Requirements for conformity assessment bodies that conduct certification audits of providers holding contracts with the Ministry of Health Disability Support Services, district health boards and/or the Accident Compensation Corporation to provide home and community support services.

Auditing Requirements

Home and community support sector Standard

NZS 8158:2012

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Preface

Home and community support services (HCSS) providers that hold a contract with the Ministry of Health, a district health board and/or the Accident Compensation Corporation must be certified against Home and community support sector Standard NZS 8158:2012 (SNZ 2012). This document, *Auditing Requirements: Home and community support sector Standard NZS 8158*, guides this certification scheme.¹

In 2015 an Oversight Committee was formed to support the ongoing development of this certification scheme. It is made up of funder representatives and a representative from HealthCERT.² One of the key changes the Oversight Committee made in 2016 was to make it easier to process HCSS audit reports through an electronic database – the Provider Regulation and Monitoring System (PRMS). Using PRMS will eventually make it possible to identify national trends in audit outcomes across HCSS providers with a view to developing quality improvement initiatives with the sector.

This is the first substantive review of the 2012 document *Auditing Requirements: Home and community support sector Standard NZS 8158*. Developing this revised document has involved significant feedback from stakeholder groups. In their feedback, stakeholders asked the Oversight Committee to consider the following areas of change:

- a risk-based approach when deciding on periods of certification
- unannounced midpoint/surveillance audits
- an integrated audit programme (as with the aged residential care sector)
- a standardised tool for 'clip-on' events (that include additional contractual elements)
- a sampling methodology that covers:
 - the number of sites when auditing large, multi-site providers
 - auditors' time on site
 - minimum file review and interviews
 - tracer methodology
- the role and function of the Independent Assessment Committee
- audit requirements when a provider sells a certified organisation.

The Oversight Committee considers that it needs to consult further with stakeholders over these areas of change.

¹ A certification scheme defines the process and criteria for deciding whether a service meets specific criteria

HealthCERT regulates overnight health services in line with the Health and Disability Services (Safety) Act 2001.

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1 Introduction

This document sets out what conformity assessment bodies (CABs) that audit and certify providers of home and community support services (HCSS) must do to audit and certify these providers against the Home and community support sector Standard (NZS 8158:2012) (SNZ 2012).

1.1 Oversight Committee

The Oversight Committee was established in 2015. It is primarily made up of HCSS funder representatives: the Ministry of Health (the Ministry), a district health board and the Accident Compensation Corporation (ACC).

The purpose of this committee is to provide oversight and direction to the HCSS certification scheme, and ultimately to improve sector outcomes. It will soon be possible to identify national trends based on audit reports as these reports are now being processed through an electronic database, the Provider Regulation and Monitoring System (PRMS). Over time, PRMS data will build a national picture of the main areas of non-conformity. This information will create the opportunity to work with the sector on key areas for improvement.

From an operational perspective, the Oversight Committee will provide advice to the Independent Assessment Committee (IAC) where required. The role of the IAC is outlined below. Please note the Oversight Committee is not responsible for the operational activities of the conformity assessment bodies.

While the Oversight Committee does not currently have dedicated representation from either a CAB or a provider, it is committed to seeking expertise from the relevant group or groups as issues arise.

See Appendix 1 for a flowchart of the process involved in certifying HCSS providers.

1.2 Independent Assessment Committee

The role of the Independent Assessment Committee is to make a recommendation to the conformity assessment body on certification, noting the CAB is responsible for the final certification decision (in line with ISO 17021-1:2015, clause 5.1.3 (ISO 2011)).³

The IAC is made up of funder representatives. Each funder (district health board, ACC and the Ministry) nominates at least one representative to participate as a member. To be a member of the IAC, the nominated representative must understand NZS 8158 and the certification process relevant to this scheme. The IAC follows Terms of Reference that the Oversight Committee reviews each year.

³ The IAC reviews certification reports of contracted providers only.

If the IAC has a complaint that it cannot resolve directly with the CAB, the IACit can escalate the issue to the CAB's independent appeals committee. HealthCERT will facilitate the process as part of its administrative function as the Oversight Committee has set out (see below).

1.3 HealthCERT

The Oversight Committee has agreed that HealthCERT – a section of the Ministry of Health – will coordinate and administer the HCSS framework on behalf of funders. HealthCERT's role is to:

- maintain a central repository and collation point for audit reports, audit summaries and progress reports for corrective actions
- · manage audit reports using the PRMS
- manage and maintain the web page for publishing audit summaries. Audit summaries will only be published if they meet the Ministry's publication standards
- channel communications between each CAB and the IAC as they review certification audit reports
- undertake other administrative functions as the Oversight Committee directs.

2. Conformity assessment bodies

The requirements in this document apply to audits of HCSS providers that hold contracts with the Ministry, a district health board and/or the ACC. The contract requires each of these providers to demonstrate through certification that it is complying with NZS 8158:2012.

Note that, in addition to the contractual requirement for HCSS providers to hold certification, a funder may choose to undertake or commission other audit and monitoring activities within the terms and conditions of its contract with a provider.

If a CAB meets the requirements in this document, funders can be assured that it follows a robust and consistent process when undertaking audits and providing audit reports that lead to the certification of HCSS providers.

Once an approved CAB audits and certifies an HCSS provider, that provider meets the certification requirements in its funder contract. Providers may become certified against standards by non-approved CABs, but those providers will not meet certification requirements in funder contracts.

The requirements in this document supplement:

- ISO/IEC 17021-1:2015 Conformity assessment (ISO 2011) requirements for bodies providing audit and certification of management systems. Note: The transition period during which bodies must adopt this amended standard ends on 15 June 2017.
- guidelines for auditing management systems (ISO 19011:2011) (ISO 2003).

Except where otherwise stated, all elements of ISO/IEC 17021-1:2015 (ISO 2011) apply.

Additional references that apply to these requirements are:

- 1. Home and community support sector standard (NZS 8158: 2012) (SNZ 2012)
- Conformity Assessment: Vocabulary and general principles (ISO/IEC 17000: 2004) (ISO 2004)
- 3. Conformity Assessment: Requirements for bodies providing audit and certification of management systems (ISO/IEC 17021-1:2015) (ISO 2011).

2.1 An approved CAB

A CAB may audit against NZS 8158: 2012 (or later versions), if it:

- 1. meets the requirements in this document
- 2. 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)
 - IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems (IAF MD2:2007) (IAF 2007b)
 - IAF Mandatory Document for Duration of QMS and EMS Audits (IAF MD5:2015) (IAF 2015)
- 3. complies with auditor guidance that the funders issue
- 4. is a designated auditing agency as authorised under the Health and Disability Services (Safety) Act 2001
- 5. holds third party accreditation with either the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) or the International Society for Quality in Health Care (ISQua) for the Health and Disability Services Standards, and meets all costs associated with this accreditation. If a CAB is ISQua accredited, the CAB must also demonstrate that, as a minimum:
 - it reports progress annually to ISQua
 - ISQua conducts a two-yearly on-site surveillance audit of the CAB.

A CAB that meets the criteria listed above is an 'approved CAB'.

If a funder asks for a copy of a CAB's third-party accreditation certificate, the CAB must provide it. CABs must work to the auditing principles and code of ethics outlined in the *Designated Auditing Agency Handbook* (Ministry of Health 2016).

2.2 Responsibilities of a CAB

As a CAB, you are responsible for:

- 1. meeting requirements outlined in ISO/IEC 17021-1:2015 (ISO 2011)
- 2. coordinating audit activities with the provider such as:
 - ensuring the provider's certification can continue where the provider achieves compliance
 - planning the audit
 - conducting the audit
 - writing the audit report
 - establishing that the provider's certification status is consistent with this document,
 ISO 19011:2011 (ISO 2003) and ISO/IEC 17021-1:2015 (ISO 2011)
- 3. contacting the funders before an on-site audit (as part of audit planning) and, seven days before the audit, giving the provider a copy of any funder feedback for follow-up
- 4. submitting the audit report to HealthCERT, who will engage no fewer than two IAC members to review the audit report
- 5. providing a draft of the audit report that covers any specific additional contractual requirements that the funder has paid you to audit
- 6. submitting an electronic audit report using a specified template into PRMS⁴
- 7. notifying funders in writing as soon as practicable (ideally at the time of audit, but within 24 hours of completion of the audit), where the audit identifies critical or high risks; and/or notifying funders where a cumulative number of corrective actions delay the awarding of certification
- 8. monitoring the provider throughout the certification period in line with surveillance requirements and any progress reporting that is required as a result of your audit
- 9. notifying funders if the provider's progress against corrective actions is inadequate, and submitting a record of progress monitoring into PRMS.

2.3 Audit teams

The audit team must follow the principles of auditing:

- ISO/IEC 17021-1:2015 Conformity Assessment: Requirements for bodies providing audit and certification of management systems (ISO 2011). Note: The transition period during which bodies must adopt this amended standard ends on 15 June 2017
- 2. the principles outlined in the *Designated Auditing Agency Handbook* (Ministry of Health 2016).

⁴ If you are an approved CAB, you will receive a link to PRMS.

The members of the audit team must be competent in areas appropriate to the particular service they are auditing. The team must have a sufficient number of auditors to complete the audit against all relevant criteria in the standards.

The audit team must include a:

- 1. team leader (or lead auditor) who is familiar with person-centred HCSS models of care
- 2. clinical/technical expert in the delivery of HCSS who has:
 - a qualification in nursing or allied health services and current annual practising certificate; or a rehabilitation qualification and home care auditing experience
 - experience in medication management (within an HCSS setting)
- consumer auditor for services for people with disabilities where a consumer auditor is a contractual requirement (for example, services contracted by Disability Support Services).

Auditors have developed sufficient knowledge and skills in quality management if they have achieved as a minimum:

- 1. a qualification of unit standard NZQA 8086 (demonstrate knowledge required for quality auditing)
- 2. two years' work experience.

Clinical/technical experts must have at least two years' work experience in HCSS or related fields; or have experience in auditing home care services.

The team leader and clinical/technical expert may be the same person and fulfil both roles and responsibilities of the audit, if the person meets the criteria for both roles above.

A consumer auditor may be a qualified auditor or a person who has been trained in auditing principles (but is not qualified as an auditor) and is a person with a disability and a lived experience of receiving residential services or HCSS; or is a family member of that person. Where the consumer auditor is qualified as an auditor, they may take on audit functions in addition to the consumer role as outlined in the *Designated Auditing Agency Handbook* (Ministry of Health 2016).

If a team of two or more is performing an audit, each team member does not have to meet all the competency criteria for the area of activity involved. However, the team as a whole must meet all the competency criteria.

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

For a surveillance audit, a:

- 1. team leader can conduct it if they are experienced in auditing home care services and, as a minimum, have access to the CAB's clinical/technical advisor
- 2. consumer auditor need not be involved.

As a CAB, you must have procedures for establishing the ongoing competence of your auditors, including auditors in the roles of team leader, clinical/technical expert and consumer auditors. You must also have a process for reviewing the performance of each auditor at least once a year through, for example, periodically observing each auditor's performance on site. Base the frequency of such observations on the need you identify from all monitoring information available.

2.4 Auditor days on site

The length of the certification audit depends on the size, nature and complexity of the organisation you are auditing. You should work out the time required on site to satisfactorily complete the audit. This time will involve at least:

- 1. 50 percent of the estimated time spent preparing for the audit (stage 1) and completing the audit report (all audits)
- 2. for a certification audit, two auditors on site for:
 - 1.5 days (or equivalent) for a single-site provider
 - 0.5 days for each additional site audited for a multi-site provider
- 3. for a surveillance audit, one auditor on site for:
 - 1 day (or equivalent) for a single-site provider
 - 0.5 days for each additional site audited for a multi-site provider.

2.5 Sampling methods

The following sampling requirements apply to consumer record reviews and interviews, and sampling multiple sites.

Minimum sample size – consumer record reviews

Consumer records are reviewed as part of the on-site audit. Ideally, the records you review will be those of the consumers you interview.

Decide on the minimum sample of consumer record reviews using this square root rule:5

⁵ See Appendix 2 for an example of sampling based on the square root rule.

- certification audit consumer record sample = 0.6 times the square root of the number of current consumers receiving HCSS (rounded to a whole number). Exception: If a service has fewer than 10 consumers, review a minimum of three records
- surveillance audit consumer record sample = 0.3 times the square root of the number of current consumers receiving HCSS (rounded to a whole number). Exception: If a service has fewer than 50 consumers, review a minimum of three records.

Stratify sampling so it is representative of:

- the current consumers receiving HCSS (that is, stratified to complex, non-complex, short term, long term and so on)
- service agreements between the provider and its funders.

Increase the sample size if you identify non-conformity with the standard.

Minimum sample size – consumer interviews

The number of consumers interviewed as part of the audit process depends on the size, nature, complexity, internal quality monitoring of consumer satisfaction and funding arrangements of the provider you are auditing. Decide on the minimum sample using the same square root rule for certification and surveillance audits as set out for consumer records above.

Conduct face-to-face interviews with consumers as part of the sample for certification audits. In addition, you may also conduct telephone interviews or surveys.

Increase the sample size for face-to-face consumer interviews if you identify non-conformity.

Minimum sample size - multiple sites

Decide on the minimum sample for multi-site reviews 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 you will rotate the sites you audit within a three-year period (initial certification audit, surveillance audit and next certification audit) so that you audit the maximum possible number of individual sites of the multi-site provider.

Funders may ask you to include or exclude their region or a particular regional site in your sample plan for any audit. Make sure that all funders have an opportunity to make such a request as part of your audit planning.

2.6 Reporting requirements

Evidence

You may use your own audit tools and workbooks to audit against NZS 8158:2012. As part of the process of collecting audit evidence, consider using standardised assessment and outcome tools consistent with the service delivery aspects of NZS 8158:2012, as required under a provider's contract with its funder.

Audit reports

For all audit reports:

- 1. use the prescribed template to complete it
- 2. the writer must be the team leader or audit team for all audits, including verification visits
- 3. include:
 - the reporting requirements outlined in ISO/IEC 17021-1:2015 (ISO 2011)
 - the level of compliance against each criterion for each outcome in the standard as set out in the auditing requirements for each type of audit
 - an executive summary for each standard, stating whether the provider achieved attained, partially attained or unattained for each criterion, and identifying criteria that were not met
 - details of non-conformities with supporting evidence
 - where criteria have not been achieved, corrective actions that are specific, measurable and relevant and contain a timeframe
 - the areas covered by the audit (for example, areas of the services provided and locations, satellite services, departments, processes, number and types of interviews), and observations made, both positive (for example, noteworthy features) and negative (for example, opportunities for improvement)
 - opportunities for improvement where criteria have been fully attained and the auditors have noted further actions that the provider could take to move towards continuous improvement
- 4. make sure the report reflects the findings of the audit
- 5. present the report in word-processed format
- 6. follow the Ministry of Health's Audit Report Writing Guide (Ministry of Health 2014).

Allow funders to review and comment on the draft audit report where it relates to any specific additional contractual elements, before you finalise the audit report. The funders have seven working days to come back to you with comments.

Submit final audit reports electronically into PRMS and copy them to funders. Submit a final report no later than eight weeks following the on-site audit, unless you identified further actions the provider needs to take before you can award certification.

The Ministry of Health intends to publish audit summaries on its website. Your audit summaries must meet the Ministry of Health publication standards and the provider must agree with the final audit summary before you submit the report into PRMS. You must have a process for dealing with situations where you and a provider cannot agree on the audit summary.

2.7 Audit costs

Funders are not liable for the cost of certification audit services.

If a funder requests you to include additional criteria in an audit, specific to a service agreement that it holds with a provider, the funder will negotiate any payment to you before the audit starts. This payment is likely to be a set price based on a time requirement the funders and you have already worked out and agreed on.

If a funder requests you to include a site within the sample for the audit, you must include this without the funder gaining additional costs, unless you cannot accommodate this additional site within the sampling equation (see 'Minimum sample size – multiple sites' in Section 2.5).

2.8 Provider regulation and monitoring system

You must:

- 1. access the PRMS via a connection to the New Zealand Health Network (Connected Health)
- 2. securely manage user-specific log-in and passwords to the PRMS
- 3. use the PRMS to download provider-specific audit reporting templates, which you then use to complete audits
- 4. use the PRMS to upload completed audit reports
- 5. complete the prescribed form in the PRMS that maintains an up-to-date register of auditors who undertake audits on your behalf. An auditor must not undertake an audit on your behalf if you have not entered them onto the auditor register
- 6. ensure the lead auditor/team leader and a peer reviewer have reviewed all audit reports before you submit them to the PRMS. The peer review process must include but is not limited to:
 - proofreading the report
 - ensuring the report is factual and accurate
 - ensuring the audit activities conducted were technically adequate and properly documented
- 7. ensure the report follows the guidelines set out in the Ministry of Health's *Audit Report Writing Guide* (Ministry of Health 2014).

3. Audit

The three types of audits of HCSS providers are:

- 1. certification audit
- 2. verification audit
- 3. surveillance audit.

In all audits, you must include the standards and related criteria listed in Table 1.

Table 1: Audit activity required by audit type

Type of audit	Description of organisations that are audited	Audit activity required	Result
Certification audit	Organisations providing home and community support services that are seeking certification against NZS 8158	Conduct a first stage audit, considering any revised or new policies and procedures against NZS 8158 Conduct a second stage on-site audit against NZS 8158	Conformity assessment body issues three-year certificate
Verification audit	Services seeking to expand their service Services with certification that have started operating from a new site	 Audit service delivery six months after a change to an existing service. This includes: conducting an on-site audit against all standards and criteria reporting the audit and issuing a certificate that includes the new location changing the existing certificate (where a verification audit relates to a change in service). 	Conformity assessment body issues three-year certificate or alters existing certificate
Surveillance audit	Services near the midpoint date of their certification period – the surveillance audit occurs in the window two months either side of this date	 Conduct an on-site audit of: non-conformities identified at the certification audit changes that have occurred since the certification audit consumer rights (seven criteria; standard 1.1) freedom from abuse and neglect (five criteria; standard 1.7) complaints (three criteria; standard 1.9) 	Contribution to monitoring that occurs within the period of certification

Type of audit	Description of organisations that are audited	Audit activity required	Result
		service management (two criteria; standard 2.2)	
		quality and risk management (five criteria; standard 2.3)	
		adverse events (four criteria; standard 2.4)	
		orientation, induction, ongoing development and competency (six criteria; standard 3.2)	
		service agreement (three criteria; standard 4.1)	
		 promoting and supporting independence (four criteria; standard 4.2) 	
		• implementation of individual service plan (three criteria; standard 4.5)	
		review of service delivery (five criteria; standard 4.11).	
		In addition, undertake at least one of the following, choosing the one that is most relevant to the provider:	
		medicine management (four criteria; standard 4.6)	
		infection prevention and control (two criteria; standard 4.7)	
		equipment, aids and enablers (two criteria; standard 4.8)	
		nutrition and safe food management (four criteria; standard 4.9)	
		skin integrity (two criteria; standard 4.10)	
		challenging behaviours (three criteria; standard 4.12).	

3.1 Attainment level

As part of the audit process, you must decide on the level of attainment the provider achieves for each relevant criterion. The levels of attainment are based on a continuous quality improvement model, so are incremental (see Table 2).

Table 2: Meaning of the attainment levels

Atta	inment level	What it means	
CI	Continuous improvement	The service has attained the criterion and demonstrates a review process, including:	
		analysing and reporting findings	
		having evidence that it has taken action based on those findings	
		• improving service provision and consumers' safety or satisfaction as a result of the review process.	
FA	Fully attained	The service demonstrates implementation (for example, practice evidence, training, records or visual evidence) of the process, systems or structures to meet the required outcome of the criterion.	
PA	Partially attained	There is evidence that the service has implemented an appropriate process (for example, a policy, procedure or guideline), system or structure without having the required supporting documentation.	
		Or	
		A documented process (for example, a policy, procedure or guideline), system or structure is evident, but the organisation or service cannot demonstrate that it has implemented it where this is required.	
UA	Unattained	The organisation or service cannot demonstrate appropriate processes, systems or structures to meet the required outcome of the criterion.	
NA	Not applicable	The criterion does not apply to the service that is being audited.	

In your audit report, record the lowest attainment level finding for each of the criteria and outcomes you are reporting on.

3.2 Evaluation methods

Auditors record evaluation methods used in their field notes. They triangulate audit evidence where possible. Table 3 lists the range of evaluation methods available.

Table 3: Evaluation methods

Abbreviation	Method
D	Documentation/record review
1	Interview
SI	Service provider interview
STI	Staff interview
МІ	Manager interview
CI	Consumer interview
Mal	Māori-focused interview
FI	Funder interview
v	Visual inspection
Q	Questionnaire
cq	Consumer questionnaire
SQ	Service provider questionnaire
STQ	Staff questionnaire
Ма	Māori-focused audit
L	Linked services, family, and referral services interview

3.3 Risk management

Identify the degree of risk to consumers' safety that is associated with the level of attainment the provider achieves for each criterion. Audit the 'risk' in relation to its possible impact on the consumer, based on the consequence and likelihood of harm occurring if the provider does not fully attain the criterion. Use the risk management matrix when the audit result for any criterion is partially attained or unattained.

To use the risk management matrix, you need to:

- consider what consequences for consumer safety might follow from the provider achieving partially attained or unattained for a criterion, within a range from extreme/actual harm to negligible risk of harm occurring
- 2. consider how likely it is that this adverse event will occur due to the provider achieving partially attained or unattained for a criterion, within a range from being almost certain to occur to rare

- 3. plot the findings on the risk assessment matrix to identify the level of risk, which may range from critical to negligible, and prioritise risks in relation to severity (for example, critical to negligible)
- 4. approve the appropriate action the provider must take to eliminate or minimise risk within the timeframe in the 'action required' section (Figure 1). Note that timeframes are set based on full resolution of the requirement, which may include a systems change or staff training programme. State anything requiring urgent attention in your report, along with any longer timeframe the provider needs to make sustainable change.

Figure 1: Risk management matrix

				Likelihood o	f adverse event	occurring	
			Almost certain	Likely	Moderate	Unlikely	Rare
	Severe	e harm	Critical	Critical	High	Moderate	Moderate
ce	Major	harm	Critical	High	Moderate	Moderate	Moderate
Consequence	Mediu	ım harm	High	Moderate	Moderate	Low	Negligible
Co	Minor	harm	Moderate	Low	Low	Low	Negligible
	Negligible harm		Low	Low	Negligible	Negligible	Negligible
Level of Action requir		Action requir	red				
Criti	cal	This requires immediate corrective action to rectify the identified issue, including documentation and sign off by the auditor within 24 hours to ensure consumer safety.				_	
High	1	This requires a negotiated plan to rectify the issue in a timeframe not exceeding four weeks. Immediate actions are undertaken to prevent further risk.					
Mod	derate	This requires a negotiated plan to rectify the issue in a timeframe not exceeding three months. Immediate actions are undertaken to prevent further risk.					
Low		This requires a negotiated plan to rectify the issue within a specified and agreed time frame (e.g., within six months).					
Neg	ligible	This would require no additional action or planning.					

4. Certification

Follow a two-stage certification decision process.

- 1. A team leader experienced in auditing home care services conducts a systematic peer review of the audit report. The peer review includes associated audit evidence (that is, field notes, workbooks or tools) where a report is ambiguous. The peer reviewer must be independent of the original audit. After the peer reviewer has completed the peer review, the CAB recommends either certification or delaying certification pending completion of corrective action requirements.
- 2. An Independent Assessment Committee, made up of two funder representatives, conducts an **independent review** of the audit report and decides whether to endorse the decision to award certification. The Independent Assessment Committee has seven working days to respond to and provide feedback on the audit report.

A provider with a 'critical' or residual high level of risk may not be certified.

You must make a decision on certification and notify the provider of your decision within eight weeks of completing the audit. You must also have an appeals process consistent with ISO/IEC 17021-1:2015 (ISO 2011).

4.1 Certification period

The certification period is three years from the date of the certification decision. A provider must have at least one on-site surveillance audit near the midpoint date of its certification period to maintain its certification. Findings are actioned in line with the risk management matrix (see Figure 1 in Section 3.3). You can schedule this surveillance audit two months either side of the midpoint.

If a provider has a 'critical' or residual high level of risk and certification proceeds, you may, in liaison with the Independent Assessment Committee, require additional surveillance activities. This may include on-site visits or yearly surveillance audits.

4.2 Certification conditions

With each certificate you issue, include conditions of certification based on risks that the audit has identified. These conditions may include requirements for the provider to make written progress reports of corrective actions or for you to verify corrective actions on site and to conduct an annual surveillance audit or other progress monitoring.

4.3 Certification document

Notify the provider of your audit report and give it a copy of the report and a certification document that includes the information outlined in ISO/IEC 17021-1:2015 (ISO 2011).

Keep an up-to-date record of all the provider's sites that have met the certification requirements. You must date certification documents from the date of your formal decision to award certification.

4.4 Monitoring

Monitor the HCSS provider during the period of certification to ensure it:

- has addressed any non-conformity that you identified at the time of the certification or surveillance audit
- 2. is maintaining its systems and processes.

Have procedures in place to ensure that the provider takes corrective action in line with the risk management matrix (see Figure 1 in Section 3.3). These procedures may include getting a written progress report from the provider or making an on-site verification visit.

If the provider does not correct a non-conformity in the timeframe agreed at the audit and to be consistent with the risk management matrix, you:

- 1. may suspend certification
- 2. must notify the funders before any such suspension.

Make available to the funders your monitoring reports on a provider. Funders may work with you in monitoring requirements that result from audits.

4.5 Additional sites

When the provider plans to add another satellite (for example, a regional site) to an existing service that holds certification, it must apply to you to complete a verification audit within six months of establishing the additional site. You must issue certification to match the expiry of the current certificate that the provider holds.

The provider must notify you before adding the new site and confirm in writing that its governance, systems, processes, policies and procedures are substantially the same as those in the current service.

4.6 Sale of a certified organisation

The current provider owns the certification. If a new organisation buys a certified organisation, it may keep that certification for a maximum of six months (unless the certification period expires before this date). The organisation shall have a CAB complete a certification audit within six months of taking possession, to issue a new certificate.

You may withdraw or suspend certification, where it has been transferred with the sale of an organisation if the systems and processes for operational management or quality and risk management differ substantially from those in the certified organisation. Before doing so, however, you must liaise with the relevant funders of the new organisation.

4.7 Audits of lead suppliers and subcontractors

In an audit of a lead supplier of HCSS, consider how that supplier manages quality and risk management systems, its organisational management, and how consistently it delivers services across its subcontractors.⁶

In auditing a lead supplier against NZS 8158:2012, establish whether the lead supplier:

- 1. has a process for subcontractor organisations to implement policies and procedures that are consistent with the lead supplier's policies and procedures
- collects high-quality monitoring information from its contractors and subcontractors and has a mechanism for regularly communicating issues with its contractors and subcontractors.

Subcontractor organisations must be certified against NZS 8158:2012 and demonstrate how they share information with a lead supplier. If a lead supplier is a supply chain management organisation providing services in the capacity of a lead supplier, it needs to be certified against NZS 8158:2012.

⁶ A lead supplier holds a service agreement with a funder. The lead supplier may, if its service agreement allows, subcontract services to an independent party where it has a contractual arrangement with the lead supplier (and not with the funder directly).

4.8 Providers certified against the Health and Disability Services Standards

In an audit against NZS 8158:2012, you may refer to conformity with the Health and Disability Services Standards (HDSS 8134:2008) (SNZ 2008) where:

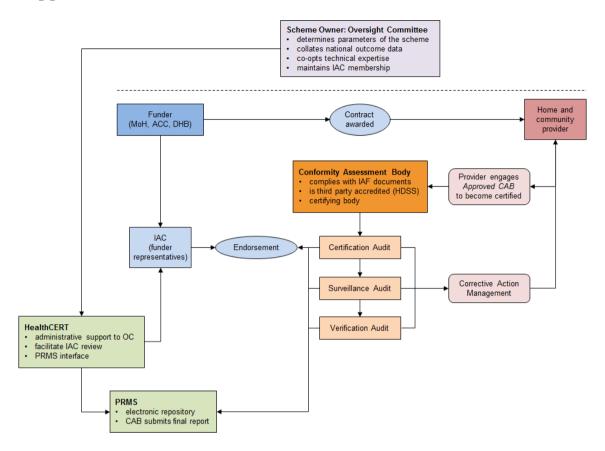
- 1. home and community support services are provided as part of a larger organisation's services and that larger organisation is certified to HDSS 8134:2008
- 2. the provider uses the same management, quality and risk management systems across its organisation
- 3. home and community support services can be identified within the management, quality and risk management systems.

An audit report against NZS 8158:2012 that refers to conformity with HDSS 8134:2008 must include additional evidence of implementation relevant to home and community support services.

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Appendix 1: Process of certification for the home and community support sector



Key:

ACC Accident Compensation Corporation

CAB Conformity assessment body

DHB District health board

HDSS Health and Disability Services Standards
IAC Independent Assessment Committee
IAF International Accreditation Forum

MoH Ministry of Health
OC Oversight Committee

PRMS Provider Regulation and Monitoring System

Appendix 2: Square root table

Use this guide to check you have followed the square root rule correctly. Note that you round up numbers with decimal points to the next whole number.

Number of home and community	Square root calculation of sample size			
support service clients currently receiving support	0.6 times the square root	0.3 times the square root		
10	3 (minimum requirement; square root rule does not apply)	3 (minimum requirement; square root rule does not apply)		
20	3	3 (minimum requirement; square root rule does not apply)		
30	4	3 (minimum requirement; square root rule does not apply)		
40	4	3 (minimum requirement; square root rule does not apply)		
50	5	3		
100	6	3		
150	8	4		
200	9	5		
250	10	5		
300	11	6		
350	12	6		
400	12	6		
450	13	7		
500	14	7		
750	17	9		
1,000	19	10		
1,250	22	11		
1,500	24	12		
1,750	26	13		
2,000	27	14		