Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Dairy: Recognition of Agencies and Persons

31 March 2017

A guidance document issued by the Ministry for Primary Industries

New Zealand Government

Title

Guidance Document: Dairy: Recognition of Agencies and Persons

About this document

This document sets out the criteria that recognised agencies and persons are to satisfy in order to:

- be confirmed as meeting the requirements of the Animal Products Notice: Dairy Recognised Agencies and Persons Specifications; and
- maintain recognition by MPI.

This document has been updated to align its format with MPI's standardised templates for guidance documents. A complete revision of the content of this document will be undertaken during 2017, and elements may be incorporated into the Animal Products Notice: Dairy Recognised Agencies and Persons Specifications.

Related Requirements

Animal Products Notice: Dairy Recognised Agencies and Persons Specifications
Animal Products Notice: Specifications for Laboratories

Document history

Version	Version Date	Section Changed	Change(s) Description
4	July 2011		
5	March 2017	All	New format and branding.

Contact Details

Ministry for Primary Industries (MPI)
Regulation & Assurance Branch
Animal and Animal Products Directorate
PO Box 2526
Wellington 6140
Email: animal.products@mpi.govt.nz

Disclaimer

This guidance does not constitute, and should not be regarded as, legal advice. While every effort has been made to ensure the information in this guidance is accurate, the Ministry for Primary Industries does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

Copyright

Contents

Page

1 Purpose

This document outlines the criteria to be followed by dairy recognised agencies and persons intending to:

a) achieve and maintain recognition under the Animal Products Act 1999; and
b) provide evaluation and verification of dairy Risk Management Programmes.

This document also outlines criteria to be followed by:

a) agencies and persons undertaking specialist functions; and
b) recognised dairy laboratories that have not yet achieved recognition under the Animal Products Notice: Specifications for Laboratories, through to 31 August 2017.

2 Background

This document sets out the criteria that recognised agencies and persons are to satisfy in order to achieve and maintain recognition by MPI. Alternatives to the criteria provided may be acceptable provided that an equivalent outcome will be achieved.

If an agency or a person proposes an alternative to the criteria set out in this document, then MPI may accept it as being equivalent provided an equivalent outcome is achieved and the requirements of the Act and any relevant regulations and specifications are met.

This document also outlines the general process for issuing conditions of recognition and where this information may be found. In this guidance document any references to a specific section refers to a section in this document unless stated otherwise.

During 2017 MPI intend to undertake a further review of this document in conjunction with further amendments to the Animal Products Notice: Dairy Recognised Agencies and Persons Specifications. As part of the further review, elements of this document may be incorporated into the Notice in order to clearly separate mandatory requirements from option criteria and guidance.

3 Definitions

(1) In this document, unless the context otherwise requires:

accreditation body means an internationally recognised, independent, non-profit organisation which is authorised to accredit organisations to certain ISO standards

Act means the Animal Products Act 1999, unless otherwise stated

evaluation means the process of independent external assessment of the validity of a risk management programme for the purposes of providing an independent evaluation report as required under section 20(2)(b) of the Act

recognition body means an organisation approved by MPI to recognise Category 2 dairy laboratories

validate in relation to a risk management programme means the process by which the operator ensures that the programme is complete, and meets the requirements of the Act and any relevant animal product regulations and specifications; and when implemented, will consistently achieve the required outcomes of the programme; and re-validate has a corresponding meaning

verification in relation to a risk management programme means the ongoing checks carried out by recognised agencies and persons described in section 35 of the Act

(2) Any term or expression defined in the Act, or regulations made under the Act that is used, but not defined, in this document has the same meaning as in the Act or regulations (as the case may be).

4 Issuing and Availability of Conditions

This document outlines criteria that apply to all dairy recognised agencies and persons.

The document sets out requirements for:

a) dairy laboratories; and
b) agencies and persons who evaluate and verify dairy risk management programmes or provide other defined specialist functions.

These criteria are in addition to those set out in the Animal Products Notice: Dairy Recognised Agencies and Persons Specifications. This document is intended to provide clarity with respect to the expectations for a successful application for recognition and for maintaining recognition.

An agency or person will be recognised for the evaluation and/or verification of risk management programmes provided they:

a) comply with any relevant specifications as well as with the criteria in this document or an approved alternative; and
b) have been accredited or recognised to the appropriate standard, e.g.:
    i) relevant Parts of the Animal Products Notice: Dairy Recognised Agencies and Persons Specifications;
    ii) ISO 17020 for evaluators and verifiers of risk management programmes; and
c) have provided a recommendation to MPI for recognition.

An agency or person will be recognised as a responsible verifier for the verification of registered farm dairy operators and depot operators under the Raw Milk for Sale to Consumers Regulations 2015 provided they meet the requirements of those regulations, relevant specifications and either the criteria set out in this document or an approved alternative.

A person will be recognised as a raw milk farm dairy assessor for the assessment of farm dairies under the Raw Milk for Sale to Consumers Regulations 2015 provided they meet the requirements of those regulations, relevant specifications and either the criteria set out in this document or an approved alternative.

A laboratory that has been recognised as a dairy laboratory will continue to be recognised through to 31 August 2017 providing they continue to comply with the Animal Products Notice: Dairy Recognised Agencies and Persons Specifications and satisfy the criteria in this document.

The Director-General will supply a notice of recognition to any successful applicant who applies for recognition as an agency or person under the Animal Products Act 1999.

Any conditions for recognition of an agency or person may be issued under the Act.

Conditions may be generic and apply to all recognised agencies and persons or may be specific to an organisation or person.

A notice of recognition will refer to all relevant criteria contained in this document as well as any specific conditions for the organisation or person.

Approved alternatives to the criteria in this document must be made available to the accreditation or recognition body by the recognised agency.

5 Approved Criteria for Recognition of Laboratories

5.1 Recognition Requirements for Dairy Laboratories

5.1.1 Categories of Laboratories

(1) Recognised dairy laboratories have been recognised as Category 1 or Category 2 laboratories.

(2) As of 1 September 2017 all laboratories must be recognised under the Animal Products Notice: Specifications for Laboratories. Category 1 and Category 2 will no longer apply.

5.1.2 Category 1 Laboratories

(1) Category 1 laboratories are recognised to test:

a) for fitness for purpose (which includes safety and truth of labelling) of dairy material, as required by the Animal Products Act 1999 and subsequent amendments; and
b) dairy material for export to meet importing country specified tests.

(2) Category 1 laboratories:

a) are accredited under the dairy testing programme by a MPI-approved accreditation body, to ISO Standard 17025;
b) maintain a standard in Inter-laboratory Comparison Programmes (ILCP), or equivalent, for the tests concerned, such that MPI has confidence in their testing ability; and
c) meet the requirements of all relevant MPI requirements.

5.1.3 Category 2 Laboratories

(1) Category 2 laboratories are recognised by MPI to test only the company's own produce for fitness for purpose which includes safety and truth of labelling:

a) for the purposes of internal quality control (including raw milk testing); and
b) for sale in the New Zealand domestic market.

(2) Category 2 Laboratories:

a) are recognised under the dairy testing programme, by an MPI-approved body, as meeting the requirements of sections 5.6 Criteria for Category 2 Laboratories;
b) maintain a standard in Inter-laboratory Comparison Programmes (ILCP), or equivalent, for the tests concerned, such that MPI has confidence in their testing ability; and
c) meet relevant MPI requirements.

5.2 Additional Laboratory Recognition Criteria

5.2.1 General Criteria

Laboratories are recognised for specific tests, test methods and products. This information is in the schedule issued by the accreditation/recognition body. Conditions may be applied to laboratory recognition. For instance, it may be recognised for a limited range of tests or for a fixed period of time. Refer to Animal Products (Dairy) Conditions for Recognition for details.

Recognised laboratories continuously meet the recognition requirements during the recognition period.

If the results from an in-process laboratory are being used to justify rationalised testing of finished product for fitness for purpose (including safety and/or truth of labelling), it is either an independently recognised laboratory or recognised as part of a Category 1 or 2 laboratory.

5.2.2 Reporting Criteria

(1) Recognised laboratories report the information concerning their performance of tests required by MPI, to MPI Systems Audit Team.

(2) The following is reported before the event occurs:

a) request to use non-approved test methods;
b) significant alterations to the laboratory.

(3) The following exception reports are reported as soon as practicable, but not later than 24 hours after the event:

a) critical non-compliances and proposed corrective actions e.g. loss of critical equipment;
b) resolution of critical non-compliances;
c) poor performance in the ILCP programme;
d) emerging trends that have the potential to affect test results; or
e) a client is exerting influence on the laboratory to alter test results or re-test, without good reason.

(4) The laboratory reports to MPI within 10 working days of month end, a summary of its own performance. The frequency of regular reporting depends on the performance assessment category to which the laboratory is allocated.

(5) These regular reports concerning laboratory performance include notification of:

a) occurrence of internal or external reviews of the quality system;
b) participation in the ILCP Programme;
c) number of complaints received and resolution status;
d) whether any retesting was required as a result of laboratory failures; and
e) any other information that would give MPI a more complete picture of the laboratory's performance.

5.2.3 Inter-laboratory Comparison Programme (ILCP)

(1) Recognised Category 1 and 2 laboratories participate in an Inter-laboratory Comparison Programme (ILCP). If one is available for the tests and products for which they are accredited/recognised, to assure competence and demonstrate reliability of analytical results. The ILCP should meet the requirements of ISO Guide 43 part 1.

(2) The laboratory manager monitors the performance of the laboratory in the ILCP and ensures that appropriate actions are taken in response to ILCP results.

(3) If ILCP is not available, other means are used to establish analytical capability, e.g. split verification samples or other split samples.

5.2.4 Pathogen Laboratories

(1) In addition to being recognised Category 1 laboratories, laboratories testing for pathogens do the following:

a) liaise directly with the client dairy companies on all quality and logistical problems;
b) always assign priority to the testing of dairy traceback samples.

(2) The pathogen laboratory has in place suitable contingency plans to enable it to carry out *Salmonella* and *Listeria* testing in the event of a sudden, major increase in workload arising from a dairy company in a traceback situation.

(3) The contingency plans:

a) conform to the management, operational, technical and quality assurance requirements of ISO Standard 17025; and
b) ensure that the increased workload does not adversely affect the validity of the test results.

(4) Where circumstances arise that result in delays in testing samples, MPI and the affected dairy company are informed.

(5) In case of a major breakdown in the pathogen laboratory which would result in excessive delays in testing, the laboratory:

a) informs the affected client dairy companies; and
b) arranges to send the samples to another laboratory facility recognised by MPI.

(6) Use only test methods currently approved by MPI, unless with the prior written consent of MPI and the affected client dairy company. A pathogen laboratory wishing to employ a test method other than one currently approved by MPI, seeks written approval from MPI for the proposed method prior to use.

5.3 Acceptable Test Methods

(1) MPI approval is required for any test method used for determining the conformance of dairy material or product with parameters specified in Schedule 1 of the Animal Products Notice: Dairy Recognised Agencies and Persons Specifications.

(2) When assessing the conformance of dairy material and dairy product, MPI only recognises results from acceptable test methods as specified in the Animal Products Notice: Dairy Recognised Agencies and Persons Specifications. Where the manufacturing/customer specification specifies an unapproved test method then these results cannot be used to confirm conformance.

The laboratory manager is responsible for demonstrating that the test method is fit for purpose and this will be assessed during laboratory accreditation/recognition.

(3) Where there is no MPI-approved method that is suitable, e.g. for testing a new product, MPI's written approval to use an unapproved test method is required. This approval is obtained prior to the testing commencing.

(4) Letters to MPI applying for interim approval of a method:

a) are accompanied by as much of the information required in section 5.5 as is currently available;
b) outline the process and plan to have the method fully approved; and
c) provide the date by which the method will be fully approved in accordance with this document.

(5) Interim approvals have an expiry date after which the method must be fully approved if it is to be used. Testing and test reporting using the method is done in accordance with the scope and restrictions specified in the interim approval.

(6) Where results from in-process testing are used to verify conformance with regulatory requirements or official assurances provided by MPI, the methods used for in-process testing are required to be MPI-approved.

5.4 Test Method Approval

5.4.1 Generally Approved Methods

(1) Test methods from the following sources are usually approved by MPI provided they are used within their scope and are unmodified:

a) international standards, e.g. ISO, IDF, Codex;
b) methods published in reputable international texts, e.g.:

i) Standard methods published by the American Public Health Association;
ii) AOAC Official Methods of Analysis;
iii) "Pearson's Chemical Analysis of Foods"; or

c) national or regional standards or legislation, e.g.:

i) New Zealand Standards;
ii) Australian Standards;
iii) British Standards;
iv) Euronorm Standards;
v) USA FDA's "Bacteriological Analytical Manual" (BAM);
vi) EU legislation.

(2) These methods are subjected to the assessment criteria outlined in section 5.5.4.

5.4.2 Other Methods

(1) Test methods from the following sources may be approved by MPI. These methods are characterised (refer section 5.4.3 below) and subjected to the assessment criteria outlined in section 5.5.4:

a) refereed scientific journals;
b) in-house methods;
c) other sources, e.g. test methods involving new technology. These methods normally come from instrument manufacturers instructions and technical publications.
d) generally approved methods (refer section 5.4.1 above) used outside their scope and/or modified; and
e) MPI-approved methods used outside their scope and/or modified.

5.4.3 Characterisation of a Test Method

(1) The party undertaking the work nominates and uses a suitable standard or code to characterise the method. The nominated standard or code specifies the principles and process being used and is demonstrated to be appropriate for the purpose.

(2) The standard or code may be obtained from:

a) international standards and guidelines;
b) national and regional standards;
c) reputable scientific publications or organisations; or
d) an MPI-approved code of practice.

(3) In the absence of a suitable standard or code, then the method is characterised using acceptable scientific principles and practices.

As method characterisation can involve considerable time and resources and is a specialist area, it is recommended that advice be obtained from an expert before commencing.

(4) The following characteristics are determined. In some situations, e.g. residue analyses, additional characteristics may be required.

Method Performance Characteristics Required for Continuous Methods

(1) Continuous methods produce results that are expressed as numbers. Examples of continuous methods are butter moisture (example of result: 15.5% moisture), and aerobic plate count (example of result: 150 colony forming units per ml).

(2) The following characteristics are required for continuous methods, where applicable (if not applicable, please include a reason why):

a) bias;
b) precision (reproducibility or intermediate precision);
c) limit of detection; and
d) range.

(3) The method is characterised across the testing range.

Bias is the average difference between the test results and the accepted reference value.

Precision is an assessment of the closeness of agreement between independent test results on the same sample obtained under specified conditions.

- Reproducibility (R) is the precision of a method where test results are obtained with the same method on identical samples in different laboratories with different operators using different equipment. In situations where only one laboratory uses the method, intermediate precision can be provided.
- Intermediate precision is a measure of method precision due to changes in one or more of time, calibration, equipment, and operator in a single laboratory. Intermediate precision lies between the two extreme measures of precision, repeatability and reproducibility.

The limit of detection is the concentration of analyte that leads to the conclusion, with a given probability of error, that the sample concentration exceeds the concentration in a blank.

The range is the range of concentrations of analyte lying beyond the limit of detection, within which the method demonstrates a satisfactory relationship with the reference method or samples of known concentration.

Method Characteristics Required for Nominal Methods

(1) Nominal methods only report the presence or absence of something. Examples of nominal methods are *Salmonella* detection (example of result: not detected per ml) and leakage of UHT containers (example of result: container leaks).

(2) The following characteristics are required for nominal methods, where applicable (if not applicable, please include a reason why):

a) specificity rate (this may vary according to the level of analyte present);
b) sensitivity rate (this may vary according to the level of analyte present); and
c) limit of detection.

(3) The method is characterised across the testing range.

The sensitivity rate (the true-positive detection rate) is the probability that the method will classify a test sample as positive, given that the sample is a "known" positive.

The specificity rate (the true-negative detection rate) is the probability that the method will classify a test sample as negative, given that the sample is a "known" negative.

The limit of detection is the concentration of analyte that leads to the conclusion, with a given probability of error, that the sample concentration exceeds the concentration in a blank.

5.5 Process for Test Method Approval

5.5.1 Application

(1) Where approval is sought for a test method, the party seeking approval:

a) completes the application form;
b) attaches the required information (refer below); and
c) submits it to MPI.

Before making application for a test method approval it is recommended that the applicant considers making a request to add the test method concerned to the MPI Consolidated List of Tests for Animal Products: meat, poultry, honey, seafood, dairy, live animals and germplasm.

5.5.2 Information Required for Generally Approved Methods

(1) For generally approved methods (refer section 5.4.1 above), the following information is provided with the completed application form:

a) a copy of the published test method;
b) a clear statement as to the proposed scope of application for the products i.e. products tested, manufacturing/customer specifications, specification limits etc;
c) a copy of the laboratory's test procedure with commentary highlighting any modifications from published procedures;
d) copies of any relevant validation report publications; and
e) copies of any method approval/recognition by other agencies.

5.5.3 Information Required for Other Methods (Characterisation)

(1) For other methods (refer section 5.4.2) above, the following information is provided with the completed application form:

a) a copy of the published test method (where relevant);
b) a clear statement as to the proposed scope of application for the products i.e. products tested, manufacturing/customer specifications, specification limits etc;
c) a copy of the laboratory's test procedure with commentary highlighting any modifications from published procedures;
d) report(s) summarising the findings of the work to characterise the method;
e) copies of any other method(s) used in the report;
f) all base data, i.e. test results etc;
g) statistical analysis and calculations; and
h) any other documentation necessary to support the application.

5.5.4 Assessment

(1) MPI receives applications for test method approval accompanied by the supporting information listed above.

(2) MPI assesses the application using the following criteria:

a) all required information is provided;
b) all references (source material), support the application

(3) For generally approved methods (international/national) methods:

a) the method provided is the same as the published method;
b) the method is adequately documented;
c) the method is current (not obsolete);
d) the method is based on sound scientific principles and procedures; and
e) there are no reports that suggest this method should not be approved. Where reports exist, there is sound scientific data that alleviates the reported concerns.

(4) For "other" methods:

a) the method provided is the same as the published method;
b) the method is adequately documented;
c) the method is current (not obsolete);
d) the method is based on sound scientific principles and procedures;
e) there are no reports that suggest this method should not be approved. Where reports exist, there is sound scientific data that alleviates the reported concerns; and

f) the method characteristics are determined correctly (this requires checking of the design, the raw data and the calculations of the characteristics).

(5) On completion of the assessment MPI may approve the test method including conditions or restrictions on method use.

5.5.5 Approval

(1) MPI reviews this information and where satisfied that the method is suitable, approves the method including its scope and any appropriate restrictions. MPI advises the applicant the outcome of the application.

(2) When the test method is approved, MPI adds the test method to the register (database) of MPI-approved test methods. A list of the MPI-approved test methods, the scope of the approval and any restrictions is published on the MPI website.

5.5.6 Review

(1) MPI reviews test methods' approvals:

a) once every five years;
b) when there is evidence that the method may no longer be fit for purpose; or
c) when there are changes to regulatory requirements or official assurances.

5.5.7 Records

(1) Records are kept, for as long as is necessary for traceback purposes, of all aspects of the test method. This includes its origin, characteristics, assessment and approval, demonstration of fitness for purpose and use.

5.6 Criteria for Category 2 Laboratories

5.6.1 Organisation and Management

(1) The laboratory shall be legally identifiable. It shall be organised and shall operate in such a way that its permanent, temporary and mobile facilities meet the requirements of this document.

The legal identity is the name of the owner given in the laboratory's registration certificate.

(2) The laboratory shall:

a) have managerial staff with the authority and resources needed to discharge their duties;

A person must have charge of the laboratory who has been given control over the accommodation, equipment, budget and staff necessary to carry out the tests for which it is recognised.

b) have arrangements to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;
c) be organised in such a way that confidence in its independence of judgement and integrity is maintained at all times;

There must be no way in which the manufacturing part of the organisation can influence the outcome of the tests.

d) specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

The arrangements made to comply with the earlier sections must be recorded in writing.

e) provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;
f) have a technical manager (however named) who has overall responsibility for the technical operations;
g) have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;

The laboratory must be managed by someone who thoroughly understands the tests being carried out. They must understand the principles on which the test works, what could go wrong and how to identify and correct any problems, and who is responsible for the results.

h) nominate deputies in case of absence of the technical or quality manager;
i) where relevant, have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights;

Clients are those for whom the laboratory produces test reports, and include MPI.

j) participate in inter-laboratory comparisons and proficiency testing programmes.

MPI has specified that laboratories must take part in ILCP for all tests for which it is available and must organise some independent sampling and duplicate testing in another recognised lab.

5.6.2 Quality System, Audit and Review

(1) The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of testing activities it undertakes. The elements of this system shall be documented. The quality documentation shall be available for use by the laboratory personnel. The quality manual shall be maintained current under the responsibility of the quality manager.

The quality documentation does not need to be elaborate but someone must be responsible for writing and keeping up to date the procedures and records which are necessary to produce results that mean something.

(2) The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

For a small laboratory it is acceptable for the annual external audit to be the only audit. The audit may be carried out by a single auditor.

(3) The quality system adopted to satisfy the requirements of this document shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

This review is independent of the audit though obviously the audit report would be part of the information considered.

(4) All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

(5) In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:

a) internal quality control schemes using whenever possible statistical techniques;
b) participation in proficiency testing or other interlaboratory comparisons;
c) replicate testings using the same or different methods.

Quality control checks should be part of the method for most tests. They include the use of positive and negative controls, standards, duplicates, house standards, checks on water quality and pH for media preparation and the like. They demonstrate the credibility of the test result.

5.6.3 Personnel

(1) The testing laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

(2) The testing laboratory shall ensure that the training of its personnel is kept up-to-date.

(3) Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

The people who are doing the testing should understand what they are doing or at least should be under the direct supervision of someone who does. This could be the result of informal, in-house training and does not mean that every person involved in testing has to have a formal qualification.

5.6.4 Accommodation and Environment

(1) Laboratory accommodation, test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

The laboratory must be housed and run in such a way that the conditions do not invalidate the results.

(2) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

(3) The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

The laboratory should make and record measurements of those factors, like temperature and bacterial air counts, which might affect the results and take action if the trigger levels are exceeded.

(4) There shall be effective separation between neighbouring areas when their activities are incompatible.

It may be necessary to separate off some areas, such as microbiology laboratories.

(5) Access to and use of all areas where the quality of the testing could be affected shall be defined and controlled.

Only authorised people should be able to enter the testing areas.

(6) Adequate measures shall be taken to ensure good housekeeping in the laboratory.

It is the laboratory's responsibility to comply with the relevant health and safety requirements. This aspect, however, is outside the scope of this document.

5.6.5 Equipment and Reference Materials

(1) The laboratory shall have all items of equipment (including reference materials) required for the correct performance of calibrations and tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this document are met.

A laboratory should have all the equipment necessary to carry out testing and calibration.

(2) All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

The laboratory should be able to show that the equipment is working properly and should have a system for dealing with equipment which is not working.

(3) Records shall be maintained of each item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include:

a) the name of the item of equipment;
b) the manufacturer's name, type identification, and serial number or other unique identification;
c) date received and date placed in service;
d) current location, where appropriate;
e) condition when received (e.g. new, used, reconditioned);
f) copy of the manufacturer's instructions, where available;
g) dates and results of calibrations and/or verifications and date of next calibration and/or verification;
h) details of maintenance carried out to date and planned for the future;
i) history of any damage, malfunction, modification or repair.

Records should be kept of the preparation, use and storage of standard reagents and microbiological media.

(4) The result of a calibration should be recorded in such a way as to identify the equipment calibrated.

5.6.6 Measurement, Traceability and Calibration

(1) All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established programme for the calibration and verification of its measuring and test equipment.

All equipment that makes measurements which are an important part of the test must be calibrated, against a standard traceable to a national standard when possible.

(2) The overall programme of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall wherever applicable indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

(3) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable programme of interlaboratory comparisons or proficiency testing.

(4) Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

(5) Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a programme of calibration and verification for reference standards.

(6) Where relevant, measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

Routine checks should be made from time to time where the measurement is known to change (e.g. electronic thermometers).

5.6.7 Calibration and Test Methods

(1) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardise the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

(2) The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

(3) Where methods are not specified, the laboratory shall, wherever possible, select methods that have are approved by MPI, have been published in international or national standards, those published by reputable technical organisations or in relevant scientific texts or journals.

The test methods should be up to date and available to anyone carrying out the test. They should be clear and should include such things as the variability (so that results are not reported with a spurious accuracy and the tester knows when a result could be close to a test limit). Methods should be approved by MPI. Any changes to the method should be justified and agreed before they are used.

(4) Where it is necessary to employ methods that have not been established as approved, these shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports.

(5) Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples.

Sampling is an important part of the testing process. The way the sample is taken and handled can critically affect the test. It is the laboratory's responsibility to make its best efforts to be sure that the sample accurately represents the lot being tested.

(6) The method of sampling and handling samples should be recorded especially those features that could affect the outcome of the test.

(7) Calculations and data transfers shall be subject to appropriate checks.

Where the method requires recording measurements and making calculations the laboratory should have a system to check that mistakes have not been made. This means that a second person should redo a proportion of the calculations and check transcriptions.

(8) Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall ensure that:

a) the requirements of this document are complied with;
b) computer software is documented and adequate for use;
c) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;
d) computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of test data;
e) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorised access to, and the unauthorised amendment of, computer records.

5.6.8 Handling of Test Items

(1) The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time.

All samples must be identified in some way which prevents confusion with other samples. Repeat samples must be given a separate identification to avoid confusion.

(2) Upon receipt, the condition of the test item, including any abnormalities or departures from standard condition as prescribed in the relevant test method, shall be recorded. Where there is any doubt as to the item's suitability for test, where the item does not conform to the description provided, or where the test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

Where the laboratory has no control over sampling it should still be aware of the condition of the sample it receives and should be careful how the samples are handled and stored. Reports should make it clear that the results relate only to the sample as received.

(3) The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the test item, during storage, handling, preparation, and test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

The tester must be sure that the sample is in good condition and that the results of the test are not likely to be falsified by the condition of the sample. If the sample is to be kept for a length of time that may lead to deterioration, the laboratory should have the facilities to keep it without any problems, for example in a refrigerator or freezer.

(4) The laboratory shall have documented procedures for the receipt, retention or safe disposal of test items, including all provisions necessary to protect the integrity of the laboratory.

The laboratory must have procedures for getting rid of samples and test materials safely.

5.6.9 Records

(1) The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the test report for an appropriate period. The records for each test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing.

The laboratory must keep all their laboratory results, including the measurements and calculations made during the test. Any changes should be made by crossing through, but not obliterating, the original result. The change should be initialled and the reason for the change recorded.

(2) All records pertaining to test equipment, certificates and reports shall be safely stored, held secure and in confidence to the client.

Records of calibration must be kept.

5.6.10 Certificates and Reports

(1) The results of each test, or series of tests, carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the test methods. The results should normally be reported in a test report and should include all the information necessary for the interpretation of the test results and all information required by the method used.

Test results must be recorded in a way that is easily understood by the person using them. The person should know when the sample was received, when the test was done, which sample was tested, what tests were done, who tested it and what the result was. If there is a pass/fail limit it should be noted alongside the result.

(2) Each certificate or report shall include at least the following information:

a) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;
b) description and unambiguous identification of the item calibrated or tested;
c) date of receipt of test item and date(s) of performance of test, where appropriate;
d) identification of the test method used, or unambiguous description of any non-standard method used;
e) any deviations from, additions to or exclusions from the calibration or test method, and any other information relevant to a specific test, such as environmental conditions;
f) measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;
g) a statement of the estimated uncertainty of the test result (where relevant);
h) a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the report (however produced), and date of issue.

(3) Where the report contains results of tests performed by sub-contractors, these results shall be clearly identified.

(4) Particular care and attention shall be paid to the arrangement of the report, especially with regard to presentation of the test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of test carried out, but the headings shall be standardised as far as possible.

(5) Material amendments to a test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Test Report (or Test Certificate), serial number ... [or as otherwise identified]", or equivalent form of wording. Such amendments shall meet all the relevant requirements of this document.

If a report needs to be changed for some reason it should be done on a separate report rather than an alteration of the original. The replacement report should have all the same features as the original plus the reason for the change and should refer to the original.

5.7 Performance Measurement of Dairy Laboratories

5.7.1 Classification

(1) Each laboratory is assigned to one of the following performance assessment categories based on their demonstrated compliance regulatory requirements:

a) Reduced Assessment;
b) Standard/Entry Assessment; or
c) Increased Assessment.

5.7.2 Reduced Assessment Category

(1) To be assigned to, and remain in, the Reduced Assessment category, the laboratory meets all the criteria for the Reduced Assessment category in Table A1.1. The laboratory has demonstrated compliance with the criteria for at least two seasons.

5.7.3 Standard/Entry Assessment Category

(1) To be assigned to, and remain in, the Standard/Entry Assessment category, the laboratory meets all of the criteria for the Standard/Entry Assessment category in Table A1.1. The laboratory has demonstrated compliance with the criteria for at least one season.

5.7.4 Increased Assessment Category

(1) A laboratory will be assigned to the Increased Assessment category if it:

a) fails to meet:

i) ISO Standard 17025; or
ii) Clause 5.3 of the Animal Products Notice: Dairy Recognised Agencies and Persons Specifications; or
iii) MPI requirements; or

b) has critical non-compliances in reporting to MPI; or
c) has critical non-compliances in management and resolution of its own non-compliances.

5.7.5 Entry Classification

(1) When a laboratory moves to the Regulatory Model system, the accreditation body reviews the laboratory's compliance. Where a laboratory demonstrates an appropriate level of compliance, they

are assigned to the Standard/Entry Assessment Category. If the laboratory fails to demonstrate compliance to one or more areas, they are assigned to the Increased Assessment Category.

(2) The accreditation body advises the manager of the laboratory of the category to which they have been assigned and the frequency of assessments.

(3) The manager of the laboratory implements performance-based assessment frequency as instructed by the accreditation body.

5.7.6 Demonstration of Compliance

(1) The laboratory demonstrates compliance at the level appropriate to the performance assessment category to which it has been assigned. Refer to Table A1.1.below for the criteria used to demonstrate compliance. Failure to meet any of the requirements will result in reclassification to a performance assessment category with higher levels of assessment (refer to Increased Assessment section below).

Table A1.1: Criteria for the Demonstration of Compliance Appropriate to each Performance Assessment Category

Area	Reduced Assessment	Standard/Entry Assessment	Increased Assessment
Assessment by accreditation/ recognition body	Compliance with ISO Standard 17025 or Clause 5.3 of the Animal Products Notice: Dairy Recognised Agencies and Persons Specifications, and MPI requirements demonstrated for two years.	Compliance with ISO Standard 17025 or Clause 5.3 of the Animal Products Notice: Dairy Recognised Agencies and Persons Specifications, and MPI requirements demonstrated.	Fails to demonstrate compliance with ISO Standard 17025 or Clause 5.3 of the Animal Products Notice: Dairy Recognised Agencies and Persons Specifications or MPI requirements.
Reporting	Regular and exception reports complete accurate and on time for at least two seasons.	Regular and exception reports complete accurate and on time for at least one season; or Regular reports occasionally incomplete or late and exception reports are complete, accurate and on time.	Regular or exception reports contain incomplete information or factual errors or are persistently late; or exceptions are not reported.
Management of critical non-compliances	Critical non-compliances identified; full traceback completed to identify root causes; corrective actions completed in a timely manner; full analysis of the risk to the operation from this type of non-compliance completed; and actions taken to eliminate the risk of potential non-compliances or monitoring systems implemented to identify potential non-compliance in the operation.	Critical non-compliances identified and managed in accordance with MPI requirements.	Critical non-compliances not identified; or critical non-compliances are identified and inadequately managed.

5.7.7 Assessment Requirements

(1) The manager of the laboratory ensures that the assessment required for the performance assessment category to which they have been assigned are undertaken as specified.

(2) The assessment requirements of each performance assessment category are specified in Table A1.2 below.

Table A1.2: Assessment Requirements for Each Performance Assessment Category

Assessment	Performance Assessment Category		
	Reduced Assessment Category	Standard/Entry Assessment Category	Increased Frequency Category
Assessment by the accreditation/ recognition body	Full assessment of the laboratory is required every two years; and a surveillance assessment is required in the alternate year.	Full assessment of the laboratory is required on an annual basis	Full assessment of the laboratory is required at least every six months. The frequency is defined by MPI and is dependent on the degree of non-compliance and risk. MPI may increase the frequency of Assessment at its own discretion or on the recommendation of the accreditation/ recognition body.
Regular reporting	Quarterly	Monthly	Monthly or more frequently, as specified by MPI.

5.8 Reclassification

5.8.1 Initiation of a Review

(1) MPI initiates a review of the category to which a laboratory is assigned on receipt of any of the following communications.

(2) MPI recommendation for reclassification to a category with decreased levels of assessment

(3) When, as a result of an assessment, the accreditation/recognition body and MPI are satisfied that the laboratory demonstrates compliance with all the criteria in Table A1.1 for the recommended reclassification category, they submit a recommendation to the accreditation body for reclassification.

(4) MPI recommendation for reclassification to a category with increased levels of assessment

(5) When, as a result of an assessment, the accreditation/recognition body or MPI identifies that the laboratory fails to comply with one or more of the criteria in Table A1.1 for the category to which it is assigned.

5.8.2 Notification of Significant Changes

(1) A report of the occurrence of any of the following significant changes is received from the laboratory, MPI or accreditation/recognition body:

a) change of ownership;
b) change of laboratory management;

c) change of authorised, accredited and approved signatories; or
d) significant alterations to the premises or equipment.

5.8.3 Report of a Critical Non-compliance

(1) A report of a critical non-compliance within the laboratory, provided in accordance with the reporting requirements specified in the criteria section of this document which applies to laboratories.

5.8.4 Request for Review by the Laboratory

(1) A request by a laboratory for MPI to review the category to which it is assigned. A laboratory may request a review by notifying MPI in writing, setting out reasons for seeking the review. A copy of the request is sent by the laboratory to the laboratory's accreditation/recognition body.

5.8.5 Request for Review by Another Party

(1) A request by any party for the accreditation body to review the category to which a laboratory has been assigned. Any party may request a review by notifying MPI in writing, setting out reasons for seeking the review. Copies of the request are sent by the party to the laboratory and the laboratory's accreditation/recognition body.

5.8.6 An Offence is Committed

(1) The accreditation/recognition body or MPI provides evidence that the laboratory has falsified a test report, deliberately withheld information or committed any other offence against the Act, or regulations and specifications made under the Act.

5.8.7 Review

(1) The accreditation body reviews the category to which a laboratory is assigned and, where appropriate, reassigns a new category.

(2) This review will consider the criteria in Table A1.1 and all the available information, including any case that has been provided in writing. The accreditation body may, for the purposes of the review, undertake or commission an assessment of the laboratory's quality system. This assessment will be at the laboratory's expense where the laboratory has requested the review.

5.8.8 Outcome

(1) The accreditation body will advise the manager of the laboratory of either:

a) the category to which they have been assigned, the frequency of assessments and the date of effect; or
b) confirmation of the existing category, if there is no change of classification.

(2) The manager of the laboratory implements performance-based assessments at the frequencies instructed by the accreditation body. This includes making the necessary contractual arrangements with the accreditation/recognition body.

6 Dairy Recognised Agencies and Persons

6.1 Technical Competency of Recognised Persons

(1) Recognised persons:

a) are trained in the skills of assessment and have successfully completed an NZQA-recognised training course within the previous three years. If training was completed more than three years previously, active involvement in assessment over the intervening years is demonstrated. The person has carried out two or more assessments under the supervision of a recognised person or the accreditation body;
b) have some formal technical training in the field for which recognition is sought, for example a tertiary qualification such as a degree or dairy diploma, or other industry-recognised training programme;
c) have a thorough understanding of the specific aspect of the dairy industry in which recognition is sought. Normally, this would mean at least two years of recent involvement in a relevant area in the industry;
d) demonstrate an understanding of the requirements of relevant dairy industry regulations and MPI requirements; and
e) have a thorough knowledge of the quality system and procedures of the agency(s) for which they are granted signatory status.

(2) The person's technical competence is determined by review of training records, experience, and on-site assessment. An MPI technical specialist, operating in conjunction with the accreditation body, assesses the technical competence of the person.

(3) Recognised persons are granted signatory status as part of a recognised agency, by the accreditation body.

6.1.1 Assessment of Continued Competence of Recognised Persons

(1) In order for recognition to continue, the recognised person demonstrates continued competence in both internal and external assessments.

6.1.2 Internal Assessments

(1) The recognised person's continued competence is internally assessed, by management review and peer review, at least annually, by the agency by which the person is employed. Where internal peer review is not possible, peer review is by an accreditation body or a recognised person working for another recognised agency.

(2) Agencies have minimum criteria against which each person's competence is internally assessed. The following areas are included in the criteria:

a) knowledge of relevant dairy industry legislation and MPI requirements;
b) knowledge and demonstrated use of the agency's quality system and procedures;
c) appropriate technical background and current knowledge;
d) adequate experience in a relevant area of industry;
e) demonstrated skills and competencies;
f) adequacy of evaluation and verification services carried out;
g) accurate, unbiased, uncensored and timely reporting of client details.

(3) Recognised persons carry out at least one assessment in each category of recognition each year, or they demonstrate continued competence in assessing in that category.

(4) As part of the management review, the agency checks that the work done by all recognised persons working for it is of a consistent standard.

6.1.3 External Assessment

(1) The recognised person's continued competence is assessed by the accreditation body and MPI, at least annually. Initially, this is a full assessment.

(2) The extent of re-assessment will be reviewed, based on performance, in accordance with MPI requirements outlined in this document. Subsequent annual assessments may be full or surveillance assessments.

(3) More frequent full assessment may be required if the accreditation body or MPI determines non-compliance.

(4) As part of the external assessment, the accreditation body and MPI check that the work done by recognised persons across all agencies, is of a consistent standard.

6.1.4 Subcontracted Assessors

(1) Persons who subcontract their services to agencies comply with all of the requirements listed above.

(2) Subcontracted persons may be recognised to provide assessment services for more than one agency. In this case, their knowledge of the quality systems and procedures used by all the agencies to which they subcontract, is assessed by the accreditation body. If they are supplying the same assessment services to all agencies, a full re-assessment of their technical knowledge may not be necessary.

(3) When a person has applied for recognition in more than one category, their performance in all categories may be assessed at the same time, if appropriate.

6.1.5 Categories for Recognition of Persons

Service

(1) Recognition is available in one or more of the following service areas:

a) Risk Management Programme Evaluation;
b) Risk Management Programme Verification;
c) Heat Treatment Evaluation;
d) Premises Evaluation.

Product groups

(1) Persons are recognised in one or more of the following product groups:

a) Cream Products (includes butter, AMF, frozen cream, PEF);
b) Cheese (includes hard and soft cheeses);
c) Milk Powder (includes baby foods based on milk powder, buttermilk powder, whey powder);
d) Casein and Caseinates;
e) Whey Protein Concentrate (and other ultrafiltration and microfiltration processes);
f) Liquid Milk Processing Plants (including UHT);
g) Cultured Foods (cream cheese, cottage cheese, quark, ricotta etc, yoghurt and other cultured foods);
h) Ice Cream;
i) Specialist category (co-packers, lactose, dairy whip etc.);
j) Stores and transport;
k) Farm Dairy Systems;
l) Unpasteurised milk products – on-farm;
m) Unpasteurised milk products – manufacture;
n) Official Assurance Verification.

6.2 Competency Requirements for Heat Treatment Evaluators

(1) The evaluation of heat treatments is undertaken by a person who has:

a) a relevant tertiary qualification or demonstrated competence as a technical professional in food processing engineering;
b) relevant process knowledge or experience;
c) adequate knowledge of food safety;
d) successfully completed a NZQA-registered course in HACCP and been assessed as competent;
e) been recognised for heat treatment evaluation:

i) in the appropriate product group in accordance with the Guidance Document: Dairy: Recognition of Agencies and Persons; and
ii) has employment or a contractual relationship with a recognised agency in accordance with the Guidance Document: Dairy: Recognition of Agencies and Persons; and

1) has practical experience validating heat treatment equipment and systems; and
2) successfully demonstrated their competence to evaluate heat treatments to the accreditation body and MPI.

6.3 Competency Requirements for Risk Management Programme Verifiers (Heat Treatment)

(1) Verification of heat treatments is undertaken during the Risk Management Programme verification by a person who has:

a) relevant process knowledge or experience;
b) adequate knowledge of food safety;
c) successfully completed a NZQA-registered course in HACCP and been assessed as competent;
d) practical experience developing and implementing HACCP plans that include heat treatment critical control points;
e) been recognised for Risk Management Programme Verification in the appropriate product group in accordance with the Guidance Document: Dairy: Recognition of Agencies and Persons;
f) has employment or a contractual relationship with a recognised agency in accordance with the Guidance Document: Dairy: Recognition of Agencies and Persons;
g) successfully demonstrated their competence to verify heat treatments as part of the Risk Management Programme verification to the accreditation body and MPI. Where reasonable doubt occurs with validator operation or systems, parameter confirmation checks may be performed.

6.4 Accreditation and Recognition of Agencies

(1) All agencies providing services to the dairy industry are accredited, by an accreditation body, to ISO Standard 17020 and the requirements of this document. The agency specifies, in its Quality System and application for accreditation, the category in section 4 of ISO Standard 17020 against which it is to be assessed.

(2) Procedures for accreditation of agencies are outlined in detail in the accreditation bodies' internal procedures. An outline of the accreditation and recognition process is provided in Table A1.3.

6.4.1 Contractual Criteria

(1) An agency contracting to provide assessment services has systems in place which ensure the contractual conditions under which it provides those services to clients are documented and agreed by both parties. These conditions include:

a) full access to relevant client records;
b) full access to the relevant personnel and facilities of the client, at any reasonable time;
c) written authority from its clients, to report relevant information to MPI;
d) conditions of payment;
e) key performance indicators, by which the client will measure the performance of the agency;
f) full access by the client to all records concerning it held by the agency; and
g) a statement clarifying ownership of all information relating to the client.

6.4.2 Management of Confidentiality

(1) The agency has a written statement, as part of the Quality System, allowing the accreditation body to release information to MPI, as required.

(2) The agency has systems to preserve the confidentiality of information from clients.

6.4.3 Management of Workload

(1) The agency has documented policies and procedures that prevent and demonstrate the absence of commercial, financial and other pressures that may lead to a conflict of interest for all areas of work. These procedures ensure that all work is completed without time constraints, intimidation or other factors that would influence assessment results (either in favour of or against the party being assessed).

(2) The agency has documented policies and procedures that prevent it from abusing its position for financial or other gain.

6.4.4 Management of Potential Conflicts of Interest

(1) The agency has documented policies and procedures that ensure the effective separation of consultancy and assessment work for the same client, to prevent conflicts of interest.

6.4.5 Management of Recognised Persons

(1) The agency has adequate numbers of full-time, competent employees to provide routine services in the category or categories for which the agency is recognised. Refer to section 6.1 Technical Competency of Recognised Persons. All personnel providing assessment services, including subcontracted staff, are individually recognised by MPI.

(2) The agency has systems to ensure that all persons for whom recognition is sought are appropriately qualified, trained and assessed, in accordance with section 6.1.

(3) Agencies have documented systems to ensure that only recognised persons provide evaluation and verification services.

(4) Agencies have minimum criteria against which each recognised person's competence is internally assessed, at least annually, by management review and internal peer review. Where internal peer review is not possible, peer review is by an accreditation body. The following areas are included in the criteria:

a) knowledge of relevant dairy industry legislation and MPI requirements;
b) knowledge and demonstrated use of the agency's quality system and procedures;
c) appropriate technical background and current knowledge;
d) adequate experience in a relevant area of industry;
e) demonstrated skills and competencies;
f) adequacy of evaluation and verification services carried out; and
g) accurate, unbiased, uncensored and timely reporting of client details.

(5) The agency has systems in place to check the consistency of work done by recognised persons within the agency, at least annually.

(6) The agency has documented systems to ensure that, when any person is deemed to be non-compliant:

a) the person does not carry out evaluation and verification services;
b) within 24 hours of the review the accreditation body and MPI are notified of any person deemed to be non-compliant;
c) a traceback is conducted on the work done by the non-compliant person to determine the corrective actions required;
d) where there is any doubt about the quality of any work done by the person, the client(s) involved are advised and the work is repeated by another recognised person;
e) agencies subcontracting the services of persons to deliver specific functions have systems in place to manage those persons in accordance with section 4.2 of ISO Standard 17020 and this document;
f) the agency has systems in place to maintain full records of all training and experience of all recognised persons providing assessment services on behalf of the agency;
g) to prevent over-familiarity with client systems and processes, the agency has systems that ensure that recognised persons do not provide the same evaluation/verification services continuously to the same client for more than three years.

6.4.6 Control of Documents

(1) The agency has documented systems to ensure adequate record-keeping and document control.

(2) The agency has systems to ensure access by relevant staff to the latest version of all relevant legislation and regulatory requirements.

(3) The agency's procedures specify the retention time for all information required by MPI requirements.

6.4.7 Management of Internal Non-compliance

(1) The agency has proactive systems for internal management review and the completion of corrective actions to rectify non-compliances. These systems have provision for monitoring the agency's own performance, and for the anticipation, identification and prevention of problems. Critical non-compliances are reported to MPI within 24 hours.

6.4.8 Management Review

(1) The agency has procedures to conduct an internal management review of its own quality system at least annually.

6.4.9 Reporting to MPI

(1) The agency's system documents the requirements for reporting to MPI. Refer to section 6.3 in Recognised Agency Responsibilities for details.

6.4.10 Industry Standardisation Sessions

(1) The agency's system requires participation in industry standardisation sessions (organised by MPI) to ensure uniformity when regulatory requirements are issued or reviewed.

Table A1.3: Outline of the Accreditation and Recognition Process

(1)	The agency applies to an accreditation body for accreditation, using appropriate documentation.
(2)	The accreditation body registers the application and requests a copy of the agency's Quality System documentation, including technical procedures.
(3)	The accreditation body appoints a Lead Assessor, who reviews the agency's Quality System documentation.

(4) The accreditation body contacts the MPI Technical Expert and forwards the agency's Quality System documentation for review.

(5) If any non-compliances are identified in the review of documentation, the agency is notified and requested to correct non-compliances.

(6) Any non-compliances are signed off by either the Lead Assessor or Technical Expert.

(7) The Lead Assessor arranges a site assessment visit with the Technical Expert and the Agency.

(8) The Assessment Team conducts a site assessment, including observation of persons seeking approval performing relevant tasks, and the agency is notified of any non-compliances. All recognised persons within the agency are assessed annually, but the depth of external assessment will be based on performance.

(9) The agency resolves non-compliances.

(10) The Assessment Team signs off non-compliances.

(11) The accreditation body grants accreditation to the agency and forwards a recommendation for approval to MPI.

(12) MPI recognises the agency and persons, and lists on the Register of Recognised Agencies and Persons on the MPI website.

6.5 Recognised Agency Responsibilities

6.5.1 Verification of Compliance with Risk Management Programmes

(1) The agency verifies the client's risk management programme (RMP) at the frequency in the section on Performance Measurement of Dairy Manufacturers in DPC 3: Approved Criteria for the Manufacturing of Dairy Material and Products.

(2) The RMP and its components are verified against the requirements in the Animal Products (Risk Management Programme Specifications) Notice 2008.

(3) Following the assessment of the RMP, including its components, the agency notifies the assessment frequency category to the client.

6.5.2 Management by Agencies of Client Non-compliances

RMP non-compliances identified during assessments

(1) The agency manages the resolution of non-compliances and critical non-compliances identified during assessment of client RMPs.

(2) The agency:

a) advises MPI of any critical non-compliances relating to non-conforming dairy material or product, where product is deemed to be affected. The agency will require written disposal instruction prior to release, within 24 hours. Initial verbal reporting is acceptable, but is to be confirmed in writing within 72 hours. The exception report is to contain all the information specified in the Dairy Processing Specification in the section on RMP Reporting Requirements. If the report received from the client is incomplete, the agency obtains the missing information;
b) agrees corrective actions proposed by the client; and
c) agrees and sets with the client, a target date for resolution of the non-compliance/ critical non-compliance by the client.

(3) On the target date for resolution, the agency:

a) confirms with the client that resolution/corrective action has been completed;

b) confirms that the RMP has been reviewed (where appropriate) and, where necessary, submitted to the agency for assessment and MPI for re-registration;
c) reports to MPI concerning resolution of critical non-compliances; and
d) increases the frequency of assessment of the client, if required.

The agency is only required to inform MPI of non-compliances, which result in non-conforming dairy material or product, requiring written disposal instructions prior to release.

(4) Refer to Table A1.4 for a diagram of the escalation process.

RMP critical non-compliances reported by clients

(1) Within 24 hours of receiving notification of a critical non-compliance, the agency:

a) notifies MPI of any critical non-compliance, relating to non-conforming dairy material or product, where product is deemed to be affected, and as such will require written disposal instruction prior to release. The exception report is to contain all applicable information specified in the DPC 1: Animal Products (Dairy) Approved Criteria for General Dairy Processing in section 7, Reporting Requirements. If the report received from the client is incomplete, the agency obtains the missing information;
b) agrees with the client, appropriate corrective actions. If the critical non-compliance results in non-conforming dairy material or product, the agency ensures that the client is following the requirements specified in the Dairy Processing Specification in the section on Non-conforming dairy material or produce; and
c) agrees and sets with the client, a target date for resolution of the critical non-compliance by the client

(2) On the target date for resolution, the agency:

a) confirms with the client that resolution/corrective action has been completed;
b) confirms that the RMP has been reviewed and, where necessary, re-registered;
c) reports to MPI concerning resolution of the critical non-compliance; and
d) increases the frequency of assessment of the client (where appropriate), in accordance with the section in the Dairy Processing Specification on Performance Measurement of Dairy Manufacturers.

The agency is only required to inform MPI of non-compliances, which result in non-conforming dairy material or product, requiring written disposal instructions prior to release.

6.5.3 Critical Situations

(1) When the agency becomes aware of a critical situation, whether as a result of a RMP assessment or from notification by the client or any other party, it immediately advises MPI. Initial verbal reporting is acceptable, but is confirmed in writing within 72 hours. Where initial notification is in writing (email or fax), the agency has a telephone conversation with MPI to confirm receipt. A message on an answering service is not sufficient. MPI is responsible for ensuring resolution of the critical situation.

6.5.4 Reporting

General requirements

(1) The agency reports information accurately and in a timely manner.

(2) The agency obtains written authority from its clients to report relevant information about them to MPI.

(3) All reports are sent directly to MPI. Faxed and emailed transmission of data is acceptable, provided it is signed/sent by an authorised signatory.

Exception reporting

(1) Within 24 hours of receipt of an exception report from a client, where product is deemed to be affected, and as such will require written disposal instruction prior to release, the agency is required to notify MPI. Initial verbal reporting is acceptable, but is to be confirmed in writing within 72 hours. The exception report contains all the information specified in the dairy Processing Specification in the section on RMP Reporting Requirements. If the report received from the client is incomplete, the agency obtains the missing information. The completed exception report is forwarded to MPI.

Regular reporting

(1) The agency reports to MPI, within 14 days of month end, a summary of activities and issues in an agreed format.

(2) Reports are brief, concise and unambiguous, and typically include the following:

a) the total number of critical non-compliances reported in each category from all contracted parties, and the status of resolution of these critical non-compliances;
b) the total quantities of mislabelled and unsafe product that were disposed of during the month;
c) the results of any relevant trend analysis (including decline in operator compliance);
d) for each party whose RMP was verified during the past month, a copy of the verification audit report identifying:

i) name of the party;
ii) a summary of the non-compliances and critical non-compliances and outstanding corrective actions;
iii) a notification concerning assessment frequency of the party;

e) any other information that would give MPI a more complete picture of safety issues in the dairy industry.

Reporting on demand

(1) The agency supplies, on demand, any additional information concerning the RMP or product, requested by MPI, to enable it to investigate product safety problems or potential risks, or to support official assurances.

6.5.5 Agency Reports

Exception reporting

A Critical Non-compliances within the Agency's Quality System

(1) The agency reports to MPI, within 24 hours, any critical non-compliances which have a potential impact on the effectiveness of the assessment services provided, which are detected within its own quality system. Critical non-compliances may arise from customer complaints, internal assessment findings, identification of non-compliant assessors and internal management review findings.

B Non-compliant Persons

(1) The agency reports to MPI, within 24 hours, the details of any non-compliant recognised persons, and the corrective actions to be taken.

C Disputes with Clients

(1) The agency reports to MPI, within 24 hours, any valid disputes with clients concerning regulatory non-compliance.

Regular Reporting

(1) The agency reports to MPI, within 14 days of month end, a summary of its own performance. The frequency of regular reporting depends on the performance assessment category to which the agency is allocated. Refer to section 6.4 Performance Measurement of Recognised Agencies and Persons in this document.

(2) Reports are brief, concise and unambiguous, and include the following:

a) a schedule of assessments planned for the coming 3 months;
b) positive verification of the agency's performance, including:

i) number of performance assessments of recognised persons;
ii) occurrence of internal or external reviews of the quality system;
iii) any proposed changes to the agency's staff or operations relevant to dairy industry assessment services;
iv) number of complaints received from dairy industry clients and resolution status;
v) any other information that would give MPI a more complete picture of the agency's performance in managing its dairy industry clients.

6.5.6 Management of Recognised Persons

(1) Full assessment of recognised persons follows the assessment of the agency by the accreditation body.

(2) Initially persons have a full assessment on an annual basis. Re-assessment frequency will be reviewed in accordance with Performance Measurement of Recognised Agencies and persons in section 6.4.

(3) The agency reviews the performance and competence of each recognised person, at least annually, by management review and internal peer review. Where internal peer review is not possible, peer review is by an accreditation body or a recognised person working for another recognised agency.

(4) The consistency of assessment work done by recognised persons within the agency is assessed at least annually. If their performance is not consistent, corrective action is taken.

(5) Agencies ensure that only recognised persons provide evaluation and verification services.

(6) The agency ensures that when the performance of any person is deemed to be non-compliant, appropriate corrective action is taken.

(7) The agency ensures that recognised persons do not become so familiar with client systems and processes that their ability to effectively assess is impaired.

(8) The agency manages potential conflicts of interest when undertaking consultancy and evaluation/verification contracts for the same client.

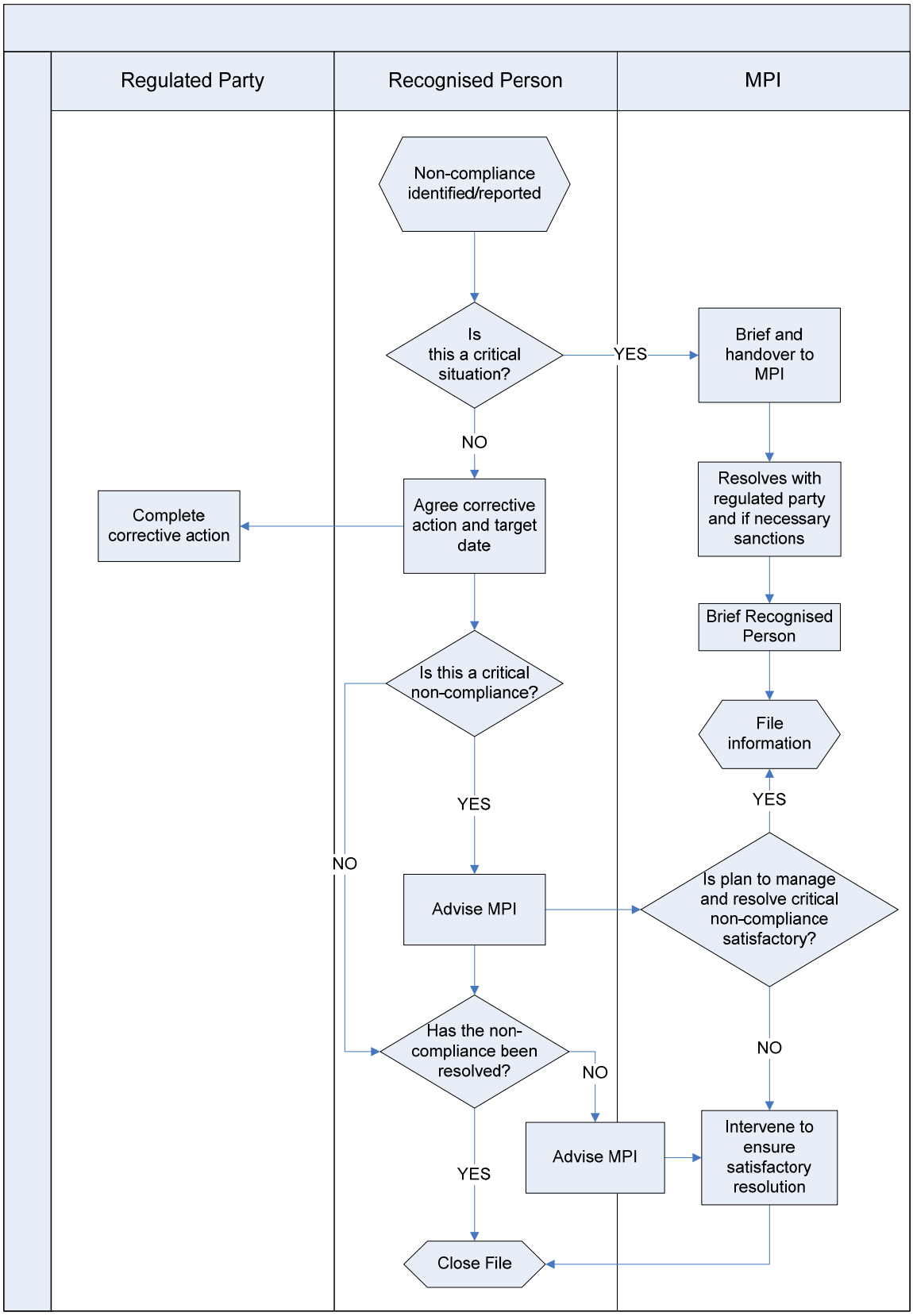
(9) Agencies participate in industry standardisation sessions (organised by MPI) to ensure uniformity when regulatory requirements are issued or reviewed.

(10) The agency maintains full records of all training and experience of all recognised persons providing assessment services on behalf of the agency.

6.5.7 Internal Review

(1) The agency conducts an internal management review of its own quality system at least annually.

Table A1.4: Diagram of the Escalation Process



6.6 Performance Measurement of Recognised Agencies and Persons

6.6.1 Classification of Agencies

(1) Based on their compliance with MPI requirements, the accreditation body will assign agencies to one of the following performance assessment categories:

a) Reduced Assessment;
b) Standard/Entry Assessment;
c) Increased Assessment.

Reduced Assessment Category

(1) To be assigned to, and remain in, the Reduced Assessment category, the agency meets all the criteria for the Reduced Assessment category in Table A1.2. The agency has demonstrated compliance with the criteria for at least two years.

Standard/Entry Assessment Category

(1) To be assigned to, and remain in, the Standard/Entry Assessment category, the agency meets all of the criteria for the Standard/Entry Assessment category in Table A1.2. The agency has demonstrated compliance with the criteria for at least one year.

Increased Assessment Category

(1) An agency will be assigned to the Increased Assessment category if it:

a) fails to meet ISO Standard 17020 and/or MPI requirements;
b) has critical non-compliances in management of client non-compliances;
c) has critical non-compliances in management of own non-compliances;
d) has critical non-compliances in management of recognised persons; or
e) provides inadequate or late reports to the accreditation body and/or MPI

6.6.2 Entry Classification

(1) When an agency applies for recognition in accordance with MPI requirements outlined in section 6.5, the accreditation body reviews the agency's compliance against the criteria in Table A1.5. Where an agency demonstrates an appropriate level of compliance, they are assigned to the Standard/Entry Assessment category. If the agency fails to demonstrate compliance to one or more areas, they are assigned to the Increased Assessment category.

(2) The accreditation body advises the manager of the agency of the category to which it has been assigned and the frequency of assessments.

(3) The manager of the agency implements performance-based assessment frequency as instructed by the accreditation body.

6.6.3 Demonstration of Compliance

(1) The agency demonstrates compliance at the level appropriate to the performance assessment category to which it has been assigned. Refer to Table A1.5 below for the criteria used to demonstrate compliance. Failure to meet any of the requirements will result in reclassification to a performance assessment category with higher levels of assessment (refer below).

Table A1.5: Agency Criteria for Each Performance Assessment Category

Area	Reduced Assessment	Standard/Entry Assessment	Increased Assessment
Assessment by accreditation body	Compliance with ISO Standard 17020 and MPI requirements demonstrated for two years.	Compliance with ISO Standard 17020 and MPI requirements demonstrated.	Fails to demonstrate compliance with ISO Standard 17020 or MPI requirements.
Management of client non-compliances	For previous two years: • Reports all observed non-compliances to the client; • agrees corrective actions and date for resolution for all non-compliances (except critical situations); • confirms resolution; • takes the action necessary to obtain resolution; • reports all critical non-compliances and critical situations to MPI; • in all critical situations, fully briefs and hands over to MPI; and • ensures all nonconforming produce is managed in accordance with MPI requirements.	• Reports all observed non-compliances to the client; • agrees corrective actions and date for resolution for all non-compliances (except critical situations); • confirms resolution; • takes the action necessary to obtain resolution; • reports all critical non-compliances and critical situations to MPI; • in all critical situations, fully briefs and hands over to MPI, and • ensures all nonconforming produce is managed in accordance with MPI requirements.	• Fails to demonstrate adequate management of client non-compliances.
Management of own non-compliances	• Critical non-compliances identified; • full traceback completed to identify root causes; • corrective actions completed in a timely manner; • full analysis of the risk to the operation from this type of non-compliance completed; and • actions taken to eliminate the risk of potential non-compliances or monitoring systems implemented to identify	• Critical non-compliances identified and managed in accordance with MPI requirements.	• Critical non-compliances not identified, or • Critical non-compliances are identified and inadequately managed.

Area	Reduced Assessment	Standard/Entry Assessment	Increased Assessment
	potential non-compliance in the operation.		
Reporting	• Regular, exception and on-demand reports complete accurate and on time for at least two seasons	• Regular, exception and on-demand reports complete accurate and on time for at least one season; or • Regular reports occasionally incomplete or late and exception and on-demand reports are complete, accurate and on time.	• Regular, exception and on-demand reports contain incomplete information or factual errors or are persistently late; • Exceptions are not reported; or • On-demand reports are not provided

6.6.4 Assessment Requirements

(1) The manager of the agency ensures that the assessments required for the performance assessment category to which they have been assigned, are undertaken as specified.

(2) The assessment requirements of each performance assessment category are specified in Table A1.6 below.

Table A1.6: Agency Assessment Requirements for Each Performance Assessment Category

Assessment	Performance Assessment Category		
	Reduced Assessment Category	Standard/Entry Assessment Category	Increased Frequency Category
Assessment by the accreditation body	Full assessment of the agency is required every two years; A surveillance assessment is required in the alternate year.	Full assessment of the agency is required on an annual basis	Full assessment of the agency is required at least every six months. Depending on performance and risk, MPI may increase the frequency of assessment at its own discretion or on the recommendation of the accreditation body. MPI may also directly monitor the agency and charge for these activities.

6.7 Recognised Persons

6.7.1 Classification of Recognised Persons

(1) Based on their compliance with MPI requirements, the accreditation body will assign recognised persons to one of the following performance assessment categories:

a) Reduced Assessment;
b) Standard/Entry Assessment;
c) Increased Assessment.

Reduced Assessment Category

(1) To be assigned to, and remain in, the Reduced Assessment category, the recognised person meets all the criteria for the Reduced Assessment category in Table A1.7. The recognised person has demonstrated compliance with the criteria for at least three seasons.

Standard/Entry Assessment Category

(1) To be assigned to, and remain in, the Standard/Entry Assessment category, the recognised person meets all of the criteria for the Standard/Entry Assessment category in Table A1.7. The recognised person has demonstrated compliance with the criteria for at least one season.

Increased Assessment Category

(1) A recognised person will be assigned to the Increased Assessment category if the person:

a) fails to meet MPI performance requirements outlined in section 6.1 and the associated MPI "Checklist for Technical Competence of TPA Individuals"; or
b) has less than one year's assessing experience.

Entry Classification

(1) When a person applies for recognition in accordance with MPI requirements outlined in section 6.5, Technical Competency of Recognised Persons, the accreditation body reviews the person's compliance against the criteria in Table A1.7. Where a person demonstrates an appropriate level of compliance, they are assigned to the Standard/Entry Assessment category. If the person fails to demonstrate compliance to one or more areas, they are assigned to the Increased Assessment category.

(2) The accreditation body advises the manager of the agency of the category to which its associated recognised persons have been assigned, and the frequency of assessments. The manager of the agency implements performance-based assessment as instructed.

6.7.2 Demonstration of Compliance

(1) The recognised person demonstrates compliance at the level appropriate to the performance assessment category to which they have been assigned. Refer to Table A1.7 below for the criteria used to demonstrate compliance. Failure to meet any one or more of the requirements will result in reclassification to a performance assessment category with higher levels of assessment (refer below).

Table A1.7: Recognised Person's Criteria for Each Performance Assessment Category

Area	Reduced Assessment	Standard/Entry Assessment	Increased Assessment
Assessment by accreditation body and MPI	For the previous three years: • compliance with MPI requirements in clause 6.1 demonstrated, and • no critical non-compliances in the performance of the recognised person	For the previous year: • compliance with MPI requirements in clause 6.1 demonstrated and • no critical non-compliances in the performance of the recognised person	One or more critical non-compliances in the performance of the recognised person in the past year.
Experience	At least 3 years' experience as an assessor/recognised person.	At least 1 year's experience as an assessor/recognised person.	Less than 1 year's experience as an assessor/recognised person.

6.7.3 Assessment Requirements

(1) The manager of the agency ensures that the assessments required for the performance assessment category to which the recognised person has been assigned are undertaken as specified.

(2) The assessment requirements of each performance assessment category are specified in Table A1.8 below.

Table A1.8: Recognised Person's Assessment Requirements for Each Performance Assessment Category

Assessment	Performance Assessment Category		
	Reduced Assessment Category	Standard/Entry Assessment Category	Increased Frequency Category
Assessment by the accreditation body	• Full assessment of the recognised person is required every two years; • A surveillance assessment is required in the alternate year.	• Full assessment of the recognised person is required on an annual basis.	• Full assessment of the recognised person is required at least every six months. • Depending on performance and risk, the accreditation body may increase the frequency of assessment at its own discretion. • The accreditation body may also directly monitor the recognised person and charge for these activities.

6.8 Reclassification

6.8.1 Initiation of a Review

(1) The accreditation body initiates a review of the category to which an agency or recognised person is assigned on receipt of any of the following communications.

Accreditation Body Reclassification to a Category with Decreased Levels of Assessment

(1) When, as a result of assessments, the accreditation body is satisfied that the agency/recognised person demonstrates compliance with all the criteria in Table A1.5/Table A1.8 for the recommended reclassification category, it informs the agency/person of the reclassification.

Accreditation Body Reclassification to a Category with Increased Levels of Assessment

(1) The accreditation body instructs the agency/recognised person to reclassify when one of the following occurs:

a) as a result of an assessment, the accreditation body identifies that the agency/recognised person fails to comply with one or more of the criteria for the category to which they are assigned;
b) the accreditation body can provide evidence that the agency has demanded, requested, suggested, or pressured the accreditation body to censor or falsify an evaluation or verification report; or
c) the accreditation body can provide evidence that the agency/recognised person has falsified a client's evaluation or verification report.

Notification of Significant Changes

(1) A report of the occurrence of any of the following significant changes is received from the agency or the accreditation body:

a) significant changes to the management structure;
b) significant changes to the volume and type of assessment work undertaken;
c) significant changes to operational procedures;
d) significant changes to staff involved in assessment activities (e.g. loss of key staff); or
e) change of ownership.

Report of a Critical Non-compliance

(1) A report of a critical non-compliance within the agency, provided in accordance with the reporting requirements specified in this document in section 6.3 Recognised Agency Responsibilities.

(2) A report of a critical non-compliance by a recognised person, provided in accordance with the reporting requirements specified in section 6.3 Recognised Agency Responsibilities.

Request for Review by the Agency

(1) An agency may request a review of the category to which it is assigned by notifying MPI in writing, setting out reasons for seeking the review. A copy of the request is sent by the agency to the agency's accreditation body.

Request for Review by the Agency on Behalf of a Recognised Person

(1) An agency may request a review of the category to which a recognised person is assigned by notifying MPI in writing, setting out reasons for seeking the review. A copy of the request is sent by the agency to the agency's accreditation body.

Request for Review by Another Party

(1) Any party may request a review of the category to which an agency or recognised person is assigned by notifying MPI in writing, setting out reasons for seeking the review. Copies of the request are sent by the party to the agency and the agency's accreditation body.

Review

(1) The accreditation body will review the category to which an agency or recognised person is assigned and, where appropriate, reassign a new category.

(2) For agencies, this review will consider the criteria in Table A1.5 and all the available information, including any case that has been provided in writing. The accreditation body may, for the purposes of the review, undertake or commission an independent assessment of the agency's quality system. This assessment may be at the agency's expense where the agency has requested the review.

(3) For recognised persons, this review will consider the criteria in Table A1.7 and all the available information, including any case that has been provided in writing.

Outcome

(1) The accreditation body will advise the manager of the agency of either:

a) the category to which the agency and associated recognised persons have been assigned, the frequency of assessments and the date of effect; or
b) confirmation of the existing category, if there is no change of classification.

(2) The manager of the agency implements performance-based assessments at the frequencies instructed by the accreditation body. This includes making the necessary contractual arrangements with the accreditation body.

7 Verification

(1) Verification of the criteria contained in this document will be performed by accreditation and recognition bodies when assessing an agency or person and MPI when it receives information to support certification.

(2) If all criteria are complied with then the accreditation or recognition body provides a recommendation to MPI for recognition.

(3) If all criteria are not complied with by an agency or person then no recommendation should be provided.

(4) MPI Systems Audit Team will also assess compliance with criteria outlined in this document as part of any allocated systems audits which are part of scheduled activities.

(5) If a critical non-compliance is identified by a recognition or accreditation body or as part of an MPI Systems Audit Team audit then recognition of an agency or person may be reviewed by MPI.

7.1 Recognition of Laboratories, Including Approved Tests

(1) MPI maintains a register of recognised laboratories and recognised persons for test results. This register is available on the MPI website. This register is used to verify that:

a) the laboratory displaying a recognition certificate is currently recognised (that is, recognition has not expired);
b) the laboratory is currently recognised for the tests it is reporting; and
c) persons signing the test reports are authorised to do so, that is, they are recognised persons.

7.2 Categories of Laboratories

(1) The accreditation/recognition body issues a certificate to the laboratory specifying its accreditation or recognition status.

a) Category 1 dairy laboratories must be accredited by an accreditation body under the dairy testing programme.
b) Category 2 dairy laboratories must be recognised by an MPI-approved recognition body under the dairy testing programme.

7.3 Accreditation Status and Approved Signatories

(1) Accredited Category 1 laboratories are issued with a certificate by the accreditation body, stating that they comply with requirements. This is accompanied by a schedule detailing the tests, test methods and products for which they are accredited, and listing the authorised signatories for those tests. This schedule is updated following the assessments.

7.4 Recognition Status

(1) Recognised Category 2 laboratories are issued with a certificate of recognition by the accreditation/recognition body, stating that they comply with requirements. This is accompanied by a schedule detailing the tests, test methods and products for which they are recognised. This schedule is updated following the assessments.

7.5 Laboratories

(1) The criteria for assessing compliance are as follows:

a) the laboratory has documented procedures that address regulatory requirements;
b) the procedures documented to meet regulatory requirements are being followed;
c) the laboratory is currently accredited to ISO Standard 17025 by an accreditation body, or recognised to requirements outlined in section 5.1 and 5.2 by an MPI-approved body, to perform specified tests on specified products;
d) recognised laboratories that perform tests, use test methods or test products which do not comply with their recognition criteria, notify MPI, in writing, before the event.

(2) For recognition to continue, laboratories must:

a) demonstrate to the accreditation/recognition body that they are continually following requirements; and
b) address non-compliances issued by their accreditation/recognition body within the agreed time.

(3) If an accreditation/recognition body withdraws, suspends or changes the accreditation/recognition status of a recognised laboratory, the accreditation/recognition body advises MPI of the change in status, and MPI may:

a) cancel recognition;
b) vary any conditions subject to which a laboratory is recognised; or
c) impose any new or additional conditions subject to which a laboratory is recognised.

(4) The recognition of a laboratory may be cancelled or amended if:

a) the occupier of the laboratory concerned asks the Director-General to do so;
b) the Director-General is satisfied that the laboratory no longer has the premises, equipment, procedures and staff necessary to ensure that the testing carried out there for the purposes of these regulations will be carried out properly and competently;
c) the Director-General is satisfied during the past 6 months there has been a breach of any conditions subject to which the laboratory was recognised; or
d) the Director-General is satisfied that the occupier has failed to comply with any order under the Act.

7.6 Test Methods

(1) The laboratory is compliant with the outcomes described in this document if:

a) MPI-approved test methods are used for testing dairy material to verify conformance of dairy material with regulatory requirements; and/or with attestations provided by MPI in official assurances; or
b) MPI's written approval to use an unapproved test method, has been obtained prior to the testing commencing and that the testing and test reporting has been done in accordance with the scope and restrictions specified in the approval.

(2) Laboratories operating in compliance with the outcomes described in this document are entitled to test dairy material:

a) for the purposes of verifying conformance with regulatory requirements; and/or
b) with attestations provided by MPI in official assurances.

(3) If a dairy laboratory does not operate in accordance with the requirements in this document:

a) a Compliance Order or Direction may be issued by an Animal Products Officer or to remedy any defects;
b) use of test results for export certification and/or use of any MPI marks may be suspended;
c) recognition of the laboratory may be cancelled or conditions varied or imposed; and/or

d) prosecution for offences may occur.