Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Recognised Laboratory Programme

(RLP)

31 August 2015

A guidance document issued by the Ministry for Primary Industries

New Zealand Government

Title

Guidance Document: Recognised Laboratory Programme

About this document

This guidance document is issued by the Animal Products group, Regulation & Assurance Branch of the Ministry for Primary Industries.

Related requirements

(1) This document should be read in conjunction with the:

a) Animal Products Notice: Specifications for Laboratories (referenced as the Laboratory Specifications Notice or Notice in this guidance); and
b) Consolidated List of Tests for Animal Products: dairy, meat, poultry, honey, seafood, live animals and germplasm (referenced as the Consolidated List of Tests in this guidance).

Document history

Previous Version Date	Current Version Date	Section Changed	Change(s) Description
N/A			

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Disclaimer

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Contents

Purpose

This guidance document has been prepared to assist laboratories to meet the requirements of the MPI Laboratory Specifications Notice.

The Notice comprises the legal requirements and should be read and referred to in the first instance.

The guidance provided in this document assists laboratories to undertake the process of application for recognition, assessment, test methods and test results for regulatory testing including official assurances.

Background

This guidance document has been developed by the Ministry for Primary Industries (MPI) and the laboratories who perform or carry out tests, associated with live animals, animal material or animal products, or the processing of animal material or animal products, under the Animal Products Act 1999 (APA).

MPI through the APA, aims to facilitate the entry of animal products etc. into overseas markets by providing the controls and mechanisms needed to give and safeguard official assurances for entry into those markets. Most importing countries require official assurances to provide confidence that their import requirements have been met. The claims made on official assurances must be substantiated in order to maintain the integrity of NZ as a trading partner and reputation as a competent authority. These assurances are provided by MPI Verification Services.

Previously three separate laboratory programmes existed under the APA. These were:

c) Laboratories which test dairy material and dairy products;
d) Laboratory Approval Scheme (LAS); and
e) Export Laboratory Programme: Requirements for Laboratories and Persons Conducting the Testing of Live Animals and Germplasm for Export (ELP).

The Laboratory Specifications Notice combined, simplified and improved clarity of the core requirements for laboratories into one document, and focussed on achieving outcomes to ensure that laboratories competently perform tests. Consequently, this Guidance Document for the Recognised Laboratory Programme (RLP) was developed to align with the new Notice and replace the existing guidance documents for the previous programmes.

Also as part of the process, a Consolidated List of Tests for Animal Products: dairy, meat, poultry, honey, seafood, live animals and germplasm was developed.

The Notice underpins the APA and not all interpretations and requirements are repeated in the Notice. However, some details of the Act are included in this Guidance for explanatory purposes e.g. a definition for Director-General.

There are some instances where the requirements of ISO/IEC 17025 are included in the Notice and hence in this guidance document. This is to ensure that those laboratories that have limited recognition still meet most of the requirements of ISO/IEC 17025. Nevertheless this Guidance does not repeat information contained in other documents e.g. IANZ Specific Criteria.

This document has been written to match the clauses of the Notice and:

Content that is enclosed in a text box are the relevant legal requirements quoted from the Laboratory Specifications Notice current at 31 August 2015.

The administration for each of the laboratory programmes is done by different MPI teams but a common email inbox is available as a contact point for anything related to the Recognised Laboratory Programme:

RLP@mpi.govt.nz

Note: Requirements in the Notice for testing live animals and germplasm does not apply to export testing in the following situations:

a) Where the test is carried out on the animal itself; or
b) Surveillance testing that is conducted on populations to determine the disease status of those populations.

These requirements are described in OMARs or the Official Assurance Programme for live animals and germplasm.

1 Guidance on requirements

1.1 Incorporation of material by reference

(1) Incorporation by reference means that the material referred to (e.g. documents published elsewhere and not attached to the Notice) are part of the requirements of the Notice e.g. ISO/IEC 17025, MPI Consolidated List of Tests.

1.2 Definitions

(1) Refer to the Notice, clause 1.2 'Definitions' for those definitions related to the Notice.

(2) In this guidance document, these are additional definitions for clarification:

closed out means the corrective action for a non-compliance(s) identified in an assessment or audit has been verified as successfully completed.

competence means a demonstrated ability to apply a person's knowledge and skills.

conflict of interest means where the duties or responsibilities of a person could be improperly affected by some other interest or duty the person may have.

Director-General (D-G) means the Chief Executive of the Ministry for Primary Industries (MPI) and the Director-General delegates powers given under the Notice e.g. the recognition of a laboratory is issued by the Manager Approvals Operations.

germplasm means semen, embryos and ova of animals.

IANZ means International Accreditation New Zealand, an accreditation body who accredit laboratories to ISO/IEC 17025.

Notice means the current Animal Products Specifications for Laboratories Notice.

official assurance means a general statement issued to a foreign government (or its agent) attesting that certain conditions apply. Only authorised persons can issue an official assurance.

OMAR means Overseas Market Access Requirement or Export Requirement. OMARs are legal documents issued by MPI (Section 60 APA) and are negotiated with the importing country.

sample matrix means the components of a sample other than the analyte of interest. The matrix can have a considerable effect on the way the analysis is conducted and the quality and accuracy of the results obtained e.g. different species for a disease test.

technical expert or assessor means an independent expert in their field that can be used as an assessor by IANZ for laboratory assessments.

test list means the Consolidated List of Tests for Animal Products published by MPI. This list of tests provides guidance on what regulatory test(s) MPI expects to need to ask laboratories to perform, and for which laboratories will need to be recognised by MPI. It is located at: www.mpi.govt.nz

2 Guidance for laboratory requirements

2.1 Application of laboratory recognition

(1) This part applies to laboratories that need to be recognised by MPI for carrying out or intending to carry out regulatory testing, including for official assurances. Regulatory tests are in legal documents produced by MPI e.g. notices, specifications, OMARs, etc. and have been summarised in the Consolidated List of Tests.

2.2 Laboratory recognition

2.2 Laboratories must be recognised

(1) A laboratory performing a test as defined under clause 1.2 of this Notice must be recognised as a laboratory under section 101 of the Act prior to performing any test.

(2) The Director-General may grant recognition to a laboratory under section 101 of the Act if the laboratory complies with either the requirements of clause 2.3 or clause 2.4 of this Notice.

(3) Notwithstanding subclause (1) and (2), under exceptional circumstances the Director-General may, by notice to the laboratory, waive the requirement for a laboratory to be recognised if satisfied that–

a) the laboratory operates to a standard equivalent to the requirements set out in this Notice; and
b) it is not practicable to require such a laboratory to be recognised.

(4) The Director-General may, by notice to the laboratory, revoke the waiver if satisfied that–

a) the laboratory no longer operates to a standard equivalent to the requirements set out in this Notice; or
b) that it is practicable to require such a laboratory to be recognised.

(1) Application for recognition:

a) A laboratory applying for recognition, including of an amendment to their scope of recognition, needs to fill out the Recognised Laboratory Application Form AP18 located on the MPI website: www.mpi.govt.nz.
b) The application form:
   i) needs to be completed by the person responsible for the laboratory (as part of the Recognised Agency provisions of the APA); and
   ii) includes the NZ Police standard vetting questionnaire which needs to be completed for the laboratory or company Director(s) responsible for the laboratory (KTPs do not need to complete this); and
   iii) is to be sent to MPI using the email address given on the form.

Note: specific requirements for Recognised Agencies can be found in section 101 of the APA.

Note: once accredited a laboratory may produce IANZ endorsed reports, however reference to MPI recognition cannot be made until MPI have confirmed recognition.

c) Laboratories need to apply for recognition under the Notice, following a successful IANZ assessment, to transition to the Notice requirements;
d) The application for recognition (excluding applications for Limited Recognition refer 2.4) needs to clearly indicate which test(s) are required by the laboratory by including a copy of the Consolidated List of Tests, or the relevant section of this list, clearly indicating which tests the

laboratory will be carrying out. MPI will then provide proof of recognition in writing and may include specific conditions e.g. regular reporting requirements.

(3) Laboratory recognition is valid for 3.5 years and should be renewed before the expiry date using this same form (AP18). Thus the renewal frequency should align following the IANZ triennial re-assessments. Once a laboratory has recognition under the RLP, the previous rules from Dairy, LAS or ELP no longer apply.

(4) Renewal applications:

a) will ensure all details are kept up to date with MPI (web listings) and provide an opportunity to review the recognised laboratory's details;
b) need to be received by MPI no later than 1 month prior to the expiry date. This is the laboratory's responsibility. MPI will endeavour to send out a reminder 1 month prior to the recognition expiry to prevent any delay or gaps in recognition;
c) turn-around time will be 20 working days for new or amendment applications, and 10 working days for renewals, for MPI to process it.

(5) A laboratory needs to apply to MPI using an AP18 form to amend or remove any conditions relating to recognition (refer to clause 2.3(1)(d) of the Notice) including:

a) The removal or addition of tests or disciplines; and
b) A change to the Quality Manager or KTP.

Note: some recognition amendments will not require an IANZ report to be included with the application and hence the term "as applicable" used in the AP18 form.

(6) A laboratory's recognition will be suspended if the laboratory has failed to pay an ongoing recognition fee, charge, or levy within 30 days after the date on which it was due (Section 112J APA) or if it has not met any of the other specific conditions.

(7) If MPI refuses to grant recognition, or suspends or withdraws the recognition, the laboratory will be notified, along with the reasons. The laboratory will be given a reasonable opportunity to make written or oral submissions prior to a final decision being made (Section 109, 112L, 112P APA).

(8) A recognised laboratory may use a phrase for communication for purposes such as endorsement on a test report or letterhead e.g. "Recognised by the Director-General of the Ministry for Primary Industries to provide [state the disciplines/tests of recognition as appropriate]".

Note: MPI publishes a list of recognised laboratories, which includes associated tests and KTPs. These are located at: www.mpi.govt.nz.

(9) Examples of exceptional circumstances where the requirement for recognition may be waived are:

a) non-accredited tests at a recognised laboratory (where tests cannot be accredited for various reasons e.g. tests on rare animal species that cannot be validated);
b) a non-recognised laboratory nominated by the D-G operating to a standard equivalent to the requirements of the Notice to conduct tests that cannot be undertaken at any current recognised laboratories;
c) a recognised laboratory nominated by the D-G to subcontract tests that cannot be undertaken at any current recognised laboratories within New Zealand, to a non-recognised laboratory.

(10) Circumstances in which a waiver may apply will be determined by the D-G, such that:

a) the D-G will notify non-recognised laboratories of their suitability to conduct testing;
b) the D-G will notify a recognised laboratory of their nomination to subcontract tests to a non-recognised laboratory; and
c) the D-G will notify this in writing.

2.3 General requirements for recognition

2.3 General requirements for recognition of laboratories

(1) The Director-General may grant recognition to a laboratory to perform tests under section 101 of the Act if the Director-General is satisfied that the laboratory–

a) is accredited to ISO/IEC 17025 by an accreditation body in accordance with ISO/IEC 17011; or
b) is a research laboratory or reference laboratory whose functions include calibration, quality assurance and specific testing parameters and that is not accredited to ISO/IEC 17025 for all tests conducted; and
c) meets any other technical requirements as specified by the Director-General under the Act, this Notice, or by Regulations, Notices, Specifications or in Directions made or issued under the Act; and
d) has suitable facilities, equipment, procedures, materials and staff to ensure that all testing and other required functions are carried out properly and competently at all times; and
e) makes payment of any fees and charges required by the Act or by Regulations made under the Act; and
f) has appointed a Quality Manager.

(1) A recognised laboratory needs to:

a) be accredited to ISO/IEC 17025 for each regulatory test unless the laboratory qualifies for limited recognition (refer to 2.4(1) of the Notice); and
b) provide evidence to MPI of a successful assessment conducted by IANZ. A copy of the assessment report from IANZ, including closed out corrective actions, needs to be supplied with the MPI Recognised Laboratory Application form AP18. The IANZ clearance letter may also need to be included if the report includes open corrective actions that have been subsequently closed out. IANZ assessment reports will also need to be submitted with each subsequent renewal application; and
c) submit any other information requested by MPI e.g. ILCP results; and
d) make payment of any fees and charges required under the Act, (refer Recognised Laboratory Application Form AP18). Fees and charges are set by regulation and are subject to change (e.g. amendments were made in 2015) – refer to the current Animal Products (Fees, Charges, and Levies) Regulations located at: http://www.legislation.govt.nz/default.aspx; and
e) appoint a Quality Manager to be identified as the primary contact for MPI (Recognised Laboratory Application Form AP18). The Quality Manager may also be an appointed KTP and will be responsible for compliance to the Notice and ISO/IEC 17025; and
f) have one or more KTP(s) appointed by senior laboratory management.

(2) A research or reference laboratory that does not have accreditation, only under extraordinary circumstances may be granted limited recognition, where there is no accredited laboratory with the capability to perform the testing. Laboratories in this category should contact MPI for further information at RLP@mpi.govt.nz.

Note: IANZ reports are required to be supplied for recognition applications i.e. new, limited and renewals. However there may be times when MPI would need to review such reports e.g. as part of an investigation.

Note: A description for KTP responsibilities can be found in the IANZ Specific Criteria located at: http://www.ianz.govt.nz/resources/documents-2/supplementary-criteria/ .

2.4 Limited recognition

2.4 Requirements for limited recognition of laboratories

(1) If the Director-General considers that urgent circumstances have arisen that require a laboratory to be able to carry out certain tests and the laboratory does not meet all the requirements of clause 2.3 of this Notice, the Director-General may grant recognition to the laboratory for a specified test under section 101 of the Act if –

a) the laboratory is currently accredited to ISO/IEC 17025 for at least one other test of a similar discipline; and
b) where a KTP is required for the specified test, the laboratory has appointed one or more KTPs for the test; and
c) the Director-General specifies a period during which the recognition applies; and
d) the laboratory makes payment of any fees and charges required by the Act or by Regulations made under the Act; and
e) appoints a Quality Manager.

(2) Any laboratory granted recognition under this clause to conduct specified tests must as soon as practicable be in full compliance with all requirements for those specified tests under clause 2.3(1) of this Notice.

(1) Circumstances for limited recognition include:

a) a new test not already covered by a laboratory scope of recognition; or
b) where recognition is needed by MPI before the next IANZ assessment; or
c) where there is no accredited laboratory with the testing capability required.

(2) MPI will assess an application (Recognised Laboratory Application Form AP18) for limited recognition.

(3) All KTP(s) appointed by the laboratory will need to be included in the application.

(4) MPI will notify the recognised laboratory if the scope of recognition has been extended to cover the test(s). The test(s) can then be conducted.

(5) Any laboratory granted limited recognition needs to be in full compliance with the Notice as soon as practicable. The laboratory would be expected to indicate when they could achieve 'full' recognition.

Note: Similar discipline means, for example, when applying for limited recognition for a new molecular biological testing process, previous experience in molecular biology would be taken into account by MPI. For further clarification MPI should be contacted in the first instance using RLP@mpi.govt.nz.

2.5 Changes to recognition

2.5 Changes to laboratory recognition

(1) A recognised laboratory must ensure that no significant changes are made to the Quality Manager, a KTP, premises, equipment, facilities, or to its discipline(s) unless –

a) the Director General has been informed of the change as soon as practicable; and
b) the change is carried out in a manner that ensures that the integrity of analytical testing is maintained.

(2) If a recognised laboratory informs the Director-General of any significant change described in subclause (1), the Director-General must, where appropriate, record the change in the register of recognised laboratories.

(1) As soon as practical, a laboratory needs to report to MPI any **significant** changes that may affect its recognition e.g. a change in:

a) Quality Manager; or

b) KTP e.g. either a new KTP or a KTP has left (check discipline is still covered); or
c) premises e.g. change in location; or
d) facilities e.g. renovations that impact on the integrity of the analytical testing; or
e) tests conducted or discipline e.g. additional tests, removal of tests from accreditation scope.

(2) A laboratory needs to report to MPI any critical non-compliances within one working day of being found out, and the issues/events that lead to that critical non-compliance using the RLP Critical Non-Compliance Form. Sources may include:

a) customer complaint; or
b) internal assessment findings; or
c) internal management review findings.

Note: Significant changes (that may impact the integrity of analytical testing) should be emailed to MPI using RLP@mpi.govt.nz.

Note: Copies of internal assessment or management review findings are currently not required.

Refer to clause 2.13.

2.6 Systems and facility requirements

2.6 Systems and facility requirements of recognised laboratories

(1) A recognised laboratory must establish, document and maintain systems and procedures that comply with the Act, and any associated Regulations, Notices, Specifications and Directions made or issued under the Act, and any conditions imposed on the laboratory's recognition by the Director-General in accordance with section 111 of the Act.

(2) If the Director-General has issued the laboratory with one or more Notices of recognition, the laboratory must ensure that each such Notice is available upon request.

(3) A recognised laboratory must comply with all directions from the Director-General issued under the Act and which relate to the functions or activities for which the laboratory is recognised.

(4) The Director-General may require a recognised laboratory to participate in a specified ILCP where the laboratory conducts tests specified by the Director-General.

(5) In deciding whether to impose a requirement under subclause (4), the Director-General must consider the following matters:

a) The need to ensure that an ongoing and consistent standard of laboratory performance is maintained by all recognised laboratories conducting tests with public health significance or high levels of market access sensitivity; and
b) The need to enable analysis and comparison by MPI of laboratory testing of animal material and animal products concerned to underpin the development of new MPI strategies to improve risk management for key tests.

(6) A recognised laboratory that is subject to a requirement under subclause (4) must comply with that requirement.

(7) A recognised laboratory must ensure that its employees and contractors performing testing and other relevant functions and activities, have access to -

a) an up-to-date version of the Act, relevant Regulations and Notices, ISO/IEC 17025, and all other relevant documents; and
b) the laboratory's own systems and procedures and appropriate records and databases.

(8) A recognised laboratory must ensure that its employees and contractors performing testing and other relevant functions and activities are able to demonstrate sound knowledge of the relevant industry practices.

(1) Laboratory personnel are expected to have access to relevant current documents. This may be in the form of hard or electronic copies e.g. internet access to NZ's legislation website using a favourite or bookmark.

(2) Laboratories will be expected to keep current with changes or updates as needed. MPI has a web site subscription facility for updates to information for various categories.

(3) Understanding of the relevant industry practices is important for a laboratory, e.g. KTP or Quality Manager, to be able to react to test results that may be out of normal range to the customer (client). The laboratory would be expected to alert the customer (client) urgently by e.g. phone or text as agreed with the customer (rather than wait for the issuing of a test report) in case it was a significant result. A record should be kept to ensure traceability e.g. email or written correspondence.

(4) Any detection of exotic pathogens should by notified to MPI using the exotic pests/diseases hotline (0800 80 99 66).

Exotic pathogens could have a legal status of notifiable or unwanted under different government departments/organisations or both notifiable and unwanted. Lists can be found at this link: http://www.biosecurity.govt.nz/pests/search/

It is recommended that you contact the pests/diseases hotline even if you are unsure of the status of a pathogen.

Where potential issues with live animal and germplasm testing are likely to compromise the integrity of export certification, the recognised laboratory should notify the Animal Exports team within 48 hours of the event.

Note: In the case of the e.g. a dairy company's own laboratory, results will not be made available to the external or final customer until product has been released for sale. In this case the customer of the laboratory is the manufacturing plant, not the purchaser of product from the manufacturing plant.

2.7 Subcontracting

2.7 Subcontracting

(1) Tests may be subcontracted:

a) to another recognised laboratory that is recognised for conducting the tests concerned under clause 2.2(2) of this Notice, or to a laboratory that is exempt from recognition under clause 2.2(3) of this Notice; or
b) to a non-recognised laboratory when circumstances arise where testing cannot be conducted by any current recognised laboratory and the Director-General approves the carrying out of tests by a non-recognised laboratory.

(2) Before approving the carrying out of tests by a non-recognised laboratory the Director-General must be satisfied that:

a) the approval relates to specific testing; and
b) the laboratory can demonstrate competence of its systems and staff, and the reliability of test results.

(1) If there is a need to subcontract out specific test/s, the original recognised laboratory should inform the customer and make them aware that it was done under the original laboratory's responsibility. This will give guarantee to the customers and importing countries of the traceability of test results. Refer to ISO/IEC 17025 requirements and IANZ Specific Criteria.

(2) Where the original recognised laboratory has subcontracted out a test to another recognised laboratory and the original laboratory does not have a KTP for that test, the original laboratory should include a copy of the subcontracted laboratory test report OR embed it electronically into the original laboratory final report, clearly showing the subcontracted laboratory results to the customer.

(3) Where the original recognised laboratory has subcontracted out a test to another recognised laboratory (e.g. due to heavy workload) and the original laboratory is recognised for that test, the original laboratory can include the test result(s) from the subcontracted laboratory in their report, and issue a test report to the customer – see reporting of subcontracted results in ISO/IEC 17025 and Procedures and Conditions for Accreditation (IANZ).

(4) The original laboratory needs to report any significant issues it becomes aware of that may affect the test results – refer 2.13 of the Notice re: misleading statements. Under ISO 17025 and this Notice, a recognised laboratory (including a subcontracted laboratory) needs to report any significant issues to MPI.

(5) Where a particular test(s) is unable to be carried out by an MPI recognised laboratory then a test can be subcontracted to a non-recognised laboratory when approved by MPI if the test is unable to be carried out in NZ. Where such a circumstance arises the laboratory needs to contact MPI for further assistance before proceeding further.

2.8 Requirements for qualified personnel and sampling criteria

2.8 Requirements of a recognised laboratory for qualified personnel

(1) Each recognised laboratory must have personnel with expertise in the disciplines covered by the laboratory accreditation.

(2) For each test for which the laboratory is recognised the laboratory must have at least one KTP who –

a) has a relevant tertiary qualification; or
b) meets the criteria specified by the accreditation body for dispensation from the requirement for relevant tertiary qualifications such as appropriate practical experience and specific training in that work.

2.8.1 Where sampling criteria are specified

(1) Where the Act or Regulations, Notices, Specifications or Directions issued under the Act specifies that the laboratory must be responsible for sampling requirements and the qualification and status of sample takers for the test concerned it must:

a) ensure samples are taken by sample takers in the manner specified in the Act or Regulations, Notices, Specifications or Directions issued under the Act; and
b) ensure sample takers comply with any requirements issued under the Act or Regulations, Notices, Specifications or Directions issued under the Act.

(1) MPI needs to be informed of the details of the KTPs appointed by the laboratory during the application process. MPI also needs to be informed of any changes to KTPs (refer 2.5 of the Notice) as soon as practicable at other times. In this case you will need to apply for an amendment to your recognition using the AP18 form.

(2) For 2.8.1, where sampling is undertaken by the laboratory, e.g. NMD samplers, the criteria or requirements will be described in the appropriate legal document e.g. a notice, OMAR, etc.

(3) For 2.8.1, where sampling is the responsibility of the laboratory, the laboratory needs to assess their samplers and sampling programme e.g. by internal audit. IANZ will assess the laboratory's processes and approval of sample takers.

2.9 Accreditation body assessment

2.9 Accreditation body assessment

(1) Each laboratory must ensure that its performance is assessed by its accreditation body in accordance with the requirements in subclauses (2) and (3).

(2) Each laboratory must ensure that the assessment by its accreditation body is undertaken in the following manner:

a) an initial full assessment to ISO/IEC 17025 requirements before applying to the Director-General for recognition; and
b) the Director-General receives the initial full assessment outcome from the applicant laboratory issued by the accreditation body to determine that the laboratory meets ISO/IEC 17025 requirements for the scope of testing applied for; and
c) following the laboratory being granted recognition by the Director General, the accreditation body carries out a surveillance visit each year for two years in succession; and
d) in the third year after being granted recognition by the Director-General, the accreditation body undertakes a full routine reassessment involving a full review of quality system documentation and a full on-site technical assessment.

(3) For continuation of recognition:

a) the three yearly assessment accreditation cycle as described in subclauses (2)(c) and (2)(d) must be repeated for the duration of the laboratory's recognition; and
b) the Director-General must receive any accreditation body reports on the laboratory.

(4) The Director-General may require additional assessments by the accreditation body and the laboratory must facilitate any such additional assessment required.

(1) A recognised laboratory needs to be assessed by IANZ to ISO/IEC 17025 including their accreditation scope (refer to clause 2.3 of the Notice).

(2) Existing recognised/approved laboratories will need to be successfully assessed by IANZ at their next scheduled assessment to transition to the new Notice. The laboratory then needs to apply to MPI for their change in recognition/approval. Refer to Part 5 of this document 'transitional provisions'.

(3) ISO/IEC 17025 accreditation reports are expected to be supplied with a laboratory's application or renewal for recognition. There may be times where this report is requested by MPI outside of the application/renewal process.

(4) The IANZ assessment process includes but is not limited to:

a) assessment of documentation; and
b) on-site assessment; and
c) assessment findings actioned.

(5) The assessors are experienced with the standards and processes of well-managed laboratories as well as ISO/IEC 17025, and may use technical experts as technical assessors to assist in assessments. Technical experts may be drawn from industry.

(6) The 3-yearly assessment cycle involves:

a) an initial full assessment (prior to an application for recognition); and
b) a surveillance visit (S1 and S2) each subsequent year by an IANZ assessment body staff member; and
c) a full routine reassessment (RR) no less than every three years involving a full review of the laboratory system documentation and a full on-site technical assessment with a technical assessor(s).

Note: These assessments do not take into account any specific market access requirements for export.

2.10 Audit or investigation requirements

2.10 Audit or investigation requirements

(1) The Director-General may carry out audits or investigations independently from the assessments by the chosen accreditation body, for the purposes of determining the recognised laboratory's compliance with the Act, this Notice, or Regulations, Notices, Specifications or Directions issued or made under the Act.

(2) The recognised laboratory must make its facilities, equipment, personnel involved in testing, and records relating to testing, readily available to –

a) a person appointed by the Director-General to undertake audits or investigations for the purposes of subclause (1); and
b) the representatives of any other competent authority as part of an assessment of compliance with the Act or Regulations, Notices, Specifications or Directions issued or made under the Act.

(1) MPI may carry out audits or investigations independently from the assessments by IANZ.

(2) Facilities, staff involved in testing, and records relating to testing, need to be available for such an audit or investigation:

a) By MPI; and
b) by any agency or person appointed by MPI; and
c) by the representatives of any other country as part of an assessment of compliance of the MPI Official Assurance Programme. MPI will notify laboratories of an impending visit by an overseas delegation where the visit is in conjunction with MPI.

2.11 Reporting requirements

2.11 Reporting requirements

(1) Each recognised laboratory must ensure that all test reports:

a) conform to the reporting requirements in ISO/IEC 17025 and to any requirements for that test in this Notice; and
b) are in a form approved by the Director General.

(2) If requested by the Director-General, each recognised laboratory must, as soon as practicable, provide the Director-General with any information requested in relation to:

a) testing activities; and
b) test method validation; and
c) the assessment of test performance including results; and
d) any assessment or analysis carried out by the ILCP provider; and
e) assessment reports or results from any assessment carried out under clause 2.9 of this Notice; and
f) significant changes made under clause 2.5 of this Notice.

(1) Test reports provided to customers can be electronic or hard copy. Electronic reports can be through an electronic approval system e.g. passwords.

(2) Where reports do not require IANZ endorsement but are still regulatory test results, e.g. direct data entry into a customer database, this is still acceptable as an IANZ endorsed report could be obtained if required by the customer.

(3) Should a Quality Manager be unclear on whether or not a report needs to be made to MPI, then the Quality Manager should contact MPI for clarification.

(4) A designated ILCP Provider is currently contracted by MPI to provide an ILCP service for the LAS programme only. The details of the LAS ILCP are described in the Consolidated List of Tests. Other laboratory programmes do not have a designated ILCP contracted provider, and there are instances where ILCP is not possible e.g. rare disease.

(5) Providing regular reports on time will be a standard condition of recognition. These reports are a source of information. They also provide an oversight of laboratories which assists MPI in providing assurance to NZ's trading partners.

(6) Currently there is annual reporting for live animals and germplasm testing for the period July to June to the Animal Exports team (AnimalExports@mpi.govt.nz). Technical information on activities to be reported is a follows:

i) name of species and the commodity (live animals or donors of germplasm, or the germplasm itself, or the group of origin) that is tested; and
ii) number and type of tests performed; and
iii) the results of those tests (number suspicious, number positive, number negative, equivocal results due to unclear cut offs for positives and negatives).

Note: Reporting requirements should not include providing information that conflicts with customer confidentiality agreements (currently).

2.12 No misleading statements

2.12 No misleading statements

(1) Each recognised laboratory must not make any –

a) statement either directly or by implication, to the effect that the laboratory's recognition is in itself an approval or assurance in relation to any animal product; or
b) other misleading statement in relation to its recognition.

(1) A laboratory is expected to ensure that:

a) reports are true and accurate; and
b) MPI logo is used appropriately in statements and reports.

2.13 Disclosure of information and confidentiality, temporary closure

2.13 Disclosure of information and confidentiality

(1) A recognised laboratory must notify the Director-General in writing at least five working days prior to -

a) any planned temporary closures; or
b) any change to organisational management or legal ownership; or
c) loss of KTP coverage for any or all of the tests in the laboratory's scope of accreditation; or
d) any other significant change or event which may have the potential to have an adverse effect on test results or operations.

(2) If requested by the Director-General, a recognised laboratory must, as soon as practicable, submit to the Director-General information requested relating to tests carried out if that information is not provided under clause 2.11.

(3) A recognised laboratory or Quality Manager at the laboratory must inform the Director-General within one working day, if –

a) the laboratory is unable to comply with any of the requirements of this Notice; or
b) as a result of its activities, the laboratory becomes aware of a situation which may pose a significant biosecurity, trade, or public health risk; or
c) the laboratory or Quality Manager becomes aware of a situation that suggests the laboratory or KTP at the laboratory has a conflict of interest, lacks impartiality in respect of testing activities or of a situation that impacts on the laboratory's credibility; or
d) the laboratory knows of any critical non-compliance that relates to testing. The laboratory must provide the Director-General with information related to the critical non-compliance (such as a copy of the accreditation assessment report); or
e) the recognised laboratory is notified by the accreditation body of suspension or withdrawal of accreditation.

(4) KTPs must maintain confidentiality of all information that comes into their possession as part of their activities as a person having responsibility for testing and reporting.

(5) KTPs must advise the Director-General within 24 hours, where practicable, of situations that might give rise to a conflict of interest, and must comply with any directions given by the Director-General regarding dealing with the situation.

(1) This clause covers exception reporting and is intended to identify any event(s) that are outside the scope of what is considered normal. The goal is to take actions that help to minimize or eliminate exceptions and/or its impact.

(2) Exception reporting requirements to MPI include but are not limited to the following:

a) significant changes e.g. failure of testing equipment such that recognised tests cannot be conducted for a significant time period;
b) testing activities (e.g. disease testing undertaken);
c) test method validation (evidence of test method validation/verification);
d) test performance (ILCP or other assessment reports);
e) temporary closures;
f) change in organisation (management or legal ownership);
g) loss of KTP coverage for any test;
h) non-compliance with the Notice;
i) any significant biosecurity, trade or public health risk (e.g. foot and mouth disease, exotic strain of Salmonella detection);
j) any conflict of interest / lack of impartiality;
k) critical non-compliance;
l) any issue known by the original laboratory relating to a sub-contracted laboratory that may affect test results.

(3) All reports specified in subclause 3 should be sent to MPI in the timeline as given in the Notice.

(4) A critical non-compliance may include but is not limited to:

a) loss or failure of critical equipment;
b) poor performance in an ILCP (e.g. indicating loss of control of a test);
c) emerging trends that have the ability to affect test results;
d) a customer exerting influence on the laboratory to alter test results or re-test, without good reason;
e) non-disclosure of unfavourable test results to customer (client);
f) substitution of samples;
g) failure to keep essential records;
h) false or altered signature;
i) failure to declare a conflict of interest.

(5) Should a Quality Manager be unclear on whether or not there is a critical non-compliance, then the Quality Manager should contact MPI for clarification.

(6) The laboratory needs to complete a risk assessment for conflicts of interest and impartiality and document this in their quality system to show how these risks are managed. Monitoring on an ongoing basis could be managed through existing personnel systems and management review type activities.

(5) Temporary closure occurs when the testing services of the laboratory are not able to be delivered within the stated operating hours for up to 3 months. A laboratory will set their hours of business as part of their commercial operation.

(6) A laboratory would be expected to notify MPI at least 5 working days prior to the closure.

(7) During temporary closure there should not be any test reports issued unless the test report was completed before closure.

2.14 Records

2.14 Records

(1) The recognised laboratory must retain records kept for the purposes of this Notice:

a) for at least four years; and
b) must ensure that the records are retrievable within two working days of a request from the Director-General or the accreditation body.

(1) A laboratory should keep a record of all relevant documentation for testing functions/activities in order to maintain an audit trail. Copies of all records need to be provided to MPI upon request. Records include but are not limited to the following:

a) issued test reports;
b) information related to samples received;
c) type of tests performed and current methods;
d) the results of those tests including number suspicious, number positive, number negative and total number tested for disease testing;
e) equivocal results due to unclear cut offs for positives and negatives for disease testing
f) original test results and/or observations;
g) qualifications and proficiency of its personnel, including KTPs and samplers as appropriate;
h) internal and external audit/assessment reports;
i) non-compliances found during internal/external audits/assessments of the recognised laboratory and the associated corrective actions;
j) circumstances and corrective actions following advice from a supplier of the inter-laboratory proficiency testing programme;
k) disputes and appeals;
l) service contracts e.g. subcontract laboratories.

(2) Electronic records should be backed up regularly and protected from hacking.

(3) Records should be:

a) retrievable as hard or electronic copies for a period of at least four years; and
b) uniquely identified, dated and traceable to the person responsible for the activity.

3 Guidance on acceptable test methods

3.1 Application of acceptable test methods

(1) This Part applies to testing requirements for a recognised laboratory. It covers specified tests, specified test methods, or where no test method is specified or approved.

3.2 General

3.2 Recognised Laboratories to use specified or approved test method for certain tests

(1) Where clause 3.1(2) applies, a recognised laboratory that conducts a test described in that subclause must use the applicable test method specified or approved without modification.

(2) Where clause 3.1(3) applies, a recognised laboratory that conducts a test described in that subclause must use the applicable test method (if any) specified in the MPI Consolidated List of Tests for Animal Products: meat, poultry, honey, seafood, dairy, live animals and germplasm, and must use the applicable test method without modification.

(3) In all cases recognised laboratories must ensure that –

a) The analysis is only undertaken in a laboratory recognised for that test; and
b) The test method used is within the scope of the laboratory's accreditation; and
c) The test method has been confirmed as suitable for the intended sample matrix.

(1) The analytical test method used needs to be identical to the test method listed in the Consolidated List of Tests and as referred to in the valid specifications held by the laboratory and for which the laboratory holds current IANZ accreditation.

(2) The specified/approved tests and test methods are listed in the Consolidated List of Tests available on the MPI website. This list of tests is not an exhaustive list of all tests for all animal material or animal products. Anyone seeking to confirm whether a test carried out in a recognised laboratory is appropriate should always check the relevant OMAR, specifications or with MPI.

(3) Process control, environmental monitoring tests would not be expected to be required as a specified or approved test.

(4) Where a recognised laboratory wishes to undertake a new specified or approved test, it needs to get the new test accredited by IANZ, and apply to MPI for recognition to undertake the test and have it added as an amendment. Application to have the test added to the laboratory's recognition is by completing the Recognised Laboratory Application Form AP18.

(5) Any new specified or approved test or test method that becomes available for export testing will be added to the Consolidated List of Tests as soon as possible.

4 Guidance on test results

4.1 Application of authorisation of results

(1) This Part applies to test results and their authorisation.

4.2 Authorisation of results

4.2 Authorisation of results

(1) The recognised laboratory must ensure that all test reports are only released by the KTP responsible for the tests to which the reports relate.

(2) If a test has been subcontracted, the original laboratory that subcontracted the test to another laboratory must ensure that the test report is:

a) signed by a KTP working for the subcontracted recognised laboratory, or;
b) where the laboratory is a non-recognised laboratory under clause 2.7 of this Notice, signed by a person qualified in the discipline the test relates to.

(3) Any report containing subcontracted test results must be traceable to the original report(s) and must contain information that enables tracing of the subcontracted laboratory and the KTP, or qualified person as per sub clause (2)(b), at that subcontracted laboratory who released the particular test result(s) to the primary client.

(1) Test reports issued by the laboratory to the customer include Product Analysis Certificates (PAC), Certificates of Analysis (COA), etc.

(2) If the customer wishes to have the subcontracted test results within the final laboratory report then traceability needs to be maintained. It is anticipated that most subcontracted laboratory reports are kept as a separate report for the customer. Also see section 2.7 Subcontracting in this document.

(3) A description of a KTPs responsibilities for test results can be found in the IANZ Specific Criteria.

5 Guidance on transitional provisions

5.1 Transitional Provisions

5.1 Transitional provisions

(1) Except as required by subclause (2) a laboratory performing tests is not required to comply with this Notice until 31 August 2017.

(2) If a laboratory's recognition or approval expires at any time during the period prior to the commencement of this notice, and the laboratory wishes to continue to perform tests:

a) the laboratory must apply for recognition under the Act and this Notice unless it is otherwise exempted under the Act or this Notice, and
b) if an application for recognition is not granted before the end of the transition period (31 August 2017), the laboratory must cease to conduct tests.

(3) A laboratory that intends to start to perform tests after the commencement of this Notice must apply for, and be granted, recognition under the Act and this Notice before it commences testing unless it is otherwise exempted under the Act or this Notice.

(4) Once a laboratory performing tests is recognised as a laboratory under section 101 of the Act for the purposes of this Notice, that laboratory must comply with the requirements in this Notice. The Animal Products (Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export) Notice 2010 and the current edition of the Laboratory Approval Scheme, as the case may be, and any other relevant requirements for recognition in any notice made under the Act, will no longer apply to that laboratory.

(1) During the 2 year transition period, dual systems of approval/recognition will operate so that laboratories have time to change over to the new Notice yet be able to maintain their recognition or approval status with MPI.

(2) New laboratories applying for recognition after the Notice commencement date will need to apply under the new Notice using the form AP18.

(3) At the end of the 2 year period the existing systems and associated documents will be superseded. This includes:

a) the ELP legal notice and guidance document; and
b) the LAS document; and
c) web sites listings for:

i) Laboratory recognised persons; and
ii) ELP Test List, etc.

(4) Some references e.g. to signatories, will be phased out of OMARs, etc. These documents are expected to reference KTPs instead. Other legal documents e.g. Notices will be updated by the end of the 2 year period (see 'Introduction: Other Information' in the Notice).