	DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES **DIRECTORATE ANIMAL HEALTH** **EPIDEMIOLOGY**
	PROCEDURE MANUAL: **DAFF APPROVAL OF VETERINARY LABORATORIES**
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APPROVED BY:	**Director Animal Health**
APPROVAL DATE:	
EFFECTIVE DATE:	

*This document replaces DAFF 001 Edition 10; DAFF 002 Edition 11; DAFF 006 Edition 10; as well as the first Procedure Manual for DAFF approval of laboratories approved in August 2015)

PART I

1. LEGISLATION

The Animal Diseases Act, 1984 (Act No. 35 of 1984) and Regulations promulgated thereunder.

2. HISTORY

Concern about discrepancies in laboratory standards was raised and actively discussed since 2003. A task group was formed to address the problem. The group consisted of representatives from the then Department of Agriculture, now known as the Department of Agriculture, Forestry and Fisheries (DAFF) and para-statal, provincial, private and tertiary institution laboratories.

The ultimate goal was to raise the standard of all the laboratories involved in diagnostics for controlled and notifiable diseases and to enable the laboratories to obtain South African National Accreditation System (SANAS) accreditation based on the South African National Standard: General requirements for the competence of testing and calibration laboratories also known as ISO/IEC 17025 (latest version).

The first round of audits commenced in 2008 and continued on a biennial basis. At the end of 2014 a total of 43/66 (65%) veterinary laboratories have been DAFF approved. This includes 16/24 (67%) government laboratories, 6/9 (67%) para-statal laboratories, 9/9 (100%) tertiary laboratories and 12/24 (50%) private laboratories.

In 2009, the legal basis for the DAFF approval system was clarified by the insertion of Regulation 12B into the Animal Diseases Regulation promulgated in terms of the Animal Diseases Act, No. 35 of 1984. Regulation 12B pertains to the 'Registration for Diagnostic Testing for Controlled and Notifiable Animal Diseases' (see Annexure B).

The DAFF approval programme as known would be used as intermediate step to get laboratories on the same level and ready for SANAS accreditation. It was never the intention to run the programme in parallel with SANAS. SANAS is the only national body responsible for accreditation in South Africa.

After discussions at a MinTech Veterinary Working Group meeting in July 2014 consensus was reached that SANAS accreditation will be implemented and compulsory for laboratories testing for controlled and notifiable diseases. In August 2014 a letter to the effect was sent out to the relevant Directors and laboratories. The routine DAFF approval programme was terminated at the end of 2014.

It is a requirement of the World Organisation for Animal Health (OIE) and the European Union (EU) that laboratories are approved by the government Veterinary Services authorities. In South Africa the national and provincial Veterinary Services authorities are represented by DAFF. Therefore DAFF will still visit laboratories and facilities for bio-safety and bio-security.

DAFF approval for laboratories will be implemented according to the following structure:

- A prerequisite for DAFF approval will be that methods for the relevant controlled and notifiable diseases will have to be accredited by SANAS;
- Laboratories in the process of applying for SANAS accreditation of methods must apply to DAFF for a dispensation to be allowed to purchase reagents for method validation;
- Once SANAS accreditation is in place DAFF will visit the laboratory and inspect the following
  - Bio-safety and bio-security aspects of the laboratory;
  - Methods utilised for testing;
  - Method validation (fit for purpose to DAFF);
  - Reagents used;
  - Reporting system;
- A certificate of DAFF approval will subsequently be issued to the laboratory if all requirements have been met. A schedule indicating the test methods for which DAFF approval was granted will accompany the certificate. The certificate will be valid for two years with an expiry date indicated on the certificate.
- Laboratories seeking extension of scope need to apply to DAFF and methods must first be accredited by SANAS.
- Laboratories seeking re- approval will need to apply and confirm the date and schedule for the audit. It is the responsibility of the laboratory to ensure that the approval does not lapse.

3. PRINCIPLE

This system will enable the Directorate to approve laboratories doing tests for controlled and notifiable animal diseases as well as monitor the bio-safety and bio-security level of laboratories.

It is the responsibility of the laboratory to carry out its activities in such a way as to meet these minimum requirements, the needs of the client, and to comply with regulatory requirements, e.g. Veterinary and Para Veterinary Professions Act (no. 19 of 1982), Animal Diseases Act (Act 35 of 1984), Occupational Health and Safety Act (Act 85 of 1993), the National Road Traffic Act (Act No. 93 of 1996) etc.

The aim is to promote implementation of internationally recognised quality standards in laboratories and facilities, resulting in subsequent approval and/ or compliance by DAFF.

This will ensure national and international confidence in the quality of test results from such laboratories.

The audit team at DAFF shall be responsible for coordination of all the activities involved in the operation of the DAFF Approved Veterinary Laboratories program. The team shall operate in collaboration with the Deputy Director: Epidemiology. The approval and withdrawal of approval shall be the decision of the Director: Animal Health, in conjunction with the recommendations from the Deputy Director: Epidemiology and the audit team.

4. PURPOSE AND SCOPE

The purpose as set out in this document is to provide general requirements that a laboratory shall meet if it is to be recognised, as competent by DAFF, to perform tests for controlled and notifiable animal diseases; a facility to meet bio-safety and bio-security requirements to work with specific pathogens; and for import / export purposes.

The Directorate Animal Health cannot accept results for controlled and notifiable diseases from laboratories that are not SANAS accredited for the particular test method, and DAFF approved. In the case of laboratories performing specific tests where no alternative testing is available, special dispensation may be granted by the Director: Animal Health to perform these tests without SANAS accreditation status. It must be noted that the validation of the test methods will be evaluated and the test(s) must be fit for purpose according to DAFF requirements.

A certificate of approval will be issued and will be valid for two years.

Laboratories handling certain pathogens will be inspected to ensure compliance with bio-safety and bio-security requirements.

5. ABBREVIATIONS AND / OR DEFINITIONS

IEC	International Electrochemical Commission
ISO	International Organisation for Standardization
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
SANAS	South African National Accreditation System.
SOP	Standard Operating Procedure
BSL	Bio-Safety Level
Accreditation	Defined as a procedure by which an authoritative body gives formal recognition that a laboratory is competent to carry out specific tasks or tests.
Accredited Laboratory	A Laboratory that was found to be competent in the performance of their scope of activities, according to ISO/IEC 17025 and SANAS regulatory requirements.
Audit	The process whereby a quality system and bio-safety are audited against a standard i.e.. ISO/IEC 17025 and 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 Approval	As set out in the Procedure Manual for DAFF Approval of Veterinary Laboratories and Regulatory requirements (Acts and Codes) and relevant checklists.
DAFF Approved Laboratory	A Laboratory that performs its activities in such a way as to meet the requirements addressed in ISO/IEC 17025; Procedure Manual for DAFF Approval of Veterinary Laboratories; National procedures and checklists. The laboratory 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.

DAFF Auditor	Person appointed by DAFF with the necessary expertise to perform audits according to a set of requirements.
Extension of Scope	Addition of methods to current schedule.
Inter-laboratory comparisons	Performance and evaluation of tests on the same or similar test samples by two or more Laboratories in accordance with determined conditions.
ISO/IEC 17025	Document that contains all the requirements that veterinary laboratories have to meet if they wish to demonstrate that they operate a quality management system, are competent, and able to generate technically valid results.
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
OIE Reference Laboratories	Laboratories recognized by the OIE as Reference Laboratories for specific diseases. These Laboratories have been designated by the OIE as centres of excellence with expertise in their particular field.
Proficiency Testing	Determination of a Laboratory's testing performance by means of partaking in a formal Proficiency Testing Scheme.
Proficiency Testing Scheme	Proficiency testing schemes are based on defined sets of highly characterized test materials which are sometimes referred to as sample panels. These panels are simultaneously sent to participating laboratories for testing. The results are collected and analysed against the intended result in order to determine the capability of a participating laboratory to conduct a diagnostic test and produce correct results.
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.

Reference Laboratory	Laboratory of recognised scientific and diagnostic expertise for a particular animal disease or testing methodology; includes capability for characterising and assigning values to reference reagents and samples.
Validation	Is a process that determines the fitness for purpose of an assay, which has been properly developed, optimised and standardised, for an intended use.

6. 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: DA 2018	Checklist: DAFF approval
FORM: RR 2018	Recommendation Report
FORM: A 2018	Attendance Register

7. PROCEDURE

7.1 Application Process – Laboratory approval / extension of scope/ re - approval:

- Establish whether the Laboratory complies with the requirements for DAFF Approval.
- Complete the relevant application form (Annexure D) for DAFF Approval.
- Submit the application form (contact details are on the form) and attach the SANAS accreditation schedule.

7.2 Application Process – DAH

- Upon receipt of application form, an audit will be scheduled with the Laboratory.
- If all DAFF requirements have been met and all findings satisfactorily cleared, a Certificate of Approval will be issued.
- Certificates are valid for two (2) years from date of issue.
- Any changes in the status of the Laboratory shall be communicated to DAH.
- Temporary suspension of test methods or follow-up audits may subsequently be required.
- The Directorate Animal Health retains the right to conduct unscheduled audits.

8. OBJECTIVES OF THIS PROCEDURE

The objectives of the requirements of this procedure are to ensure:

- compliance with international standards to ensure confidence in test results;
- contributing to the improvement of animal health and disease surveillance in South Africa;
- that laboratories performing tests for controlled and notifiable diseases, can independently demonstrate their competence and be recognised by DAFF as approved laboratories;
- International trade confidence.

Laboratories that comply with DAFF requirements shall be audited every two years in order to maintain their DAFF approval status. It is the responsibility of the laboratory to schedule the audit for re-approval.

PART II

9. LABORATORY

The laboratory shall have:

- adequate funding for operation;
- safety, security, as well as emergency procedures;
- personal protective equipment (PPE) for use by personnel;
- fire extinguishing equipment that meets the requirements of local authorities;
- adequate space for performing tests and for storage;
- adequate equipment and space for refrigeration and freezing of samples waiting to be analysed;
- adequate lighting;
- appropriate and dependable environmental control, monitoring and records (where applicable), e.g. adequate and/or appropriate controlled ventilation, temperature as required;
- electrical power supply and an alternative (emergency) power supply;
- effective separation between incompatible activities (e.g. between administration and sample reception);
- good housekeeping;
- waste management (storage and disposal);
- appropriate storage and archiving of documents; and
- quarantine procedures when required.

10. PERSONNEL

NOTE: the Occupational Health & Safety Act (85 of 1993) and all amendments and Regulations include all statutory aspects of safety to which all laboratories must conform.

The Laboratory shall have the following available for staff:

- defined and appropriate organisational structure and responsibilities;
- sufficient number of permanent and temporary staff to do the work;
- appropriate education, experience, training to do the work to the required standard and where applicable, the appropriate scientific, technical and managerial credentials (including veterinary specialist qualifications);
- current Job descriptions, training and competence records with effective dates and signatures;
- ongoing training for all staff (including temporary staff) to maintain expertise and to learn new processes;
- professional and technical staff must be registered with / authorised by the South African Veterinary Council and the registration must be up to date;
- Changes in personnel shall be reported to DAFF.

11. EQUIPMENT

- The Laboratory shall be furnished with appropriate equipment and all related items for the correct performance of the tests.
- Equipment shall be operated by competent and authorised personnel.
- Up-to-date instructions for the use shall be readily available to the appropriate laboratory personnel.
- Equipment shall be calibrated / serviced according to a schedule

- Interim checks must be in place where applicable.
- Each item of equipment shall be uniquely identified and records of each item of equipment shall be maintained.
- Verification / Calibration programs shall be established for key equipment where these properties have a significant effect on the results.
- Calibration of equipment shall be performed by competent and approved service providers at a frequency dependent upon the pathogens being handled.
- Verifications shall be performed according to a defined procedure.
- Equipment that has been damaged, or has been shown to malfunction, shall be removed from service and clearly labelled, until it has been repaired and shown to perform correctly.

12. SAMPLES

The laboratory/ facility shall have procedures for recording relevant data and operations relating to samples received and sample identification. These records shall include receipt, sample registration, handling, safeguarding and storage of samples.

Submission forms must be completed to capture vital information. Refer to the letter (Annex C) dated 17-10-2016 from the Director Animal Health regarding reporting of test results for controlled and notifiable disease as stipulated in the Animal Diseases Act, 1984 (Act No 35 of 1984).

Bio-safety and bio-security for the handling of potentially infected samples and disposal methods shall be addressed (e.g. work in Biosafety Cabinet Class II).

13. TEST METHODS

Selection of test methods shall be according to the intended use and based on the following factors:

- reference to a recognised source;
- scientific acceptance;
- performance characteristics (e.g. sensitivity, specificity, limit of detection) and precision (repeatability, reproducibility and accuracy);
- species dependence and sample size;
- performance time/ turn- around time;
- type of sample required (serum, tissue, etc.) and sample quality;
- resources and technology required in the laboratory/ facility to perform a test method;
- nature of the intended use (export, import, domestic control, field screening, confirmatory, etc.);
- client requirements and/or specifications;
- safety precautions;
- availability of reference standards, including access to reference materials;
- National reference methods (harmonised SOPs); and
- where specific test methods are prescribed by the Director Animal Health, verification will be done.

14. VALIDATION

Validation shall be done to ensure "*fit for purpose*" according to OIE requirements (The OIE Terrestrial Manual Chapter 1.1.6 *Principles and Methods of Validation of Diagnostic Assays for Infectious Diseases)* and may include, but not be limited to, the following:

- Sample numbers;
- comparison with other methods, reference methods or methods approved by International bodies (OIE);
- comparison with reference standards (if available);
- determining performance characteristics (e.g. diagnostic sensitivity, diagnostic specificity; limit of detection etc.);
- Proficiency testing or inter laboratory comparisons (using reference samples with known values) with SANAS Accredited / DAFF Approved Laboratories;
- "experimental challenge" studies.

15. VALIDITY OF RESULTS

Laboratories are required to demonstrate validity of results, by the following:

- inter laboratory comparisons; and/or
- "formal" Proficiency Testing Program
- The use of certified reference material
- The use of Nationally prescribed reagents and controls where applicable.

16. DATA CONTROL AND RECORDS

The Laboratory shall ensure:

- the appropriate procedures are in place to ensure test data and reports are secure, retrievable and appropriately used by authorized personnel;
- confidentiality is maintained;
- computers and automated equipment are maintained to ensure proper functioning and operating conditions to maintain the integrity of test data; and
- records, raw data and applicable documents are archived for a period of five (5) years, as required by the Veterinary and Para-Veterinary Act.

17. REPORTS

Reports to clients shall contain the minimum information as described in the letter dated 17-10-2016 from the Director Animal Health regarding reporting of test results for controlled and notifiable disease as stipulated in the Animal Diseases Act, 1984 (Act No 35 of 1984). Refer to Annex C.

Reporting of controlled and notifiable animal diseases to the State Veterinarian is compulsory.

18. OIE REFERENCE LABORATORIES IN SOUTH AFRICA

Laboratories approved by the OIE as reference Laboratories are required to comply with the OIE Standard and National requirements.

REFERENCES

SANS 17025:2005; ISO/IEC 17025:2005 ED 2. General Requirements for the Competence of Testing and Calibration Laboratories. 2005.

ISO 8402. Quality Management and Quality Assurance – Vocabulary. 1994.

OIE Terrestrial Manual – Internet version.

Approved by:

DAH _____ Date 07/08/18

agriculture,
forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

Private Bag X138, Pretoria, 0001

Delpen Building, c/o Annie Botha & Union Street, Riviera, 0084

From: Directorate Animal Health

Tel: +27 12 319 7456

Fax: +27 12 329 7218

E-mail: SandraDAC@daff.gov.za

Enquiries: Dr Mpho Maja

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)
- Contagious 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

Mmaja.

Dr Mpho Maja

DIRECTOR OF ANIMAL HEALTH

Date: 2016-02-22

ANNEXURE B

GOVERNMENT NOTICES
GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF AGRICULTURE
DEPARTEMENT VAN LANDBOU

No. R. 527 **15 May 2009**

ANIMAL DISEASES ACT, 1984
(ACT No. 35 OF 1984)

REGULATIONS: AMENDMENT

The Minister of Agriculture has under Section 31 of the Animal Diseases Act, 1984 (Act No. 35 of 1984), made the regulations in the Schedule.

SCHEDULE

Definitions

1 In this Schedule "the Regulations" means the regulations published by Government Notice No. R. 2026 of 26 September 1986, as amended by Government Notices Nos. R. 2208 of 24 October 1986, R. 266 of 13 February 1987, R. 2343 of 16 October 1987, R. 884 of 5 May 1988 (as corrected by Government Notice No. R. 1043 of 3 June 1988), R. 394 of 1 March 1991 (as corrected by Government Notice No. R. 931 of 3 May 1991), R. 2358 of 10 December 1993, R. 1023 of 27 May 1994, R. 254 of 6 February 1997, R. 1136 of 11 September 1998, R. 361 of 7 April 2000, R. 443 of 25 May 2001, R. 885 of 21 September 2001 (as corrected by Government Notice No. R. 1386 of 21 December 2001), R. 162 of 24 February 2006, R. 163 of 24 February 2006, R. 864 of 1 September 2006 (as corrected by Government Notice No. R. 1059 of 27 October 2006), R. 204 of 16 March 2007, R. 371 of 26 April 2007 and R. 543 of 6 July 2007.

Amendment of regulation 12 of the Regulations

2. Regulation 12 is hereby amended by the insertion of Regulation 12B.

Registration for diagnostic testing for controlled and notifiable animal diseases

12B (1) A person or a laboratory that does diagnostic testing or screening for a controlled animal disease or a notifiable animal disease in any animal species, shall be registered with the director.

(2) A veterinarian, person or a laboratory that does diagnostic testing or screening for a controlled animal disease or a notifiable animal disease, shall comply with the prescriptions for the diagnostic testing or screening for a controlled animal disease or a notifiable animal disease as prescribed by the director.

(3) A veterinarian, person or a laboratory that does diagnostic testing or screening for a controlled animal disease or a notifiable animal disease, shall report on all the diagnostic testing or screening for such animal diseases and the results thereof in the format as prescribed by the director.

(4) A person producing, distributing and or importing any reagents or kits for the diagnostic testing or screening of controlled animal diseases or notifiable animal diseases, shall be registered with the director and shall comply with the standards and the reporting procedures as prescribed by the director.

Lulama Xingwana

Minister of Agriculture

agriculture,
forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

Directorate Animal Health, Department of Agriculture, Forestry and Fisheries
Private Bag X138, Pretoria 0001

Enquiries: Dr Grietjie de Klerk • Tel: +27 12 319 7412 • Fax: +27 12 319 7470 •
E-mail: Epidemiology@daff.gov.za

To all Laboratory Managers

RE: Reporting of Test Results for Controlled and Notifiable disease as stipulated in the Animal diseases Act 1984 (Act 35 of 1984)

Dear Colleagues,

The purpose of this letter is to clarify the confusion regarding the requirements for reporting of **controlled and notifiable diseases** in the Animal Diseases Act 1984 (Act 35 of 1984) and stipulated in Regulation 12B under the Act:

> *12B A veterinarian, person or a laboratory that does diagnostic testing or screening for a controlled animal disease or a notifiable animal disease, shall report on all the diagnostic testing or screening for such animal diseases and the results thereof in the format as prescribed by the director.*

1. Reporting structure of results

In order to simplify matters, samples will be classified as follows:

1. Samples paid for by the government (Department of Agriculture, Forestry and Fisheries or Provincial Government): These test results will be reported only to the relevant state veterinarian.
2. Samples sent in and paid for by a private veterinarian or another laboratory: Results will be sent simultaneously to the state veterinarian and the private veterinarian or laboratory.

2. Reporting format for results

All samples have to be accompanied by a fully completed laboratory submission form. The information is crucial for immediate follow-up action in case of positive results or as epidemiological background in case of negative results.

The result sheet should also contain basic information to allow for proper analysis of the information. The minimum information that is considered crucial and has to be included on the submission form and the result sheet is as follows:

- Name and contact details of sender
- Name and contact details of owner and/or manager of the animal(s)
- State Veterinarian
- Origin of sample: Farm or village name
- Location of the farm/village (preferably the coordinate but if not available, the name of the nearest town or village)
- Species sampled
- Purpose of sampling
- Sample type
- Date of sample collection
- Date of sample registration at laboratory
- Test requested and test performed
- Test method
- Date of the test result
- Test result

3. Requirements for complete information

The requirements for the reporting of results for controlled and notifiable diseases will be communicated to SANAS and will be included in the scope of their audits. Compliance will also be verified during DAFF approval audits.

The above requirements will be implemented as from 1 January 2017. Please inform all clients of the requirements and the set cut-off date for full compliance. After 1 January 2017, no test results may be made available if the required information has not been submitted to the laboratory. Urgent requests for tests for which the laboratory is unable to obtain the required information should be communicated to DAFF

For enquiries please sent an e-mail to Epidemiology@daff.gov.za or contact Dr Grietjie de Klerk at 012-319 7412.

Kind regards

Dr Mpho Maja
DIRECTOR OF ANIMAL HEALTH
Date: 2016 -10- 17

ANNEXURE D

APPLICATION FOR DAFF APPROVAL OF VETERINARY LABORATORIES FOR TESTING OF CONTROLLED/NOTIFIABLE ANIMAL DISEASES	
DATE OF APPLICATION	

PART 1: GENERAL ***This form should be completed in CLEAR PRINT or in type and returned:***

This form should be completed in CLEAR PRINT or in type and returned to:
Dr Julie-Anne Koch / Ms Keneilwe Raseleka / Ms Riette Theron
Tel: 012 319 7453/ 012 319 7636 / 012 319 7498
Fax: 012 319 7470
E-mail: Julie-AnneK@daff.gov.za / KeneilweR@daff.gov.za / RietteT@daff.gov.za
Courier Address: Delpen Building Room G70, c/o Annie Botha and Union Street, Riviera, 0001

Please complete ALL the applicable sections of the form. Please ensure that you are familiar with the instructions for completing this form before proceeding any further. DAH does not accept responsibility for confidentiality of information or for receipt of applications submitted electronically.

Note 1: If you do not receive acknowledgement of receipt of this form within 2 weeks of dispatch, you should contact the office.
Note 2: Audits will be scheduled according available dates.

Laboratory			
Contact Person		Title	
Position			
Physical Address			
	Tel		
Postal Address			
	Fax		
	E-mail		
	Cell		

LIST OF CONTROLLED/NOTIFIABLE DISEASES FOR WHICH APPROVAL IS SOUGHT					
African Horse Sickness		African Swine Fever		Anthrax	
Any disease in cloven-hoofed animals with vesicular symptoms		Any skin condition in sheep showing crusts & itching		Avian Influenza	
Blue Tongue		Bovine Contagious Pleuropneumonia (Lung sickness)		Bovine Spongiform Encephalopathy	
Brucellosis		Classical Swine Fever (European swine fever, Hog cholera)		Contagious Equine Metritis	
Corridor / Buffalo Disease		Dourine		East Coast Fever	
Equine Infectious Anaemia		Equine Viral Arteritis		Foot and Mouth Disease	

Psittacosis		Johne's Disease		Lumpy Skin Disease	
Nagana		Newcastle Disease		Rabies	
Rift Valley Fever		Rinderpest		Salmonella enteritidis	
Scrapie		Sheep Scab		Swine Vesicular Disease	
Tuberculosis		Other *(specify)*:			
Other *(specify)*:					
SECTIONS FOR WHICH APPROVAL IS SOUGHT					
Chemical Analysis		Haematology		Histopathology	
Microbiology		PCR		Protozoology	
Parasitology		Pathology		Reproduction	
Serology		Toxicology		Virology	
Other *(specify)*:					

TEST METHODS FOR WHICH APPROVAL IS SOUGHT	

PART 2: INFORMATION REGARDING YOUR LABORATORY			
Government ☐	Parastatal ☐	Private ☐	Tertiary Institution ☐
Attach an organogram indicating the structure of the areas to be approved and their relation to the rest of the laboratory and/or organisation. ☐			
Laboratories			
Please provide the SANAS accreditation number			
Have the methods been validated according to DAFF requirements?			
In which Proficiency Testing schemes or Inter Laboratory Comparisons do you participate?			
Scheme	For which test methods?	How often?	

ANNEXURE E

APPLICATION FOR RE – APPROVAL / EXTENSION OF SCOPE OF DAFF APPROVED LABORATORIES	
DATE OF APPLICATION:	
DAFF NO:	

This form should be completed in CLEAR PRINT or in type and returned to:
Dr Julie-Anne Koch / Ms Keneilwe Raseleka / Ms Riette Theron
Tel: 012 319 7453/ 012 319 7636 / 012 319 7498
Fax: 012 319 7470
E-mail: Julie-AnneK@daff.gov.za / KeneilweR@daff.gov.za / RietteT@daff.gov.za
Courier Address: Delpen Building Room G70, c/o Annie Botha and Union Street, Riviera, 0001

Note 1: If you do not receive acknowledgement of receipt of this form within 2 weeks of dispatch, you should contact the office.
Note 2: Audits will be scheduled according available dates.

Laboratory			
Contact Person		Title	
Tel			
Fax			
E-mail			

TEST METHODS TO BE ADDED TO THE SCHEDULE (VALIDATION DATA MUST BE ATTACHED.	~~VALIDATION DATA~~ ~~(yes/no)~~	PT/ ILC provider

Note: for re-approval ongoing validation data must be provided, for extension of scope original data demonstrating fitness for purpose according to DAFF requirements is needed).

TEST METHODS TO BE REMOVED FROM THE SCHEDULE

Signed:	
Name:	
Position:	
Date:	

Approved by:

DAH _____ Date _____

PART 3: DECLARATION *Documentation to be submitted prior to approval as follows:*	
Complete all parts of the application form	☐
Information on participating in Proficiency Testing or Inter Laboratory Comparison	☐
Procedure for validation of methods	☐
Upon approval the Laboratory agrees to comply with the DAFF Approved Laboratories requirements. I declare the information given in this application is correct to the best of my knowledge and belief. I undertake to inform DAH immediately of any changes with respect to the approval.	

Signed:	
Name:	
Position:	
Date:	