Laboratory Biosafety Inspection Report

Oklahoma State University
Institutional Biosafety Committee
219 Cordell North, Stillwater, OK 74078

Lab Director:	IBC Protocol Number(s):	Inspection Date:
Lab Location (Bldg/Rm Nos.):	Department:	Inspection Type: ☐Initial ☐Annual ☐Special
Lab Safety Officer:	College/Department Safety Officer:	Inspected By:

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

Recommended Lab Biosafety Level for Listed Agents:

☐**Biosafety Level 1 (BSL-1):** Suitable for working with well-characterized nonpathogenic agents that pose minimal risk to lab personnel or the environment. Lab does not have to be separated from general building traffic patterns. Work generally conducted on open bench tops using standard microbiological practices. No requirement for special containment equipment or facility design. Lab personnel are trained in general microbiological procedures/practices.

☐**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.

☐**Biosafety Level 2 Plus (BSL-2+):** Suitable for routine diagnostic procedures involving the propagation of a BSL-3 agent for identification, typing, susceptibility testing, etc. may be performed in a BSL-2 facility provided: (1) lab has no recirculated air [100% makeup air & 100% exhaust to outside], (2) lab relative air pressure is negative to adjoining rooms, (3) access to lab is restricted when work is in progress, and (4) BSL-3 standard microbiological practices, special practices, and safety equipment are used. Use of this biosafety level classification is restricted to OADDL and BVMTH clinical pathology labs.

☐**Biosafety Level 3 (BSL-3):** Applicable to clinical, diagnostic, teaching, research or production facilities working with indigenous or exotic pathogenic agents that pose a moderately high risk of serious or potentially lethal disease to lab personnel when inhaled. Lab access is restricted when work is in progress. Extreme precautions are taken regarding the use of sharps. All procedures involving the manipulation of infectious materials are performed in a biosafety cabinet, other equivalent physical containment device, or by personnel wearing appropriate PPE (*e.g.*, respirators). Lab has special engineering and design features. Lab personnel are trained to handle potentially lethal pathogens.

☐**Biosafety Level 4 (BSL-4):** Applicable to work with dangerous and exotic pathogenic agents that pose a high risk for aerosol-transmitted lab infections and lethal disease to lab personnel. Lab access is strictly controlled. Lab is located in a separate building or totally isolated area within a building. Extreme precautions are taken regarding the use of sharps. All procedures involving the manipulation of infectious materials are performed in a Class III BSC or a Class II BSC used with 1-piece positive pressure personnel suits ventilated by a life support system. Lab has special engineering and design features to protect the environment. Lab personnel are trained to handle extremely lethal pathogens.
NOTE: BSL-4 work is not authorized at OSU at the present time.

BSL	AGENTS	PRACTICES	SAFETY EQUIPMENT	FACILITIES
1	Not known to consistently cause disease in health adults	Standard microbiological practices.	None required	Open bench top Sink required
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
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL-2 practices plus: ●Controlled access ●Decontamination of all waste ●Decontamination of lab clothing before laundering ●Baseline serum	**Primary Barriers:** Class I or II BSCs or other physical containment devices used for all open manipulations of agents; **PPE:** Protective lab clothing, gloves, respiratory protection as needed.	BSL-2 plus: ●Physical separation from access corridors ●Self-closing, double-door access ●Exhausted air—not recirculated ●Negative airflow into lab
4	Dangerous/exotic agents that pose high risk of life-threatening disease, aerosol-transmitted lab infections, or related agents with unknown risk or transmission.	BSL-3 practices plus: ●Clothing change before entering ●Shower on exit ●All material decontaminated on exit from facility.	**Primary Barriers:** All procedures conducted in Class III BSCs or Class I or II BSCs <u>in combination with</u> full-body, air-supplied, positive pressure personnel suit.	BSL-3 plus: ●Separate building or isolated zone ●Dedicated supply and exhaust, vacuum, and decon systems ●Other requirements outlined in BMBL

INSPECTION CHECKLIST	BIOSAFETY LEVEL			
1. STANDARD MICROBIOLOGICAL PRACTICES	**1**	**2**	**3**	**4**
1.1. Lab access limited/restricted when experiments or work with cultures/specimens are in progress				
1.2. Lab personnel wash hands after handling viable materials, removing gloves, or leaving lab				
1.3. No eating, drinking, smoking, handling contact lenses, applying cosmetics, or storing human food in lab				
1.4. Contact lens users wear safety glasses, goggles or face shields				
1.5. Food stored outside lab in designated cabinets/refrigerators				
1.6. Mechanical pipetting devices are used (*i.e.*, no mouth pipetting)				
1.7. Sharps handling policies/practices in place				
1.8. Procedures minimize splashes/aerosols				
1.9. Work surfaces are decontaminated at least daily and/or at completion of work				
1.10. Work surfaces are decontaminated after any spill/splash of viable material				
1.11. Disinfectants are labeled for agents being used				
1.12. Cultures/stocks/regulated wastes are decontaminated by approved method (*e.g.*, autoclaving) before disposal				
1.13. Materials decontaminated outside of lab are transported in durable, leak-proof, closed containers				
1.14. Infectious waste is decontaminated before removal for off-site disposal				
1.15. Biohazard signage posted at lab entrance when infectious agents are present (signage lists agents and PI name/phone)				
1.16. Insect/rodent control program in effect				
2. SPECIAL PRACTICES	**1**	**2**	**3**	**4**
2.1. Lab doors kept closed when experiments in progress				
2.2. Lab access is limited by secure locked doors				
2.3. Personnel at risk of acquiring infections or for whom infections may have serious consequences are denied access to lab				
2.4. All personnel are advised of potential hazards prior to entering/working in lab				
2.5. Minors not allowed in lab				
2.6. Pregnant women not allowed in lab				
2.7. Minimum requirements to enter/work in lab are established and enforced.				
2.8. Posted biohazard signage includes biosafety level, required immunizations, required PPSE, and required lab exit procedures				
2.9. Lab personnel are appropriately immunized against or tested for the agents being used (e.g., HBV vaccinations, Tb skin test)				
2.10. Baseline and periodic serum samples are collected/stored as required				
2.11. Lab Director has incorporated biosafety procedures into lab SOPs or has adopted/prepared a lab-specific Biosafety Manual				
2.12. Lab Director has adopted/prepared a lab-specific Biosafety Manual and incorporated biosafety procedures into lab SOPs				
2.13. Lab personnel have read and follow biosafety procedures/practices				
2.14. Lab personnel are trained on the potential hazards, precautions to prevent exposures, & exposure evaluation procedures				
2.15. Lab personnel receive annual refresher training and/or additional training as necessary				
2.16. Needle/syringe use is kept to absolute minimum				
2.17. Only needle-locking syringes or syringes w/ permanently affixed needles are used for injection/aspiration of infectious materials				
2.18. Syringes that "re-sheath" the needle or needless systems are used when appropriate				
2.19. Disposable needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated prior to disposal				
2.20. Plastic ware is substituted for glassware whenever possible				
2.21. Sharps containers are labeled, conveniently located, and puncture resistant				
2.22. Nondisposable sharps containers are hard-walled and leak proof				
2.23. Broken glassware is only handled by mechanical means				
2.24. Sharps containers are decontaminated (e.g., autoclaved) prior to disposal or reprocessing				
2.25. Written policy/procedure on who can enter lab				
2.26. Lab personnel are periodically tested for agent being worked with and/or periodic serum specimens are banked				
2.27. Lab personnel have demonstrated proficiency for all procedures they will perform before working with BSL-3 agents				
2.28. Lab personnel have demonstrated a high proficiency for all procedures they will perform before working with BSL-4 agents				
2.29. Cultures, tissues, specimens, or infectious wastes are kept in covered, leak-proof containers during collection, handling, processing, storage, transport or shipment.				
2.30. Lab equipment and work surfaces decontaminated on routine basis w/ effective disinfectant				
2.31. Lab equipment is decontaminated prior to sending it for repair/maintenance, or packaging it for shipment				
2.32. Spills/accidents are immediately reported to the lab director				
2.33. Animals not involved in work are not allowed in lab				
2.34. Plants not related to work are not allowed in lab				
2.35. All open work with infectious materials is performed in a BSC or equivalent				
2.36. Plastic-backed absorbent paper is used to line BSC work surfaces				
2.37. Spills of infectious materials are decontaminated by professional staff or personnel trained/equipped to handle concentrated infectious material.				
2.38. Spill cleanup procedures are developed and posted.				
2.39. All potentially contaminated lab materials (*e.g.*, waste, gloves, lab coats, *etc*.) are decontaminated before disposal or reuse.				
2.40. Logbook is maintained to document the date/time of each person who enters/exits the lab.				
2.41. Accidental exposures are documented (i.e., medical evaluations, surveillance, treatment)				
2.42. Lab has a writt4en emergency/accident response plan				
2.43. Personnel enter/exit lab only through clothing change & shower rooms				
2.44. Personnel remove ALL street clothes in outer clothing change room and don lab clothing before entering lab				
2.45. Personnel exiting the lab remove ALL lab clothing in inner clothing change room and take a decontaminating shower				
2.46. Soiled/used lab clothing is autoclaved before laundering				
2.47. Supplies/materials are brought into the lab via a "pass-thru" autoclave, fumigation chamber, or airlock that is decontaminated between each use.				
2.48. All material is autoclaved or decontaminated before it is removed from the lab (see 2.49 below for exception)				
2.49. Viable/intact biological materials removed from the Class III BSC or BSL-4 lab are packaged in a sealed non-breakable primary container inside a sealed non-breakable secondary container and removed from lab via disinfectant dunk tank, fumigation chamber, or air lock.				

2.50. Lab has plan for reporting accidents, exposures, employee absenteeism				
2.51. Lab has plan for medical surveillance of potential lab-associated illnesses				
2.52. A medical facility is available for quarantine, isolation, and treatment of personnel w/ lab-associated illnesses.				
3. SAFETY EQUIPMENT (Primary Barriers)	**1**	**2**	**3**	**4**
3.1. Lab coats, gowns, or uniforms are worn				
3.2. Solid-front/wrap-around gowns, scrub suits, or coveralls are worn				
3.3. Lab coats, gowns, or uniforms are removed and left in lab before leaving for non-lab areas				
3.4. Protective clothing is changed when overtly contaminated				
3.5. Protective clothing is either disposed of in the lab or laundered on-site by the institution.				
3.6. Reusable clothing is decontaminated before laundering				
3.7. Gloves are worn if skin on hands is broken or has rash				
3.8. Gloves are worn if hands are at risk of contacting infectious materials, infected animals, or contaminated surfaces/equipment.				
3.9. Gloves are not worn outside lab or when touching "clean' surfaces (*e.g.*, telephones, keyboards, elevator buttons, *etc*.)				
3.10. Gloves are disposed of when overtly contaminated, work w/infectious materials is completed, or integrity is compromised.				
3.11. Disposable gloves are not reused.				
3.12. Safety glasses are worn when performing procedures that pose a splash risk				
3.13. Goggles or face shield used when performing procedures that pose a splash risk outside of a BSC				
3.14. Respirators and face protection are used when in rooms containing infected animals.				
3.15. Class II BSC or equivalent are used for procedures that have potential to create aerosols or splashes				
3.16. Class II BSC or equivalent are used for work w/ high concentrations ($>10^8$ cfu/ml) or large volumes (>1 liter) of infectious agent				
3.17. 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.				
3.18. All procedures are conducted in Class III BSC or Class II BSC used in conjunction w/ 1-piece positive pressure suits w/ ventilated life support system.				
4. LABORATORY FACILITIES (Secondary Barriers)	**1**	**2**	**3**	**4**
4.1. Lab has adequate lighting				
4.2. Labs have doors for access control				
4.3. Labs where "select agents" are used or stored have lockable doors (See 42 CFR 72.6).				
4.4. Lab entrance from access corridor is via a series of two self-closing doors				
4.5. Lab has a sink for hand washing				
4.6. Lab hand washing sink has hands-free, foot, knee, or automatic controls				
4.7. Lab sink is located near exit door				
4.8. Lab designed to be easily cleaned (*e.g.*, no carpets/rugs, spaces between cabinets/equipment/furniture are accessible, *etc*.)				
4.9. 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*.)				
4.10. Bench tops are impervious to water and resistant to heat, organic solvents, acids, alkalis, and disinfectants.				
4.11. Lab furniture/equipment is suitable for intended use/loads.				
4.12. No fabric upholstered/covered furniture or chairs				
4.13. Lab windows that open to the outside are fitted w/ fly screens.				
4.14. Lab windows are closed and sealed.				
4.15. Labs are located away from public areas.				
4.16. BSC not located near doors or windows that can be opened				
4.17. BSC not located near air supply grills or high lab traffic areas				
4.18. Eyewash station is readily available				
4.19. Eyewash station is readily available inside lab				
4.20. Method for decontaminating lab waste is available in building (*i.e.*, autoclave, incinerator, *etc*.)				
4.21. Method for decontaminating equipment is available.				
4.22. Waste transported outside of lab is in sealed containers and not transported in public corridors.				
4.23. Lab HVAC system provides 100% make-up air, 100% ducted exhaust, and maintains lab at a negative relative air pressure.				
4.24. Outside exhaust is dispersed away from occupied areas and building air intakes, or is HEPA filtered.				
4.25. Lab equipped w/ visual device that allows lab personnel to verify that lab is negative at lab entry				
4.26. HVAC system is designed to prevent the lab from being positively pressurized.				
4.27. Lab equipped with audible HVAC failure alarms				
4.28. BSC are tested and certified at least annually.				
4.29. Class II BSC (Types B1, B2, & B3) are connected to building exhaust in a manner that prevents interference w/ either the BSC's or the lab's air balance (*e.g.*, air gap)				
4.30. Class III BSC are connected to building exhaust in a manner that prevents positive pressurization of the BSC.				
4.31. Equipment that may produce aerosols (e.g., continuous flow centrifuges) are contained in devices that exhaust air through HEPA filters before air is discharged into lab and HEPA systems are tested and certified at least annually.				
4.32. Vacuum lines and portable vacuum pumps are protected with liquid disinfectant traps and HEPA filters or their equivalent.				
4.33. Facility design and operational procedures are documented, facility commissioned/validated prior to becoming operations, and re-validated at least annually.				
4.34. Facility has personnel showers (depends on specific agent recommendations, risk assessment, site conditions, & applicable regulations)				
4.35. Facility exhaust air is HEPA filtered (depends on specific agent recommendations, risk assessment, site conditions & applicable regulations)				
4.36. Facility effluent can be decontaminated and piped services are contained (depends on specific agent recommendations, risk assessment, site conditions, & applicable regulations)				
4.37. Lab meets all BMBL requirements for a BSL-4 "Cabinet Laboratory" or "Suit Laboratory" as applicable				

INSPECTION FINDINGS

Code M = Minor Deficiency Code S = Significant Deficiency

Checklist Number	Code	Deficiencies	Recommended Corrective Actions	Suspense

IBC Disposition:

☐Approved for Work at: .....☐BSL-1 ☐BSL-2 ☐BSL-2+ ☐BSL-3 ☐BSL-4

☐Provisionally Approved for Work at:.....☐BSL-1 ☐BSL-2 ☐BSL-2+ ☐BSL-3 ☐BSL-4

Comments:

IBC Chair Signature:	Date:	Biological Safety Officer Signature:	Date: