

Requirements Relating to Laboratories 2021



1. Background

- a. On 15 November 2021, the Accreditation Council operating as International Accreditation New Zealand (IANZ) was appointed as the laboratory accreditation body by the Chief Executive of Taumata Arowai—the Water Services Regulator (Taumata Arowai) under section 74 of the Water Services Act 2021 (the Act).
- b. Taumata Arowai has a duty to prescribe requirements relating to laboratories under section 75 of the Act.
- c. This document is secondary legislation for the purpose of the Legislation Act 2019.
- d. Under Schedule 1 Transitional, savings and related provisions of the Act, a laboratory recognised by the Director-General of Health under section 69ZY of the Health Act 1956 immediately before the commencement date is an accredited laboratory for the purposes of section 73 of the Water Service Act until the earlier of the following:
 - the date on which the laboratory is accredited under section 77 of the Water Services Act
 - the date that is 3 years after the commencement date of 15 November 2021.
- e. IANZ accredited laboratories under the IANZ Drinking Water Testing Laboratory Programme at the date this Notice comes into force will continue to be accredited.
- f. Level 2 recognised laboratories complying with the Supplementary Criteria for Accreditation: MoH Register of Water Testing Laboratories will continue to be recognised for the purposes of the Water Services Act for 3 years from 15 November 2021. At this point, these laboratories must be accredited under IANZ accreditation criteria requirements.
- g. Level 2 recognised laboratories must continue to comply with the Supplementary Criteria for Accreditation: MoH Register of Water Testing Laboratories until full accreditation is granted.
- h. For the purposes of this Notice and for the avoidance of doubt, the term:
 - ‘accredited laboratory’ means accredited laboratories (being fully accredited by IANZ) and laboratories that were previously Level 2 recognised laboratories now deemed accredited under the Water Services Act.
 - ‘accredited’ or ‘accreditation’ means the IANZ accreditation process against the requirements of ISO/IEC 17025 or the IANZ recognition process under the Supplementary Criteria for Accreditation.
- i. Taumata Arowai may, by notice, amend, revoke, or replace the prescribed requirements at any time.

2. Commencement

The requirements set out below commence on 22 December 2021.

3. Requirements for laboratories

The following requirements apply to IANZ as the laboratory accreditation body and the laboratories seeking and maintaining accreditation under the IANZ Drinking Water Testing Laboratory Programme.

3.1 Criteria and standards

- a. If the criteria and standards for accreditation of a laboratory change, IANZ will inform all accredited laboratories of the changes and require them to confirm their compliance with the changes within 3 months of the changes coming into effect. IANZ will verify compliance in their next assessment of the laboratory.

Criteria

- b. The criteria for accreditation are those listed in the following documents. The current versions are accessible from the IANZ website or available for purchase:

General criteria:

- [ISO/IEC 17025 General Requirements for the competence of testing and calibration laboratories](#)
- [AS1 Procedures and Conditions for Accreditation](#)
- [AS TP1 Traceability of Measurement](#)
- [AS TP2 Participation in Proficiency Testing Activities](#)

Specific criteria:

- [AS LAB C1 Specific Criteria – Biological Testing](#)
- [AS LAB C2 Specific Criteria – Chemical Testing](#)

Supplementary criteria

- [AS LAB C1.2/C2.2 Supplementary Criteria for Accreditation MoH Register of Water Testing Laboratories](#)

- c. IANZ will advise Taumata Arowai of any proposed changes to the Specific Criteria and Supplementary Criteria and the rationale for these changes prior to publishing updated criteria on its website.

Standards

- d. Sampling and/or analysis undertaken by accredited laboratories must be carried out in accordance with the drinking water standards and compliance rules in force.
- e. All tests used for the analysis of source water, raw water and drinking water must be carried out in accordance with the methods set out in the accredited laboratory's scope of accreditation.
- f. All methods in the scope of accreditation must be either:
 - an internationally recognised method; or
 - an appropriately validated modified or in-house method.
- g. Accredited laboratories must document the method and relevant processes used for the analysis of the same determinand(s) in source water, raw water and drinking water.
- h. All test methods must be sufficiently sensitive to ensure that the determinand can be tested to a detection level that is as low as practicable but to at least half of the Maximum Acceptable Value stated in the drinking water standards.

- i. Accredited laboratories must ensure that all samples used for compliance testing are identified by the unique identifier allocated by Taumata Arowai for the water supply and its components (as identified in the Register of Drinking Water Supplies) where the sample has been taken. The unique identifier must be included in the laboratory's test report to the water supplier and any report to Taumata Arowai.
- j. Accredited laboratories must advise their customers within 24 hours of any non-conforming work that has, or is likely to have, affected the results of analysis. The information must include:
 - Date and times of the affected or potentially affected test results.
 - Likely impact of the non-conformance.
 - Steps taken to resolve the cause of the non-conformance.
- k. Accredited laboratories must carry out a minimum of four *E. coli* analyses per year as part of their proficiency testing plans. In the event of two or more consecutive rounds with unsatisfactory performance, the laboratory must notify IANZ directly on receipt of the second set of results.
- l. Accredited laboratories must ensure (where possible) that the sample containers of the appropriate type for the drinking water, source water or raw water being collected and for the type of testing concerned are used (i.e. sterile containers or those with the correct preservative).
- m. Where accredited laboratories cannot ensure the sample containers are of the appropriate type, a disclaimer is included with the sample results indicating that the results may be affected by the container used.

3.2 Classes of accreditation

- a. Laboratories undertaking analysis of source water, raw water and drinking water under the drinking water standards and compliance rules must be accredited under one of the classes specified.
- b. The following classes apply to the IANZ Drinking Water Testing Laboratory Programme:

Class 1: Drinking Water Laboratories

- Provide services in relation to analysis of source water, raw water and drinking water as part of a range of services or as their sole service.
- The range of determinands may be limited or extensive.

Class 2: Drinking Water Specialist Laboratories

- Provide services in relation to analysis of specific determinands in source water, raw water and drinking water, using specialist equipment not readily available in other laboratories or recognised as Reference Laboratories for other relevant programmes.
- Accreditation under the IANZ Drinking Water Testing Laboratory Programme is not required when testing the specified determinands listed below.
- Laboratories must be accredited under another IANZ programme or by an organisation with which IANZ has a mutual recognition arrangement.
- Determinands that this Class applies to are: Radiological

3.3 Timeframe for validity and required renewal of accreditation

- a. Following the initial accreditation, accredited laboratories, will be confirmed as continuing to be accredited on the completion of each annual assessment in the four-year assessment cycle as per the relevant accreditation.

3.4 Minimum frequency of assessments to be conducted

Frequency of assessments

- a. Accredited laboratories will follow a four-year assessment cycle as per IANZ accreditation processes.
- b. IANZ retains the right to assess an accredited laboratory, with or without technical experts, at any time should there be due cause to do so.
 - Due cause is any matter, supported by evidence, that could affect the integrity of the testing processes and the laboratory's ability to provide results the drinking water supplier can rely on for the protection of public health and safety.
- c. IANZ may, at the request of an accredited laboratory and based on an assessment of risk and scope of accreditation, reduce the frequency of some surveillance assessments for accredited laboratories.
- d. A technical assessment must be undertaken on:
 - fully accredited laboratories at least every second year
 - Level 2 recognised laboratories each year.

Scope of assessments

- e. In addition to the scope for each of the four-year cycle assessments, each assessment will include:
 - compliance with the requirement under section 73(2) of the Water Services Act 2021 for accredited laboratories to notify Taumata Arowai and the drinking water supplier of non-compliant drinking water test results.
 - completion of required proficiency tests and reporting of unsatisfactory *E. coli* proficiency results to IANZ.

3.5 Forms and procedures that relate to accreditation

- a. Laboratories applying for accreditation and seeking to maintain accreditation must use the forms and follow the procedures set out by IANZ and referenced by this notice.
- b. IANZ must maintain and make available the current forms and procedures on its [website](#).

3.6 Procedures for the investigation by a laboratory accreditation body of complaints relating to laboratories

Complaints raised by customers or other laboratories

- a. When IANZ receives a formal complaint from a customer or another laboratory, about an accredited laboratory, IANZ will follow the procedures set out in AS1 Procedures and Conditions for Accreditation.
- b. Taumata Arowai will forward complaints received about laboratories to IANZ.

Complaints raised by Taumata Arowai

- c. Taumata Arowai may request IANZ to investigate one or more accredited laboratories undertaking analysis of drinking water, source water or raw water in response to complaints, concerns or other information received from drinking water suppliers, laboratories or other parties.
- d. Complaints, concerns or information received may relate to any matter that could affect the integrity of the results being provided to water suppliers and their ability to rely on those results to deliver safe drinking water.
- e. IANZ shall investigate those complaints and concerns and provide a report on the outcome of those investigations by an agreed date, which will be within 3 months of the issue being raised.

3.7 Notification requirements for laboratories relating to analysis of source water, raw water or drinking water

- a. Under s73(2) of the Act if the results of an accredited laboratory's analysis indicate that drinking water does not comply with the drinking water standards or compliance rules, the laboratory must notify Taumata Arowai and the drinking water supplier as soon as practicable after the results of the tests are known.
- b. Laboratories should notify Taumata Arowai using the Taumata Arowai online portal: Hinekōrako. If the laboratory considers there are immediate risks to public health, they should alert Taumata Arowai by telephone. Contact information is available on the Taumata Arowai website: www.taumataarowai.govt.nz.
- c. If a laboratory is unable to use Hinekōrako for any reason, they must contact Taumata Arowai by telephone or email.
- d. If insufficient information is provided in the notification, Taumata Arowai will contact the laboratory to request additional information.

4 Other matters

Reporting and information sharing

In addition to specified reporting and information sharing set out in the criteria, the following reporting and information sharing obligations will apply. This information enables Taumata Arowai to maintain an overview of the performance of the accredited laboratories sector with respect to source water, raw water and drinking water.

4.1 Obligation on IANZ to notify concerns to Taumata Arowai that could lead to suspension or revocation of accreditation

- a. Under section 80(3) IANZ must notify Taumata Arowai of concerns it believes could lead to suspension or revocation of the accreditation of a laboratory. Notification should be as soon as practicable after concerns arise and should be via email.
- b. Suspension may apply to a part or the full scope of accreditation.
- c. For the purpose of this clause, concerns are defined as actions or inaction that would impact on the service delivered by the laboratory to drinking water suppliers that directly or indirectly affects the validity of test results. This includes but is not limited to:
 - Systemic issues, eg, concerning the accuracy of test results, implementation of corrective actions not sustained

- Availability of, or competency of, key technical people to assure and supervise the analysis
 - Essential equipment failure that affects the delivery of valid test results
 - Incorrect validation processes.
- d. IANZ will provide the following information to Taumata Arowai as soon as the concern has been identified and immediate actions have been taken with the laboratory to stop the continuation of the cause of the concern:
- name of laboratory
 - description of the concern
 - name of the drinking water supplier(s) affected by the concern
 - confirmation that the laboratory has notified the drinking water supplier(s) of concerns that affect their test results and any required actions by those suppliers (eg, can no longer rely on certain reports, etc)
 - actions taken by IANZ with the laboratory to respond to concerns
 - response by laboratory
 - timeframe for corrective action to be completed
 - likely next steps if not complied with.
- e. IANZ will notify via email Taumata Arowai once a decision has been made but no later than 7 working days after notifying the laboratory of the decision, of any suspension (partial or full) or revocation of accreditation being advised to the laboratory.

4.2 Laboratories must notify IANZ of non-conformances that affect test results

- a. Laboratories must report to IANZ any identified non-conforming work relating to compliance testing that is shown to either directly or indirectly have an effect on the validity of test results produced by the laboratory and advise:
- Water supplier affected
 - Water supply(ies) affected
 - Nature of non-conformity
 - Actions taken and dates
 - Current status of non-conformity
- b. IANZ must review the notification and identify whether the actions have adequately addressed the cause and removed the risk, or an additional assessment is required.
- c. IANZ must notify Taumata Arowai by the next working day of any non-conforming work that has or is likely to have affected test results and the actions taken to confirm the laboratory has addressed the cause of the non-conformance.

4.3 IANZ reporting requirements to Taumata Arowai

- a. IANZ will provide Taumata Arowai with quarterly summary reports on:
- Appeals of IANZ decisions, complaints against accredited laboratories, complaints about IANZ where they relate to analysis of water samples and/or accredited laboratories undertaking analysis of source water, raw water and drinking water, including:
 - Name of the laboratory

- Description of appeal/complaint
- Outcome
- Dates received and resolved.
- Technical non-conformances identified during assessments in the drinking water testing laboratories or reported by laboratories that:
 - Affected the integrity and quality of analysis by category and number of non-conformances
 - Related to any laboratory's non-compliance with the duty in section 73(2) to report non-compliant drinking water results to Taumata Arowai.
- b. The reporting timeframe, content and format will be documented in the Memorandum of Understanding between IANZ and Taumata Arowai.

4.4 Information sharing of trends and good practice arising from assessments to improve practices across the sector

- a. IANZ will monitor the outcomes of assessments and laboratories' reporting of non-conformances through its existing internal channels to identify areas of good practice or trends in non-conformances that directly impact the reliability of results provided to drinking water suppliers.
- b. Subject to (c) below, IANZ will communicate this information to laboratories accredited under the IANZ Drinking Water Testing Laboratory Programme through an appropriate mechanism quarterly. Individual laboratories will not be identified.
- c. Where a non-conforming practice creates significant risks to the effectiveness of source water, raw water and drinking water analysis, and there is the potential that other laboratories may be following similar practices, IANZ must immediately communicate the issue to all accredited laboratories under the IANZ Drinking Water Testing Laboratory Programme and required practice to the accredited laboratories and to Taumata Arowai.

Sub-contracting

4.5 Sub-contracting analysis of samples on behalf of a water supplier

- a. An accredited laboratory may sub-contract analyses to another accredited laboratory.
- b. The laboratory with the direct client relationship with the drinking water supplier retains the responsibility for communicating the test results to the water supplier and for notifying any non-compliant results to Taumata Arowai.



Dated at Wellington the 14th day of December 2021

WILLIAM BAYFIELD, Chief Executive of Taumata Arowai—the Water Services Regulator