak proof		
2.18.	Disinfectants are labeled for agents being used		
2.19.	Refrigerators/freezers containing biohazards are labeled with a biohazard sign.		
2.20.	All the lab equipment that may be contaminated is labeled with a biohazard sign.		
2.21.	All containers holding biohazards are labeled with a biohazard symbol.		
2.22.	The front grills of the BSCs are not blocked or covered.		
2.23.	All biohazard waste receptacles are closed/covered when not in use.		
Visual Inspection		**Yes**	**No**
2.1.1	Lab windows that open to the outside are fitted w/ fly screens.		
2.1.2.	Eyewash station is readily available		
Visual Inspection		**Yes**	**No**
2.2.1	Lab access is limited by secure locked doors		
2.2.2.	Lab entrance from access corridor is via a series of two self-closing doors		
2.2.3.	Logbook is maintained to document the date/time of each person who enters/exits the lab.		
2.2.4.	There is a documented inventory of all biohazards onsite (Verify purpose of use and who removes or replaces agent in inventory.)		
2.2.5..	All training provided adequately documented.		
2.2.6.	Spill cleanup procedures are developed and posted.		
2.2.7.	Lab hand washing sink has hands-free, foot, knee, or automatic controls located near exit door		
2.2.8.	Eyewash station is readily available inside lab		

2.2.9.	Walls, floors, ceilings can be easily cleaned/decontaminated (e.g., seamless, free of imperfect junctions, smooth, resistant to water/chemicals, sealed penetrations, floors are slip resistant and have covered base, etc.)		
2.2.10.	Lab windows are closed and sealed.		
2.2.11.	BSC not located near air supply grills or high lab traffic areas		