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He Whakaora.
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ACC Requirements for Conformity Assessment Bodies to audit against

NZS 8171:2005 Allied Health Services Sector Standard, or

The ACC requirements for Physiotherapy, Hand Therapy and Podiatry Services

1 November 2024

The ACC Requirements for Conformity Assessment Bodies to audit against

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Version

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Reviewers

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Purpose of this document

- ACC's Allied Health Contract includes a requirement for suppliers to demonstrate they are meeting certification requirements under either NZS 8171: Allied Health Services Sector Standard or the ACC Requirements for Physiotherapy, Hand Therapy and Podiatry Services.

From 1 November 2024, the option for certification under NZS 8171: Allied Health Services Sector Standard is being progressively removed, as current certification expires. In future all suppliers will be certified under the ACC Requirements for Physiotherapy, Hand Therapy and Podiatry Services.

By requiring CABs to meet the requirements of this document ACC can be assured that a robust and consistent process is followed by those agencies that audit against and provide audit reports to certify allied health professional services.

Conformity Assessment Bodies (CABs)

Conformity Assessment Body means an organisation carrying out testing, inspection or certification that has been accredited by an accreditation authority. CABs who wish to audit against the NZS 8171:2005 (or subsequent revised versions), and any defined auditing scope of ACC suppliers, are required to meet the following criteria:

1. Meet the requirements of this document.
2. Hold third-party accreditation with either the International Society for Quality in Health Care (ISQua) or the Joint Accreditation System of Australia and New Zealand (JAS-ANZ).
3. Is a designated auditing agency as authorised under the Health and Disability Services (Safety) Act 2001.
4. Complies with the following International Accreditation Forum (IAF) documents:
   - IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling (IAF MD1:2007) (IAF 2007a), and
   - IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems (IAF MD2:2007) (IAF 2007b).

ACC is not liable for the cost of audit services. On completion of audit services, the CAB shall invoice the ACC Supplier (the organisation being audited).

Definitions

The following definitions apply to this document.

Allied Health Professional
Is as defined in NZS 8171:2005.

Business

A business (or Supplier) is the legal entity which intends to hold the Allied Health Services contract and be certified to provide services.

Site

A site is a permanent location where an organisation carries out work or a service.

Main Location site (business site)

A specific location where the allied health professional service is provided from and is the primary premises of that business. There are administration and support services (reception, cleaning, laundry etc) which form part of the business.

Satellite Location (site)

The allied health professional service provided away from its main location (business site) as an extension of the services provided by that business and where these services operate as a standalone clinic and are certified.

Off Site Location

The allied health professional service provided away from its main business site or satellite site as an extension of the services provided by that business and where these services are delivered for a prescribed population at another location which is not part of the practice (supplier) certification.

Independent Gym or Pool Facility

Commercial Gym and Public Access Pool facilities that are not owned and/or operated by the provider but utilized by the provider to deliver treatment and rehabilitation services.

Multisite

When a supplier has a common quality management system and the main site manages and monitors all sites, that is common policies and procedures, centralised systems for appointment and training, managing complaints and monitoring of services, then the square root calculation will be applied for each audit. Site selection will include the main site at each on site audit/visit and different sites each audit/visit. For the avoidance of doubt, a multisite operation does not include separate businesses.

On-site audit

An on-site audit is either conducted by visiting the premises or can be completed via a remote / virtual visit.

Overview of Audit Process

CABs that meet the criteria may audit ACC suppliers seeking certification who supply allied health professional services. Certification by an ACC approved CAB allows a supplier to meet ACC's certification contract criteria. The CAB is responsible for:

- Coordinating audit activities with the ACC supplier to ensure maintenance of certification. Audit planning, auditing, writing an audit report and determining certification status consistent with this document, ISO 19011 and ISO/IEC 17021.
- Monitoring the supplier throughout the certification period in accordance with surveillance requirements and progress reporting that the CAB generates a requirement for.

Certification Period

The certification period is for a maximum period of 4[1] years from the date of the certification decision (refer section 'certification decision'). Certification for a period of less than 4 years should be determined by the CAB based on the level of non-conformity and risk as identified through the audit process.

[1] ACC acknowledges that this is a departure from ISO/IEC 17021.

Surveillance Audit

A minimum of one surveillance audit at the midpoint of certification is required to maintain certification. This audit can be scheduled two months either side of the due date.

Remote / Virtual Audit Approach

Any audit, except a Provisional Audit, can be conducted using a remote / virtual audit approach providing that it can be conducted to the same level of information gathering, evidence and access to records and personnel. This includes access to a sample of clinical records which may depend on the type of records management system being used.

For multi-site services a hybrid approach is preferred where at least the main or key locations are visited with a mix of others that can be completed remotely.

Monitoring

Findings shall be provided with the audit report and have an allocated risk to indicate the priority and timeframe for action in accordance with the Risk Management Matrix (refer page 13). Monitoring activities of the organisation shall occur within the period of certification to ensure any non-conformity has been adequately addressed as identified at the time of the certification or surveillance audit and to support that systems and processes are being maintained throughout the period of certification. The CAB shall have procedures in place to ensure that corrective action has been taken in accordance with the Risk Management Matrix, where indicated in the report, whether by an onsite verification visit, or written progress report. If the supplier does not rectify the non-conformity in the timeframe as agreed in the Risk Management Matrix, the certification may be suspended by the CAB. In the event that certification is suspended for any reason the CAB will notify ACC.

Types of Audits and Certification Results

Type of Audit	Description	Audit Activity Required	Results In
Initial Certification audit	Organisations providing Allied Health services seeking certification.	A full two-stage[2] audit is undertaken against: • either the NZS 8171:2005 or for ACC Requirements for Physiotherapy Services, or other supplier contract with ACC with a requirement to achieve certification.	4 year certificate issued by the CAB. A mid-point on-site surveillance is required.
Re- Certification audit	Organisations providing Allied Health services seeking re-certification.	A full audit is undertaken against: • either the NZS 8171:2005 or for ACC Requirements for Physiotherapy Services, or other supplier contract with ACC with a requirement to achieve certification.	4 year certificate issued by the CAB. Identify if qualifies for an off-site mid-point surveillance audit.
Provisional audit	Newly established services prior to the commencement of service delivery.	Does not represent a full audit as services are not being delivered. Includes those requirements of certification that can be met through: • Document review On-site visit	6 month provisional certificate as issued by the CAB.

[2] Refer ISO/IEC17021

Verification audit – post provisional	Newly established services following provisional audit.	Post provisional audit: All criteria within NZS8171:2005 that was not audited at the provisional audit.	4 year certificate issued by the CAB from date of the provisional certificate. A mid-point on-site surveillance is required.
Verification audit for a change to an existing certified service	Existing services seeking to expand their service; or who have commenced operating from a new site.	Changes to an existing service: On-site audit of the on-site surveillance audit scope plus all environmental criteria.	Addition or alteration to an existing certificate.
Surveillance audit	Occurs at the midpoint within the period of certification.[3]	Audit includes: • Quality and risk management systems including complaints and client satisfaction. • Advertising and marketing including the use of marks and/or other reference to certification. • Service delivery including sampling of clinical records. • Health and safety and equipment. • Interview discussions with principal or lead therapist • Non-conformities identified at the certification audit and any changes that have occurred since the certification audit.	Contributes to monitoring that occurs within the period of certification. Issue any new conditions to the certification.

Additional sites to be added during the audit period

When adding an additional site (i.e. satellite site) to an existing service that holds certification, the supplier shall apply to the CAB to undergo a verification audit within 6 months of the establishment of the new service. Certification shall be awarded to match the expiry of the current certificate held by the supplier.

The supplier shall notify the CAB prior to the establishment of the new site and confirms that governance, systems, processes, policies and procedures are substantially the same as the current service. If this is not the case, a provisional audit will be required in addition to the verification audit.

Until certification of the additional site is achieved (either through the addition of the service to the existing certificate or provisional audit resulting in provisional certification) the business may not advertise the services as such.

Certified business transferring services to a new site/premises

An onsite certification or surveillance audit to check that the policies and procedures have adapted to the new site will be required at the time of the next scheduled audit cycle.

[3] Note this is not consistent with ISO/IEC17021 requirements.

Certified business purchases a certified business

An onsite certification or surveillance audit to check the policies and procedures will be required at the time of the next scheduled audit cycle.

Sale of a certified business

The current supplier owns the certification. A new business owner may purchase a certified business and may maintain the certification for a maximum of 6 months (unless the certification period expires prior to this date). The business shall have a CAB complete a certification audit within 6 months of taking possession to continue the certification.

Independent Pool and Gym Facilities to be Audited

Independent Pool and Gym Facilities do not need to undergo a site visit for certification. Suppliers shall submit the policies and procedures supporting them for evaluation with supporting evidence at the time of survey of the main business site. Should these services be developed after a full audit and certification the business shall send in documentation relevant to the service to the CAB for consideration.

Adding a new service to an existing certification

Should a certified business be adding a new service to an existing certification then the following applies:

1. If the new service is being added and it does not align with the surveillance audit due date or the certification expiry then a verification audit is required.

2. If this is at the existing certification's surveillance audit then this becomes a surveillance / verification audit and includes the the new service's polices / procedures and implementation.

3. If this is at the certification audit expiry then the next certification audit includes the new service.

Audit Process requirements

The audit process needs to align with the scope of the audit for either the NZS 8171:2005 or for ACC Requirements for Physiotherapy, Hand Therapy and Podiatry Services.

Auditor days on site

The duration of the certification audit is dependent upon the size, nature and complexity of the organisation to be audited. There is also flexibility if, for example, there is remote access to clinical records prior to the on-site visit. The below guidelines are based on the audit being undertaken by a single Lead auditor for a single site (and this is subject to size). The CAB shall determine the time required on site to satisfactorily complete the audit.

Sampling – clinical file reviews

The sampling methodology for clinical file reviews will represent a minimum sample as follows:

- Certification audits = the square root of the number of ACC clients seen within a three month period rounded to the upper whole number.
- Surveillance audits = 0.6 times the square root of the number of ACC clients seen within a three month period rounded to the upper whole number.
    - This assumes that the provider has not qualified for an off-site surveillance.

Refer to appendix one for a quick reference guide for determining square root calculations.

Sampling shall be representative of current Allied Health Professionals working within the organisation being audited and shall include clients who have exited the service.

Sample sizes shall be widened where nonconformity is identified.

For the full scope of certification to NZS 8171 the sample may include non-ACC clients.

Sampling – multiple sites

Decide on the minimum sample for multi-site audits using this square root rule:

- certification audit site sample = the main site plus the square root of the number of satellite sites.
- surveillance audit site sample = the main site and 0.6 times the square root of the number of satellite sites.

It is expected that sites are rotated within the four-year period (certification audit, surveillance audit and next certification audit) so that all sites have an on-site visit.

Auditor and Audit team requirements

The audit team shall follow the principles of auditing as outlined in ISO 19011 and ISO/IEC 17021.

The audit team shall have the competence appropriate to the particular service. The number of auditors shall be sufficient to complete the audit against all criteria requirements in the standards. The audit team shall include a:

(a) Team Leader (or Lead auditor) with the following clinical / technical expertise: A qualification in the allied health area to be audited, hold registration with their professional registration board and a current annual practising certificate. e.g. when auditing a physiotherapy business, the technical expert will be registered with the Physiotherapy Board of New Zealand, and hold a current annual practising certificate.

(b) Alternatively, the audit could include a team leader with a Clinical/Technical expert who meets the requirements in (a) above.

Auditors are required to meet the competencies of ISO 19011, as listed below:

(a) have completed education sufficient to acquire the knowledge and skills of quality management systems.

(b) have had work experience (minimum of 2 years) to develop the knowledge and skills in the quality management field.

(c) have had work experience (minimum of 5 years) in the allied health profession if acting as the technical expert in the audit team or 2 years with a relevant post graduate qualification.

(d) have completed auditor training that contributes to the development of the knowledge and skills in quality management systems.

(e) have had audit experience in the above activities.

Where an audit is being performed by a team of two or more it is not necessary for each team member to meet all of the competence criteria for the area of activity involved. However, the team as a whole must meet all competence criteria above.

The requirements for audit team competence apply to all types of audits.

CAB's shall have procedures in place for determining the ongoing competence of auditors/clinical technical experts. This includes:

- Orientation / induction with review following the induction period.
- A process to review the performance of each auditor/clinical technical expert. After two years in the role, and with meeting expected performance, this is a two-yearly review.
- Periodic observations of each auditor's performance on-site. The frequency of such observations shall be based on the need determined from all monitoring information available.

Reporting Requirements

Evidence

CABs may use their own audit tools and reporting templates to audit against NZS 8171:2005 or ACC requirements.

In the process of auditing service delivery, the CAB shall include consideration of the use of outcome tools (consistent with the ACC service schedule requirements) to support clinical decision making.

Audit reports

Audit reports shall be written up by the team leader/audit team for all audits, including off-site surveillance audits. Evidence and supporting documents are required for each standard to substantiate the report. The report shall reflect the findings at the time of the audit. Reports are to be typed and written in the present tense.

All reports shall include as a minimum:

- The level of compliance against each criterion for each outcome within the standard as per the auditing requirements for the differing types of audit.
- An executive summary for each standard, identifying if the standard has been achieved and which criteria where achievement against it was not achieved (partial attained or unattained).
- Where criteria have not been achieved, corrective actions that are specific, measurable, relevant, and contain a time frame are listed.
- Areas covered by the audit (e.g. areas of the services provided and locations / satellite services / processes).
- Observations made, both positive (e.g. noteworthy features) and negative (e.g. not fully achieved).
- Opportunities for improvement where criteria have been fully attained and the auditors have noted further actions that could be taken to move towards continuous improvement.

Criteria within NZS8171 that can be marked as not applicable

The CAB is responsible for determining criteria that is not applicable to the audit. There shall be a clear rationale kept within audit records for any criteria marked as not applicable. For the purpose of Physiotherapy, Hand Therapy and Podiatry Service audits, the following criteria may be rated as not applicable without reference to a rationale:

- 5.3 - Medicines, therapeutic goods and medical devices management (5 criteria)
- 5.6 - Management of waste and hazardous substances (6 criteria)
- 5.7 - Radiation management

Examples of the level of explanation required as to a rationale are provided below:
5.1.3 – Not applicable – private practice.
5.5.2 – Not applicable – no sterilisation is conducted by this practice.
5.5.3 – Not applicable – no sterilisation occurs through out-sourcing.
5.5.9 – Not applicable – physiotherapists do not diagnose medical illness and therefore could not reliably report a suspected notifiable disease.
6.4.2 – Not applicable – a building WOF is not required

Audit framework

The audit process requires the CAB to determine the level of attainment the business achieves for each relevant criterion. The levels of attainment are based upon a continuous quality improvement model and are incremental.

Attainment Level		Interpretation
CI	Continuous Improvement	Having fully attained the criterion the service can in addition clearly demonstrate a review process including analysis and reporting of findings, evidence of action taken based on those findings, and improvements to service provision and consumers safety or satisfaction as a result of the review process.
FA	Fully Attained	The service can clearly demonstrate implementation (practice evidence, training, records, visual evidence etc.) of the process, systems or structures in order to meet the required outcome of the criterion.
PA	Partial Attainment	1. There is evidence of appropriate process (policy/procedure/guideline etc.), system or structure implementation without the required supporting documentation. Or 2. A documented process (policy/procedure/guideline etc.), system or structure is evident but the organisation or service is unable to demonstrate implementation where this is required.
UA	Unattained	The organisation or service is unable to demonstrate appropriate processes, systems or structures to meet the required outcome of the criterion.
NA	Not Applicable	The criteria do not apply to the particular group of allied health professional that is being audited.

Evaluation methods

One or more evaluation methods or process may be chosen to audit criteria and/or provide evidence of compliance. The CAB shall identify the methods most appropriate to evaluate the business with regard to the business setting and consumer group. The following list of options has been developed to assist with recording the evaluation method chosen.

Abbreviation	Method
D	Documentation/record review

I	Interview SI = Service provider interview STI = Staff interview MI = Manager interview CI = Consumers interview MaI = Māori focused interview
V	Visual inspection
Q	Questionnaire CQ = Consumers questionnaire SQ = Service provider questionnaire STQ = Staff questionnaire
Ma	Māori focused audit
L	Linked services, family, and referral services interview

Risk management

This process requires the CAB to identify the degree of risk to consumer's safety associated with the level of attainment achieved by the business for each criterion.

The "risk" shall be audited in relation to the possible **impact on the consumer**, based on the consequence and likelihood of harm occurring as a result of the criterion not being fully implemented.

The risk management matrix shall be used when the audit result for any criterion is partially attained (PA) or unattained (UA).

To use the risk management matrix you shall:

(a) Consider the consequence on consumer safety of the criterion being only Partially Attained (PA) or Unattained (UA) - ranging from **extreme/actual harm to no significant risk of harm** occurring.

(b) Consider the likelihood of this adverse event occurring as a result of the criterion being only Partially Attained (PA) or Unattained (UA) - ranging from the occurrence being **almost certain to rare.**

(c) Use the Risk Assessment Matrix in order to identify the level of risk – ranging from **Critical to Negligible.**

(d) Prioritise risks in relation to severity (e.g. **Critical to Negligible**).

(e) Take appropriate action to eliminate or minimise risk within the time frame indicated by the **Action required** column.

Risk management matrix

Consequence	Likelihood						
	Level of Risk	**almost certain**	**is likely**	**is moderate**	**is unlikely**	**is rare**	**Action Required**
	would put consumers at an **extreme risk of harm or actual harm is occurring**	**Critical**	**Critical**	**High**	**Moderate**	**Low**	**Critical** *This would require immediate corrective action in order to rectify the identified issue including documentation and sign off by the auditor **within 24 hours** to ensure consumer safety*
	would put consumers at **significant risk of harm**.	**Critical**	**High**	**Moderate**	**Low**	**Negligible**	**High** *This would require a negotiated plan in order to rectify issue **within 4 weeks** or as agreed between the service and auditor*
	would put consumers at **moderate risk of harm**	**High**	**Moderate**	**Moderate**	**Low**	**Negligible**	**Moderate** *This would require a negotiated plan in order to rectify issue **within 3 - 6 months**.*
	would put consumers at **minimal risk of harm**	**Moderate**	**Low**	**Low**	**Low**	**Negligible**	**Low** *This would require a negotiated plan in order to rectify issue within a specified and agreed time frame and that most will be expected to have completed the action or made significant progress **within 6 months.***
	Risk of harm is insignificant even if these criteria are not met.	**Low**	**Low**	**Negligible**	**Negligible**	**Negligible**	**Negligible** *This would require no additional action or planning*

Certification decision

The CAB shall adopt procedures that provide an objective and systematic process for peer reviewing audit reports and review of evidence gathered during the audit.

All audit reports shall be peer reviewed by at least one Team Leader / Lead Auditor who also holds a current clinical qualification (with an annual practicing certificate) in the allied health specialty being audited or by an equivalent audit team as defined in the 'audit team requirements' section of this document.

The peer reviewer recommends a decision on certification. Where the peer reviewer considers insufficient evidence has been gathered, the peer reviewer shall request further information from the team leader responsible for the audit.

The CAB shall use the "Audit Framework, Risk Management and Risk Management Matrix" as outlined above when evaluating whether a business has achieved certification. Certification shall not be given to any business that achieves a level of risk of 'Critical' on the Risk Management Matrix. Any 'high' risk shall be reduced to moderate or low risk before certification can be awarded.

ACC may request a copy of the audit reports and the supporting evidence (including completed questionnaires / checklists / observation logs / auditor notes) from the CAB along with the evidence on how the decision was made. ACC may request the CAB to provide the audit report in an electronic format.

Certification decisions are to be made within 6 weeks of the completion of the audit.

The audited business is to be informed of the audit outcome and is to receive the final report and a letter confirming the outcome of the audit within 30 working days of completion of the audit.

In the instance where certification is not attained, or is cancelled, ACC will be notified within 5 working days of the change in status.

Certification document

The CAB shall notify and provide the practice with a copy of the audit report and a certification document which includes the list of sites that achieved certification, the effective date of certification and the term for which the certification is valid. CABs are to maintain an up to date record of all sites which have been approved for that business as meeting the certification requirements.

Certification documents should be dated from the date of the formal decision by the peer reviewer or assessment committee, or from the date of expiry.

Appendix One – square root calculations

A calculator easily determines the square root calculation required. This **guide** should be used to ensure you have correctly determined the square root calculation.

Number of clients seen within a 3 month period. (Note this is the number of clients, not the number of visits)	Square Root Calculation (Certification Audit)	0.6 times the Square Root Calculation Surveillance Audit)
10	3	2
20	5	3
30	6	4
40	7	4
50	8	5
60	8	5
70	9	6
80	9	6
90	10	6
100	10	6
110	11	7
120	11	7
130	12	7
140	12	8
150	13	8
160	13	8
170	13	8
180	14	9
190	14	9
200	15	9
210	15	9
220	15	9
230	16	10
240	16	10
250	16	10
260	17	10
270	17	10
280	17	11
290	18	11
300	18	11
310	18	11
320	18	11
330	19	11