



agriculture,
forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

**VETERINARY DIAGNOSTIC LABORATORIES: STRATEGIC
IMPLEMENTATION PLAN TO THE SOUTH AFRICAN
VETERINARY STRATEGY**

DRAFT



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PART I

DEFINITIONS

Approved laboratory

A private, government, parastatal and tertiary laboratory approved by the Director of Laboratory services under the designation of the National Executive Officer (NEO) (Meat Safety Act, 2000) and/or Director of Animal Health (DAH) to carry out analyses of samples taken from facilities and designated animal species.

Designated official laboratory

A private, government, parastatal and tertiary laboratory designated by the Director of Laboratory services to carry out analyses of samples for regulatory controls.

Prescribed Laboratory methods

Listed laboratory methods complying with the requirements of the Accreditation for conformity assessment, calibration and good laboratory practice Act, 2006 (Act No 19 of 2006) and used to detect and monitor presence of specified substances (physical, chemical and microbiological) in animals, environment, meat and animal products.

Prescribed Laboratory facilities

Means any registered specialised confined environment used for the performance of scientific work, including laboratories involved in testing work in conformance at minimum to the requirements of the Accreditation for conformity assessment, calibration and Good Laboratory practice Act, 2006 (Act No 19 of 2006).

Foodborne pathogen

A biological agent that is associated with serious illness or death when ingested with food or that is resistant to one or more critically important antibiotics for human medicine.

Specified substance

Any biological or chemical agent, foreign matter, or other substance not intentionally added to food that may compromise food safety and or suitability.

Food safety hazard

Biological, chemical or physical agent or condition of food, with the potential to cause an adverse health effect.

Other Definitions

For the purpose of this Laboratory approval program, definitions in the Accreditation to conformity assessment, calibration and good laboratory practice Act, 2006 (Act No 19 of 2006) shall apply.

PART II

1. INTRODUCTION

The Branch Agricultural Production, Health and Food Safety of the Department of Agriculture, Forestry and Fisheries promote productivity and growth in the agricultural sector and facilitate food trade. Adequate laboratory infrastructure is required to support monitoring, surveillance and enforcement activities. This includes adequately equipped animal health and food control laboratories, trained analysts, and the implementation of the Quality Assurance System that meets international standards. To strengthen capacity for animal health and food safety in South Africa, the following eleven priority areas are identified as critical laboratory capacity priorities: Assessing needs of laboratories, Critical Role of Laboratories in National animal health diagnostics and Food Safety Progress, Safety (personnel and laboratory), Quality Assurance/Validation, Lab Accreditation, Analytical Methods, Data Analysis and Interpretation, Sampling, Laboratory, Management, Maintenance and Troubleshooting as well as Metrology.

Approval of laboratories which analyse meat, meat products, abattoir water, environmental samples as well as animal samples for controlled and notifiable diseases and export is therefore of utmost importance. Through the Director Laboratory services, the Directorate of Veterinary Public Health and Directorate of Animal Health require certain testing to be carried out by approved laboratories hence the need to establish a veterinary diagnostic laboratory strategic implementation plan to the Veterinary strategy to ensure that testing laboratories meet high- quality standards. When laboratories analyze samples, it is the responsibility of the regulated establishment/sender- to ensure that testing methodologies and practices meet their needs. Establishments/veterinarians/owners that select a laboratory that does not apply appropriate testing methods or effective Quality Assurance (QA) practices may not receive reliable or useful testing results.

2. LEGISLATION

Meat Safety Act, 2000 (Act No 40 of 2000) and Regulations promulgated there-under (available on the following website: <http://www.daff.gov.za>). Veterinary and Para Veterinary Professions Act, 1982 (Act No 19 of 1982), Animal Diseases Act, 1984 (Act No 35 of 1984), Occupational Health and Safety Act, 1993 (Act No 85 of 1993); Accreditation to conformity assessment, calibration and good laboratory practice of Act, 2006 (Act No 19 of 2006)

3. SCOPE

The veterinary diagnostic laboratory strategic implementation plan to the Veterinary strategy and designation of official laboratories is an integral part of the system that the branch Agricultural Production, Health and Food Safety have in place to enable market access. The program applies to laboratories undertaking microbiological testing of meat and meat products, abattoir water and environmental samples required to ensure public safety as well as testing for diseases to protect national herds and ensure trade

Government, parastatal, tertiary and private labs that meet requirements are eligible to be included on the approved and designated official laboratory lists respectively. Private laboratories must have SANAS accreditation for the test methods used in order to participate. There is no limit on the number of approved/designated laboratories.

PART III

4. APPROVAL OF PRIVATE, PARASTATAL AND TERTIARY LABORATORIES AND DESIGNATION OF OFFICIAL LABORATORIES

- 4.1 The Director Laboratory services shall approve laboratories and designate official laboratories to carry out the laboratory analyses, tests and diagnoses on samples taken during controls and other official activities in the country.
- 4.2 Director Laboratory services may designate a laboratory located in another country as a designated official laboratory subject to compliance with the following conditions:
- (a) acceptable arrangements are in place under which the Director Laboratory services is enabled to perform audits and inspections or delegate the performance of such audits and inspections to the competent authorities of the country where the laboratory is located;
 - (b) the laboratory is already designated as an official laboratory by the competent authorities of the country on whose territory it is located.
- 4.3 The designation/approval shall be in writing and shall include a detailed description of:
- (a) the tasks that the laboratory shall carry out as official laboratory;
 - (b) the conditions under which it shall carry out those tasks;

- (c) the arrangements necessary to ensure efficient and effective coordination and collaboration between the laboratory and the competent authorities.
- 4.4 The Director Laboratory services may only designate or approve a laboratory which:
- (a) has the expertise, equipment and infrastructure required to carry out analyses or tests or diagnoses on samples;
 - (b) has a sufficient number of suitably qualified, trained and experienced staff;
 - (c) is impartial and free from any conflict of interest as regards the exercise of its tasks as official laboratory;
 - (d) can deliver timely the results of the analysis, test or diagnosis carried out on the samples taken during official controls and other official activities;
 - (e) operates in accordance with the standard ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories' and is assessed and accredited in accordance with that standard by the South African National Accreditation system (SANAS).
- 4.5 The scope of the assessment and accreditation of a laboratory at minimum:
- (a) shall include all the methods of laboratory analysis, test or diagnosis required to be used by the laboratory for analyses, tests or diagnoses;
 - (b) may comprise one or more methods of laboratory analysis, test or diagnosis or groups of methods;
- 4.6 Where no approved/designated laboratory in South Africa has the expertise, equipment, infrastructure and staff necessary to perform new or particularly uncommon laboratory analyses, tests or diagnoses, the competent authorities may request a laboratory or diagnostic centre which has not been approved/designated to carry out those analyses, tests and diagnoses, provided all necessary assurances and quality controls for the analyses, tests and diagnoses at hand are in place.

5. OBLIGATIONS OF APPROVED AND DESIGNATED LABORATORIES WITH REGARD TO PUBLIC HEALTH RISKS

Official laboratories shall immediately inform the Director Laboratory services or his/her designate within the stipulated timeframe as in the National Health Act, 2003 (Act No 61 of 2003) as amended where the confirmed results of an analysis, test or diagnosis carried out on samples indicate non-compliance or point to the likelihood of non-compliance.

- 5.1 The laboratory manager of the Laboratory shall be responsible for the following:
- (a) ensure that the staff of the respective units adhere to existing statutory laws, keep an electronic data base of all potential hazards for Category 3 Notifiable Food Safety and Zoonotic Conditions (Annexure A) and;
 - (b) to report laboratory confirmed potential hazards for Category 1 Notifiable Food Safety and Zoonotic Conditions (Annexure A) within 24 hours to the Director Veterinary Laboratory services.
 - (c) to report laboratory confirmed potential hazards for Category 2 Notifiable Food Safety and Zoonotic Conditions (Annexure A) within 7 days the Director Veterinary Laboratory services.
 - (d) to report Category 3 Notifiable Food Safety and Zoonotic Conditions (Annexure A) on a monthly basis to the Director Veterinary Laboratory services .
- 5.2 Upon request by a South Africa Veterinary reference laboratory or national reference laboratory, approved laboratories shall take part in inter-laboratory comparative tests organised for the analyses, tests or diagnoses they perform as official laboratories in addition to formal Proficiency Testing scheme(s).
- 5.3 Any approved/designated laboratory shall keep records for at least 5 years and render returns as may be requested by the Director Laboratory services indicating all analyses done and summary of all specified tests results on a format rendered by the Director Laboratory services.
- 5.4 Approved laboratories must make available to the public the list of methods used for analyses, tests or diagnoses performed in the context of monitoring and verification of regulatory controls and other official activities.
- 5.5 The laboratory's QA system should address how the combination of screening versus confirmation test results are interpreted and reported.

PART IV

6. PROCEDURE FOR APPROVAL AND DESIGNATION OF LABORATORIES

6.1 Application

- (a) A laboratory seeking to be recognised as an approved/designated laboratory must apply by completing the relevant application forms (Annex 1) obtainable from the Director Laboratory services
- (b) All laboratories seeking to be recognised as approved/designated laboratories must make available any documentation requested to verify the testing methods used by the laboratory.
- (c) Application should include:
 - (i) The laboratory's scope of accreditation (if applicable to the relevant testing program)
 - (ii) Details of approved methods that the laboratory intends to use for the testing of samples (with appropriate accreditation documentation if applicable)
 - (iii) Agreement to participate in inter-laboratory and proficiency testing programs
 - (iv) An application form signed by an authorised laboratory representative
- (d) SANAS accreditation for specified methods is a requirement but should a laboratory not be accredited, the Director Laboratory services may approve/designate the laboratory after consultations with regards to extended approval procedures to ensure compliance to ISO 17025 requirements.
- (e) After receipt of application, Director Laboratory services will provide written acknowledgment of application within 30 working days.
- (f) The acknowledgement letter to the applicant must include the process(es) to be taken by the Director Laboratory services with regards to granting the laboratory approval/designation
- (g) An audit of the laboratory by a team selected by the Director Laboratory services must be conducted before the laboratory can be approved. The Director laboratory services may grant approval without conducting an audit if there is sufficient grounds to suggest that the laboratory meets the set standard(s).
- (h) The Director laboratory services must grant the approval in writing and no laboratory must analyse, test or diagnose official samples without written approval.

6.2 Maintaining Approval/designation

- (a) In order to remain an approved/designated laboratory, a laboratory must meet the requirements specified in this document and any other document specified by Director Laboratory services. This includes but is not limited to:

- (i) Maintenance of accreditation for the specified approved methods
- (ii) Annual assessment by Director Laboratory services
- (iii) Participation in proficiency testing as required by Director Laboratory services
- (b) An approved/designated laboratory can identify itself as an approved laboratory for the purpose of testing meat and meat products for export certification/ testing samples for specific diseases
- (c) A laboratory must never state or imply that being an approved/designated laboratory is an endorsement by Director Laboratory services of its performance in relation to testing outside the testing carried out under the Laboratory Approval Program (LAP).
- (d) The laboratory that complies with the stipulated requirements will remain an approved/designated laboratory until it requests to be removed from the list or until such time as the laboratory is removed from the list by Director Laboratory services.
- (e) Any requests by the laboratory to change the conditions or scope of its approval/designated must be made in writing to the Director Laboratory services as appropriate. The Director Laboratory services will then consider changes to the laboratory's scope of approval.
- (f) Approved/designated laboratories must notify Director Laboratory services of any changes in their scope of accreditation or any other changes that may reasonably be expected to impact on the competency of the laboratory in relation to tests carried out as part of LAP.

6.3 Audits and inspections of laboratories

- (a) The Director Laboratory services or his/her designate who is a registered Veterinarian, Laboratory diagnostician, Food Scientist, Laboratory technologist/scientist or related speciality (as approved by SANAS) and registered in the relevant category by a national statutory body must organise audits and or inspections of the approved and designated officially laboratories:
 - (i) on a regular basis;
 - (ii) any time they consider that an audit or inspection is necessary.
- (b) The Director Laboratory services may immediately withdraw the approval/designation of a laboratory, either completely or for certain tasks, where it fails to take appropriate and timely remedial action following the results of an audit or an inspection, , or if the laboratory:
 - (i) no longer complies with the conditions provided for;
 - (ii) does not comply with the obligations provided for;
 - (iii) is underperforming at inter-laboratory comparative tests and or proficiency tests

referred to.

- (c) The audit team must prepare a report after the audit and submit it to the Director Laboratory services within 1 month after the audit.
- (d) If the audit team is of the opinion that a non compliance observed during an audit is of a nature that it poses an imminent and serious risk to the safety of the food intended for sale and requires immediate intervention, such a report must be availed to the Director Laboratory services immediately for appropriate action laboratory.

6.4 Suspension/revocation of approval

- (a) Director Laboratory services will automatically suspend or remove a laboratory from the list of approved laboratories if the laboratory is suspended or de-accredited by SANAS or upon notification for voluntary suspension by the respective laboratory. The laboratory is required to re-apply to the Director Laboratory services as soon as corrective action measures are implemented as per SANAS requirements and as the accreditation status is reinstated.
- (b) Director Laboratory services may suspend or remove a laboratory from the list if it does not meet all the requirements of an approved/designated laboratory.
- (c) Director Laboratory services may suspend or remove a laboratory from the list if it considers that a laboratory is not competent in any aspect of its work that would reasonably be expected to impact on the reliability of test results.

6.5 Procedure for suspension of approval/designation

- (a) On notification from Director Laboratory services of suspension or removal of a laboratory from the list, the laboratory must immediately cease all testing relating to scope of approval and notify relevant customers of its suspension or removal.
- (b) In order for the laboratory to be reinstated as an approved/designated laboratory it must meet all conditions specified by Director Laboratory services in relation to its suspension/removal and re-apply for consideration as an approved/designated laboratory following the procedures set out in this document.

PART V

7.ASSESSMENT AND ACCREDITATION

Laboratories testing meat and meat products, abattoir water, environmental or animal samples for diseases must be accredited by SANAS to undertake such testing and meeting the ISO 17025 standard. Laboratories not accredited by SANAS may also be recognised as approved/designated laboratory to undertake specific testing if they comply with the

requirements set out in ISO 17025 and or subject to other specified requirements. Refer to DAFF Approval documents DAFF 002.

Pathogen testing laboratories should follow at minimum requirements for biosafety Level (BSL) II laboratory operation, restrict access to the laboratory to trained staff and ensure the laboratory is operating under the supervision of a registered diagnostic veterinarian (in case of testing for animal diseases). In some cases, depending on the pathogen, BSL3 and above level is required and the laboratory will be inspected and, if satisfactory, a compliance certificate is issued (DAFF 012-F08)

7.1 Accreditation body

- (a) SANAS is recognised by the South African Government as the single National Accreditation Body that gives formal recognition that Laboratories, Certification Bodies, Inspection Bodies, Proficiency Testing Scheme Providers and Good Laboratory Practice (GLP) test facilities are competent to carry out specific tasks in terms of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act (Act 19 of 2006).
- (b) SANAS accreditation requires laboratories to meet the standard ISO/IEC 17025:2005 “General requirements for the competence of testing and calibration laboratories” .
- (c) Requirements for laboratories that are not accredited by SANAS are according to the standard ISO/IEC 17025:2005.
- (d) LAP requirements include assessment of management systems, quality programs and other technical requirements as maybe specified by the Director Laboratory services.
- (e) Laboratories must maintain their accreditation/approval/designated status and ensure that staff have appropriate qualifications.

7.2 VPH and Animal Health assessments

- (a) Director Laboratory services will undertake assessments of approved laboratories every two years depending on the type of testing involved and SANAS accreditation. Laboratories that do not have SANAS accreditation will be assessed annually. VPH/Animal Health Assessment may be carried out on laboratories where the Director Laboratory services deem it necessary.
- (b) For assessments, a minimum of one month's notice will be given where possible.

- (c) Director Laboratory services assessments may focus on quality systems and approved methods.
- (d) The laboratory must make available, on request by Director Laboratory services, all documents relevant to the laboratory's participation in the LAP, including proficiency testing reports.
- (e) A technical assessor may be appointed by the Director Laboratory services to help with the assessment. In such a case the technical assessor will be provided with such documentation as necessary to perform their task. Only records relevant to the technical assessor's responsibilities are to be provided to the technical assessor.
- (f) Laboratories performing tests for controlled and notifiable diseases will be audited according to ISO 17025 requirements as contained in checklist DAFF 012-F01 and Witness form DAFF 012-F02

7.3 On-site assessment

- (a) On the day of the audit, the schedule of the audit as well as planning of activities, must be discussed at the opening meeting
- (b) An attendance register must be signed (DAFF 012-F07)
- (c) Information on the performance of the laboratory will be collected through interview with staff, examination of documents/records and witnessing of test methods.
- (d) Technical assessors/ Auditors must witness laboratory staff while performing tests for which the laboratory is to be approved/designated.
- (e) Where applicable all signatories for tests included in the assessment are to be available on the day unless otherwise agreed by the Director Laboratory services.
- (d) Where sample collection is part of the laboratory's scope the assessors must review:
 - The procedure for identifying samples for testing, training records and approval for individuals undertaking sample collection, including non-laboratory staff involved in sampling, traceability of samples and cold chain maintenance, e.g., using temperature data loggers.

7.4 Assessors

- (a) The lead assessor (auditor) may be a full time employee of the Department of Agriculture, Forestry and Fisheries and familiar with all the requirements of the LAP.
- (b) Technical assessors (auditors) must have minimum qualifications as specified by SANAS and/or relevant statutory bodies such as South African Veterinary Council (SAVC).

7.5 Assessment (auditing) findings

- (a) Assessment (Audit) findings must be discussed in a closing meeting with the laboratory's authorised representative on the day of the assessment, including reference to all non-conformities and applicable requirements.
- (b) Corrective action requests must be issued and include a time frame in which the laboratory is required to demonstrate that the corrective action has been implemented.
- (c) A non-conformance report (DAFF 012-F03) will be issued to the laboratory as well as a recommendation report that has been signed by the Director Laboratory services (DAFF 012-F04)

7.6 Assessment/audit reports

- (a) A final report will be provided to the laboratory within 7 – 10 working days after the assessment.
- (b) Laboratories must ensure that they:
 - (i) Take the required corrective actions within the agreed time frame
 - (ii) Provide the lead assessor with supporting documentation demonstrating that non conformances have been addressed.
- (c) The Director Laboratory services may extend the time allowed for corrective actions but only under special circumstances where extension has been required with motivation and where he or she is satisfied that progress is being made in implementing corrective actions and that the non-conformance will not impact on the reliability of analytical test results.

7.7 Follow up assessment

- (a) Follow-up on-site assessments may be required to verify the implementation of corrective actions that have arisen as a result of the outcomes of the assessment.
- (b) The time frame for follow-up assessments will be discussed with the laboratory at the time of the assessment.
- (c) Follow-up assessments can be undertaken by the Director Laboratory services either to verify corrective actions or to confirm on-going competency of the laboratory.
- (d) Follow-up assessment reporting will follow the same protocol as outlined in section 6.

7.8 Derogations from the condition for the mandatory assessment and accreditation for certain official laboratories

- (a) By derogation, the Director Laboratory services may approve/designate the following as official laboratories irrespective of whether they fulfil the condition provided for in that point:
- (i) Laboratories whose sole activity is the detection of *Trichinella* in meat;
 - (ii) Laboratories that carry out the detection of *Trichinella* under the supervision of the competent authorities or of a designated official laboratory, assessed and accredited in accordance with the standard EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories' for the use of the methods referred to;
 - (iii) Laboratories which only carry out analyses, tests or diagnoses in the context of other official activities like not controlled animal diseases, provided that they:
 - Carry out the analyses, tests or diagnoses under the supervision of the Director Laboratory services or of the national reference laboratories for the methods used.
 - Participate regularly in the proficiency testing programme(s) organised by the national reference laboratories for the methods they use in addition to participation in formal PT scheme(s) as prescribed by SANAS;
 - Have a quality assurance system in place to ensure sound and reliable results from the methods for laboratory analysis, test and diagnosis used.
- (b) Where the methods used by the laboratories require confirmation of the result of the laboratory analysis, test or diagnosis, the confirmatory laboratory analysis, test or diagnosis shall be carried out by an official accredited laboratory.

7.9 Temporary derogations from the condition for the mandatory assessment and accreditation of official laboratories

- (a) By derogation, the Director Laboratory services may temporarily approve/designate a laboratory for the use of a method of laboratory analysis, test or diagnosis for which it has not obtained SANAS accreditation:
- (i) When the use of that method is newly required in South Africa; or,
 - (ii) When changes to a method in use require a new accreditation or an extension of the scope of the accreditation obtained by the laboratory or,

- (iii) In cases where the need for the use of the method results from an emergency situation or an emerging risk to human, animal or, animal welfare.
- (b) The temporary designation referred to in paragraph (a) shall be subject to the following conditions:
 - (i) The laboratory is already accredited in accordance with the standard EN ISO/IEC 17025 for the use of a method which is similar to the one to be approved/designated for;
 - (ii) A quality assurance system is in place in the official laboratory to ensure sound and reliable results;
 - (iii) The analyses, tests or diagnoses are carried out under the supervision of the Director Laboratory services or another competent authority within the Republic of South Africa or the national reference laboratory.
- (c) The temporary designation provided for, must not exceed a period of one year, and may be renewed once for a further period of one year.

PART VI

8. LABORATORY METHODS AND TESTING

8.1 Sampling

Sample collection is generally outside the scope of approval and/or accreditation of laboratories. However, all approved/designated laboratories must ensure that the condition of samples on arrival at the laboratory is consistent with the requirements of the specific program to which they apply. The laboratory must have a quality assurance system to alert clients where it is suspected that the sampling procedure was not adhered to. The laboratory may not receive and analyse samples that were not aseptically collected.

- (a) Where sample collection is part of the laboratory's accreditation/approval/designation, the laboratory must ensure that it is carried out according to the technical requirements for the programme.
- (b) Laboratories must ensure that sampling carried out for specific programmes is undertaken by trained persons and must keep appropriate training records.

8.2 Approved analysing methods

- (a) Approved methods must be followed without modification, unless such modifications have been agreed to by Director Laboratory services and are under the laboratory's scope of accreditation/approval/designation.
- (b) Any approved/designated laboratory may undertake testing using approved methods if their scope of accreditation/approval includes the specific tests to be used and the method is included in the regular assessments by SANAS and or the Director Laboratory services. Approved laboratories must notify the Director Laboratory services of any changes to approved methods used by the laboratory for testing as part of LAP before implementing the methods.
- (c) A laboratory may "sub-contract" specific aspects of testing, including confirmation of presumptive positive samples, however contract laboratories must be approved laboratories, must be acknowledged on the report of test results and must be instructed to report results to the Director Laboratory services at the same time that they are reported to the contracting laboratory.

8.3 Methods used for sampling, analyses, tests and diagnoses

- (a) Methods used for sampling and for laboratory analyses, tests and diagnoses during regulatory controls and other official activities must comply with South African rules establishing those methods or the performance criteria for those methods.
- (b) In the absence of rules in the Republic of South Africa, laboratories may use methods for their specific analytical, testing and diagnostic needs, taking into account:
 - (i) The most recent available methods complying with relevant internationally recognised rules or protocols, including those that the ISO/SANAS or where applicable the Scientific committee for standardisation has accepted; or,
 - (ii) In the absence of the rules or protocols referred to in point (i), the relevant methods developed or recommended by South African reference laboratories and validated in accordance with internationally accepted scientific protocols; or,
 - (iii) In the absence of the rules or protocols referred to in point (i) and the methods referred to in point (ii), the methods which comply with relevant rules established by other regulatory organs of State within the Republic of South Africa; or,
 - (iv) In the absence of the rules or protocols referred to in point (i), the methods referred to in point (ii) and the national rules referred to in point (iii), the relevant methods developed or recommended by national reference laboratories and validated in accordance with internationally accepted scientific protocols; or,

- (v) in the absence of the rules or protocols referred to in point (i), the methods referred to in point (ii), the national rules referred to in point (iii) and the methods referred to in point (iv), the relevant methods validated in accordance with internationally accepted scientific protocols.
- (c) In the context of screening, targeted screening and of other official activities, any of the methods referred to in paragraph (ii) may be used in the absence of rules referred to in paragraph (i).
- (d) Where laboratory analyses, tests or diagnoses are urgently needed and none of the methods referred to in paragraphs (a) and (b) exists, the relevant national reference laboratory or, if no such national reference laboratory exists, any other laboratory designated may use methods other than those referred to in paragraphs (a) and (b) until the validation of an appropriate method in accordance with internationally accepted scientific protocols.
- (e) Wherever possible, methods used for laboratory analyses shall be characterised by the appropriate criteria set out.
- (f) Samples must be taken, handled and labelled in such a way as to guarantee their legal, scientific and technical validity.
- (g) The Director Laboratory services may, by means of a Veterinary Procedural Notice (VPN), lay down and or refer to rules for:
- (i) The methods to be used for sampling and for laboratory analyses, tests and diagnoses;
 - (ii) Performance criteria, analysis, test or diagnosis parameters, measurement uncertainty and procedures for the validation of those methods;
 - (iii) The interpretation of analytical, testing and diagnostic results.

8.4 Second expert opinion

- (a) Where relevant and technically feasible, having regard in particular to the prevalence and distribution of the hazard in the animals or food, to the perishability of the samples or the food and to the amount of available substrate, the operator may apply to the Director Laboratory services for a second expert opinion to subject the product to re-sampling, analysis, test or diagnosis in the context of official controls,
- Such an application may include:
- (i) That a sufficient number of additional samples from the consignment be taken for a second expert opinion, in accordance with standard operating procedure or,
 - (ii) Where it is not possible to take a sufficient additional number of samples as referred to in point (i), that an independent second analysis selected by the Director

of Laboratory services, test or diagnosis on the initial sample(s) be carried out.

- (b) The application by the operator for a second expert opinion shall not affect the Director Laboratory services or the NEO or Director Animal Health to take prompt action to eliminate or contain the risks to human, animal and plant health, or for environmental and animal welfare.
- (c) The Director Laboratory services may, by means of an SOP, lay down procedures for the uniform application of the rules provided and for the presentation and handling of applications for a second expert opinion.

PART VII

9. PROFICIENCY TESTING (PT) PROGRAM

The primary purpose of proficiency testing is stipulated in the OIE code under laboratories and in ISO 17025 clause 5.9.

9.1 PT Providers

The Director Laboratory services will stipulate approved proficiency testing service providers within the Republic of South Africa. As a reference point, SANAS Accredited Proficiency Scheme providers must be used.

9.2 Participation in PT Programs

- (a) Approved/designated laboratories are required to participate in PT programs that relate directly to tests included in their scope.
- (b) The minimum frequency for participation in PT programmes is specified by SANAS.

9.3 Performance

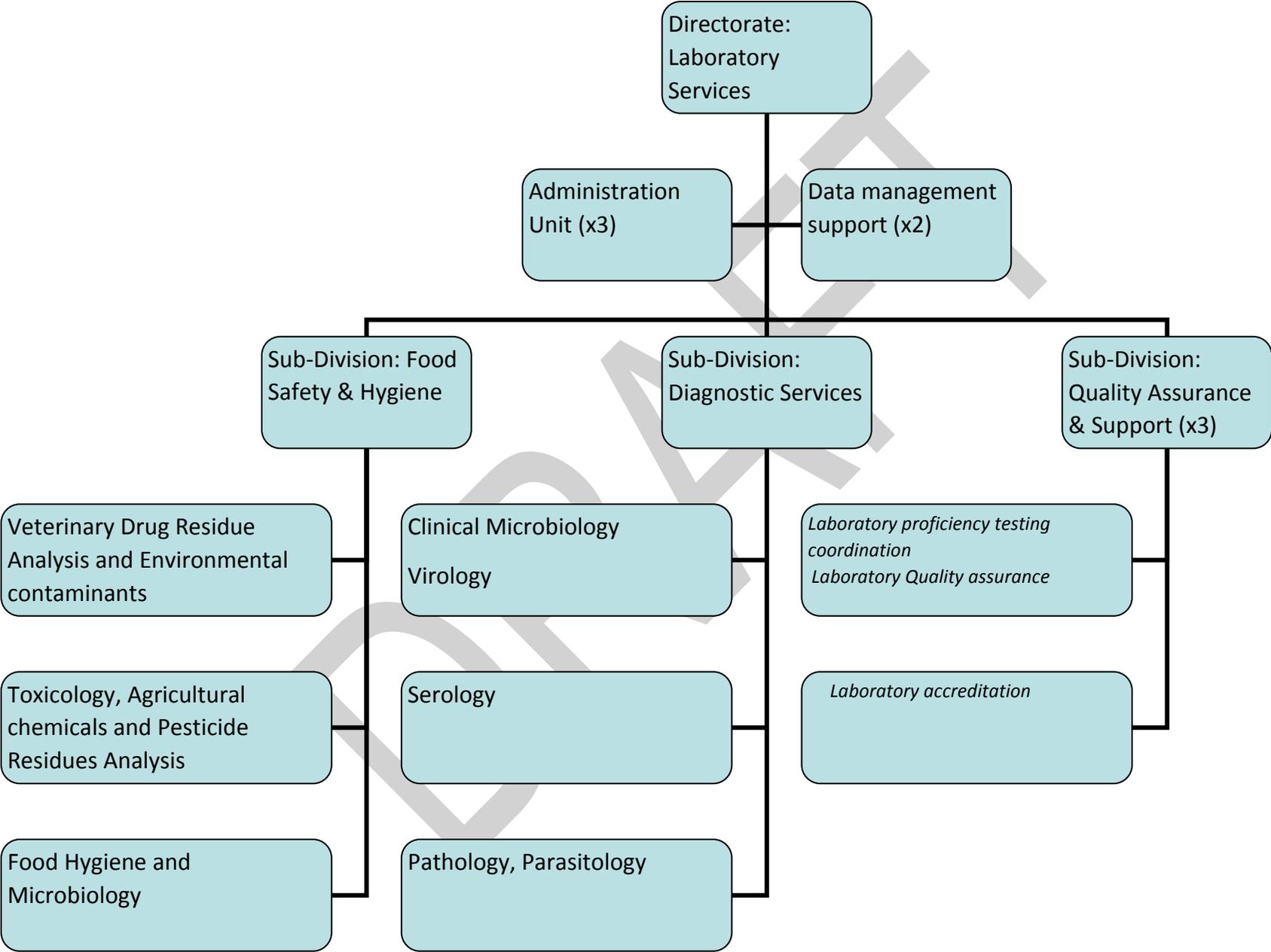
- (a) Performance criteria will be established in line with the policies of the PT provider.
- (b) The PT provider will inform the laboratory of results it deems to be inadequate i.e. results that fall outside the set of tolerance interval established for that round of testing.
- (c) All PT results and the corrective actions taken by the laboratory must be evaluated during the assessments by the Director Laboratory services.

CONFIDENTIALITY

Confidentiality of all records shall be maintained. Any records supplied to the Director Laboratory services by an approved/designated laboratory shall be dealt with in terms of the Meat Safety Act, 2000 (Act No 40 of 2000) and/or the Animal Diseases Act, 1984 ((Act No 35 of 1984). Where necessary, officials may be requested to sign a confidentiality clause to receive the laboratory results.

DRAFT

THE PROPOSED STRUCTURE: VETERINARY LABORATORY SERVICES



ANNEXURE A

Table 1: Category 1 Food Safety and Zoonotic Conditions that need immediate (within 24hours) as a laboratory-confirmed case (by laboratory)

	Notifiable condition	ICD 10	Notifiable as a laboratory-confirmed case by laboratory
1.	Anthrax	A22.0 – A22.9	✓
2.	Feed borne illness outbreak		✓
3.	Plague	A20	✓
4.	Brucellosis		✓
5.	Avian and Swine Influenza		✓
6.	Rabies (human)	A82.0 – A82.9	✓
7.	Rift Valley fever (human)	A92.4	✓
8.	Waterborne illness outbreak		✓

N/A: not applicable

* Viral haemorrhagic fever diseases: Ebola or Marburg viruses, Lassa virus, Lujo virus, novel or new world arenaviruses, Crimean-Congo haemorrhagic fever

Table 2: Category 2 Food Safety and Zoonotic Conditions to be notified within seven (7) days of diagnosis as a laboratory-confirmed case (by laboratory).

	Notifiable condition	ICD-10	Notifiable as a laboratory-confirmed case by laboratory
1.	Schistosomiasis	B65.0 – B65.9	✓
2.	Brucellosis	A23.0 – A23.9	✓
3.	Hepatitis A	B15.0 – B15.9	✓
4.	Hepatitis E	B17.2	✓
5.	Environmental contaminants (Lead, Cadmium, Arsenic, Radionuclides, polychlorinated biphenyl (PCB), dioxins)	T56.0	
6.	Mercury	T56.1	✓
7.	Soil-transmitted helminthic infections		✓
8.	<i>Clostridium botulinum</i>	A33 - A35	✓
9.	Bovine Tuberculosis	A15. 0 - A16.9	✓

N/A: not applicable

Table 3: Category 3 Food safety and Zoonotic Conditions that private and public laboratories need to keep a database on and report monthly

	Notifiable condition	Human ICD-10	Pathogen/s to notify
1.	Other zoonotic pathogens		Any other uncategorized zoonotic pathogens listed as controlled and notifiable in the Animal Diseases Act
2.	Endemic arboviral diseases		West Nile virus, Sindbis virus, Chikungunya virus, other imported arboviruses of medical importance
3.	Invasive disease caused by <i>Streptococcus pneumoniae</i>		
4.	Shiga toxin-producing <i>Escherichia coli</i>		Shiga toxin-producing <i>Escherichia coli</i>
5.	Non-typhoidal Salmonellosis		<i>Salmonella</i> spp. other than <i>S. Typhi</i> and <i>S. Paratyphi</i>
6.	Leptospirosis		<i>Leptospira</i>
7.	Campylobacteriosis		<i>Campylobacter jejuni/coli/lari</i>
8.	Bovine and Porcine Cysticercosis		
9.	Toxoplasmosis		<i>Toxoplasma gondii</i>
10.	Tickborne illness		
11.	John's disease		Mycobacterium avium subspecies paratuberculosis (MAP)
12.	Botulism		
13.	Veterinary Medicines, Pesticides, Agricultural or stock remedy above Maximum Residue Limits		
14.	Shigellosis	A03.0 – A 03.9	<i>Shigella</i> spp.
15.	Healthcare-associated infections or multi drug-resistant organisms of public health importance		<ul style="list-style-type: none"> • Carbapenemases-producing <i>Enterobacteriaceae</i> • <i>Staphylococcus aureus</i>: • <i>Clostridium difficile</i> • <i>E.coli</i> • <i>Salmonella</i> spp • <i>Campylobacter</i> spp • <i>Listeria monocytogenes</i>



agriculture, forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

ANNEXURE B

LABORATORY APPROVAL PROGRAM APPLICATION FORM

Laboratory Name		Email	
Laboratory Physical & Postal address		Phone	
Name of person responsible for laboratory approvals e.g. Laboratory QA Manager		Fax	
Name of person responsible for laboratory testing			
Approved testing methods intended to be used under Laboratory Approval Program (full names and references). Indicate whether SANAS accredited or not.	<input checked="" type="checkbox"/> SANAS accredited or <input type="checkbox"/> Not SANAS accredited		
Type of products tested			
List ¹ of registered abattoirs and/or Ports of Entry using this laboratory			

¹= Attach list if space is not sufficient

I _____ (insert name and surname) wish to apply for the above named laboratory to be listed as an approved/designated laboratory for the purpose

of testing meat and meat products, abattoir water and environmental samples using approved methods listed above.

- I declare that this laboratory will grant the National Executive Officer (NEO) and/or Director of Animal Health (DAH) access to the laboratory, including access to laboratory methods and records relevant to the above tests for the purpose of review of the accreditation system.
- I grant the NEO/DAH access to SANAS records relevant to its accreditation in relation to tests covered by the scope of approval/designation.
- I grant the NEO/DAH access to records of proficiency testing results held by the laboratory or by the proficiency testing service provider.
- I agree that this laboratory will report relevant test results to the NEO/DAH at the same time that they are reported to the client or periodically as the NEO/DAH determine.
- I understand that I am required to participate in proficiency testing programmes to demonstrate competency and that the frequency of proficiency testing is determined by the NEO/DAH or SANAS. I will inform the NEO/DAH of any non-conforming proficiency test results and provide documentary evidence of any corrective action taken.
- I understand that failure to meet any of the requirements for approval may result in suspension or withdrawal from the lists of approved and designated laboratories

I have attached:

- ✓ Evidence of accreditation by SANAS for the approved methods listed above (if applicable).

Signature: _____

Date : _____ (dd/mm/yyyy)

Designation: _____

Witness : _____ (signature)

Date : _____ (dd/mm/yyyy)

I understand that giving false or misleading information is a serious offence.

Application should be sent to:

Director: Veterinary Public Health (NEO)
Department of Agriculture Forestry and Fisheries
Private Bag X138
Pretoria (RSA)
0001
Email: TebogoMON@daff.gov.za
Fax: 012 319 7699