
Australian Government

Department of Agriculture

# General Requirements for On-Plant Laboratories

## PART I

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# Part I:

# Laboratories Testing Export Meat and Meat Products

## 1.1 Introduction

The Australian Government Department of Agriculture (the department) provides inspection, verification and certification services to the export meat industry in Australia through the Australian Export meat Inspection System (AEMIS). A requirement of AEMIS is that establishments must collect samples for microbiological testing as part of the verification of their process control. This sampling and testing must be performed in a laboratory approved by the department using testing methodologies also approved by the department.

The department requires that laboratories are assessed against AS ISO/IEC 17025-2005 "General requirements for the competency of testing and calibration laboratories" which details requirements for laboratories carrying out testing. Generally the department requires laboratories undertaking *E. coli* and *Salmonella* carcase testing or other pathogen testing such as for *Listeria monocytogenes* be accredited to AS ISO/IEC 17025-2005 by a recognised accreditation body (NATA).

This document details the minimum requirements for on-plant laboratories undertaking testing carried out as part of department certification and applies only to laboratories that are not NATA accredited. General requirements for approved laboratories and accreditation bodies can be found in "Approved Laboratory Program (Export meat and meat products)", available on the department's web site.

# 1.2 General Information

## 1.2.1 Scope

1.2.1.1 This document applies to laboratories undertaking microbiological testing as part of department certification of meat and meat products and in some cases testing for pathogens that is part of market or customer requirements. In addition, where a laboratory is not NATA accredited, other testing that is part of a company's approved arrangement (AA) and that has an impact on the final quality or safety of any product must be carried out in a laboratory that meets the requirements of this document.

# 1.3 Management Requirements

## 1.3.1 Organisation

1.3.1.1 The responsibilities of key personnel in the organisation that have an involvement or influence on the testing activities of the laboratory must be documented in the company's Approved Arrangement.

1.3.1.2 The laboratory must have documented arrangements that ensure that laboratory personnel are free from undue internal and external commercial, financial and other pressures or influences that may adversely affect the quality of their work. The laboratory manager must have direct access to the highest level of management and should not be answerable directly to the production manager.

1.3.1.3 The laboratory must provide adequate supervision of its entire staff.

## 1.3.2 Management system

1.3.2.1 The laboratory shall establish, implement and maintain a (laboratory) quality manual that details policies, systems and procedures necessary to ensure the quality of the test result.

1.3.2.2 The quality manual shall contain detailed work instructions for all methods used by the laboratory including quality control procedures.

1.3.2.3 The laboratory shall establish and maintain a procedure for the control of all documentation relating to the management system, including procedures for approval and document changes.

1.3.2.4 The laboratory shall have a policy and procedure for selection and purchasing of supplies that ensures that the quality of the test results is maintained.

1.3.2.5 The laboratory manager shall participate in plant management meetings and actively seek feedback on performance.

1.3.2.6 The laboratory shall have a written policy and procedure that must be implemented when any aspect of the testing does not conform to the procedures.

1.3.2.7 The laboratory must record non-conformities and corrective actions taken. This must include an assessment of the significance of the non-conformity on the analytical results.

1.3.2.8 Internal audits of the laboratory management system shall be undertaken annually.

### 1.3.3 Control of records

1.3.3.1 The laboratory shall establish and maintain procedures for the identification, safe storage and disposal of records.

1.3.3.2 The laboratory shall retain records of original observations and other records required to establish an audit trail. This must include calibration records and test reports.

1.3.3.3 Where mistakes in recording are made such mistakes must be crossed out with a single line (not erased) and initialled and dated by the person making the correction.

1.3.3.4 Calculations and data transfer must be subject to appropriate transcription checks by someone other than the person making the calculation or entry.

1.3.3.5 Where calculations are made automatically safeguards to ensure formula are not altered must be in place.

## 1.4 Technical Requirements

### 1.4.1 Personnel

1.4.1.1 Laboratory management shall ensure the competency of all staff based on appropriate education, training, experience and/or demonstrated skills as appropriate.

1.4.1.2 The laboratory shall maintain current job description for all staff involved in testing.

1.4.1.3 Laboratories shall maintain records of relevant staff competencies including training.

### 1.4.2 Accommodation and environment

1.4.2.1 Laboratory management shall ensure that the environmental conditions in the laboratory do not compromise the validity of the test results and monitor conditions as required.

1.4.2.2 The laboratory must be effectively separated from the rest of the plant and the work flow designed to minimise cross-contamination.

1.4.2.3 Access to the laboratory must be restricted to authorised personnel.

1.4.2.4 Laboratories shall be well lit, air-conditioned and free from draughts (i.e. no opened windows).

1.4.2.5 The laboratory must be kept clean and free from dust.

1.4.2.6 A dedicated hand wash station must be provided.

## 1.4.3 Test Methods

1.4.3.1 The laboratory must use appropriate methods for the analyses being performed. Department approved methods must be used (see Approved Methods Checklists Manual available on the department's web site).

1.4.3.2 In-house methods must be validated by the laboratory and approved by the department before being used for the analysis of test samples.

1.4.3.3 Validation data must be made available to the department, upon request.

1.4.3.4 Methods must be documented in sufficient detail to provide clear, stepwise instructions to staff and should contain the following information:

- unique identification;
- scope (including reference to standard methods if appropriate);
- type of sample to be tested using the method (e.g. swab);
- acceptance and rejection criteria for relevant aspects of the analysis (e.g. sample receipt);
- apparatus and equipment required including performance requirements (e.g. incubator running at 37 ± 1°C);
- reference standard and quality control required;
- environmental conditions required and any stabilisation required (e.g. tempering of molten agar prior to use);
- description of procedure including labelling of samples, recording and calculation of results (including a worked example) and reporting requirements.

## 1.4.4 Equipment

- The laboratory must be furnished with all equipment necessary to ensure the validity of the test results.
- Equipment must be capable of achieving the accuracy required by the relevant test being carried out (including routine quality control tests).
- All equipment must be uniquely identified.
- All equipment must be appropriately calibrated and any correction factors relating to calibration must be applied.

1.4.4.1 pH Meter

- pH meters must be accurate to 0.1 units
- Calibration of pH meters must be undertaken daily when in use using two buffers, generally pH 4 and pH 7.
- Records of calibration must be kept that provide an auditable link to specific batches of media and tests.

1.4.4.2 Balances

- The balances must meet the accuracy requirements of the test being carried out.
- Three yearly external calibrations must be performed by an accredited certification body.
- Zero points are to be checked each time the balance is used.
- A single point near the capacity of the balance must be checked monthly.
- Repeatability readings must be carried out every 6 months.
- Appropriate reference masses must be available and must be re-calibrated every 3 years.
- Records shall be kept of all calibration data.

1.4.4.3 Thermometers

- Thermometers must have an appropriate range and graduation and must be calibrated externally every 5 years (2-years for digital thermometers).
- Ice point checks or checks in the working range of all working thermometers must be carried out every 6 months.
- Digital reference thermometers must be calibrated externally every 2 years.
- All digital working thermometers must be checks against the reference thermometer at the temperature of use every 6 months.
- Records shall be kept of all calibration data.

1.4.4.4 Incubators and Temperature Controlled Equipment

- All incubators and temperature controlled equipment (i.e. incubators, refrigerators etc) must be monitored daily when in use.
- Monitoring results must be recorded and readily available to staff. It is recommended that records are displayed on the equipment where possible.
- All equipment shall be checked for spatial temperature variation when first put in use and after major repairs.

1.4.4.5 Autoclaves

- Autoclave temperature profile must be checked annually.
- Load profiles for typical loads must be determined.
- Records shall be kept of autoclave cycles, including load type, temperature and time.
- Indicators shall be used with each load to demonstrate correct operation.

1.4.4.6 Pipettors

- Accuracy and precision must be checked every 3 months at the volume delivered. As a guide an acceptability criterion of ± 2% can be used.
- Sterile blanks should be periodically included during testing to verify sterility.

## 1.4.5 Sampling

1.4.5.1 The laboratory shall have appropriate documentation and procedures for the collection, transportation, receipt, handling, protection, storage and disposal of samples.

1.4.5.2 The laboratory shall monitor sample conditions that may affect the validity of the test result, e.g. time between collection and analysis, temperature on arrival etc.

## 1.4.6 Assuring the quality of test results

1.4.6.1 The laboratory shall have appropriate documentation and procedures for monitoring the validity of test results including media quality control and verification of test results.

1.4.6.2 The laboratory shall have a documented procedure for handling, preparation and use of control cultures. Control cultures for each test being performed must be included with each batch of tests or run at least daily.

1.4.6.3 The laboratory shall participate in external proficiency testing programs for all tests under their scope of approval, where available, at a minimum frequency of once every 6 months.

## 1.4.7 Reporting of results

1.4.7.1 The laboratory shall have appropriate documentation and procedures for the reporting of results. This must include procedures for reporting results directly to department on-plant staff or central office at the same time that they are reported to the establishment management. In the case of third party laboratories sub-contracted to perform certain tests the laboratory must instruct such laboratories to report results directly to the department at the same time they are reported to the establishment.

1.4.7.2 All reports issued by the laboratory should have as a minimum the following information:

- unique report number;
- laboratory/establishment name;
- date of report;
- identification of the method used;
- identification of any ambiguous conditions associated with the test;
- date of receipt of the sample including unique sample identification;
- date of testing;
- test results including units e.g. CFU/$cm^2$;
- Name and signature of the person authorising the report.

1.4.7.3 If requested the laboratory can include in the report as needed opinions and interpretations. Justification for these opinions and interpretations shall be documented by the laboratory.

# Part II:

# Laboratories Undertaking General Testings

## 2.1 Introduction

The department provides inspection, verification and certification services to the export meat industry in Australia through the Australian Export meat Inspection System. As a part of this system, establishments must collect samples for microbiological testing as part of the verification of their process control. This sampling and testing must be performed in a laboratory approved by the department using testing methodologies also approved by the department. On-plant laboratories undertaking testing to verify their HACCP program, that is not covered under Part I of these guidelines, should adopt the minimum requirements detailed in this part of the guidelines.

## 2.2 General Information

### 2.2.1 Scope

This document applies to laboratories undertaking limited microbiological testing e.g. of contact surfaces and personal equipment, that underpins the establishments HACCP program. These guidelines also apply to laboratories undertaking *Trichinella* testing as part of export certification.

## 2.3 Management Requirements

### 2.3.1 Organisation

2.3.1.1 The roles and responsibilities of personnel involved in testing must be clearly defined in the company's AA.

2.3.1.2 Management must ensure that personnel undertaking testing are free from undue internal and external commercial, financial and other pressures or influences that may adversely affect the quality of their work.

### 2.3.2 Management system

2.3.2.1 The laboratory shall establish, implement and maintain a quality manual that contains detailed work instructions for all methods used by the laboratory including quality control procedures.

2.3.2.2 The laboratory must record non-conformities and corrective actions taken. This must include an assessment of the significance of the non-conformity on the test results.

2.3.2.3 The laboratory shall have a policy and procedure for selection and purchasing of supplies.

2.3.2.4 Internal audits of the laboratory shall be undertaken annually by plant management as part of their internal audit schedule.

### 2.3.3 Control of records

2.3.3.1 The laboratory shall establish and maintain procedures for the identification, safe storage and disposal of records.

2.3.3.2 The laboratory shall retain records of original observations and other records required to establish an audit trail. This must include calibration records and test reports.

2.3.3.3 Where mistakes in recording are made such mistakes must be crossed out using a single line (not erased) and initialled and dated by the person making the correction.

## 2.4 Technical Requirements

### 2.4.1 Personnel

2.4.1.1 Personnel undertaking testing in the laboratory must be appropriately trained.

2.4.1.2 Laboratories shall maintain records of relevant staff competencies including training.

### 2.4.2 Accommodation and environment

2.4.2.1 The laboratory must be in a dedicated area that is separated from the rest of the plant and designed to minimise cross-contamination.

2.4.2.2 Laboratories shall be well lit and air-conditioned.

2.4.2.3 The laboratory must be kept clean and free from dust.

2.4.2.4 A dedicated hand wash station must be provided.

## 2.4.3 Test methods

2.4.3.1 The laboratory must use appropriate methods for the analyses being performed. Where applicable accredited/approved methods should be used for all testing carried out by the laboratory.

2.4.3.2 Methods must be documented in sufficient detail to provide clear, stepwise instructions to staff and should contain the following information:

- Unique identification;
- Scope (including reference to standard methods if appropriate);
- Type of sample to be tested (i.e. equipment swab);
- Apparatus and equipment required including performance requirements (i.e. incubator running at 35 ± 1°C);
- Quality control required; and
- Description of procedure including labelling of samples, checks of equipment to be performed, recording of observations, calculation of results (including a worked example) and reporting.

## 2.4.4 Equipment

- The laboratory must be furnished with all equipment necessary to ensure the validity of the test results.
- All equipment must be appropriately calibrated and any correction factors relating to calibration applied.

2.4.4.1 pH Meter

- pH meter should be accurate to 0.1 units;
- Calibration of pH meter should be undertaken daily when in use using buffers generally pH 4 and pH 7;
- Records should be kept of all calibration data.

2.4.4.2 Balances

- The balances should meet the accuracy requirements of the test being carried out;
- Zero points are to be checked each time the balance is used;
- A single point near the capacity of the balance must be checked monthly;
- Appropriate reference masses must be available;
- Records shall be kept of all calibration data.

2.4.4.3 Thermometers

- A reference thermometer with appropriate range and graduation must be available;
- Working thermometers must be calibrated at least every 6-months;
- Records shall be kept of all calibration data.

2.4.4.4 Incubators and Temperature Controlled Equipment

- Temperatures of all incubators must be monitored daily or when in use;
- Monitoring results must be recorded and readily available to staff. It is recommended that records are displayed on the equipment where possible.

2.4.4.5 Pipettors

- Pipettors must be calibrated by weight using distilled water every 3 months. The acceptability criterion is ± 2%.

## 2.4.5 Sampling

2.4.5.1 The laboratory shall have appropriate documentation and procedures for the collection, transportation, receipt, handling, protection, storage and disposal of samples.

## 2.4.6 Assuring the quality of test results

2.4.6.1 The laboratory shall have appropriate documentation and procedures for media/reagent quality control. Where possible all media/reagents should be sourced from NATA accredited suppliers.

2.4.6.2 The laboratory shall participate in external proficiency testing programs for all tests under their scope of approval at a minimum frequency of once every 6 months.

## 2.4.7 Reporting of results

2.4.7.1 The laboratory shall have appropriate documentation and procedures for the reporting of results. This must include procedures for reporting results to the on-plant veterinarian for test relating to export eligibility of the tested product at the same time as the result is reported to the company.