Australian Government

Department of Agriculture, Fisheries and Forestry

Report on reassessment visit to approved laboratories

ORGANISATION: _____

FACILITY: _____

NATA ACCREDITATION NO: _____

CORPORATE SITE NO: _____

DATE OF VISIT: _____

AUTHORISED REPRESENTATIVE: _____

LEAD ASSESSOR: _____

TECHNICAL ASSESSOR: _____

AGREED RESPONSE DATE
(to conditions for Approval) _____

Signed by _____

Name _____

Date _____

Time on-site:

Codes used in this report:

O =	Observation	This may be a recommendation or a reminder or flag for follow-up/review at the next assessment
M =	Minor Condition	A description of the action taken or intended must be provided in the time negotiated for response. Supporting evidence of this action will not be required as it will be reviewed at the next assessment. The laboratory is encouraged to include the Minor Condition in their corrective action and internal audit program.
C =	Condition	A response on action taken is required with supporting evidence of the action. This must be provided in the time that has been negotiated for response.

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1 GENERAL REQUIREMENTS

Requirements in this document reflect those specified in the current version *of ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories* (equivalent to AS/ISO/IEC 17025).

1.1 NATA Scope

1.1.1 Does the current NATA scope of accreditation reflect the scope of DAFF approval? _____

1.2 Impartiality and Confidentiality

1.2.1 Does the laboratory identify risks to its impartiality (e.g. commercial or financial pressures) and eliminate or minimise these risks when they are identified? _____

1.2.2 Is information generated by the laboratory in the performance of its activities regarded as confidential, except when the information is made publicly available with the consent of the customer? _____

2 STRUCTURAL REQUIREMENTS

2.1 Organisation

2.1.1 Is the organisation and management structure defined? _____

2.1.2 Does the laboratory define and document the range of activities for which it conforms with this document, excluding activities undertaken by externally provided laboratory activities on an ongoing basis? _____

2.1.3 Does management communicate to personnel their duties, responsibilities and authorities? _____

3 RESOURCE REQUIREMENTS

3.1 Personnel

Requirement:
NATA General Accreditation Criteria - ISO/IEC 17025 Standard Application Document, Resource Requirements
NATA Specific Accreditation Criteria Life Sciences ISO/IEC 17025 Annex – On-Site Abattoir Facilities and Contract Testing Facilities Approved by the Department of Agriculture, Fisheries and Forestry (DAFF) to Test Carcass Hygiene Samples and Export Meat Samples

3.1.1 Is the personnel complement sufficient for the laboratory's workload and operation? _____

3.1.2 Does the laboratory document the competence requirements of its personnel, including requirements for education, qualifications, training, technical knowledge, skills and experience? _____

3.1.3 Does the laboratory ensure that personnel have the competence to perform activities for which they are responsible? _____

3.1.4 Does the laboratory authorise personnel to perform specific activities including verification and validation of methods, analysis of results and authorisation of results? _____

3.2 Facilities and Environmental Conditions

3.2.1 Are the facilities and environment suitable for the laboratory activities and do not adversely affect the validity of results?

3.2.2 For on-plant laboratories is the laboratory physically separated from the operational activities?

3.2.3 Is the flow of work designed to minimise cross contamination?

3.2.4 Is access to the laboratory restricted to approved personnel only?

3.2.5 Does the laboratory have records demonstrating it monitors and controls environmental conditions that may influence the validity of test results?

3.2.6 Are measures to control facilities periodically reviewed, such as access, prevention of contamination and effective separation of incompatible areas?

3.3 Equipment

Facilities are encouraged to develop an in-house documented equipment assurance program which will allow the emphasis to move from a high reliance on demonstration of equipment performance at the time of calibration to:

- having a greater contribution from more frequent checks against reference items or materials;
- cross-checking against similar systems;
- checking of particular critical features.

If such a program is not established, the minimum requirements for calibration and check periods are those documented in NATA's General Accreditation Guidance - General Equipment - Calibration and Checks, General Equipment Table.

Requirement:

NATA General Accreditation Criteria - ISO/IEC 17025 Standard Application Document

Reference:

NATA General Accreditation Guidance - General Equipment - Calibration and Checks, General Equipment Table

Calibration

3.3.1 Is all measurement equipment capable of achieving the necessary measurement accuracy and/or measurement uncertainty required to provide a valid result?

3.3.2 Is all measurement equipment calibrated when it has been identified as significantly affecting the validity of the reported result and/or when calibration is required to ensure the metrological traceability of the reported result?

3.3.3 Has the laboratory established a calibration program which is reviewed and adjusted as necessary to ensure the confidence in the status of calibration?

General Equipment Checklists

3.3.4 **pH meter**

3.3.4.1 At what frequency are buffer checks undertaken?

3.3.4.2 Is pH traceable to specific batches of media and samples?

3.3.5 **Balances**

Ref. NATA General Accreditation Guidance - User Checks and Maintenance of Laboratory Balances

3.3.5.1 Does the balance meet the accuracy required by the methods and other procedures?

3.3.5.2 How often are the calibration, single point check and repeatability of the balance checked?

3.3.5.3 Are records kept of balance calibration?

3.3.6 **Masses**

Ref. NATA General Accreditation Guidance - User Checks and Maintenance of Laboratory Balances

3.3.6.1 At what frequency are calibrations undertaken for reference masses?

3.3.7 **Temperature measuring equipment**

Reference:
NATA General Accreditation Guidance - Liquid-in-Glass Thermometers – Selection, Use and Calibration
Note: Reference to thermometers in the section includes both liquid-in-glass and electronic temperature recording devices unless specifically stated otherwise.

3.3.7.1 Are reference thermometer(s) available and are appropriate checks of calibration carried out?

3.3.7.2 Are working thermometers appropriately calibrated and/or checked?

3.3.7.3 Is the accuracy of working thermometers suitable for the temperature(s) being monitored?

3.3.7.4 Are records available for calibrations/checks of all thermometers?

3.3.8 **Thermocyclers**

3.3.8.1 Are appropriate checks and/or calibrations carried out?

3.3.9 **Incubators and water baths**

3.3.9.1 Have the operational characteristics of the incubators been appropriately validated, i.e. spatial temperature variation?

3.3.9.2 Are temperatures monitored and recorded daily?

3.3.10 **Refrigerators**

3.3.10.1 Do the units available for storage provide separation of clean from potentially contaminated material (e.g. media reagents and samples)?

3.3.10.2 Are the temperatures monitored and recorded daily?

3.3.11 **Pipettors/Dispensers**

3.3.11.1 Are pipettors appropriately calibrated and checked for accuracy?

3.3.12 **Culture media**

Media purchased from NATA-accredited manufacturers

Note: The manufacturer of 3M Petrifilm is not NATA accredited

3.3.12.1 Is a quality control report or certificate either available online or provided?

3.3.12.2 Does the laboratory keep a log of receipt dates of media, type and batch number?

3.3.12.3 Is media stored in accordance with manufacturer's instructions?

3.3.12.4 Does the laboratory check such reports for relevant parameters (e.g. volume checks, recoveries, microbial performance etc.)?

Media prepared in-house

Note: media purchased from non-NATA accredited suppliers must undergo the same quality control testing as required for media prepared in-house

Reference:

ASM Guidelines for Assuring Quality of Food & Water Microbiological Culture Media (2nd edition 2014)

3.3.12.5 Are records kept of the date received, date opened and shelf life for raw materials i.e. dehydrated media?

3.3.12.6 Are all prepared media stored appropriately?

3.3.12.7 Are all prepared media labelled with date of preparation and/or shelf-life?

3.3.12.8 Are records kept of all aspects of each batch of prepared medium? Do records include:

- Medium name
- Batch number
- Date of preparation
- Ingredients, manufacturer and/or batch number
- Date medium QC tested
- Number of units tested (AS 1191)
- Operator's signature and date
- Method of preparation
- Sterilisation time and temperature
- Volume dispensed (before and after sterilisation)
- Number of units dispensed
- Media Quality Control
- Has the laboratory documented guidelines for determining acceptable sterility and microbial performance test results for each medium?

3.3.12.9 Is each batch of medium checked for sterility, final pH and is a physical examination made for colour, clarity, and gel strength as appropriate?

3.3.12.10 For each batch of non-selective media, are records kept of biochemical reactions and colony morphology? For quantitative non-selective media is recovery of target organisms compared against a non-selective reference media?

3.3.12.11 For each batch of selective media, are records kept of biochemical reactions and colony morphology? For quantitative selective media is recovery of target organisms compared against non-selective media?

3.3.12.12 Are all quality control test results recorded?

3.3.12.13 Are general comments regarding acceptance / rejection recorded?

3.4 Externally Provided Products and Services

3.4.1 Does the laboratory have a procedure and retain records for reviewing, approving and communicating the laboratory's requirements for externally provided products and services?

4 PROCESS REQUIREMENTS

4.1 Methods and Procedures

Requirement:
NATA General Accreditation Criteria - ISO/IEC 17025 Standard Application Document
NATA Specific Accreditation Criteria Life Sciences ISO/IEC 17025 Annex – On-Site Abattoir Facilities and Contract Testing Facilities Approved by DAFF to Test Carcass Hygiene Samples and Export Meat Samples

4.1.1 Are current DAFF approved methods used for testing export samples (without modification unless approved by the DAFF and accepted by the customer in writing)?

4.1.2 Before a new standard method is used, does the laboratory perform an appropriate verification study and keep records of this study for review?

4.1.3 Are methods documented in sufficient procedural detail that provides clear stepwise instructions to an operator?

4.1.4 Can the laboratory demonstrate that its methods and procedures are under sufficient control?

4.1.5 Do the methods include instructions for routine quality control (e.g. daily use of positive controls)?

4.1.6 Where in the analyses are controls introduced and what is the inoculation level (10-100 cfu)?

4.1.7 Does the laboratory identify contributions to uncertainty, including analytical and sampling components, where sampling is under the control of the laboratory? (Worked examples in the procedure are recommended.)

4.2 Sample Handling

Requirement:
NATA General Accreditation Criteria - ISO/IEC 17025 Standard Application Document
DAFF Microbiological Manual for Sampling and Testing of Export Meat and Meat Products, Section 6

4.2.1 Does each sample receive a unique identifier which is used throughout the testing process?

4.2.2 Is the date of sample collection and receipt recorded?

4.2.3 Are samples stored appropriately if not tested immediately?

4.2.4 Does the laboratory document its sampling plan and method, including appropriate acceptance/rejection criteria for samples arriving at the laboratory?

4.3 Technical Records

Requirement:
NATA General Accreditation Criteria - ISO/IEC 17025 Standard Application Document

4.3.1 Does the laboratory maintain an information management system designed to suit its particular requirements which includes information on samples received, raw test data, quality control data, measurement uncertainty, final results and a traceable link between the samples as received and the report issued regarding that sample (or set of samples)?

4.3.2 Is an unambiguous identifier quoted on all documentation associated with the sample e.g. worksheets, work books, reports etc., and available for external audit?

4.3.3 Are all details regarding tests performed, dilutions analysed and identity of analyst recorded?

4.3.4 Are original records/observations recorded at the time of testing retained?

4.3.5 Are final results calculated and results and transcriptions checked, preferably by another analyst?

4.3.6 Is the information management system protected from unauthorised access and maintained so that it protects data and information integrity?

4.4 Ensuring the Validity of Results

Requirement:
NATA General Accreditation Criteria - ISO/IEC 17025 Standard Application Document
NATA General Accreditation Criteria – Metrological Traceability
NATA Specific Accreditation Criteria Life Sciences ISO/IEC 17025 Annex – On-Site Abattoir Facilities and Contract Testing Facilities Approved by DAFF to Test Carcass Hygiene Samples and Export Meat Samples

Control Culture Management

4.4.1 Does the laboratory use reference material and/or quality controls to validate results?

4.4.1.1 Does the laboratory have an appropriate culture management program i.e. a tiered system?

4.4.1.2 Are control cultures used for all methods?

4.4.1.3 Are records maintained that show the identity, date of acquisition, source and maintenance conditions of control cultures?

Proficiency Testing

4.4.2 Is the laboratory enrolled in a relevant proficiency testing (PT) program?

4.4.3 Is proficiency for each test organism undertaken at least six monthly?

4.4.4 Are all test methods for a particular analyte rotated through the PT program?

4.4.5 Does the lab have a policy for rotating analysts through the PT program?

4.4.6 Is performance in PT programs satisfactory?

4.4.7 Does the laboratory assess its performance under the PT program and undertake corrective actions when performance in PT is found to be unsatisfactory?

4.5 Reporting of Results

Requirement:
NATA General Accreditation Criteria - ISO/IEC 17025 Standard Application Document

4.5.1 Are reports appropriately reviewed and authorised prior to release?

4.5.2 Do test reports provide a clear, unambiguous statement of results including the following information?

- A title
- Name and address of the testing laboratory
- Name and contact information of the customer
- Unique report identification
- Date sampled
- Date and time received (if critical to the validity of the result)
- Date and time analysed (if critical to the validity of the result
- Date reviewed and a statement that the report only relates to the particular sample tested (where the laboratory is not responsible for sampling)
- A disclaimer if the sample was received outside specified conditions, but the customer nonetheless required the sample to be tested
- Test methods used
- Results, including unit of measurement and measurement uncertainty (measurement uncertainty is reported when it is relevant to the validity or application of the test results, it is required by the customer or it affects conformity to a specification limit)
- Date of test report
- Signature of authorised person

4.5.3 How are DAFF relevant test results reported directly to the DAFF at the same time that they are sent to the client/plant management?

4.6 Complaints and Non-Conforming Work

Requirement:
NATA General Accreditation Criteria - ISO/IEC 17025 Standard Application Document

4.6.1 Does the laboratory have a documented process to receive, evaluate and make decisions on complaints, including;

- Tracking corrective actions and verifying their effectiveness?
- Ensuring, where practical, the outcomes are reviewed and communicated to the complainant by an individual not involved in the original laboratory activities in question?

4.6.2 Does the laboratory have a procedure for handling non-conforming testing and/or calibration work?

4.6.3 Have non-conformances been investigated and appropriate action taken?

4.7 Control of Data and Information Management

Requirement:
NATA General Accreditation Criteria - ISO/IEC 17025 Standard Application Document

4.7.1 Does the laboratory have access to the data and information required to perform its activities i.e. applicable standards and procedures?

4.7.2 Are calculations and data transfers checked in an appropriate and systematic manner?

5 MANAGEMENT SYSTEM REQUIREMENTS

5.1 General Requirements

5.1.1 Does the laboratory maintain and document a management system either in full compliance with ISO/IEC 17025 or in compliance with ISO 9001?

5.1.2 If the laboratory is operating under the requirements of ISO 9001 are appropriate records available for its compliance with this standard as certified by a JAS-ANZ accredited certification body, including any corrective actions taken in relation to audit findings?

5.1.3 If complying with ISO/IEC 17025 does the management system address the following;

- Management system documentation
- Control of documents
- Control of records
- Actions to address risks and opportunities
- Improvement
- Corrective actions
- Internal audits
- Management reviews

5.2 Management Review

5.2.1 Does the laboratory management periodically conduct a review of the laboratory's management system and testing and/or calibration activities?

5.2.2 Does the management review include the following:

- Changes in internal and external issues that are relevant to the laboratory
- Fulfilment of objectives
- Suitability of policies and procedures
- Status of actions from previous management reviews
- Outcome of recent internal audits
- Corrective actions
- Assessment by external bodies

- Changes in the volume and type of work or in the range of laboratory activities _____
- Customer and personnel feedback _____
- Complaints _____
- Effectiveness of any implemented improvements _____
- Adequacy of resources _____
- Results of risk identification _____
- Outcomes of the assurance of the validity of results _____
- Other relevant factors, such as monitoring activities and training _____