CHECKLIST: BIOBANK

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

No	REQUIREMENTS	C/ NC/ NA (compliance/ non-compliance/ not applicable)	COMMENTS
1.	**GENERAL PRACTICES**		
1.1	Registration with / knowledge of the Non-Proliferation Secretariat of the Department of Trade and Industry		
1.2	Access is limited or restricted.		
1.3	Access to biobank sample information is limited / restricted.		
1.4	There must be a biobank manager or equivalent person who is responsible for the content of the biobank.		
1.5	If the biobank is available for use by multiple Researchers there must be a process for accountability for content.		
1.6	An up to date inventory must be available at all times.		
1.7	A biosafety manual is available and adopted.		
1.8	Personnel should be trained in the procedures at the biobank, and this should be documented.		
1.9	There is a procedure for temperature monitoring.		
1.10	A notification system is in place for instances when temperatures are outside required parameters (e.g. sms).		

1.11	A pest control program (insects and rodents) is in effect.		
1.12	Animals and plants are not permitted in the facility.		
1.13	The interior surfaces of walls, floors, doors and ceilings are non-porous and easily cleaned.		
1.14	A work surface is available where applicable.		
1.15	Surfaces are decontaminated with disinfectants that are effective against the pathogen of concern.		
1.16	There is a procedure for equipment service and decontamination.		
1.17	Cultures, tissues, and specimens are stored in a container that prevents leakage during handling, storage or transport.		
1.18	The sample packaging is appropriately disinfected prior to movement from the facility.		
1.19	Records are available to provide full traceability for the samples (including sample description, date of collection, origin where sample was collected, species, circumstances of collection, quantity, etc.)		
1.20	Material may not be transferred from the biobank to another approved facility without prior permission from DAFF.		
1.21	Material transferred from the biobank may not be returned to the biobank for storage (in the event that material is "returned" to the biobank it must immediately be destroyed).		
1.22	Records must be available for material transfer.		
1.23	Section 20 permission is in place for use of samples from the biobank and records are available.		

1.24	Are samples transported in accordance with the National Road Traffic Act and Regulations (triple packaging)?		
1.25	Personnel wash / disinfect their hands after handling pathogens, after removing gloves, and before leaving the facility.		
1.26	Specimens in freezers and refrigerators or other storage units are appropriately packaged and marked to identify the specimen and the hazard.		
1.27	Emergency power supply is available.		
1.28	A schedule is available for the biobank maintenance ensuring integrity of samples.		
1.29	There is a procedure in place for cleaning the biobank (e.g. when defrosting is required).		
2.	**WASTE MANAGEMENT**		
2.1	An SOP is available for disposal of all biohazardous / biological wastes from the biobank by an approved method (e.g. approved biohazardous waste disposal company)		
2.2	Materials to be disposed off-site are packaged in accordance with the National Road Traffic Regulations before removal (triple packaging).		
3.	**SAFETY EQUIPMENT (PRIMARY BARRIERS) / FIRE / EMERGENCY EVACUATION PROCEDURES**		
3.1	Procedure for handling of sharps available. Adequate sharps containers are available.		
3.2	Does personal protective equipment (PPE) used include the following: a) Gloves b) Laboratory coats c) Cryogenic gloves (-80°C freezer) d) Other		

3.3	PPE decontaminated before laundering.		
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	There is a disaster management plan regarding the fate of samples in the event of a fire or other emergency.		
3.8	Are first aid facilities (properly stocked first aid box) available in the Laboratory?		
3.9	Are records available to demonstrate that the person in charge of first aid is suitably qualified?		
3.10	Has a designated safety officer been appointed?		
3.11	Are inspection records of safety audits available?		
3.12	Are there policies regarding prevention of injury on duty and diseases contracted through exposure at work.		
3.13	Personnel receive appropriate training on the potential biological hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures (training records).		
3.14	Where applicable staff screened, vaccinated (e.g. Rabies) and trained (records available).		
3.15	All handling of potentially infectious material is done in at least a Class II biosafety cabinet.		

4.	**FACILITY FEATURES**		
4.1	A room or area where PPE can be kept while preventing cross contamination with personal clothing is available.		
4.2	All windows are closed and sealed.		
4.3	The Biosafety cabinets are calibrated six monthly or annually depending on the agent involved and checked intermediately if still functioning correctly (e.g. smoke test)?		
4.4	Autoclave (or other approved method) for sterilising waste is available within the Facility.		
4.5	Materials are transferred to the autoclave in a covered leak-proof container whose outer surface has been decontaminated.		
4.6	Methods for sterilisation are verified (tested) periodically according to a schedule (records available).		
4.7	All procedures are carefully preformed to minimize the creation of aerosol.		
4.8	Is an eyewash station available where applicable?		
4.9	Is an emergency shower available where applicable?		
4.10	Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.		
5.	**CHEMICAL SAFETY**		
5.1	The Material Safety Data sheets are readily available to personnel.		
5.2	Personnel receive appropriate training on the potential hazards associated with the work (LN2) involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures (training records).		
5.3	Compressed gas cylinders are secured.		

6.	NOTES

DAFF Auditors:	Signature:	Date:

7.	General:
7.1	**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.