DIRECTORATE ANIMAL HEALTH

CHECKLIST: BIOSAFETY LEVEL (BSL 3)

FACILITY / LABORATORY:		**DAFF NO:**
Representative:		
DAFF Auditor(s):		
Date:		
Agents Used:	Bacterial ☐ Viral ☐ Parasitic ☐ Fungal ☐ Rickettsial ☐ Prions☐	

No	REQUIREMENTS	C/ NC/ NA (compliance/ non-compliance/ not applicable)	COMMENTS
1.	**GENERAL PRACTICES**		
1.1	Access is limited or restricted.		
1.2	A biosafety manual is available and adopted.		
1.3	Eating, drinking, application of cosmetics and smoking not permitted.		
1.4	A pest control program (insects and rodents) is in effect.		
1.5	Animals and plants are not permitted in the facility.		
1.6	The interior surfaces of walls, floors, and ceilings are water resistant so that they may be easily cleaned.		
1.7	Laboratory doors are kept closed when tests are in progress and hazardous signs are displayed.		
1.8	There is a procedure for decontamination and spills. Disinfectants appropriate to pathogen.		
1.9	Work surfaces are decontaminated with disinfectants that are effective against the agents of concern.		
1.10	There is a procedure for equipment service and decontamination.		

1.11	Cultures, tissues, and specimens of body fluids are placed in a container that prevents leakage during collection, handling, processing, storage or transport.		
1.12	The sample packaging is appropriately disinfected prior to movement from the facility.		
1.13	Are samples transported in accordance with the National Road Traffic Act and Regulations (triple packaging)?		
1.14	Each laboratory contains a hand washing sink which is operated hands- free or automatically and is located near the room exit door.		
1.15	Personnel wash / disinfect their hands after handling animals / pathogens, after removing gloves, and before leaving the animal facility.		
1.16	Specimens in freezers and refrigerators or other storage units are appropriately packaged and marked to identify the specimen and the hazard.		
2.	**WASTE MANAGEMENT**		
2.1	A method for decontaminating all laboratory waste is available and utilised (autoclave, chemical disinfection, incineration, other approved methods).		
2.2	All potentially contaminated waste materials (e.g. gloves, PPE) are decontaminated before disposal or reuse. SOP available.		
2.3	All media, reagents and other regulated wastes are decontaminated (e.g. autoclaving) before disposal.		
2.4	All wastes from facility are appropriately decontaminated or sterilized, preferably by autoclaving, before disposal (depending on method of waste disposal).		

2.5	Materials to be decontaminated off-site are packaged in accordance with the National Road Traffic Regulations before removal (triple packaging).		
2.6	Liquid effluent must be sterilized or treated to inactivate the pathogen(s) of concern and is evidence available to support this		
3.	**SAFETY EQUIPMENT (PRIMARY BARRIERS) / FIRE / EMERGENCY EVACUATION PROCEDURES**		
3.1	Procedure for handling of sharps available. Adequate sharps containers.		
3.2	Does personal protective equipment (PPE) used include the following: a) Goggles b) Mask c) Gloves d) Coats e) Boots f) Other		
3.3	PPE and clothing removed prior to shower-out and exit, collected and decontaminated before re-use.		
3.4	Is there sufficient firefighting equipment available, including the correct type of fire extinguisher?		
3.5	Are fire extinguishers service and maintenance records up to date?		
3.6	Is there an emergency evacuation plan available?		
3.7	Has a designated safety officer been appointed?		
3.8	Are inspection records of safety audits available?		
3.9	Are there policies regarding prevention of injury on duty and diseases contracted through exposure at work.		

3.10	Personnel are proficient to work in a BSL 3 Facility.		
3.11	Personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures (training records).		
3.12	Where applicable staff screened, vaccinated and trained (records available).		
3.13	All manipulations of potentially infectious materials, including embryonated eggs, are conducted in a Class II or Class III biosafety cabinet.		
4.	**FACILITY FEATURES**		
4.1	The facility is separated from areas that are open to unrestricted traffic flow within the building and access to the laboratory is restricted.		
4.2	A clothes change room may be included in the passageway.		
4.3	All windows in the laboratory are closed and sealed.		
4.4	A method for decontaminating all laboratory waste is available and utilised (autoclave, chemical disinfection, incineration, other approved methods).		
4.5	Class II or III biosafety cabinets are required and are located away from doors, from room supply louvers and from heavily-traveled laboratory areas.		
4.6	Biosafety cabinets calibrated six monthly and checked intermediately if still functioning correctly (e.g. smoke test)?		
4.7	Autoclave (or other approved method) for sterilising wastes is present within the Facility.		

4.8	Materials are transferred to the autoclave in a covered leak-proof container whose outer surface has been decontaminated.		
4.9	Methods for sterilisation are verified (tested) periodically according to a schedule (records available).		
4.10	A non-recirculating ventilation system is provided.		
4.11	The airflow must be negative (-30Pa or less) and directional from area of lowest risk to area of highest risk.		
4.12	The exhaust air is discharged directly to the outside through HEPA filtration.		
4.13	The negative airflow must be monitored.		
4.14	A validation certificate is available for the airflow system which is verified annually.		
4.15	The Facility is designed and constructed to facilitate cleaning and housekeeping.		
5.	**THE FOLLOWING ENHANCEMENTS OR REQUIREMENTS FOR BIO-SECURITY ARE DEPENDENT ON THE BIOLOGICAL AGENT:**		
5.1	Access control and restrictions for visitors according to the pathogen involved.		
5.2	Shower out system in place/ decontamination.		
5.3	Treatment of exhaust air is through HEPA filtration which effectively removes infectious agents prior to release of exhaust air from the facility.		
5.4	Treatment of supply air is through a HEPA filtration which effectively protects the environment in the event of reverse air flow during mechanical failures.		
5.5	The HEPA filters must be verified at least annually.		
5.6	A notification system should be considered to notify personnel of		

	HVAC system failure.		
5.7	Exhaust air from Class II biosafety can be discharged to the outside through the building exhaust air system, but the cabinets must be connected such that there is no interference with the air balance of the cabinets or the building exhaust system (e.g. air gap between the cabinet exhaust and the exhaust duct).		
5.8	Class III biosafety cabinets must be directly connected to the exhaust system without affecting the pressure inside the cabinet.		
5.9	The supply and exhaust air of a Class III biological safety cabinet must be HEPA filtered.		
5.10	Equipment that may produce aerosols are contained in devices that prevent discharge of aerosol directly into the Facility. Such devices must only be opened in the Class II Biosafety Cabinet		
5.11	All procedures are carefully preformed to minimize the creation of aerosol.		
5.12	Is an eyewash and emergency shower available where applicable?		
5.13	Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.		
6.	**CHEMICAL SAFETY**		
6.1	The Material Safety Data sheets are readily available to personnel.		
6.2	Personnel receive appropriate training on the potential hazards (e.g. pathogens; chemical) associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures (training records).		
6.3	Compressed gas cylinders are secured.		

7.	**NOTES**		
DAFF auditors:		Signature:	Date:

8.1	**Biosafety Level:**
8.1.1	Biosafety Level **1** – represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a hand washing sink.
8.1.2	Biosafety Level **2** – practices, equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, and other laboratories in which work is done with a broad spectrum of indigenous moderate risk agents that are present in the community and associated with animal disease of varying severity. Biosafety Level 2 is appropriate when work is done with any animal-derived blood, body fluids, tissues, or primary animal cell lines where the presence of an infectious agent may be unknown. Laboratory personnel working with animal derived materials should refer to the OSHA Bloodborne Pathogen Standard for specific requirements.
8.1.3	Biosafety Level **3** – is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents, and are supervised by competent scientists who are experienced in working with these agents. All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices, or by personnel wearing appropriate personal protective clothing and equipment. The laboratory has special engineering and design features. It is recognised, however, that some existing facilities may not have all the facility features recommended for Biosafety Level 3 (i.e., double-door access zone and sealed penetrations). In this circumstance, an acceptable level of safety for the conduct of routine procedures, (e.g., **diagnostic procedures involving the propagation of an agent for identification, typing, susceptibility testing, etc.), may be achieved in a Biosafety Level 2 facility, providing:** **1) the exhaust air from the laboratory room is discharged to the outdoors,** **2) the ventilation to the laboratory is balanced to provide directional airflow into the room,** **3) access to the laboratory is restricted when work is in progress, and** **4) the recommended Standard Microbiological Practices, Special Practices, and Safety Equipment for Biosafety Level 3 are rigorously followed.**
9.	**General:**
9.1	**Risk assessment** takes into consideration that BT Agents may be modified by biotechnology and exhibit characteristics different from the known agents. **The biosafety level may be increased due to increased virulence,** enhanced stability, increased infectivity, drug or vaccine resistance, modified route of transmission, modified diagnostic characteristics, modified host range infecting increased number of species, or multiple agents, chimeric agents or combinations of biological and chemical agents. **Biocontainment and safe handling is primary consideration.** Security and chain of custody is also a priority. **Security from unauthorised access** includes a single point of separation between authorised personnel and the public or individually secure rooms for each lab employee. **Freezers used to store microbiological agents (Select Agents) must be locked.** Locked storage space meets chain-of-custody requirements. Chain of custody is a sequential record of each person who has control of a material, including the validity and security of the facility, equipment, test records, and data associated with any observation, collection, handling, testing and storage of the evidence. The BSL3 lab has two self-closing doors that are spaced so that they are not both open simultaneously during routine entry or egress. Penetrations through walls, ceilings or floors must be sealed (or be sealable) so that the laboratory rooms can be decontaminated (gas decontamination procedures, e.g. with paraformaldehyde). The ante-room is used as a transition room, where gowns, gloves, respirators, etc. are put on and where frequently needed laboratory supplies are stored. BSL3 labs are not accessible to the general public or to personnel not authorised to enter.