



ACC Requirements for Conformity Assessment Bodies to audit against

**NZS 8171:2005 Allied Health
Services Sector Standard**

Contents

ACC Requirements for Conformity Assessment Bodies to audit against	1
ACC Contact Information.....	4
Purpose of this document	5
Criteria	5
Alternative 3 rd Party Accreditation	5
ACC appointment of approved CAB's.....	5
Organisations changing CAB.....	6
Additional References	6
Definitions	7
Allied Health Professional.....	7
Is as defined in NZS 8171:2005.....	7
Audit Process.....	8
Certification Period.....	8
Monitoring.....	8
Process requirements.....	9
Auditor days on site.....	9
Sampling – clinical file reviews.....	9
Sampling – multiple sites.....	10
Auditor and Audit team requirements.....	10
Types of Audits	11
Additional sites to be added during the audit period	13
Sale of a certified business	13
Certified business transferring services to a new site/premises.....	14
District Health Board audits	14
Criteria within NZS8171 that can be marked as not applicable	14
Cross referencing of criteria within NZS8171.....	15
Auditing Service delivery	16

Off site services	16
Reporting Requirements	17
Evidence	17
Audit reports	17
Audit framework	17
Evaluation methods.....	18
Risk management.....	19
Risk management matrix.....	21
Certification decision.....	22
Certification document.....	23
Transition process	23
Appendix One – square root calculations	25

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Purpose of this document

This document outlines the requirements ACC has for Conformity Assessment Bodies (CABs) who are undertaking audits and issuing certification against NZS 8171: Allied Health Services Sector Standard that meet the contractual obligations of vendors who hold a Physiotherapy Services agreement or other agreement with ACC that has a requirement to comply with NZS 8171.

The requirements of this guideline supplement ISO/IEC 17021 and ISO 19011. All elements of ISO/IEC 17021 apply with the exception of information as outlined in this document.

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.

Criteria

CABs who wish to audit against the NZS 8171:2005 (or subsequent revised versions) are required to meet the following criteria:

1. Meet the requirements of this document including compliance with any IAF referenced documents; and
2. Sign a letter of agreement with ACC to audit against NZS8171:2005 (or subsequent revised versions) and
3. Be accredited by JAS-ANZ to audit against NZS8171:2005 and as such comply with ISO/IEC 17021 or
4. Be accredited by ISQua against the ISQua International Organisation Standards for Healthcare, external evaluation of organisations.

Note if ISQua accredited, the CAB must demonstrate that as a minimum, annual progress reporting to ISQua occurs and a two yearly on-site surveillance audit of the CAB conducted by ISQua occurs.

Alternative 3rd Party Accreditation

Note that if a CAB wishes to hold alternative third party accreditation, this must be agreed by ACC in writing. Note unless equivalency to JAS-ANZ and ISQua can be established, approval will not be provided.

ACC appointment of approved CAB's

ACC will appoint CAB's who can demonstrate the requirements of this document are met. The basis of the appointment is that ACC will provide ACC vendors with a list of CAB's who are approved by them to audit services against the Allied Health Sector Standard which will

then allow ACC vendors to select any CAB from that list and arrange audits directly with them.

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

The letter of agreement that appoints CAB's shall also outline any additional terms and conditions a CAB is required to met.

Organisations changing CAB

Note that if an organisation wishes to change CAB, this will require the CAB to conduct such audits as are necessary for the CAB to assure itself that the organization satisfies the standards of performance of the ACC. CABs may refer particular cases to the ACC for guidance.

Additional References

The following references apply to requirements within this document:

- NZS 8171:2005 Allied Health Services Sector Standard
- ISO 19011:2003 Guidelines for Quality and /or Environmental Management Systems Auditing
- ISO/IEC 17000:2004 Conformity assessment – vocabulary and general principles
- ISO/IEC 17021:2006 Conformity assessment – Requirements for bodies providing audit and certification of management systems.
- International Accreditation Forum (IAF) Inc Mandatory Document for duration of QMS and EMS Audits. IAF MD5:2009.
- International Accreditation Forum (IAF) Inc Mandatory Document for the Certification of Multiple Sites Based on Sampling. IAF MD1:2007.
- International Accreditation Forum (IAF) Inc Mandatory Document for the Transfer of Accredited Certification of Management Systems. IAF MD2:2007.
- ISQua - International Organisation Standards for Healthcare - External Evaluation of Organisations, 3rd Edition, January 2008
- Other Acts, Regulations, codes and guidelines relevant to the auditors practice.

Definitions

Where terms and definitions are not otherwise specified in this document, terms and definitions are the same as those found within ISO/IEC 17000, ISO/IEC 17021 and ISO 19011.

Allied Health Professional

Is as defined in NZS 8171:2005.

Site

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

Main 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 Service

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

Off Site Service

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 such as a sports stadium, school, rest home or private hospital, operating for up to 12 hours per week¹. Note that off-site services may be classified as a satellite service where these services are provided for more than 12 hours per week and therefore represent a standalone clinic (site).

¹ This is an absolute value that occurs on a per week basis.

Audit Process

CABs that meet the criteria may audit ACC vendors seeking certification who supply allied health professional services. Certification by an ACC approved CAB allows a vendor to meet ACC's certification contract criteria, for example for the Physiotherapy Services agreement. Vendors may become certified against standards by non-ACC approved CABs but those businesses will not meet ACC's certification criteria for ACC contracts.

The ACC vendor is responsible for meeting the client requirements as outlined in ISO/IEC 17021.

The CAB is responsible for:

- Coordinating audit activities with the ACC vendor to ensure maintenance of certification. Audit planning, audits, writing an audit report and determining certification status consistent with this document, ISO 19011 and ISO/IEC 17021.
- Monitoring the vendor 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 4² years from the date of the certification decision made by either the peer reviewer or the assessment committee (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.

A minimum of one on-site surveillance³ audit at the midpoint of certification is required to maintain certification. Findings shall be actioned in accordance with Risk Management Matrix. This audit can be scheduled two months either side of the due date.

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Monitoring

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** systems and processes are being maintained throughout the period of certification (e.g. annual reporting to the CAB or internal

² ACC acknowledges that this is a departure from ISO/IEC 17021.

³ *ibid*

monitoring activities⁴ undertaken by the organisation recognised by the CAB as being sufficient to meet this requirement that are then reviewed as part of the surveillance or recertification activities).

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 on site verification visit, or written progress report.

If the vendor 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 a nonconformity is not rectified within the timeframes agreed with the CAB, the CAB will notify ACC.

Process requirements

Auditor days on site

The duration of the certification audit is dependent upon the size, nature and complexity of the organisation to be audited.

On-site audit time is expected to be a minimum of 5 hours duration if undertaken by a single auditor.

The CAB shall determine the time required on site to satisfactorily complete the audit. The IAF MD 5 for the Duration of QMS and EMS audits shall be used as guide. CAB's are directed to carefully read 6.1 of this document as the duration for a recertification audit may be less than an initial certification 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.

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 existed the service.

⁴ This could include use of on-line reporting tools through an organisation separate to the CAB that supports the organisation to maintain and develop their quality systems.

Sample sizes shall be widened where nonconformity is identified.

Sampling – multiple sites

The IAF MD 1 for the Certification of Multiple Sites Based on Sampling shall be used as a guide to determine the sampling.

For a District Health Board where there are multiple sites within the same hospital (e.g. departments within a hospital) and it has been determined that all sites are substantially of the same kind and are operated with similar methods and procedures, the site that conducts the greater number of processes than the others will likely be subject to audit however this is not an absolute and additional sites may be visited.

The CAB will determine whether any other satellite sites (e.g. regional hospitals) will require to be audited as per IAF MD1 for the Certification of Multiple Sites Based on Sampling. It is expected that other sites will be audited periodically.

For private practices that operate multiple sites the IAF MD1 for the Certification of Multiple Sites Based on sampling formula shall be used.

Auditor and Audit team requirements

The audit team shall follow the principles of auditing as outlined in ISO 19011:2003 and as required by 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 Leader⁵. The team leader shall meet the requirements of ISO 19011:2003 clause 7.4.2
- (b) Clinical/Technical expert with 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.

Auditors are required to meet the competencies of ISO 19011:2003, 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

⁵ May also be referred to as the Lead Auditor

- (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 meeting all of the criteria above the team leader and clinical/technical expert may be the same person and fulfill both roles and responsibilities of the audit.

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 a process to review the performance of each auditor/clinical technical expert at least annually and this includes 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. CAB's shall have procedures in place for determining the ongoing competence of auditors/clinical technical experts.

Types of Audits

Type of Audit	Description	Audit activity required	Results in
Initial Certification audit	Organisations providing Allied Health services seeking certification against NZS 8171:2005	A full two-stage ⁶ audit is undertaken against NZS 8171:2005	4 year certificate as issued by the CAB
Re- Certification audit	Organisations providing Allied Health services seeking re-certification against	A full audit is undertaken against NZS 8171:2005	4 year certificate as issued by the CAB

⁶ Refer ISO/IEC17021

Type of Audit	Description	Audit activity required	Results in
	NZS 8171:2005		
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 NZS8171:2005 that can be met through: <ul style="list-style-type: none"> • Document review • On-site inspection or photographic evidence as deemed acceptable to the CAB 	6 month provisional certificate as issued by the CAB
Verification audit	Newly established services who hold a provisional audit seeking certification; OR Existing services seeking to expand their service; OR Existing services with certification who have commenced operating from a new site.	Includes an audit of service delivery 6 months post a provisional audit or change to an existing service. Includes: <ul style="list-style-type: none"> • All criteria within NZS8171:2005 that was not audited at the provisional audit (where a provisional audit has occurred) • On-site audit • Audit reporting and issuance of a certificate • Changes from the existing certificate (where a verification audit relates to a change in service) 	4 year certificate as issued by the CAB; OR Addition or alteration to an existing certificate
Surveillance audit	Occurs at the midpoint within the period of certification ⁷	Includes an on-site ⁸ audit of: <ul style="list-style-type: none"> • Non-conformities 	Contributes to monitoring that occurs

⁷ Note this is not consistent with ISO/IEC17021 requirements.

Type of Audit	Description	Audit activity required	Results in
		identified at the certification audit <ul style="list-style-type: none"> • Any changes that have occurred since the certification audit • 2.4: Quality and risk management systems including client satisfaction • 2.5 Advertising and marketing including the use of marks and/or other reference to certification • 4.0 Service delivery including sampling of clinical records 	within the period of 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 vendor shall apply to the CAB to undergo a verification audit 6 months post the establishment of the new service. Certification shall be awarded to match the expiry of the current certificate held by the vendor.

The vendor shall notify the CAB prior to the establishment of the new site and will be required to confirm in writing 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.

Sale of a certified business

The current vendor 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

⁸ Note off-site surveillance auditing is not acceptable under ISO/IEC17021 and an on-site audit for surveillance must therefore be conducted.

certification period expires prior to this date). The business shall have a CAB complete a certification audit within 6 months of taking possession to issue a new certificate.

Certified business transferring services to a new site/premises

An onsite verification audit to check policies and procedures have adapted to the new site by the CAB is required within the first 6 months of the business occupying the new premises.

District Health Board audits

Where a District Health Board holds certification against NZS8134:2008, the following parts of NZS8171:2005 need not be additionally audited with the exception of any corresponding partially attained criteria from the NZS8134 audit (as noted on the MOH certificate):

- NZS8171:2005 Part 1 – Consumer Focused Services
- NZS8171:2005 Part 3 – Pre-entry to services
- NZS8171:2005 Part 6 – Safe and appropriate environment

The following parts of NZS: 8171 will need to be audited irrespective of certification held against NZS: 8134:

- NZS8171:2005 Part 2 – Organisation Management criteria 2.4.1, 2.4.2, 2.4.3, 2.4.7, 2.4.8⁹
- NZS8171:2005 Part 4 – Service delivery
- NZS8171:2005 Part 5 – Managing Service Delivery

Note that a District Health Board may request NZS8171:2005 to be audited concurrently with an audit against NZS8134:2008.

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 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

⁹ Note other criteria within Part 2 can be marked as not applicable.

6.4.2 – Not applicable – a building WOF is not required

Cross referencing of criteria within NZS8171The CAB may use cross referencing within the audit process.

Cross referencing may only be used where the auditor has determined one criterion with documented evidence supporting a full attainment of that criterion is equivalent to evidence required to support another criterion.

Examples of criteria that may be cross referenced include:

Criteria audited with evidence documented:	Evidence may also be cross referenced to:	Rationale
1.1.2	1.1.5	Where 1.1.2 has included reference to right 5 and people with disabilities evidence is sufficient to include 1.1.5
1.2.3	1.3.3	Where process for identifying and eliminating barriers for Maori has been evidenced and the same process is used for other cultures then no further evidence needs to be provided for 1.3.3
13.4	1.2.4	Where specific reference has been made to Maori consumers rights to practice within 1.3.4 this can be cross referenced to 1.2.4
2.2.3	6.2.3	On the basis that Health and Safety legislation is complied with and includes identification of service providers and others, 6.2.3 can be cross referenced to 2.2.3
2.1.5	2.4.4	Where evidence is supplied that risks are identified, assessed and minimized this can be cross referenced to 2.4.4.
3.2.3	3.2.1	Where the process for declining entry to services includes both notification to the service user and provider evidence can be grouped under 3.2.3
4.3.1	4.5.2	Where 4.3.1 evidences service delivery plans are up to date this supports achievement of 4.5.2

4.6.1	4.6.2; 4.4.5	Where 4.6.1 is fully achieved, this supports achievement of 4.6.2 and 4.4.5.
4.6.3	5.2.7	Where recall processes are included within 4.6.3 this supports achievement of 5.2.7
5.1.1	5.1.4; 5.2.2	In meeting the requirements of 5.1.1, this supports achievement of 5.14 and 5.2.2
5.5.4	5.5.7	Where 5.5.4 includes reference to staff being informed of risk of infections and vaccination programmes, 5.5.7 can be cross referenced.
6.3.1	6.3.4	In meeting the requirements of 6.3.1, 6.3.4 is required and can therefore be cross referenced.
6.3.7	6.3.8	Where 6.3.7 references provision of emergency lighting as part of the evidence, 6.3.8 can be cross referenced.

Auditing Service delivery

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.

Information on the use of outcome tools is available on the ACC website.

Off site services

Off site services do not need to undergo a site visit for certification. Vendors shall submit the policies and procedures supporting them for evaluation with supporting evidence at the time of survey of the main business site.

Should an off site service be developed after a full audit and certification the business shall send in documentation (policies and procedures relevant to the delivery of off-site services) supporting and requesting the off site service be added to the certification documentation by the CAB.

A decision shall be made by the CAB assessment committee or jointly by the Team Leader/Technical expert and peer reviewer before the off site service can be added to the businesses certification and advertised as such.

Should an 'off site service' develop into a 'site' (see definitions) then an onsite verification audit shall be required of the site within a 6 month period of providing such a service.

Reporting Requirements

Evidence

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

As part of the collection of audit evidence, CABs are required to consider the use of outcome tools consistent with the service delivery aspects of NZS8171.

Audit reports

Audit reports shall be written up by the team leader/audit team for all audits, including verification visits. Evidence and supporting documents are required for each standard to substantiate the report.

All reports shall include as a minimum the reporting requirements outlined in ISO17021 and in addition to this:

- 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 / departments / processes including those for off site services of the auditor) including significant audit trail followed
- Observations made, both positive (e.g. noteworthy features) and negative (e.g. opportunities for improvement)
- 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; and
- Report (details) of any nonconformities identified supported by objective evidence.

The report shall reflect the findings at the time of the audit. Reports are to be typed and written in the present tense.

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.

The report shall record the lowest attainment level finding of for criterion and outcomes being reported upon.

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 for each criterion.

D	Documentation/record review
I	Interview SI = Service provider interview STI = Staff interview MI = Manager interview CI = consumers interview MaI = Maori focused interview
V	Visual inspection
Q	Questionnaire CQ = consumers questionnaire SQ = Service provider questionnaire STQ = Staff questionnaire
Ma	Maori focused audit
L	Linked services, family, and referral services interview

Risk management

This process requires the CAB to identify the degree of risk to consumers' 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) Plot your findings on 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.

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Risk management matrix

		Likelihood					
		The likelihood of this occurring is almost certain	The likelihood of this occurring is likely	The likelihood of this occurring is moderate	The likelihood of this occurring is unlikely	The likelihood of this occurring is rare	Action Required
Consequence	The consequence of these criteria not being met would put consumers at an extreme risk of harm or actual harm is occurring	Critical	Critical	High	Moderate	Low	Critical <i>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</i>
	The consequence of these criteria not being met would put consumers at significant risk of harm.	Critical	High	Moderate	Low	Negligible	High <i>This would require a negotiated plan in order to rectify issue within 6 weeks or as agreed between the service and auditor</i>
	The consequence of these criteria not being met would put consumers at moderate risk of harm	High	Moderate	Moderate	Low	Negligible	Moderate <i>This would require a negotiated plan in order to rectify issue within 6 months.</i>

The consequence of these criteria not being met would put consumers at minimal risk of harm	Moderate	Low	Low	Low	Negligible	Low <i>This would require a negotiated plan in order to rectify issue within a specified and agreed time frame e.g. within one year</i>
Risk of harm is insignificant even if these criteria are not met.	Low	Low	Negligible	Negligible	Negligible	Negligible <i>This would require no additional action or planning</i>

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 certification audit reports shall be peer reviewed by at least one Team Leader 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 need not be independent of the CAB.

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. In the event of non-agreement the report will be reviewed by an assessment committee.

An assessment committee of at least three members consisting of:

- an auditor who also audits against these standards, independent of this practice audit and any prior peer review of this practice audit;
- a clinical expert; and
- a consumer/lay person who has been a past service user of allied health services or another auditor with experience of physiotherapy services audit

will be formed by the CAB.

Note the committee can comprise two members if the auditor is also the clinical expert.

The role of the assessment committee is to assess certification audit reports submitted for review. The assessment committee shall assess a minimum of 10 % of all audits undertaken

on an annual basis by the CAB including a sample of 5 % of audit reports that have been peer reviewed prior to the award of the certificate; and additionally any audit reports where the peer reviewer is unable to make a determination for the period of certification.

The team leader who participated in the audit can attend if required as can the peer reviewer (where applicable) to discuss any issues that might arise but can not participate in the decision making.

Alternatively, the CAB can use an assessment committee for all its certification decisions. This does not negate the need for peer review.

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.

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 specified by ACC consistent with the agreement between ACC and approved CAB’s.

Certification decisions must 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 15 working days of completion of the audit or 6 weeks where the decision has been referred to an assessment committee. Note that where a decision has been referred to an assessment committee, the organisation that was audited should be notified of this within 7 working days of completion of the audit.

Certification document

The CAB shall notify and provide the practice with a copy of the audit report and a certification document which includes the information as outlined in ISO/IEC 17021 and shall also include the list of sites and off site services 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, including off site services, which have been approved for that business as meeting the certification requirements.

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

Transition process

CAB’s are able to award a four year period of certification from enactment of this document (16th November 2009).

CAB's are able to extend the current period of certification for existing services on the following basis:

1. The risk is sufficiently low to support a four year period of certification (i.e. where a high level of non-conformity has been identified from the previous audit, the period of certification could not be extended).
2. Where a surveillance audit has occurred between 15 April 2009 – 15 November 2009 the certificate can be extended by six months.
3. Where a certification audit has occurred between 15 April 2009 – 15 November 2009 the certificate can be extended by twelve months with a 24 month surveillance audit occurring.
4. At any surveillance audit post 16 November 2009, a new certificate can be issued that extends the period of certification by six months .
5. The CAB must ensure that the timeframe between audits (certification or surveillance) is not more than two years.

Note that extension to the current period of certification is at the discretion of the CAB as the issuer of the certificate.

The CAB may use an application process to assist in assessing whether it is appropriate to extend the period of certification.

The CAB may apply a cost for the re-issue of a certificate and time taken to assess the appropriateness to extend the period of certification

CAB's have three months from the enactment of this document to ensure they are fully compliant with new requirements which therefore allows for any auditor training or notifications of change in processes to their clients.

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	0.6 times the Square Root Calculation
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