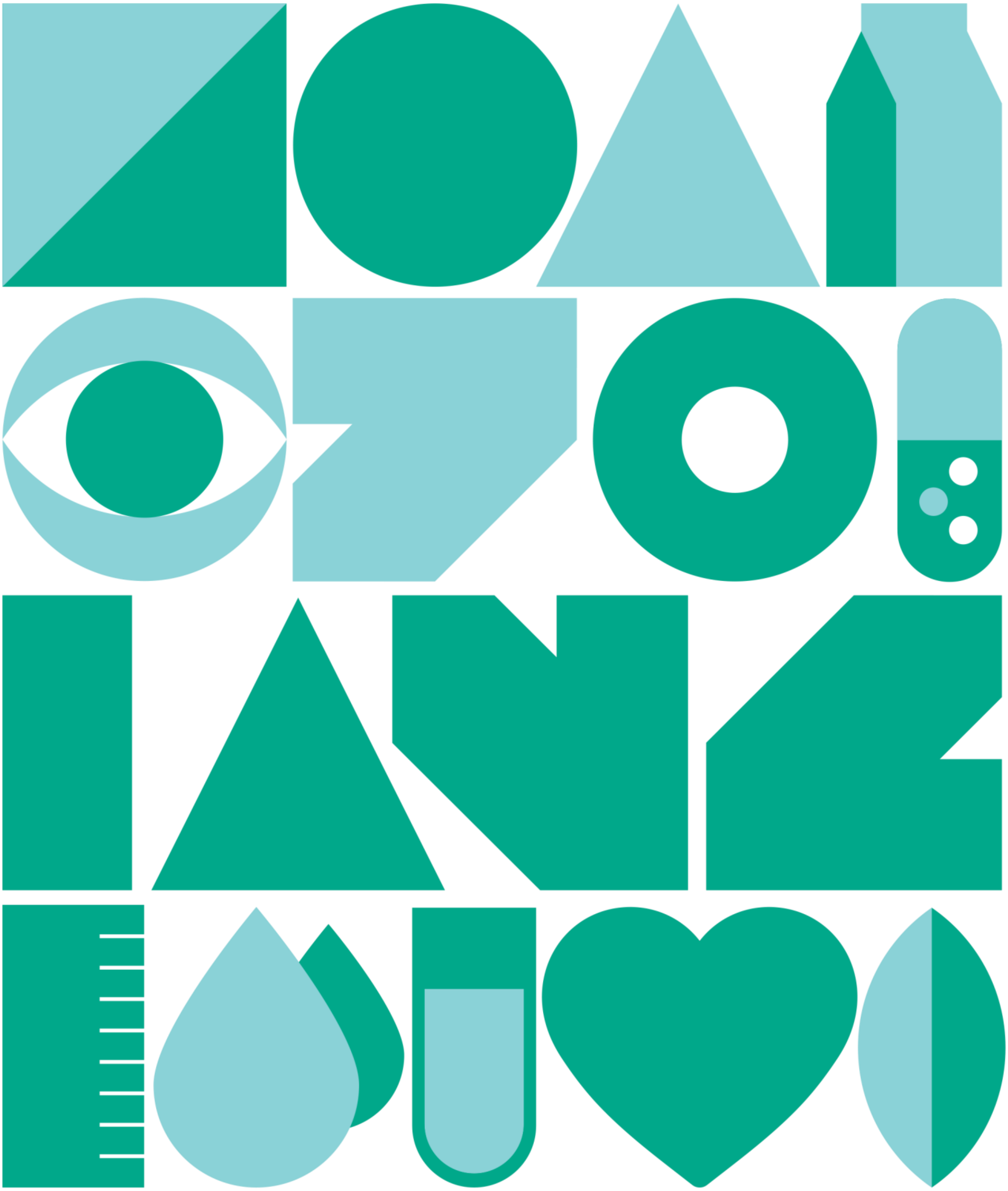

Supplementary Criteria for Accreditation
Ministry of Health
Register of Water Testing Laboratories

The NZ mark of competence
Tohu Matatau Aotearoa

Sixth Edition November 2020

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Supplementary Criteria for Accreditation

Ministry of Health

Register of Water Testing Laboratories

AS LAB C1.2 / AS LAB C2.2

Sixth Edition November 2020

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Contents

1 Introduction

1.1 Supplementary Criteria published by International Accreditation New Zealand (IANZ) amplify or particularise the general criteria for accreditation for specific fields of technology.

1.2 Supplementary Criteria for Accreditation No. C1.2/C2.2 defines the specific criteria for the approval of laboratories for entry into the Ministry of Health Register of Water Testing Laboratories.

The Ministry of Health carries out grading of community drinking water supplies through the Drinking-water Online database, which is administered by the Institute of Environmental Science and Research (ESR). Results of testing conducted on the drinking water supply are entered into this database, and are used in the grading of the supply. The Ministry requires that only results from approved laboratories are used to grade supplies, and thus have implemented this Register of Water Testing Laboratories. Only those results from approved laboratories will be accepted into the Drinking-water Online database.

Section 2 of this document describes the overall operation of this Register, and particular note should be made of the two mechanisms for laboratories to be listed in the Register – namely full accreditation as an IANZ Accredited Laboratory, or recognition by IANZ as complying with Ministry of Health Level 2 Criteria.

For laboratories which have sought Level 2 recognition only, this document is intended as a stand-alone document (with appropriate cross references) describing the criteria for approval.

For laboratories already accredited under the IANZ chemical testing and/or biological testing accreditation programmes or intending to be accredited under this water testing programme, this document is supplementary to the *Specific Criteria for Accreditation* (AS LAB C1.0) (Biological) and *Specific for Criteria Accreditation* (AS LAB C2.0) (Chemical), which describe the general criteria for IANZ accreditation in the respective fields of testing.

1.3 For laboratories which have sought recognition as a Level 2 laboratory only, this document must be applied in conjunction with the conditions detailed in the current issue of *AS1 Procedures and Conditions for Accreditation*, except where they are otherwise specifically excluded in this document.

For accredited laboratories, this document and the Specific Criteria documents referred to in 1.2 above, must be read in conjunction with current issues of IANZ documents, General Criteria for Accreditation ISO/IEC 17025 *General Requirements for the Competence of Testing and Calibration Laboratories* and *Procedures and Conditions for Accreditation* AS1, the latter document describing the organisation and operation of IANZ's Laboratory Accreditation Programme.

1.4 This document is essentially divided into two parts:

Section 4: This section sets out the criteria for recognition of laboratories against the Ministry of Health Level 2 Criteria only, and subsequent entry into the Ministry of Health Register. It sets out the procedures for recognition and the criteria against which laboratories are assessed and identifies the restrictions placed on Level 2 recognised laboratories compared with laboratories having full accreditation status.

Section 5: This section is intended for laboratories which have or intend to seek full accreditation status under this water testing accreditation programme. It attempts to detail the additional requirements (over and above the more general requirements for accreditation called up in Section 1.3 above) these laboratories need to meet in order to be listed in the Ministry of Health Register.

2 Background and Operation

2.1 Laboratories wishing to be listed in the Ministry of Health Register will be required to apply for accreditation under the IANZ water testing accreditation programme.

Presently, entry onto the Register continues to be by two mechanisms:

(a) Accreditation by IANZ under the water testing programme. Such laboratories will have demonstrated compliance with the full accreditation criteria (primarily ISO/IEC 17025 *General Requirements for the Competence of Testing and Calibration Laboratories*) and have the full status as an IANZ Accredited Laboratory

(b) Recognition by IANZ following assessment against the Ministry of Health Level 2 Criteria (detailed in Appendix 1). While listed in the Register as approved laboratories, such laboratories are not IANZ

Accredited and will remain applicants under the water testing accreditation programme until compliance with the full accreditation criteria can be demonstrated.

2.2 Laboratories are registered in Drinking-water Online and IANZ makes changes to the scopes of approval as necessary. The database administrators (ESR) should be contacted directly for further information if required.

Laboratories recognised as Level 2 laboratories only will have their scopes of approval maintained in the Drinking-water Online database only.

Fully accredited laboratories will have their scopes of accreditation maintained within both the Drinking-water Online and IANZ databases, and will also appear as Accredited Laboratories in the IANZ Accreditation Directory published on the IANZ website.

3 Scope

The scope of application of the Ministry of Health Register of Water Testing Laboratories (the “water testing accreditation programme”) is restricted to the following:

(a) Laboratories which conduct testing of drinking water from community drinking water suppliers for the purpose of grading water supplies

(b) Accreditation or Level 2 recognition will be granted only for those determinands detailed in the *Drinking-water Standards for New Zealand* (against which community drinking water supplies are graded).

With reference to point (a), the grading of community drinking water supplies is carried out in the Drinking-water Online database. Thus the water testing programme is essentially restricted to only those laboratories which contribute or intend to contribute results (either directly or indirectly) to Drinking-water Online.

Application for accreditation under the Ministry of Health Register of Drinking Water Laboratories programme is open to any chemical and/or biological laboratory which fulfils the above criteria.

Testing of waters (whether potable or other types of waters) for any other purpose or for any other determinands is not within the scope of this water testing programme. Accreditation for such testing can be sought under the IANZ Chemical and/or Biological testing accreditation programmes.

4 Recognition of Level 2 Laboratories

4.1 Criteria for Recognition – General

Non-accredited laboratories seeking recognition as a Level 2 Laboratory will be assessed against the Ministry of Health Level 2 Criteria detailed in Appendix 1.

The assessment standard has been prepared by IANZ and is based on the assessment criteria used by previous providers of Level 2 approval of laboratories. The base document from which it is referenced is ISO/IEC 17025 *General requirements for the Competence of Calibration and Testing Laboratories.*

4.2 Recognition procedures

Laboratories are referred to Section A of the IANZ publication *Procedures and Conditions for Accreditation* (PCA) which describes the overall operation of IANZ’s accreditation programmes.

In general, the policies and procedures outlined therein will apply to recognised Level 2 laboratories but the following exceptions and clarifications should be noted.

4.2.1 Section A of PCA describes the function and role of the Accreditation Advisory Committee and the (Chemical and Biological Testing) Professional Advisory Committee (PAC). These functions will generally be applicable to the Ministry of Health Register of Water Testing Laboratories, but because Level 2 laboratories are being recognised rather than accredited, committees will not be asked to conduct technical reviews of assessment reports and responses from applicant laboratories.

However, should a Level 2 laboratory seek full accreditation status the full processes described in PCA will be implemented.

4.2.2 Set out in PCA are the standards for accreditation. These are not applicable to Level 2 laboratories and are superseded by Section 4.1 above.

It should be noted that the practice of identifying Key Technical Personnel does not apply to Level 2 laboratories.

4.2.3 PCA refers to a comprehensive review of the laboratory's quality and technical system documentation. For Level 2 laboratories, IANZ will attempt to bypass this step and review the documentation (against the requirements set out in Appendix 1) as part of the on-site assessment.

4.2.4 PCA refers to the use of technical experts. For the majority of Level 2 laboratories (which conduct only a limited range of the basic chemical and/or microbiological tests) it is unlikely the services of a technical expert will be called upon. In these cases, the assessment of the laboratory's technical operations will be carried out by an IANZ Lead Assessor.

IANZ will still reserve the right to bring a technical expert onto the assessment team where it is considered necessary.

4.2.5 The IANZ Programme Specialist will review the assessment report. The reports will not generally be reviewed by PAC members.

PCA refers to allowing accredited laboratories to endorse reports in the name of IANZ. Laboratories which have been recognised as complying with Level 2 requirements but which are not accredited by IANZ **are not permitted to endorse reports or any other publication or advertising material in the name of IANZ nor use the IANZ logo.**

4.2.6 With reference to PCA, the scope of recognition of Level 2 laboratories will be in accordance with the determinands specified in the *Drinking–water Standards for New Zealand.*

4.2.7 PCA describes the surveillance programme for accredited laboratories. Laboratories that have Level 2 recognition only will be subject to full assessments on an annual basis i.e. the assessment will encompass a full on-site assessment of the quality and technical management systems against the Level 2 recognition criteria.

4.3 Rights and Duties of Level 2 Recognised Laboratories

Laboratories are referred to Section B of the IANZ publication *Procedures and Conditions for Accreditation* (PCA) which describes the rights and duties of accredited organisations along with the procedures for complaints and appeals.

In general, the policies and procedures outlined therein apply to Level 2 recognised laboratories but the following exceptions, clarifications and additions should be noted.

4.3.1 Further to Appendix 1 of PCA, Level 2 recognised laboratories which are not accredited may not use the IANZ logo or name to endorse test reports or in advertising or promotional material.

Level 2 recognised laboratories are reminded of the requirements detailed in Section B, *Procedures and Conditions for Accreditation* which require laboratories to inform IANZ of changes in key personnel or other factors that may affect their compliance status with Level 2 recognition criteria.

4.3.2 An estimate of fees may be provided on request. Assessments are charged at the IANZ hourly rate with travel at 50% of the hourly rate. For Level 2 laboratories, assessment expenses are recovered at actual cost.

The Annual Administration Fee is not payable by Level 2 recognised laboratories. The Accreditation Fee becomes payable should a laboratory attain full accreditation status.

4.3.3 Level 2 recognised laboratories will be issued with a letter of recognition from IANZ and an entry in the Drinking-water Online database detailing their scope of recognition. No certificates will be issued. This letter of recognition is renewable annually.

4.4 Criteria for Recognition – Specific

4.4.1 Reporting and Endorsement

As previously stated, Level 2 laboratories which are not accredited are not permitted to endorse test reports in the name of IANZ. Therefore, Appendix 1 of PCA is not applicable to Level 2 laboratories.

Reporting procedures, formats and contents will be assessed in accordance with the criteria set out in Appendix 1 (clause 13) of this document and Section 4.4.7 below.

4.4.2 Equipment Calibration and Traceability of Measurement

Refer also clauses 8 and 9 in Appendix 1.

Laboratory equipment, and its suitability ranks on a level equal to the competence of the staff using it. A recognised laboratory will be expected to possess and maintain all equipment necessary to carry out the tests requested for inclusion in the scope of recognition.

Guidelines on calibration requirements and recalibration intervals for specific items of equipment are detailed in Appendix 2. The guidelines set out **maximum** periods of use before equipment must be recalibrated. These periods have been established by accepted industry practice and, in most instances, are the maximum permitted recalibration intervals as laid down by international convention. Where a test method or operating environment requires a more stringent recalibration period than given here, more frequent calibrations will be expected.

IANZ may accept reduced or extended calibration intervals based on factors such as history of stability, accuracy required and ability of staff to perform regular checks. It is the responsibility of the laboratory to provide clear evidence that its calibration system and any changes to an existing system will ensure that confidence in equipment can be maintained.

4.4.3 Traceability of Measurement

Traceability requires that there is a chain of equipment whose calibrations to known levels of uncertainty are traceable from one item to the next and eventually to a national standard of measurement. The concept of traceability also includes the competence of all the people involved, the fitness of each measurement environment, the suitability of the methods used and all other aspects of the quality management systems involved at each step in the chain of measurements.

Traceability must be established for all critical measurements and calibrations either:

(a) Directly to the national standards laboratory (Measurement Standards Laboratory) or another such national body (e.g. National Measurement Institute, Australia) acceptable to the Measurement Standards Laboratory, or

(b) To a third party accredited calibration laboratory which is accredited by IANZ or by an organisation with which IANZ has a mutual recognition arrangement.

The calibration certificates issued by accredited calibration laboratories must be endorsed in accordance with the requirements of the accreditation bodies concerned. This constitutes proof of traceability to national standards.

Please note, critical measurements/calibrations are those which will significantly affect the accuracy, uncertainty or proper performance of tests.

4.4.4 Test Methodology

Refer also clause 10 in Appendix 1.

As previously stated in Section 3, recognition will be granted only for those determinands detailed in the *Drinking-water Standards for New Zealand.*

For the purposes of testing for *E.coli* only test methods which have been approved by the Ministry of Health may be used. A list of these approved methods is available from IANZ and the Ministry of Health.

4.4.5 Proficiency Testing

Refer also clause 4.2(d) and 5.3(a) in Appendix 1.

All laboratories in the Ministry of Health Register of Water Testing Laboratories are required to participate in suitable inter-laboratory comparison programmes (ILCP) for those tests within their scope of recognition, where suitable programmes are available. Suitable programmes will be on potable water samples and for the microbiological and/or chemical determinands of interest.

Laboratories which hold approval (Level 2 recognition) for the analysis of samples for *E.coli* are required to participate in at least four rounds of proficiency testing per year for that particular analysis. If the laboratory has more than two or more consecutive rounds with unsatisfactory performance, the laboratory is required to inform IANZ directly on receipt of the second set of results. IANZ will then decide on what additional information the laboratory may need to provide such as completed non-conforming work/corrective actions records detailing the root cause and subsequent actions taken to resolve the poor performance in the proficiency testing programme.

At the annual assessments, the IANZ assessment team will review overall performance of the laboratory over the past year along with the laboratory's investigation and management of unsatisfactory performance, including non-participation in available programme rounds.

4.4.6 Quality Control

Refer also to clause 5.3 of Appendix 1.

Laboratories will be assessed against the quality control requirements detailed in either:

(a) The referenced methodology and/or

(b) Manufacturer's recommendations or instructions and

(c) Specific requirements detailed in the *Drinking-water Standards for New Zealand*.

Where quality control requirements are not stipulated in any of the above, current "best practice" principles will apply.

4.4.7 Sample Management

Refer also clause 11 of Appendix 1.

The *Drinking-water Standards for New Zealand* clearly states the supply code be stated on all communications with the Ministry of Health and the Drinking Water Assessors (DWA's). Therefore all approved laboratories must ensure that all samples used for compliance testing are identified by the unique site identification code listed in the *Register of Community Drinking-Water Supplies in New Zealand.* This unique site identification code must then be included in the laboratory's test report as a sample identifier.

This requirement is expected to be implemented without difficulty where the laboratory is part of the same organisation that supplies the water or where the laboratory is responsible for the sampling itself.

Where the laboratory is providing a commercial testing service independent of the water supplier and is not responsible for sampling, it is still expected to make all reasonable attempts to obtain these unique site identification codes from the water supplier (their client) and to report them on its test reports to its clients.

Testing for microbiological determinands should start within six hours of sample collection, and where this is not possible must not be delayed more than 24 hours after collection. To be valid for compliance testing, samples must not be frozen and need to arrive at the laboratory at a temperature not higher than 10°C, or not higher than the temperature of the water being sampled. Other analyses should be conducted as per the test method reference requirements.

The temperature of samples must be measured with a calibrated thermometer and the result recorded along with the arrival date and time on receipt at the testing laboratory. If samples cannot be processed immediately on arrival in the laboratory, they need to be refrigerated at a temperature not exceeding 5°C and processed within 24 hours of collection.

4.4.8 Reporting

Refer also to clause 13 of Appendix 1.

The laboratory needs to have documented procedures for the reporting of transgressions with regard to the Maximum Acceptable Values (MAVs) set out in the *Drinking-water Standards for New Zealand*.

Under Section 69ZZ (2) of the Health Act (1965), the laboratory is required to report the results of any analysis or test carried out (for the purposes of testing for compliance with the *Drinking-Water Standards for New Zealand* that indicates any non-compliance (transgression) with the MAVs to the Drinking Water Assessor by the operator of the laboratory or the person performing the test as soon as practical after the test is conducted.

In addition, the *Drinking-water Standards for New Zealand* requires if testing water supply for other than compliance purposes indicates a possible health risk, the results must be reported to the Drinking Water Assessor.

4.4.9 Non-conforming Work

Refer also to clause 5 of Appendix 1

Should laboratories identify non-conforming work which is shown to either directly or indirectly have an effect on the validity of Drinking-water results produced by the laboratory; the laboratory is required to promptly inform IANZ of the nature of the non-conformance.

Under the Memorandum of Understanding between IANZ and the Ministry of Health, IANZ is obliged to inform the Ministry of major non-conformances which are likely to affect the validity of Drinking-water sample results.

5 Accredited Laboratories

The following sections set out the additional requirements that accredited laboratories need to implement in order to be included on the Ministry of Health Register of Water Testing Laboratories (that is, to be accredited under this water testing programme). IANZ will assess against these requirements in its routine accreditation assessments.

5.1 Criteria for Accreditation – General

As for IANZ’s Chemical testing and Biological testing accreditation programmes, accredited laboratories are required to comply with ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories.*

5.2 Accreditation Procedures

Accredited laboratories are required to comply with the conditions in the IANZ publication PCA and these policies and procedures remain for accredited laboratories in the Ministry of Health Register of Water Testing Laboratories.

Laboratories which are already accredited under one or more of the IANZ Chemical testing and Biological testing accreditation programmes, and/or the Ministry for Primary Industries Recognised Laboratory Programme will not be permitted to seek Level 2 recognition in the Ministry of Health Register of Water Testing Laboratories and are obliged to seek full accreditation status in this programme.

Accredited laboratories are reminded the scope of accreditation offered by this programme is as detailed in Section 3 above.

5.3 Rights and Duties of Accredited Laboratories

The rights and the duties of accredited laboratories are detailed in Section B of PCA and apply in full to this programme.

Where accredited laboratories also maintain similar accreditations for water testing under the chemical testing and/or biological testing programmes, assessments will be conducted at the same time.

5.4 Criteria for Accreditation – Specific

Specific technical criteria applied to chemical testing and/or biological testing accredited laboratories in general are detailed in the IANZ Specific Criteria for Accreditation publications for Chemical Testing (AS LAB C2.0) and Biological Testing (AS LAB C1.0) respectively. These criteria also apply to accredited laboratories in the Ministry of Health Register of Water Testing Laboratories.

In addition, the following requirements will also need to be implemented for accreditation to be considered under this programme.

5.4.1 Test Methodology

As previously stated in Section 3, recognition will be granted only for those determinands detailed in the *Drinking-water Standards for New Zealand.*

For the purposes of testing for *E.coli* only test methods which have been approved by the Ministry of Health may be used. A list of these approved methods is available from IANZ and the Ministry of Health.

5.4.2 Proficiency Testing

All laboratories in the Ministry of Health Register of Water Testing Laboratories are required to participate in suitable inter-laboratory comparison programmes (ILCP) for those tests within their scope of recognition, where suitable programmes are available. Suitable programmes will be on potable water samples and for the microbiological and/or chemical determinands of interest.

Laboratories which hold approval (accreditation or Level 2 recognition) for the analysis of samples for *E.coli* are required to participate in at least four rounds of proficiency testing per year for that particular analysis. If the laboratory has more than two or more consecutive rounds with unsatisfactory performance, the laboratory is required to inform IANZ directly on receipt of the second set of results. IANZ will then decide on what additional information the laboratory may need to provide such as completed non-conforming work / corrective actions records detailing the root cause and subsequent actions taken to resolve the poor performance in the proficiency testing programme.

5.4.3 Quality Control

Laboratories will be assessed against the quality control requirements detailed in either:

(a) The referenced methodology and/or

(b) Manufacturer's recommendations or instructions and

(c) Specific requirements detailed in the *Drinking-water Standards for New Zealand*.

Where quality controls requirements are not stipulated in any of the above, current "best practice" principles will apply.

5.4.4 Sample Management

The *Drinking-water Standards for New Zealand* clearly states the supply code be stated on all communications with the Ministry of Health and the Drinking Water Assessors (DWA's) therefore approved laboratories must ensure that all samples used for compliance testing are identified by the unique site component code listed in the *Register of Community Drinking Water Supplies and Suppliers in New Zealand.* This unique site component code must then be included in the laboratory's test report as a sample identifier.

This requirement is expected to be implemented without difficulty where the laboratory is part of the same organisation that supplies the water or where the laboratory is responsible for the sampling itself.

Where the laboratory is providing a commercial testing service independent of the water supplier and is not responsible for sampling, it is still expected to make all reasonable attempts to obtain these unique site identification codes from the water supplier (its client) and to report them on its test report to its clients.

Testing for microbiological determinands should start within six hours of sample collection, and where this is not possible must not be delayed more than 24 hours after collection. To be valid for compliance testing, samples must not be frozen and need to arrive at the laboratory at a temperature not higher than 10°C, or not higher than the temperature of the water being sampled. Other analyses should be conducted as per the test method reference requirements.

The temperature of samples must be measured with a calibrated thermometer and the result recorded along with the arrival date and time on receipt at the testing laboratory. If samples cannot be processed immediately on arrival in the laboratory, they need to be refrigerated at a temperature not exceeding 5°C and processed within 24 hours of collection.

5.4.5 Reporting

The laboratory needs to have documented procedures for the reporting of transgressions with regard to the Maximum Acceptable Values (MAVs) set out in the *Drinking-water Standards for New Zealand.*

Under Section 69ZZ (2) of the Health Act (1965), the laboratory is required to report the results of any analysis or test carried out (for the purposes of testing for compliance with the *Drinking Water Standards for New Zealand* that indicates any non-compliance (transgression) with the MAVs to the Drinking Water Assessor by the operator of the laboratory or the person performing the test as soon as practical after the test is conducted.

In addition, the *Drinking-water Standards for New Zealand* requires if testing water supply for other than compliance purposes indicates a possible health risk, the results must be reported to the Drinking Water Assessor.

5.4.6 Non-conforming Work

Should laboratories identify non-conforming work which is shown to either directly or indirectly have an effect on the validity of Drinking-water results produced by the laboratory; the laboratory is required to promptly inform IANZ of the nature of the non-conformance.

<u>Under the Memorandum of Understanding between IANZ and the Ministry of Health, IANZ is obliged to inform the Ministry of major non-conformances which are likely to affect the validity of Drinking-water sample results.</u>

5.4.7 Accommodation and Environment

Accredited testing laboratories that undertake testing of potable and non-potable waters will need to ensure that effective separation between sample types can be demonstrated at all phases of process from sample receipt through the testing.

6 Sampling

Accreditation for the sampling of potable water under the IANZ Drinking Water Programme is open to any testing laboratory conducting chemical and/or biological testing and which conducts sampling in support of compliance with the *Drinking-water Standards for New Zealand 2005* (revised 2018).

6.1 Competence of samplers

For a laboratory to be accredited for sampling activities under the IANZ Drinking Water Testing Accreditation Programme the laboratory needs to take responsibility for the sampling to the extent necessary it can demonstrate the competence of the samplers and adherence to the requirements of the DWSNZ.

Laboratory samplers will need to be formally trained and have training records retained on file at the laboratory. Samplers will need to be monitored regularly and records of this monitoring will need to be retained on file at the laboratory.

6.2 Containers

Sample containers of the appropriate type for the water source being collected and for the type of testing concerned i.e. sterile containers or those with the correct preservative will need to be used. If the laboratory provides containers to its customers then procedures and records must be available for the management of those containers.

6.3 Collection

The laboratory will need to have a sampling plan provided, or agreed to, by the drinking water supplier or access to a sampling plan e.g. a customer supplied sampling plan for all different types of water sources from which samples for compliance testing may be collected. Sampling should be carried out in accordance with an internationally / nationally recognised method.

Details such as the sampling date, time, sampler name and sampling details and conditions should be recorded during collection of the samples. The temperature of the water source needs to be measured during sample collection with a calibrated thermometer and recorded. Records arising from the sampling activities need to be retained on file at the laboratory.

6.4 Transport

For microbiological samples, these shall be transported in a dark container and kept chilled at all times. For chemical compliance samples transport shall be appropriate for the subsequent testing.

Appendix 1: Ministry of Health Level 2 Criteria for Recognition

Introduction

The Ministry of Health Register of Water Testing Laboratories currently allows for non-accredited laboratories to gain approval and be listed in the Register. Such laboratories are required to meet the following criteria and be recognised by IANZ as Level 2 Laboratories.

1 Scope

1.1 This Criteria document sets out the general requirements with which a laboratory has to demonstrate that it operates if it is to be recognised as a Level 2 Laboratory in the Ministry of Health Register of Water Testing Laboratories.

1.2 Additional requirements and information which have to be disclosed for assessing competence or for determining compliance are specified in the International Accreditation New Zealand (IANZ) document AS LAB C1.2/C2.2: *Supplementary Criteria for Accreditation - Ministry of Health Register of Water Testing Laboratories.*

1.3 This Criteria document will be used by IANZ for assessing the competence of laboratories seeking Level 2 recognition.

2 References

ISO/IEC 17025 *General Requirement for the Competence of Calibration and Testing Laboratories.*
Drinking-water Standards for New Zealand

3 Definitions

Refer to ISO/IEC 17025
Drinking-water Standards for New Zealand Drinking-water Standards for New Zealand 2005 (Revised 2018)

4 Organisation and Management

4.1 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 Criteria document.

4.2 The laboratory shall:
(a) Have managerial staff with the authority and resources needed to discharge their duties

(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) Where appropriate, nominate deputies in case of absence of key technical and quality personnel

(d) Participate in available inter-laboratory comparison programmes and proficiency testing programmes.

5 Quality System

5.1 The laboratory's quality system documentation shall state the laboratory's policies and operational procedures established in order to meet the requirements of this Criteria document and shall also contain:

(a) Identification of the laboratory's approval signatories

(b) The laboratory's procedures for achieving traceability of measurements

(c) Where appropriate, arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work

(d) Reference to test procedures used

(e) Procedures for handling samples

(f) Where appropriate, reference to the major equipment and reference measurement standards used

(g) Procedures to be followed for feedback and corrective action wherever testing discrepancies are detected, or departures from documented policies and procedures occur

(h) Procedures for dealing with complaints

(i) Where appropriate, procedures to protecting confidentiality and proprietary rights.

5.2 Where corrective action procedures need to be implemented these shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescales.

5.3 The laboratory shall ensure that quality of the results provided to clients by implementing checks.

These checks shall be reviewed and shall include but not be limited to:

(a) Participation in proficiency testing and other inter-laboratory comparison

(b) Regular use of certified reference materials and/or in-house quality control using secondary reference material

(c) Where appropriate, re-testing of retained samples.

6 Personnel

6.1 The testing laboratory shall have sufficient personnel having the necessary education, training, technical knowledge and experience in their assigned functions.

6.2 The testing laboratory shall ensure training of its personnel is kept up-to-date.

6.3 Records on the relevant qualifications, training, skills, experience and competence of the technical personnel shall be maintained by the laboratory.

7 Accommodation and Environment

7.1 Where appropriate, the laboratory accommodation, test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of the tests.

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

7.3 Where appropriate, there shall be effective separation between neighbouring areas when the activities therein are incompatible.

7.4 Where appropriate, access to and use of all areas affecting the quality of the activities shall be defined and controlled.

7.5 Where appropriate, adequate measures shall be taken to ensure good housekeeping in the laboratory.

8 Equipment and Reference Materials

8.1 The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of the tests. In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the relevant requirements of this Criteria document are met.

8.2 Where appropriate, all equipment shall be properly maintained and maintenance procedures shall be documented. Any item of the equipment which has been subject 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 specific 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 tests.

9 Measurement Traceability and Calibration

9.1 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.

9.2 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.

9.3 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.

9.4 Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

10 Test Methods

10.1 The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples for testing, and on the test procedures, where the absences of such instructions could jeopardize the 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 staff.

10.2 The laboratory shall use appropriate methods and procedures for all tests and related activities within its responsibility (including sampling, handling, transport, storage and preparation of samples).

10.3 Where it is necessary to employ methods that have not been established as standard, 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.

10.4 Where sampling is carried out as part of the test method, the laboratory shall use documented procedures. Where applicable, appropriate statistical techniques shall be used to select samples.

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

(a) The requirements of this Criteria 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 environmental and operating conditions necessary to maintain the integrity of calibration and 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.

10.6 Where appropriate, documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.

11 Handling of Samples

11.1 The laboratory shall have a documented system for uniquely identifying the samples to be tested to ensure that there can be no confusion regarding the identity of samples at any time.

11.2 Where there is any doubt as to a sample's suitability for test, where the sample does not conform to the description provided or where the test required is not fully specified, the laboratory shall, where appropriate, consult the client for further instruction before proceeding. Where appropriate, the laboratory shall establish whether the sample has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

11.3 The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the sample during storage, handling, preparation or test; any relevant instructions provided with the sample shall be followed. Where samples have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a sample or portion of a sample 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 samples or portions concerned.

11.4 Where appropriate, the laboratory shall have documented procedures for the receipt, retention or safe disposal of samples, including all provisions necessary to protect the integrity of the laboratory.

12 Records

12.1 The laboratory shall maintain a record system to suit its particular circumstances and comply with any particular regulations. It shall retain on record all original observations and calculations and a copy of the test report for an appropriate period. The records for each test shall contain sufficient information to permit their repetition. Where appropriate, records of derived data and of calibration records shall also be retained for an appropriate period.

12.2 Where appropriate, all records and reports shall be safely stored, held secure and in confidence to the client.

13 Reports

13.1 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.

13.2 Each report shall include at least the following information:

(a) A title, e.g. "Test Report"

(b) Name and address of laboratory and location where testing was carried out

(c) Unique identification of the report (such as serial number) and of each page, and the total number of pages

(d) Where appropriate, the name and address of the client

(e) Description and unambiguous identification of the samples tested

(f) Where appropriate, the characterisation and condition of the samples tested

(g) Where appropriate, the date and time of receipt of the sample, and date and time of performance of the test

(h) Where appropriate, identification of the test method used or unambiguous description of any non-standard method used

(i) Where appropriate, reference to the sampling procedure

(j) Where appropriate, any deviations from, additions to or exclusions from the test method, and any other information relevant to a specific test, such as environmental conditions

(k) Measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified

(l) Where appropriate, a statement of the estimated uncertainty of the test

(m) 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

(n) Where relevant, a statement to the effect that the results relate only to the samples tested

(o) A statement that the report shall not be reproduced except in full, without the written approval of the laboratory.

13.3 Where the report contains results of tests performed by subcontractors, these results shall be clearly identified.

13.4 Where appropriate, 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.

13.5 Where appropriate, material amendments to a test report after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Test Report, serial number … (or as otherwise identified)", or equivalent form of wording. Such amendments shall meet all the relevant requirements of clause 13 of this Criteria document.

13.6 Where appropriate, the laboratory shall notify clients promptly in writing of any event, such as the identification of defective measuring equipment that casts doubt on the validity of results given in any test report or amendment to a report.

13.7 Where appropriate, the laboratory shall ensure that, where clients require transmission of test results by telephone, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of the Criteria document are met and that confidentiality is preserved.

14 Sub-contracting of testing

14.1 Where a laboratory sub-contracts any part of the testing, this work shall be placed with a laboratory complying with this Criteria document. The laboratory shall ensure and be able to demonstrate that its sub-contractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect of the work being sub-contracted. Where appropriate, the laboratory shall advise the client in writing of its intention to sub-contract any portion of the testing to another party.

Appendix 2: Equipment Calibration Intervals

The following table sets out the normal periods between successive calibrations for a number of reference standards and measuring instruments. It must be stressed that each period is generally considered to be the maximum appropriate in each case providing the other criteria as specified below are met:

(a) The equipment is of good quality and of proven adequate stability, and

(b) The laboratory has both the equipment capability and staff expertise to perform adequate internal checks, and

(c) If any suspicion or indication of overloading or mishandling arises, the equipment is checked immediately and thereafter at frequent intervals until it can be shown that stability has not been impaired.

Where the above criteria cannot be met, appropriately shorter intervals may be necessary. IANZ is prepared however, to consider submissions for extension of calibration intervals based on the factors outlined in Section 6 of the Biological and/or Chemical Specific Criteria's.

Items marked * in the table are those which may be calibrated by staff of a laboratory if it is suitably equipped and the staff is competent to perform such recalibrations. Where calibrations have been performed by the staff of a laboratory, adequate records of these measurements must be maintained.

IANZ has produced a number of Technical Guides with further information on some calibration procedures (e.g. balances, thermometers). Contact IANZ for further details.

Equipment	Maximum period between successive calibrations	Procedures
Automatic burettes, dispensers and pipettors	* Initial and three monthly	Accuracy and repeatability of delivery at required volumes.
Automated microbiological test equipment	* On going	Verify automated dispensing and/or enumeration of bacterial suspension regularly by appropriate manual or other techniques.
Balances	Initial calibration and three yearly recalibrations	By an accredited calibration laboratory or *Calibration using traceable certified masses. IANZ Technical Guide AS TG 2: *Laboratory Balances – Calibration Requirements.* Staff performing calibrations need to be formally trained. Annual servicing is recommended.

Equipment	Maximum period between successive calibrations	Procedures
Balances	Accompanied by (a) *Each weighing (b) *One Month (c) *Six months	 Zero check. One point check using a known mass close to balance capacity. Repeatability checks at the upper and lower ends of the scale. The standard deviation of the results can be compared against the results recorded on the last external calibration certificate.
Masses	Initial Three years (first recalibration) Five years (successive recalibrations)	By a calibration authority recognised by IANZ By a calibration authority recognised by IANZ By a calibration authority recognised by IANZ
pH meter	* Daily (or on use) *Note: If a temperature compensation probe is used, it must be calibrated. See thermometers.*	Calibrate using at least two appropriate standard buffers as per the Drinking-water Standards for New Zealand 2005 (Revised 2018). Buffers need to be stored in appropriate containers and marked with an expiry date
Refrigerators	* Daily	Monitor with temperature reading device and record.
Spectrophotometer	Six monthly	Wavelength and absorbance accuracy check by: • IANZ accredited laboratory or • * Calibrated filters or • MSL Technical Guide No. 38 Reference Materials for the Calibration of UV/Visible Light Spectrophotometers.

Equipment	Maximum period between successive calibrations	Procedures
Sterilisers Autoclaves	Initial and following repair or maintenance * Each use	Check heating profiles of typical loads with respect to chamber temperatures to determine lag times (see Appendix 6), by an accredited calibration laboratory; or; *Using appropriately calibrated equipment following a fully documented procedure. Annual servicing of steam sterilisers is strongly recommended. Check the time and temperature of the cycle. Discard loads should be autoclaved for at least 30 minutes at 121°C.
• Hot Air Sterilising Ovens	* Each use	Check of time and temperature. At least 160°C for 2 hours.
Thermocouples (probe only) • Rare metal • Base metals	100 hours use or three years whichever is the sooner Calibration intervals to suit the particular application	Single point within the working range against a reference thermometer or thermocouple.
Thermometers (Liquid-in-glass) • Reference	Five years (complete) *Six months	By an accredited calibration laboratory, followed by an ice point check on receipt. Ice point. (See Technical Guide 3 AS TG 3). Check against reference thermometer / thermocouple across working range or at points of use. (See Technical Guide 3 AS TG 3
• Working	Five years (complete) *Six months	Check at ice point

Equipment	Maximum period between successive calibrations	Procedures
Thermometers (Resistance)	Five (full calibration) or when the ice point drift is more than five times the uncertainty of calibration *Six months	By an accredited calibration laboratory, followed by an ice point check on receipt. Ice point. If outside five times the uncertainty of the calibration, complete recalibration is required.
Thermometers (Handheld non-resistance electronic) *Note: Handheld non-resistance working thermometers are generally considered of insufficient quality to be used as reference thermometers*	*One year	Check against reference thermometer across working range or at points of use (See Technical Guide 3 AS TG 3).
Thermostatically controlled equipment (incubators, ovens, water baths)	* Daily * Two years	Monitor with temperature reading device and record. Temperature variation within working space by an accredited calibration laboratory or *Using appropriately calibrated equipment following a fully documented procedure.
Volumetric glassware	* Initial only	Volume check using weighed distilled water.