



Report on surveillance visit to AQIS approved facility

ORGANISATION: _____

FACILITY: _____

NATA ACCREDITATION NO: _____

CORPORATE SITE NO: _____

DATE OF VISIT: _____

AUTHORISED REPRESENTATIVE: _____

LEAD 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 in required with supporting evidence of this action. This must be provided in the time that has been negotiated for response.

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1. MANAGEMENT REQUIREMENTS

Requirement: AS ISO/IEC 17025:2005

References: AS ISO/IEC 17025:2005, Clause 4

1.1 General**1.1 Does the current NATA scope of accreditation reflect the scope of AQIS approval?****1.2 Organisation**

1.2.1 Is the organisation and management structure defined? _____

1.2.2 Are personnel adequately supervised? _____

1.2.3 Are personnel aware of their roles and responsibilities? _____

1.3 Purchasing service and supplies

1.3.1 Does the laboratory have a policy for the purchase of service and supplies? _____

1.4 Internal audits and non-conforming work

1.4.1 Does the laboratory undertake systematic internal audits of its activities? _____

1.4.2 Does the laboratory have a documented policy for handling non-conforming testing and/or calibration work? _____

1.5 Management review

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

– suitability of policies and procedures _____

– reports from managerial and supervisory personnel; _____

– the outcome of internal audits; _____

– corrective and preventive actions; _____

– assessments by external bodies; _____

– the results of interlaboratory comparisons or proficiency tests; _____

– changes in the volume and type of the work; _____

– customer feedback; _____

– complaints; _____

– recommendations for improvement; _____

– other relevant factors, such as quality control activities, resources and staff training. _____

2. MEDIA

Requirement: Biological Testing Field Application Document clause 4.6, ISO/IEC 17025 clause 4.6.

References: *ASM Guidelines for Assuring Control of Food and Water Microbiological Culture Media (August 2004)*

2.1 In-house media preparation and testing**NA**

2.1.1 Are records kept of the date received, date opened and shelf life for raw materials ie dehydrated media? _____

2.1.2 Are all prepared media stored appropriately? _____

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

2.1.4 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) _____

– No. of units dispensed _____

2.2 Media purchased from NATA-accredited manufacturers**NA**

(The manufacturer of Petrifilm is not NATA accredited - see Section 7.4 of AQIS Meat Notice 2000/09 for QA requirements)

2.2.1 Is media obtained from a NATA accredited supplier and is a quality control report or certificate either available online or provided? _____

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

2.2.3 Is media stored in accordance with manufacturer's instructions? _____

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

2.3 Media Quality Control

2.3.1 Has the laboratory documented guidelines for determining acceptable sterility and microbial performance test results for each medium? _____

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

2.3.3 For each batch of selective media, are records kept of biochemical reactions colony morphology and quantitative recovery against non-selective media. _____

2.3.4 Are all quality control test results recorded? _____

2.3.5 Are general comments regarding acceptance / rejection recorded? _____

3. RECORDS

Requirement: Biological Testing Field Application Document clause 4.13, ISO/IEC 17025 clause 4.13

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

3.2 Is such identification quoted on all documentation associated with the sample e.g. worksheets, work books, reports etc and available for external audit? _____

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

3.4 Are final results calculated and results and transcriptions checked preferably by another analyst? _____

4. PERSONNEL

Requirement: Biological Testing Field Application Document clause 5.2,
ISO/IEC 17025 clause 5.2

4.1 Is the staff complement sufficient for the laboratory's workload and operation? _____

4.2 Are up-to-date job descriptions and training records available for all staff? _____

5. TESTING ENVIRONMENT

Requirement: Biological Testing Field Application Document clause 5.3,
ISO/IEC 17025 clause 5.3

5.1 Is the laboratory physically separated from the operational activities? _____

5.2 Is the laboratory space adequate to accommodate the equipment, range of tests, number of samples analysed and members of staff? _____

5.3 Is the flow of work designed to minimise cross contamination? _____

5.4 Is there a hand wash station? _____

5.5 Is access to the laboratory restricted to approved personnel only? _____

5.6 Is the laboratory clean, well lit, air-conditioned and free of draughts (ie no open windows)? _____

5.7 Is the finish of surfaces (benches and floor) suitable for cleaning and disinfection ie sealed? _____

6. TEST METHODS

Requirement: Biological Testing Field Application Document clause 5.4,
ISO/IEC 17025 clause 5.4

6.1 Methods and procedures

6.1.1 Are AQIS approved methods used for testing export samples (without modification)? _____

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

- 6.1.3 Are methods under document control? (ie date of adoption, issue, authorisation by a senior member of staff etc)? _____
- 6.1.4 Do the methods include instructions for routine quality control (e.g. daily use of positive controls)? _____
- 6.1.5 Where in the analyses are controls introduced and what is the inoculation level (10-100 cfu)? _____
- 6.1.6 Do the methods describe how to calculate results? (A worked example in the procedure is recommended) _____

7. GENERAL LABORATORY EQUIPMENT

Facilities are expected to identify critical and non-critical equipment based on the contribution/input from any particular piece of equipment used during a test to the accuracy of the final result. 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:

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

.If such a program is not established, the minimum requirements for calibration and check periods are those documented in Section 4 of the Biological Testing Field Application Document.

Requirement: Biological Testing Field Application Document clauses 5.5 and 5.6, ISO/IEC 17025 clauses 5.5 and 5.6

- 7.1 pH meter** NA
- 7.1.1 At what frequency are buffer checks undertaken? _____
- 7.1.2 Is pH traceable to specific batches of media and samples? _____
- 7.2 Balances**
- (Ref. User checks and maintenance of laboratory balances – NATA Technical Note 13)
- 7.2.1 Does the balance meet the accuracy required by the methods and other procedures? _____
- 7.2.2 How often are the calibration, single point check and repeatability of the balance checked? _____

7.2.3	Are records kept of balance calibration?	_____
7.3	Masses (Ref. User checks and maintenance of laboratory balances – NATA Technical Note 13)	
7.3.1	At what frequency are calibrations undertaken for reference masses?	_____
7.4	Thermometers (and thermocouples) (Ref. Liquid-in-glass thermometers – selection, use and calibration checks – NATA Technical Note 19) Note: Reference to thermometers in the section includes both liquid-in-glass and electronic temperature recording devices unless specifically stated otherwise.	
7.4.1	Are reference thermometer(s) available and are appropriate checks of calibration carried out?	_____
7.4.2	Are working thermometers appropriately calibrated and/or checked?	_____
7.4.3	Is the accuracy of working thermometers suitable for the temperature(s) being monitored?	_____
7.4.4	Are records available for calibrations/checks of all thermometers?	_____
7.5	Incubators	
7.5.2	Have the operational characteristics of the incubators been appropriately validated, i.e. Spatial temperature variation?	_____
7.5.3	Are temperatures monitored and <u>recorded</u> daily?	_____
7.6	Water baths	NA
7.6.1	Have the operational characteristics of the water baths been appropriately validated, i.e. Spatial temperature variation?	_____
7.6.2	Are temperatures monitored and <u>recorded</u> daily?	_____
7.7	Autoclaves	NA

7.7.1 Are appropriate records kept (ie of operating conditions, load profiles, maintenance etc)? _____

7.8 Refrigerators

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

7.8.2 Are the temperatures monitored and recorded daily? _____

7.10 Pipettors/Dispensers

7.10.1 Are appropriate checks made of the accuracy of pipettors? _____

8. CONTROL CULTURE MANAGEMENT

Requirement: Biological Testing Field Application Document clause 5.6, ISO/IEC 17025 clause 5.6, Policy Circular 34 – Maintenance of Microbiological Reference Culture Collections (MRCC)

8.1 Does the laboratory have an appropriate culture management program ie a tiered system? _____

8.2 Are control cultures used for all methods? _____

8.3 Where are reference cultures sourced? _____

9. SAMPLE HANDLING

Requirement: Biological Testing Field Application Document clause 5.8,
ISO/IEC 17025 clause 5.8 and AQIS Notice 2000/09

- 9.1 Does each sample receive a unique identifier which is used throughout the testing process? _____
- 9.2 Is the date of sample collection, receipt and analysis recorded? _____
- 9.3 Are samples stored appropriately if not tested immediately? _____
- 9.4 Are acceptance/rejection criteria available for samples? _____

10. VERIFICATION OF TEST RESULTS

Requirement: Biological Testing Field Application Document clause
5.9, ISO/IEC 17025 clause 5.9

- 10.1 Is the laboratory enrolled in a relevant proficiency programs? _____
- 10.2 Is proficiency for each test organism undertaken at least six monthly? _____
- 10.3 Are all test methods for a particular analyte rotated through the PT program? _____
- 10.4 Does the lab have a policy for rotating analysts through the PT program? _____
- 10.5 Is performance in proficiency programs satisfactory? _____
- 10.6 Is there a documented procedure for corrective actions when performance in PT is found to be unsatisfactory? _____

11. REPORTING

Requirement: Biological Testing Field Application Document clause 5.10,
ISO/IEC 17025 clause 5.10

- 11.1 Do test reports provide a clear, unambiguous statement of results including the following information? _____
- 11.1.1 Unique identification of testing laboratory? _____
- 11.1.2 Unique report identification? _____

11.1.3 Full sample identification, including date sampled, date received, date analysed and a statement that the report only relates to the particular sample tested? _____

11.1.4 Test methods used? _____

11.1.5 Results? _____

11.1.6 Date of test report? _____

11.1.7 Signature of NATA approved signatory (if applicable)? _____

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

Comments: