	DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES **DIRECTORATE ANIMAL HEALTH** **EPIDEMIOLOGY**
	PROCEDURE MANUAL: **LABORATORY / FACILITY BIOSAFETY AND BIOSECURITY INCLUDING BIOBANKS AND VECTOR PROTECTION**
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FIRST DOCUMENT	**June 2018**
VERSION:	**1-2018***
APPROVED BY:	**Director Animal Health**
APPROVAL DATE:	**June 2018**

PART I

1. LEGISLATION

The Animal Diseases Act, 1984 (Act No. 35 of 1984) and Regulations promulgated there-under.

2. PRINCIPLE

This procedure manual will enable the Directorate Animal Health to monitor the biosafety and biosecurity level of:

- diagnostic laboratories doing tests for controlled and notifiable diseases; and
- research facilities conducting research in terms of Section 20 of the Animal Diseases Act, 1984 (Act No. 35 of 1984);
- laboratories and facilities handling high risk pathogens / vectors.

3. PURPOSE AND SCOPE

The purpose as set out in this document is to provide general requirements that a laboratory / facility shall meet if it is to be recognized, as compliant by DAFF, to meet biosafety and bio-security requirements to work with specific pathogens / vectors.

Laboratories and research facilities handling bio-safety level 3 (BSL3) pathogens will be inspected to ensure compliance with BSL3 requirements. A certificate of compliance will be issued, containing the expiry date and will be valid for two years. Vector protected

facilities, biobanks; and research facilities (not handling high risk pathogens / BSL 3 pathogens) will receive a project specific recommendation report that is valid for two years.

Laboratories and research facilities seeking re- approval will need to schedule an audit and confirm the date as well as details of the audit.

Inspections of laboratories and facilities housing laboratory animals are undertaken by DAFF to ascertain compliance to requirements regarding containment, bio-security, animal health and waste management. BSL 3 quarantine facilities will receive a certificate containing the expiry date and will be valid for two years. Other animal facilities will receive a project specific recommendation report that may be valid for two years.

4. ABBREVIATIONS AND DEFINITIONS

DAFF	Department of Agriculture, Forestry and Fisheries
DAH	Directorate Animal Health
NC	Non Conformance / Finding
OIE	Office International Des Epizooties (World Organisation for Animal Health)
QMS	Quality Management System
SOP	Standard Operating Procedure
BSL	Bio-Safety Level
VPN	Veterinary Procedure Notice
Audit Inspection	The process whereby a quality system and bio-safety / biosecurity and a facility are audited and inspected against a standard i.e. National procedures and checklists.
Bio-safety	The containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents and toxins, or their accidental release.
Bio-security	The protection, control and accountability for valuable biological materials within laboratories, in

	order to prevent their unauthorized access, theft, misuse, diversion or intentional release.
Competence	Demonstration through skills and/or expertise to produce valid results.
Controlled Animal Diseases of South Africa	Refer to List (Annexure A)
DAFF Auditor	Person appointed by DAFF with the necessary expertise to perform audits according to a set of requirements.
DAFF Compliance	As set out in the Procedure Manual for Laboratory Biosafety and Biosecurity / Vector Protection / Biobanks; relevant checklists and VPNs.

DAFF Compliant Facility	A facility that performs its activities in such a way as to meet the requirements addressed in the Procedure Manual for Laboratory Biosafety and Biosecurity / Vector Protection / Biobanks; National procedures and checklists. The facility also meets the needs of the client, and conforms to regulatory requirements, such as the Veterinary and Para Veterinary Professions Act (no 19 of 1982); Animal Diseases Act (Act 35 of 1984); Health and Safety Act (Act 85 of 1993); etc.
Decontamination	A process to remove contamination. Decontamination renders an area, device, item or material safe to handle, that is, reasonably free from a risk of disease transmission.
Laboratory Protocols, Work Instructions or SOPs	▪ Detailed descriptions of how to perform and record tasks. ▪ SOPs may be detailed written descriptions, flowcharts, templates, models, technical notes incorporated into drawings, specifications, equipment instruction manuals, pictures, videos, checklists, or combinations thereof. ▪ SOPs should describe any materials, equipment and documentation to be used. When relevant, SOPs should include acceptance criteria.
Non-Conformance (NC)	When specific requirements are not met.
OIE	The OIE is an intergovernmental organization coordinating, supporting and promoting animal disease control. It is the World Trade Organisation (WTO) reference organisation for standards relating to animal health and zoonoses.
Quality Assurance	Part of quality management focused on providing confidence that quality requirements will be fulfilled.

Quality Management System	A management system to direct and control the laboratory with regard to quality.
Sterilisation	An act or process, physical or chemical, that destroys or eliminates all forms of life, especially microorganisms. The definition is categorical and absolute – an item is either sterile or it is not.

5. RELEVANT DOCUMENTATION

Relevant documentation is available on the DAFF website (http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Animal-Health/Epidemiology).

FORM: QRF 2018	Questionnaire for a Research Facility
FORM: DAFF BSL 2	Checklist: Biosafety Level BSL 2
FORM: DAFF BSL 3	Checklist: Biosafety Level BSL 3
FORM: AF BSL 3	Checklist: Animal Quarantine (BSL3)
FORM: DAFF BB	Checklist Biobanks
FORM: VPF 2018	Checklist Vector Protected Facility
FORM: RR 2018	Recommendation Report
FORM: AR 2018	Attendance Register

6. APPLICATION PROCESS – BIO-SAFETY LEVEL

6.1 Application Process:

- Complete the relevant application form (Application for DAFF Approval of Veterinary Laboratories for Testing of Controlled / Notifiable Animal Diseases) **OR**;
- supply a copy of the submitted Application for Permission Under Section 20 of the Animal Diseases Act, 1984 (Act No.35 of 1984) to Perform Research / Study.
- Submit the application forms (contact details are on the forms).

6.2 Application Process – DAH

- An audit inspection will be scheduled with the facility.
- If all DAFF requirements have been met and all findings satisfactorily cleared, a Certificate of compliance or a recommendation report will be issued.

- Certificates and recommendation reports are valid for two (2) years from date of issue.
- Any changes in the status of the facility or pathogens / vectors involved shall be communicated to DAH.
- Temporary suspension of compliance or follow-up audit inspections may subsequently be required.
- The Directorate Animal Health retains the right to conduct unscheduled audit inspections.

7. OBJECTIVES OF THIS PROCEDURE

The objectives of this procedure are to ensure that research facilities; biobanks and vector protected facilities comply with DAFF requirements.

Laboratories and research facilities that comply with DAFF requirements shall be audited / inspected on every two years or upon request in order to maintain their DAFF compliance status.

PART II

Biosafety Level 3 (BSL3)

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 (secondary containment by means of facility design).

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 in humans (e.g. Anthrax and tuberculosis) as a result of exposure by the inhalation route. It is also applicable to agents for which the disease has been shown to have a significant impact on the health of domestic animals at the level of a country or a zone taking into account the occurrence and severity of the clinical signs, including direct production losses and mortality and trade consequences (eg. Foot and mouth disease; avian influenza and African swine fever).

In South Africa the Onderstepoort Veterinary Research Transboundary Animal Diseases Programme is the only DAFF approved laboratory allowed to handle diagnostics and research for foot and mouth disease and African swine fever.

An acceptable level of safety for the conduction of routine procedures, (e.g., diagnostic procedures involving the propagation of an agent (e.g. zoonotic agents) 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

Critical biological agents

Category A includes organisms that pose the highest risk. These can be easily disseminated or transmitted person-to-person, cause high mortality (i.e., death) with potential for major public health impact, and require special action for public health preparedness.

- *Bacillus anthracis* (anthrax)

- *Yersinia pestis* (plague)
- Clostridium *botulinum* toxin (botulism)
- *Francisella tularensis* (tularaemia)
- Filoviruses (Ebola, hemorrhagic fever and Marburg fever)

Category B includes microorganisms that are moderately easy to disseminate, have moderate morbidity (i.e., ability to cause disease) and low mortality, but require enhanced disease surveillance.

- *Coxiella burnetti* (Q fever)
- *Brucella* spp. (brucellosis)
- *Burkholderia mallei* (glanders)
- Alphaviruses (Venezuelan encephalomyelitis and eastern and western equine encephalomyelitis)
- Ricin toxin (castor beans)
- Epsilon toxin (from *Clostridium perfringens*)
- *Staphylococcus* enterotoxin B

A **subset of Category B** includes the food- and water-borne pathogens:

- *Salmonella* species
- Shigella dysenteriae
- Escherichia coli O 157:H7
- Vibrio cholera
- Cryptosporidium parvum

Category C, includes emerging pathogens that could be engineered for mass dissemination because of availability, ease of production and dissemination, and the potential for high morbidity and mortality and consequent major health impact

- *Nipah* virus
- Hantaviruses
- Tick-borne hemorrhagic fever viruses
- Tick-borne encephalitis viruses
- Yellow fever
- Multi-drug resistant Mycobacterium tuberculosis

Any propagation of controlled and notifiable or exotic pathogens needs to be conducted in a BSL3 facility, except where the Director gives permission to perform this in a BSL2+.

A checklist is available (http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Animal-Health/Epidemiology), indicating the points looked at during an inspection.

Biosafety Level 2+ (BSL2+)

A biosafety level that results from adoption of certain BSL 3 practices and procedures by a BSL 2 laboratory. The practices and procedures adopted depend on the pathogen handled in the facility. This is not appropriate for pathogens that are infectious via the inhalation route or for animal facilities. BSL 2+ status will only be granted after consideration by the Director. For example, Brucella or TB propagation could be approved by the Director Animal Health to be conducted in a BSL2+.

No shower-out is required, but full PPE must be available and used.

BSL2+ facilities usually consist of one room.

Biosafety Level 2 (BSL2)

This is a normal Veterinary Laboratory where diagnostic work is done. Examples are diagnostic work were no propagation of the agents is involved (e.g. serological tests, general bacteriology, parasitology, PCR,).

All the relevant conditions as stipulated in the Procedure Manual and accompanying checklists apply.

Biosafety Level 1 (BSL1)

This biosafety level is not suitable for research or diagnostic laboratory activities.

REFERENCES

1. Procedure Manual: DAFF Approval of Veterinary Laboratories. March 2018
2. Office International Des Epizooties (OIE) Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases. Latest edition.
3. The World Organisation for Animal Health (OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. Latest edition.
4. ISO/IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories. Latest edition.
5. ISO 8402. Quality Management and Quality Assurance – Vocabulary. 1994.
6. Guidelines for the Evaluation of Veterinary Services. OIE Terrestrial Animal Health Code 2013.
7. Academy of Science of South Africa (ASSAf). The State of Biosafety and Biosecurity in South Africa. 2015.
8. AGSecure Africa Programme: Biosafety and Biosecurity in the Laboratory – Instructor Manual
9. VPN/47/2014-01: Standard for the registration of vector-protected equine quarantine facility for export

Approved by:

DAH _____ Date 2018 -07- 19

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LIST OF CONTROLLED AND NOTIFIABLE ANIMAL DISEASES IN TERMS OF THE ANIMAL DISEASES ACT, 1984 (ACT NO 35 OF 1984)

Controlled Animal Diseases

- Any animal disease or infectious agent that is not known to occur in South Africa
- African horse sickness (AHS)
- African swine fever (ASF)
- Anthrax
- Aujeszky's disease
- Bacterial kidney disease (in fish)
- Bovine contagious pleuropneumonia (CBPP)
- Bovine spongiform encephalopathy (BSE)
- Brucellosis (in all animal species)
- Classical swine fever (CSF)
- Contagious equine metritis (CEM)
- Contagious haemopoeitic necrosis (in fish)
- Contaglous pancreatic necrosis (in fish)
- Corridor or Buffalo disease (Theilerioses)
- Dourine
- East Coast fever
- Equine infectious anaemia (EIA)
- Equine influenza (EI)
- Equine viral arteritis (EVA)
- Foot and mouth disease (FMD)
- Glanders
- Haemorrhagic septicaemia (in fish)
- Johne's disease (in sheep, cattle and goats)
- Koi herpes virus disease
- Nagana (Trypanosomiasis)
- Newcastle disease
- Notifiable avian influenza (NAI)
- Porcine reproductive and respiratory syndrome (PRRS)
- Psittacosis
- Rabies
- Rinderpest
- Salmonella Enteriditis
- Salmonella Gallinarum (Fowl typhoid)
- Salmonella Pullorum (Bacillary white diarrhoea)
- Scrapie
- Sheep scab
- Skin conditions in sheep
- Swine vesicular disease
- Tuberculosis (in all animal species)

Notifiable Animal Diseases

- Bovine malignant catarrhal fever (Snotsiekte)
- Bluetongue
- Lumpy skin disease
- Rift Valley fever
- Strangles
- Swine erysipelas

Maja.

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Date: 2016 -02- 22