MINISTRY OF HEALTH
MANATŪ HAUORA

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Designated Auditing Agency Handbook

Ministry of Health Auditor Handbook (revised 2015)

For Health and Disability Services Standards NZS 8134:2008

Ministry of Health requirements for auditing and audit reporting for certification under the Health and Disability Services (Safety) Act 2001.

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Contents

1 Introduction

The key purpose of this handbook is to state the Ministry of Health's (the Ministry's) requirements of designated auditing agencies (DAAs) for auditing and audit reporting for certification of health care services under the Health and Disability Services (Safety) Act 2001 (the Act).

This version of the *Designated Auditing Agency Handbook* replaces all prior versions. This handbook will be updated periodically and, where necessary, in collaboration with DAAs.

If there is any doubt as to any interpretation or requirement specified within this handbook, DAAs shall request written guidance from HealthCERT (a business unit within the Ministry) in advance of any action.

1.1 Keeping the handbook updated online

This handbook will be updated periodically online, in order to keep it accurate. To get the latest version, please access or download the online handbook at www.health.govt.nz/publication/designated-auditing-agency-handbook

1.2 Additional reading

1. AS/NZS ISO 19011:2011 – Guidelines for quality and/or environmental management systems auditing.
2. Code of Health and Disability Services Consumers' Rights 1996 and the Health and Disability Services (Safety) Act 2001.
3. Health and Disability Services (General) Standards, NZS 8134.0:2008.
   - Health and Disability Services (Core) Standards, NZS 8134.1:2008.
   - Health and Disability Services (Restraint Minimisation and Safe Practice) Standards, NZS 8134.2:2008.
   - Health and Disability Services (Infection Prevention and Control) Standards, NZS 8134.3:2008.
4. IAF MD2: 2007 – International Accreditation Forum Mandatory Document for the Transfer of Accredited Certification of Management Systems.
5. IAF MD5: 2013 – International Accreditation Forum Mandatory Document for Duration of Quality Management Systems and Environmental Management Systems Audits.
6. ISO/IEC 17021:2011 Conformity assessment – requirements for bodies providing audit and certification of management systems.
7. ISO/IEC 17065:2012 Conformity assessment – requirements for bodies certifying products, processes and services.

8. International Accreditation Programme (IAP) Standards for External Evaluation Organisations 4th edition, Version 1.1, 2014 (ISQua's standards).

9. Other Acts, regulations, codes and guidelines relevant to the service being audited and the auditors' practice.

10. Ministry of Health, *Audit Report Writing Guide*, 2010.

11. Auditor Guidelines – Audits undertaken on hospital-level services for Occupational Right Agreement[1] (ORA) premise based Residential Care Services dated 14 August 2013.

Note: Cited publications are current at the time of publishing this *DAA Handbook*. Refer to the most recent publication.

1.3 References

Forms and templates referenced in this handbook that are available on the HealthCERT website are:

- declaration forms
- provider self-assessment forms and templates
- provider document review templates
- environmental check template
- DAA annual plan template for the coming year's audit activities (submitted annually by 29 January).

Referenced requirements in this handbook that are available within the Provider Monitoring and Regulation System (PRMS) are:

- auditor register
- audit reporting templates
- corrective action monitoring.

[1] ORA may also be known as 'Care Suites', Licence to Occupy (LTO) and Rent to Occupy (RTO).

2 Definitions within this document

The Act	The Health and Disability Services (Safety) Act 2001
Age Related Residential Care (ARRC)	Services provided in accordance with an Agreement held with a district health board (DHB) to provide 24-hour provision of hotel services and personal care in continuing care (hospital care), specialist dementia services and rest home care. Hospital care is as defined in section 4 of the Health and Disability Services (Safety) Act 2001. Rest home care is as defined in section 6(2) of the Health and Disability Services (Safety) Act 2001. Also known as Aged Residential Care Services.
Aged Residential Hospital Specialist Services (ARHSS)	Aged residential hospital specialised services, provided in accordance with an Agreement held with a district health board to provide 24-hour provision of hotel services and personal care, in the category of psychogeriatric care. Psychogeriatric care is a form of hospital care as defined in section 4 of the Health and Disability Services (Safety) Act 2001. Also known as Aged Residential Care Services (psychogeriatric).
Agency	A designated auditing agency, also referred to as a DAA.
Annual service provider declaration	A declaration by a provider (other than DHBs) to the DAA in any calendar year in which a certification or surveillance audit has not occurred.
Audit	A systematic, independent, objective and documented evaluation of the extent to which health care providers meet standards and processes, based on particular audit criteria.
Audit reporting template	A Ministry of Health document supplied electronically to DAAs to be completed and submitted by them as a record of the audit.
Auditor with clinical expertise	An auditor holding a qualification in quality auditing that meets HealthCERT minimum requirements and in addition holds a current annual practising certificate in a health professional field pertinent to the service being audited. Note: This is the minimum requirement where specific requirements are not additionally set out by service type within this handbook.
Client	Organisation being audited.
Complex care in a DHB setting	Patients that have received clinical care from intensive care, high dependency, coronary care, interventional radiology and acute assessment units until transfer to a ward.
Consumer/kiritaki	A person who uses or receives a health or disability service.
Consumer auditor	A full member of the audit team who either is a service user of the type of service being audited (eg, residential physical or psychiatric) or is a family member or primary carer of such a person. Where a provider is certified for multiple kinds of services, someone who reflects the primary nature of the service is acceptable as a consumer auditor.
Corroboration/verification of evidence	The process an auditor follows to confirm their conclusions, which should involve triangulation of evidence wherever possible.
Critical risk	A risk requiring immediate corrective actions, including documentation and sign-off by an auditor within 24 hours and notification to the Ministry, in the interests of consumer safety.

The Act	The Health and Disability Services (Safety) Act 2001
Current clinical expertise	A health professional who holds a relevant annual practising certificate and can demonstrate practical experience within the past two years and professional development in the service relevant to the audit and if a: • registered nurse or allied health professional, has been assessed as competent within an approved professional development programme at level 3 equivalent or higher, where level 2 is competent in a programme of either 4 or 5 levels • registered medical practitioner, holds membership as a fellow of the relevant college and meets the requirements of the continuing medical education activities and assessments of competence as required by the college.
DAA annual self-declaration	Declaration that internal audit, appeals process, conflict of interest, auditor register and auditor qualifications validation are current and comply with Ministry requirements.
Designated auditing agency (DAA)	An auditing agency for the time being designated under section 32(1) of the Health and Disability Services (Safety) Act 2001.
Director-General	The chief executive of the Ministry of Health.
Doctor	A person registered by the Medical Council of New Zealand to practise medicine in New Zealand.
Episode of care	A period between defined intervals (eg, from admission to discharge, or for the duration of specific management of an illness).
Executive summary	A preview of the main points from the audit report. It is written in plain English and contains enough information for a reader to familiarise themselves with the content of the full report. It should not contain information about anything that has occurred subsequent to the audit.
Evidence-based approach	The rational method for reaching reliable and reproducible audit conclusions in a systematic audit process. This may include sampling of a subset of a population, in order to provide a representative depiction from which it is possible to confidently generalise conclusions.
HDSS	The Health and Disability Services Standards.
Health care services	Hospital care, rest home care, residential disability care or other specified health (including mental health) or disability services.
HealthCERT	The section of the Ministry of Health responsible for the administration of the Health and Disability Services (Safety) Act 2001.
Highly relevant criteria	See streamlined audit.
Hospital care	Children's health services, geriatric services, maternity services, medical services, mental health services or surgical services (or a combination of two or more of those services), where the services are provided: • in premises held out by the person providing or intending to provide them as being capable of accommodating two or more of the people for whom the services are provided for continuous periods of 24 hours or longer • in consideration of payment (whether made or to be made, and whether by the Crown, the people for whom the services are provided or any other person).
IAF	International Accreditation Forum.
Incidental sampling	A sample based on the collection of evidence from whomever or whatever comes along (eg, through informal talks with consumers on a tour of the facility). Incidental sampling can supplement other information collected throughout the audit process.
Issue	A deviation from a known standard.
Lead auditor / team leader	The person holding a qualification in auditing assigned to managing the audit team and audit process and responsible for authorising the final audit report before it is submitted to the Ministry of Health. The lead auditor holds a qualification in auditing that enables them to undertake the team leader role. Note that 'team leader' is the equivalent term for 'lead auditor' in ISO 19011.
Ministry	Ministry of Health.
Ministry's Disability Services	Part of the National Services Purchasing section of the Ministry of Health, responsible for the planning and funding of disability support services.
Multi-site	Structure of an organisation that has a central location at which certain activities are planned, controlled or managed and a network of local offices, branches and services (sites) at which such activities are carried out.

The Act	The Health and Disability Services (Safety) Act 2001
Multi-site audit	A process carried out under a written, pre-negotiated agreement between a multi-site provider of residential disability care and HealthCERT, which establishes that an agreed percentage or number of the provider's premises/sites will be audited. The methodology for determining the number of facilities to be audited is based on IAF MD 1:2007 where there is not a requirement to submit a multi-site audit plan to the Ministry prior to the audit.
National Services Purchasing (NSP)	See Ministry's Disability Services.
Observed audits undertaken by HealthCERT	Process in which an official from the Ministry observes an audit being conducted by a DAA for the purposes of determining competence of the audit team or implementation of audit process.
On-site audit	A physical visit by an audit team to a provider organisation to audit conformity against all standards applicable to that provider.
Peer reviewer	An auditor acting as an independent expert who is not a member of the audit team and whose function is to critically review the audit report to ensure that audit activities conducted were technically adequate, properly documented and satisfy established quality requirements.
Problem	A deviation from a known standard.
Provider surveillance declaration	A declaration completed by a residential disability provider as a condition of certification. The declaration is made following an internal assessment of progress towards completing corrective action requirements arising from a certification audit and any relevant reports that followed a developmental evaluation prior to the mid-point of certification.
Resident	A person who uses/receives a health or disability service in a residential setting. Otherwise known as a consumer.
Residential disability care	Residential care provided in any premises (including aged care premises) for five or more people with an intellectual, physical, psychiatric or sensory disability (or a combination of two or more such disabilities) to help them function independently.
Rest home care	Services that: • are residential care services provided for the care or support, or to promote the independence, of people who are frail (whether because of their age or for some other reason) • neither include, nor are provided together with, geriatric services • are provided for three or more people unrelated by blood or marriage (or a relationship in the nature of marriage) to the person providing the services • are provided in premises held out by the person providing the services as being principally a residence for people who are frail because of their age • are provided in consideration of payment (whether made or to be made, and whether by the Crown, the people for whom the services are provided, or any other person) • may include dementia care services.
Self-assessment: Increased capacity for Aged Care Residential Care	A process undertaken by a provider who is proposing to increase the number of beds for a certified service. Examples of providers who may undertake this form of self- assessment are: • a provider who is currently certified for 20 hospital-level beds and wishes to increase their capacity to 30 beds.
Self-assessment: Reconfiguration of certified services	A process undertaken by a provider who is certified to provide more than one kind of service. Examples of providers who may undertake this form of self- assessment are: • hospitals and rest homes who want to have the ability to use hospital-level care beds to deliver rest home care when these beds are not required for hospital-level care and vice versa • rest home care services wishing to reconfigure services to provide dementia care • residential disability service providers relocating an existing service to another site or increasing capacity that does not include a new service type.

The Act	The Health and Disability Services (Safety) Act 2001
Service kind	Health and disability services that are one of the following: • hospital care – children's health services • hospital care – geriatric services • hospital care – maternity • hospital care – medical services • hospital care – mental health services • hospital care – surgical services • rest home care • residential disability – psychiatric • residential disability – physical disability • residential disability – sensory • residential disability – intellectual • mental health services • mental health services – drug or alcohol abuse services.
Service provider	An individual who is responsible for performing a service either independently or on behalf of an organisation. In this definition, 'service' includes the provision of direct and indirect care or a support service to the consumer. 'Service provider' covers all service providers and management who are in any of the following categories: • employed • self-employed • visiting • honorary • seasonal • contracted • voluntary • responsible for or accountable to an organisation when providing a service to a consumer. For the purpose of auditing against the HDSS, informal/unpaid and family and whānau networks are excluded.
Site visit	A physical visit by an auditor to a provider to audit applicable standards, or parts of standards. This includes verifying the implementation at each site of generic policies, procedures and systems, following a review of organisation-wide policy and procedures. HealthCERT must approve the site sampling of particular providers before site visits may be undertaken. For a certification audit, a site visit is stage two of the audit.
The Standards (HDSS)	NZS 8134.0:2008, NZS 8134.1:2008, NZS 8134:2:2008 and NZS 8134.3:2008 and any amendments or additional standards in accordance with the Act.
Streamlined audit	An audit that focuses on HDSS and specified criteria that are most relevant to the service type being audited. All Standards and specified criteria are rated. All Standards have evidence of conformity and non-conformity reported. Criteria have evidence reported where there is non-conformity or continuous improvement (ie, fully attained ratings do not have evidence reported at criterion level).
Systems tracer	Looks at one system or programme sampling across multiple consumers. Systems-based tracer methodology can be applied to programmes such as falls management or the deteriorating patient.
Technical expert	A person who provides specific knowledge or expertise to the audit team but does not act as an auditor in that team. See also 'Consumer auditor'.
Technical expert assessor	A senior clinician with relevant specialist knowledge of district health board systems and current practice working as an expert in delivery of services who is nominated by a DHB to be on the Ministry register of technical expert assessors.

The Act	The Health and Disability Services (Safety) Act 2001
Tracer methodology	A tracer follows the actual care experience of the consumer who is receiving care and treatment at the time of the audit. Selection of a tracer should include a consumer who is receiving complex care and treatment as their experience shows how the provider's systems and processes support the care they receive.
Transition plan	A plan that is developed where a provider is purchasing a health or disability services as a going concern. The plan includes how information about the change in ownership is being communicated and how any intended changes to the service are to be implemented (eg, staffing changes, changes to policies and procedures).
Triangulation of evidence	A process of drawing information from three sources (interviews, observations and documentation) in order to gather reliable evidence.
Witnessed audits undertaken by DAAs	Process in which an individual is assigned by the DAA to assess the competence, skills, knowledge and ability of an audit team member through observation of the auditor conducting an audit in accordance with audit process requirements. The observer shall hold qualifications equivalent to or greater than the auditor being observed. The observer shall use established criteria to evaluate the auditor under observation and complete a report that is then used to inform a performance review of the auditor.
Young person	Is under 65 years of age, has a physical, intellectual or sensory disability or a combination of these, which is likely to remain even after provision of equipment, treatment and rehabilitation, continue for at least six months and result in the need for ongoing support.

3 Auditing principles

The Ministry of Health requires auditors to follow the principles of ethical conduct, fair presentation, due professional care and support, independence and an evidence-based approach as outlined in AS/NZS ISO 19011. In addition, the following principles apply.

1. **Consumer focus:** Care, support and services meet the needs and preferences of consumers consistent with currently accepted practice.

   Auditors shall use their technical and clinical expertise to collect audit evidence directly from consumers, relatives and providers and include a review of care and support received, considering both the episode of care and individual components of care.

2. **Outcomes focus:** The context for service provision must be considered, acknowledging that outcomes can be achieved through various inputs, processes and outputs.

   Audit evidence shall reflect the inputs, activities and outputs that contribute to outcomes, giving due consideration to contractual requirements in the case of any government-funded services that also rely on the Health and Disability Services Standards (HDSS) as a means of measuring or monitoring standards of services and care and support.

3. **Systems and process focus:** Effective systems and processes are implemented to support the delivery of services and care.

   Auditors will determine through the collection of audit evidence that standards of service and care and support delivery are not dependent on any one person, but rather on the systems and processes present.

4. **Openness and transparency:** Information is effectively communicated throughout the audit process.

   Auditors ensure stakeholders involved in the audit process are fully informed.

4 Designated auditing agency responsibilities

Each DAA shall meet the requirements listed below.

Legislative

1. Meet all requirements of designation as outlined in the Act and in the *Gazette* notice.
2. Comply with relevant legislation, including but not being limited to the:
   a. Health and Disability Commissioner Act 1994
   b. Health and Disability Services (Safety) Act 2001
   c. Health and Safety in Employment Act 1992 and amendments
   d. Health Practitioners Competence Assurance Act 2003
   e. New Zealand Public Health and Disability Act 2000
   f. Privacy Act 1993
   g. Health Information Privacy Code 1994.

Third-party accreditation

3. Hold 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) and meet all costs associated with this accreditation.
4. Provide to the Ministry upon receipt, all reports and requirements generated by its third-party accreditation body, together with associated action plans that are a result of third-party accreditation activities.
5. Notify HealthCERT immediately of any application made for third-party accreditation, or any suspension or conditions imposed by a third-party accreditation body.
6. Ensure that the third-party accreditation body undertakes an on-site surveillance audit at the mid-point of the accreditation period or at more frequent intervals, as determined by the third-party accreditation body.

Client management

7. Follow IAF MD2:2007 for the transfer of clients where the client has previously received services from another DAA.
8. Ensure clients of the DAA are aware that the Ministry of Health or a recognised third-party accrediting body (JAS-ANZ or ISQua as applicable) may accompany DAA auditors on any audit as part of their observation audit or witnessed audit, performance monitoring process, accreditation or designation/re-designation process.
9. Ensure all information obtained or created during the performance of certification activities is maintained confidentially.

Auditors

10. Employ or contract with competent auditors who have gained the New Zealand Qualifications Authority (NZQA) Unit Standard 8086[2] (demonstrate knowledge required for quality auditing) qualification (or equivalent as recognised by the Ministry) in auditing quality management systems (QMS) and have a demonstrated ability to comply with the requirements of AS/NZS ISO 19011.

11. Determine competence of auditors and technical experts in accordance with ISO/IEC 17021:2011. Auditors may demonstrate competence through successful completion of NZQA Unit Standard 8084 (audit quality management systems for conformity with quality standards). This course is focused on competence assessment, involving assessment of workplace-based audits followed by written examinations containing questions relating to workplace-based audit records.

12. Ensure auditors employed or contracted by the DAA comply with the code of conduct as outlined in section 5.

13. Ensure auditors employed or contracted by the DAA can demonstrate continual professional development through regular participation in audits and completion of at least eight hours per calendar year of professional development education and training relevant to their area of audit.[3]

14. Ensure that requirements for continual professional development are consistent with ISO 19011.

15. Ensure that auditors with clinical expertise include, within their professional development, activities that keep them up to date with current QMS auditing and best practices for service delivery. Such professional development shall cover but is not limited to knowledge of:

    a. all legislation and regulations relevant to the service setting (for example, auditors undertaking residential care auditing require knowledge of enduring power of attorney in the context of personal care and welfare, and how this should be approached within a residential care setting)

    b. the current management of commonly occurring medical conditions relevant to the service setting (for example, auditors undertaking residential care auditing require knowledge of congestive heart failure, chronic obstructive respiratory disease, diabetes, delirium, upper and lower respiratory tract infections and urinary tract infections)

    c. current nursing care management (for example, auditors undertaking residential care auditing require knowledge of medication management, wound care, continence management, constipation, falls management, nutrition/hydration and pain management).

16. Complete an annual performance review of all employed and contracted auditors which must at a minimum include a witnessed audit[4] undertaken by the DAA of their staff and contractors.

[2] Assessments against NZQA standards must be undertaken by an NZQA provider of auditor training that has a health and disability focus.

[3] Those health professionals who are auditors regulated through the Health Practitioners Competence Assurance Act 2003 also need to meet the requirements of professional development to maintain their annual practising certificates, which may be in addition to or part of this eight-hour requirement.

[4] This can be a surveillance audit or a certification audit.

17. Ensure that the auditor undertaking a witnessed audit that is contributing to a performance appraisal is additional to the audit team and does not participate in the audit process. The person undertaking the witnessed audit does not need to be present for the full audit. Ensure a witnessed audit of a lead auditor includes at a minimum the opening meeting, audit of organisational management, quality management, end of day meeting with audit team, preparation for the closing meeting, and the closing meeting itself.

18. Ensure auditors undertake performance based monitoring. A DAA may move to two-yearly reviews if the following criteria are met.
    - No complaints are made relating to the auditor's performance, including outcomes of report reviews and Ministry feedback. For example, if the Ministry returns a report then this is an indication of poor performance.
    - No non-conformities are identified during witnessing by either the accreditation body or Ministry.
    - Auditors can only be considered for eligibility for performance based monitoring after two years.
    - Auditors must undertake a minimum of 20 audits within a 12-month timeframe to be eligible for reduced monitoring.

19. Ensure newly qualified auditors work in a trainee capacity for a provisional period of no fewer than four audits where they are fully supervised by an experienced auditor. Auditors must not work independently until such time as they have been assessed as competent.

20. Ensure auditors with lead auditor or team leader qualifications are assessed as competent to work in the capacity as a lead auditor by the DAA. This assessment must include a minimum of four observed certification audits totalling a minimum of eight on-site days before they undertake this role.

21. Disseminate all relevant Ministry updates to auditors employed or contracted.

Audit teams

22. Ensure the audit team comprises competent auditors, auditors with clinical or technical expertise and consumer auditors, as appropriate to the service. Auditors shall be on the DAA auditor register and be approved by the Ministry to audit for specific service types. Minimum requirements are outlined in section 6.

Provider Regulation and Monitoring System

23. Access the Provider Regulation and Monitoring System (PRMS) via a connection to the New Zealand Health Network (connected health).

24. Securely manage user-specific log-in and passwords to the PRMS.

25. Use the PRMS to download provider-specific audit reporting templates that are then used to complete audits.

26. Use the PRMS to upload completed audit reports.

27. Use the PRMS to report progress on corrective actions arising from audits where the DAA is responsible for progress reporting.

28. Complete the prescribed form in the PRMS that maintains an up-to-date auditor register of auditors and clinical/technical experts who undertake audits on behalf of the DAA. Upload any supporting documentation (for example, CVs) to the PRMS as required. An auditor is not to undertake an audit on behalf of a DAA if they have not been entered onto the Ministry auditor register.

29. Maintain the auditor register within the PRMS ensuring all professional development activities have been recorded into the PRMS upon their completion. The first entry could be a reference to the organisation's own record. APC expiry and performance review dates are mandatory.

Reporting requirements

30. Ensure the Ministry holds an up-to-date copy of their specific policies and procedures[5] for auditing against NZS 8134 and recruiting or contracting with audit team members.

31. Provide the Ministry with an audit schedule for the coming year's audit activities, using the prescribed form on the HealthCERT website by 29 January each year and provide an update of this schedule on a quarterly basis.

32. Provide to the Ministry, 20 working days prior to a scheduled audit, an audit plan and timetable for all audits where multi-site sampling occurs, to be approved by HealthCERT.[6]

33. Complete the prescribed annual self-declaration using the prescribed form on the HealthCERT website before 29 January each year and upload all supporting documents that may be subsequently requested by the Ministry of Health.

34. Ensure all audit reports have been reviewed by the lead auditor / team leader **and** a peer reviewer before they are submitted to the Ministry of Health. The peer review process shall include but is not limited to:
    a. proofreading the report
    b. ensuring the report is factual and accurate and meets standards for reporting audit evidence (see section 10)
    c. ensuring the audit activities conducted were technically adequate and properly documented
    d. ensuring the report follows the guidelines set out in the Ministry of Health's *Audit Report Writing Guide*.

35. Notify the Ministry of any client who has not satisfactorily completed an annual service provider declaration, using the prescribed form available on the HealthCERT website to enable the Ministry to determine whether an additional surveillance audit is required.

36. Comply with any benchmarking requirements, including those concerning publication of results.

37. Meet all time requirements for submission of information/reports as outlined in this handbook.

5 These can be submitted to the Ministry electronically.

6 Multi-site sampling is not applicable to aged residential care services.

Managing conflicts of interest

38. Appoint and use a committee for safeguarding impartiality, consistent with the requirements of ISO/IEC 17021.

39. Ensure all auditors complete a conflict-of-interest declaration before every audit.

40. Have established processes to specifically manage conflicts of interest at an organisational level – noting that:

    a. a DAA must not provide any consulting services[7] to an organisation that is also a client[8] receiving auditing services

    b. individual auditors must not provide auditing services where they have provided consultancy or educational services within the last two years to the same client

    c. a DAA may arrange and participate in training courses provided that these courses relate to quality assurance, management systems or auditing. They shall provide only generic information and advice that is freely available in the public domain and includes a range of options or approaches the client could then act on.[9] A DAA must not provide specific advice to any client or provide a particular system for implementation for a client receiving auditing services from the DAA

    d. providing internal, ongoing professional development training to auditors employed or contracted by the DAA is a legitimate DAA activity and does not pose a conflict of interest.

41. Ensure there is rotation of auditors whereby at least 50 percent of the members of the full audit team for the re-certification audit differ from the team members who undertook the prior certification or re-certification audit of any particular premise.

7 'Consulting services' include, but are not limited to, designing, implementing or maintaining a quality or management system (for example, preparation of manuals or procedures; undertaking a gap analysis; conducting internal audits; providing specific advice, instruction or solutions towards the development and implementation of a quality or management system; or participating in the decision-making system regarding such matters).

8 Legal entity.

9 This requirement also applies to any separate organisation established by the DAA or its directors for the purpose of training or education.

5 Code of conduct for DAA auditors

Under the code of conduct, an auditor is required to:

1. act professionally and accurately, and report findings in a consistent and unbiased manner and in accordance with Ministry requirements
2. undertake audits in accordance with Ministry requirements, procedures and guidelines, and with AS/NZS ISO 19011. Ministry requirements are to supersede any other requirements
3. strive to increase the competence and prestige of auditors by continuing to develop their own auditing skills
4. not misrepresent their own or any other individual's qualifications, competence or experience, nor undertake auditing work beyond the scope of their own qualifications
5. disclose to the DAA any current or prior working or personal relationships that may be seen as a conflict of interest or that may influence their judgement
6. not enter into any activity that may be in conflict with the best interests of the Ministry or the DAA, or that would prevent the performance of their duties in an objective manner
7. adhere to the requirement of the Health and Disability Services (Safety) Act 2001, the Privacy Act 1993 and the Health and Disability Commissioner's (HDC) Code of Health and Disability Services Consumers' Rights and all other relevant legislation, regulations, guidelines, codes and best practice standards
8. not promote or represent any business interests or any entity with which they have an interest or may have an interest while conducting audits
9. not accept any inducement, commission or gift or any other benefit from any interested party while conducting audits
10. not communicate false, erroneous or misleading information that may compromise the integrity of any audit
11. not act in any way that would prejudice the reputation of the Ministry or the DAA
12. cooperate fully with any inquiry in the event of a complaint about their performance as an auditor, or any alleged breach of this code
13. make clear to providers that the decision about certification status rests solely with the Director-General of Health and that the DAA is not able to make comment or support an appeal concerning the determination made regarding certification
14. accept that providers have the freedom to select and change their DAA, and not to place any undue influence on providers when they are making a decision in this respect
15. refrain from making any comments on any auditors or DAA, including Ministry or DHB auditors
16. respect consumers' rights during any interaction especially when assessing vulnerable populations such as those in disability or mental health services.

6 Audit teams

6.1 Audit team requirements

The requirements for every DAA audit team are outlined below.

1. The composition of the audit team must reflect the characteristics of the service and its users – for example, in terms of cultural background and service type.
2. Every audit team must include a qualified and experienced lead auditor / team leader.
3. Where audits require technical expertise, the level of expertise shall meet the definitions in section 2 for an auditor with current clinical expertise or technical expert or technical expert assessor. Clinical/technical experts shall have recognised health qualifications and experience in the health field or services area to be audited. Note: One person may be both the lead auditor and a clinical/technical expert.
4. Minimum audit team requirements by service kind are outlined below.

Service kind	Specific service level expertise required
Hospital care	Qualified lead auditor / team leader must meet the role description in Appendix 4 and, if auditing a DHB, be approved by the Ministry to be a lead auditor in DHBs. Auditor must meet the specific role description if auditing a DHB (see Appendix 6).
Hospital care – children's health services	Auditor with clinical expertise or technical expert shall have current paediatric experience including management of children with complex presentations.
Hospital care – medical services	Auditor with clinical expertise or technical expert shall have current medical care experience.
Hospital care – surgical services	Auditor with clinical expertise or technical expert shall have current surgical care experience.
Hospital care – maternity services	Auditor with clinical expertise or technical expert shall have current midwifery or obstetric care experience.
Hospital care – mental health services	Auditor with clinical expertise or technical expert shall have current mental health experience.
Hospital care – geriatric services	Auditors shall be conversant with the relevant contracts held between the funder and provider of services. Auditor with clinical expertise or technical expert shall have current experience in at least one of the following: medical care, rehabilitation nursing, gerontology or psychogeriatric care. Where an auditor with clinical experience does not meet the minimum requirements (see definition of this role in section 2), an exception can be applied if the person is: • not currently practising but has held a clinical role working in aged residential care or gerontology less than five years ago at an advanced/senior level (ie, level 4 or above on a Professional Development and Recognition Programme (PDRP) or equivalent) • currently practising in aged residential care or gerontology with less than two years' experience in this field but was previously working as an advanced/senior practitioner (ie, level 3 or above on a PDRP or equivalent)

Service kind	Specific service level expertise required
Hospital care – geriatric services (continued)	• an auditor who has been approved by the Ministry to audit in geriatric services and rest home, having provided evidence that they: – have three or more years' experience auditing this type of service and – are a registered nurse with at least two years' clinical experience in medical or gerontological nursing and – hold an annual practising certificate and – have completed one-third of the New Zealand Nursing Council's required professional development hours to maintain an annual practising certificate that are specific to aged care, comprising recognised short courses, seminars, conferences, online learning, internet-based courses or degree courses.
Rest home care	Auditors shall be conversant with the relevant contracts held between the funder and provider of services. Auditor with clinical expertise or technical expert shall have current experience in at least one of the following: medical care, rehabilitation nursing, gerontology or psychogeriatric care. Where dementia services are being audited, specific dementia care or psychogeriatric expertise is required. Where a contract for five or more residents is held and YPD services are being audited specific expertise in this area is required Where an auditor with clinical experience does not meet the minimum requirements (see definition of this role in section 2), an exception can be applied as for hospital care – geriatric services above.
Residential disability care – intellectual, physical or sensory	Auditor or technical expert with demonstrated knowledge and understanding of the UN Convention on the Rights of Persons with Disabilities 2008 and the NZ Disability Action Plan; and current experience of disability services relevant to the sub-category (ie, intellectual, physical or sensory). Note this requirement also applies where residential disability care is provided in an aged residential care service or hospital level services and a contract to provide services for five more YPD residents is held.
Residential disability care – psychiatric care	Auditors shall be conversant with the relevant contracts held between the funder and provider of services. Auditor with clinical expertise or technical expert shall have current experience of mental health services. Where an auditor with clinical experience does not meet the minimum requirements (see definition of this role in section 2), an exception can be applied if the person is: • not currently practising but has held a senior clinical role working in mental health services less than five years ago at an advanced/senior practitioner level (ie, level 4 or above on a PDRP or equivalent) • currently practising in mental health services with less than two years' experience in this field but was previously working as an advanced/senior practitioner (ie, level 3 or above on a PDRP or equivalent) • an auditor who has been approved by the Ministry to audit in mental health services and residential disability – psychiatric, having provided evidence that they: – have three or more years' experience auditing this type of service and – are a health professional qualified to work in mental health services with at least two years' clinical experience in mental health services or another services that has mental health clients and – hold an annual practising certificate and – have completed one-third of the professional development hours to maintain an annual practising certificate that are specific to mental health services, comprising recognised short courses, seminars, conferences, online learning, internet-based courses or degree courses.
Mental health services – drug or alcohol services	Auditor with clinical expertise or technical expert shall have current experience of alcohol or drug rehabilitation services or acute mental health services.

5. For **hospital care** of any kind and **rest home care** of any kind, NZS8134.1.3:2008, NZS8134.2.3:2008 and NZS8134.3:2008 shall be audited either by an auditor with clinical expertise or by an auditor with either a technical expert or technical expert assessor.
6. For **hospital care – mental health services** and **residential disability care** of any kind, including where it is provided as a dual service, certification audits shall include a consumer auditor. See section 6.6 for the responsibilities of the consumer auditor.
7. Note that where a mental health consumer has been assessed to receive rest home level care, the audit team shall meet the requirements for **rest home care**.
8. The audit team must have a working knowledge of current contracts held by the provider to ensure the relevance of contracted requirements are considered as part of the certification audit process.

6.2 Lead auditor / team leader

The lead auditor / team leader shall coordinate the audit. While their roles and responsibilities are not limited to the following, the lead auditor / team leader must:

1. confirm the membership of the audit team is appropriate to the type of audit being conducted
2. ensure each team member has completed a conflict-of-interest declaration
3. ensure the audit is conducted in accordance with DAA policies and procedures and consistent with AS/NZS ISO 19011
4. for all announced audits, including those where multi-site sampling is included and for all DHB audits, ensure an audit plan has been developed prior to the audit and the client has received a copy. Note also the requirement to submit audit plans and timetables where multi-site sampling, as agreed by HealthCERT, is included and for all DHB audits
5. confirm audit arrangements with clients, as specified by AS/NZS ISO 19011, where an audit is announced
6. review provider information, such as:
    a. document review
    b. last certification audit
    c. any surveillance or other (for example, partial provisional) audit event since the last certification audit
    d. progress reports
    e. developmental evaluations or other assessments undertaken by third parties
    f. accreditation or audits undertaken by third parties, for example, HACAAP
    g. any information requested for review by HealthCERT
7. contact the funder/s (DHB/NSP) if an audited client holds a contract to deliver services for that funder. This contact will include but is not limited to:
    a. notifying the funder of the intended date of the audit
    b. asking the funder to provide the DAA with any relevant information that may contribute to the audit process
    c. determining with the funder the level of involvement it would like to have in the audit (for example, witnessing the audit) with provider agreement.

Where there are issues in respect of one or more of the certified facilities, it may be necessary to include them in the sampling plan (if applicable).

Residential disability, intellectual disability, physical disability and sensory services contracts are held by the Ministry of Health; psychiatric services contracts are held by DHBs

8. chair opening and closing meetings with the client, maintaining a record of these
9. ensure the opening and closing meetings conform with the requirements of ISO/IEC 17021/17065 and ISO 19011, and include a discussion with the client about the audit objectives
10. ensure substantiation and validation of information gathered by the audit team that is then used as audit evidence
11. ensure the service provider receives a copy of the audit findings and corrective action required at the closing meeting. Where a service holds a service contract with a DHB and/or NSP, forward a copy of the corrective actions report generated on site to the DHB and/or NSP within 24 hours if there are any high-risk findings
12. ensure the service provider has obtained verbal consent from consumers for the audit team to interview consumers
13. notify the Ministry about the progress of the audit where a high or critical risk has been identified at the time of the audit
14. coordinate the audit team and be a resource to the team (see AS/NZS ISO 19011), for example in helping to validate information collected
15. be the central point of contact for the client throughout the audit, liaising with them as appropriate to ensure openness and transparency throughout (see AS/NZS ISO 19011)
16. review the full audit report prior to peer review of the report, and any changes following peer review, and before submission to the Ministry
17. provide any auditor performance feedback to the DAA.

6.3 Role of audit team members

The role of audit team members shall include but is not limited to:

1. working as a team and as a group of individuals who maintain good communication with the lead auditor / team leader and with others as specified by AS/NZS ISO 19011
2. conducting the audit according to the principles and requirements set out in this handbook and AS/NZS ISO 19011
3. undertaking audit activities and tasks as assigned to them, as specified in AS/NZS ISO 19011
4. working to timeframes, as specified in AS/NZS ISO 19011
5. supporting other auditors as necessary, as specified in AS/NZS ISO 19011
6. accurately reporting evidence and ensuring that documents are proofread before submitting them to the lead auditor or team leader
7. providing feedback to the DAA as applicable.

6.4 Auditors with clinical expertise

A qualified quality auditor with clinical expertise can audit those parts of the HDSS that require a level of expertise in the service area being audited. Where an auditor is acting as an auditor with clinical expertise, the auditor must hold a current annual practising certificate and meet the specific competency requirements as set out in section 6.1 above.

6.5 Technical experts

A technical expert is a competent health professional with an annual practising certificate or equivalent who has demonstrated knowledge, skills and experience in the service area being audited but does not necessarily hold an auditing qualification and does not act as an auditor within the audit team. For example, when auditing a paediatric service, the DAA shall have available to it as a resource, a technical expert who currently works or has recently worked for that service type. The technical expert need not attend the audit in order to provide technical advice, except in the case of audits of the following services:

- forensic services
- forensic intellectual disability services
- alcohol and other drug services including detoxification services
- maternity services with birthing units.

A technical expert shall:

1. have demonstrated knowledge and skills related to and recent experience of working within the service area being audited
2. be competent to reach an informed opinion on the appropriateness of the services being offered in the service being audited
3. be able to identify trends in relation to service delivery
4. where they are not a qualified quality auditor and are not completing the Ministry audit reporting template, complete a report that forms part of the audit evidence
5. complete a conflict-of-interest declaration.

6.6 Consumer auditors

A consumer auditor, when used, is expected to:

1. be involved in the planning and preparation of methods of service user participation in the audit and in evaluating the need for independent support for service users
2. participate as a full audit team member
3. focus on the experience of people who use the services
4. be included in key meetings with the organisation, management, staff and consumers
5. facilitate meetings and interviews with service users and consumer groups
6. interview service users independently and work under the direction of the lead auditor / team leader when completing any other aspects of the audit

7. be engaged under the normal principles of employment related to term of appointment, contract, remuneration, job description and adherence to codes of conduct such as those on confidentiality, non-disclosure protocols and conflict-of-interest declarations, in the same way that those principles apply to all other team members
8. be trained in auditing principles, the use of the approved standards and audit tools as a member of the audit team
9. have the following knowledge, skills and attributes:
    - knows the legislative and regulatory requirements for the service being audited
    - understands continuous improvement concepts, methodologies and planning processes
    - understands quality management systems
    - is able to communicate effectively in writing or orally or to use alternative communication systems with all parties involved in the audit process.

For all certification audits of residential disability (psychiatric, intellectual, physical or sensory) care, hospital care or residential mental health services (including alcohol and drug services), the audit team shall comprise a minimum of two members: a lead auditor / technical expert (combined role) and a consumer auditor; or a lead auditor / consumer auditor (combined role) and a technical expert.

Surveillance audits do not require a consumer auditor but will still require the audit team to include a lead auditor / technical expert. For larger services requiring more than one auditor with technical expertise, a consumer auditor shall be used for a surveillance audit.

The consumer auditor shall be a full participant, visit each site subject to audit and be fully involved in the audit (including audits for which HealthCERT has agreed to a sampling plan) and subsequent audit reporting. Involvement of consumer auditors shall be traceable in the audit report submitted to HealthCERT.

The Health Information Privacy Code 1994 states that the disclosure of a person's private health information is permitted only to the extent necessary for the particular purpose.

Given the scope of their role, the consumer auditor shall not review clinical information, for example:

- medical specialist letters
- medical records
- medication records.

They may view personal plans, for example:

- support / activity / goal plans
- consent forms
- information about services

in conjunction with service user interviews.

7 Certification audit process

7.1 Two-stage audit process for certification audit

All certification audits will include a two-stage initial audit. The first stage of the audit will incorporate off-site activities, including a document review of:

- policies and procedures (covering, for example, management systems and clinical systems) and
- prior certification and relevant contractual audits (where supplied by a DHB or Disability Support Services).

The purpose of this review is to allow the DAA to collect sufficient verifiable information to contribute to the second stage of the audit. The DAA is required to provide written feedback to the provider to allow them to remedy any minor non-conformities prior to the on-site audit.

Documents requested for review as part of stage one can be supplied or accessed electronically. The DAA shall ensure that the provider does not send documents electronically that contain confidential information unless these are accessed through a secure server. Note that dropboxes and cloud applications are not acceptable for the transfer of confidential information as they may not meet current information security requirements.

Unless an exemption is granted by the National Health IT Board, all personally identifiable health information and core operational data must be fully domiciled in New Zealand.

Stage one may include activities in addition to a document review that are consistent with ISO/IEC 17021/17065.

Where an audit is a certification audit undertaken by a particular DAA, the DAA will provide its client (the service provider) with a findings report of the stage one results at least one week before starting stage two of the audit. The content of the findings report will include whether documents required for the review were present and, if so, whether they displayed sufficient content to represent current accepted practice consistent with requirements of the HDSS.

When conducting a provisional audit, the DAA will document whether the policies reviewed are those of the current provider or the potential provider. Where the potential provider intends to implement their own policies or staffing, rather than following the approach of the current provider, a transition plan and implementation timetable are required.

If a large number of non-conformities are identified in stage one, the DAA will contact the Ministry to discuss appropriate timing for the next stage of the audit.

7.2 Audit duration

The time required to conduct an on-site audit shall be determined considering the following aspects (as applicable):

1. the fact that an auditor day is a minimum of eight hours
2. the size and complexity of the service being audited, including geographic spread between regional and outreach services from the primary service
3. results of prior audits
4. multi-site considerations
5. requirements to meet the standards of auditing practice required of the DAA
6. use of technical experts and technical expert assessors
7. the requirement that time on site comprises at least 50 percent of the estimated total audit time.[10]

For guidance on aspects of audit duration not covered in this handbook, see IAF MD5 International Accreditation Forum Mandatory Document for Duration of Quality Management Systems and Environmental Management Systems Audits.

7.3 Streamlined audit approach

The DAA takes a streamlined audit approach for all certification and surveillance audits. See appendices 1 and 2 for a full list of criteria that must be audited along with the HDSS.

The streamlined audit process requires a shift from a 'line by line' auditing style to considering how audit evidence can be collected and triangulated to reflect the intent of each Standard and associated highly relevant criteria (ie, the sum of the parts rather than each part in isolation).

1. Each Standard shall be apportioned a level of attainment and associated risk rating. The risk rating attributed to a Standard must take into consideration highly relevant criteria and levels of attainment and risk apportioned to them. This means that a risk rating apportioned at a Standards level may be higher or lower than that of any one individual criterion. A Standard cannot be awarded as fully attained (FA) if there is a criterion that has been awarded a partial attainment (PA).
2. To award a continuous improvement (CI) rating to a Standard or criterion, the auditor must collect evidence that clearly demonstrates the interpretation for this level of attainment as set out in part 10, audit framework of NZS 8134.0:2008.

[10] At least 50 percent of the total audit time recorded as in the audit reporting template should be time spent on site.

8 Types of audits

8.1 Provisional audit

Definition	A provisional audit is undertaken to establish: • a prospective provider's preparedness to provide a health and disability service, **and** • the level of conformity of the existing provider's service that is under offer to the prospective provider.
Applies to	The audit applies to: • a prospective provider applying for certification of an existing service.
Scope	The audit should include an: • interview with the prospective provider (or contact person) to establish their preparedness to deliver a health and disability service (see Appendix 3 – audit report should include interview guidance and criteria / Standards evidence should be reported on) • audit of the current facility against all Standards.
Provider roles and responsibilities	The prospective provider must: • submit an application, signed declaration and prescribed fee to HealthCERT • provide a certificate of incorporation (or other relevant legal documentation of a business entity) to HealthCERT • engage a DAA to undertake the provisional audit.
DAA roles and responsibilities	The DAA must: • notify the relevant DHB portfolio manager, at least 10 working days prior to audit, of the intention to audit where the provider holds or has applied to hold a contract for services • notify the Ministry's National Services Purchasing, National Health Board at least 20 days before the audit of the intention to audit where the provider holds or has applied to hold a contract for disability services • submit the audit report to HealthCERT within 20 working days of the audit (refer to 10.4.1) • ensure the provider receives a copy of the final audit report.
Outcome	A certificate is issued for a period of one year. A surveillance (announced or unannounced) audit may be required. Note: The current provider will be forwarded the corrective action report after the audit. The current provider is responsible for any corrective actions identified at the provisional audit until the settlement or transfer to the new provider has occurred.

8.2 Partial provisional audit

Definition	A partial provisional audit is undertaken to establish the level of preparedness of a provider (certified or prospective) to provide a new or reconfigured health and disability service.
Applies to	The audit applies to a: • certified provider applying to add a new kind of service to an existing certificate (eg, certified rest home adding a hospital) • certified provider applying to change the configuration of existing services (eg, adding dementia services in a rest home that has previously not had dementia care or increasing the number of beds within an existing service type) • certified provider or prospective provider applying for certification of a new premise (eg, adding a new building as an extension to an existing site or for a building that is not currently providing health and disability services on a new site). Note: It is recommended that providers liaise directly with HealthCERT prior to engaging a DAA as an audit may not be required or HealthCERT may approve a combined audit where other audit activity is imminent. If a partial provisional audit is combined with an unannounced surveillance audit, the latter audit must still be unannounced.
Scope	The audit should include an: • interview with the provider (or contact person) • audit against the following: – HDSS 1.2.1 – HDSS 1.2.2 (Service management) – HDSS 1.2.7 (Human resource management) – HDSS 1.2.8 (Service provider availability) – HDSS 1.3.12 (Medicine management) – HDSS 1.3.13 (Nutrition, safe food and fluid management) – HDSS 1.4.1–1.4.8 (Safe and appropriate environment) – HDSS 3.1 (Infection control management) – for existing providers, any criteria that were partially attained in their most recent audit. The following Standards **must** be rated as fully attained prior to occupation: • 1.4.2 – Certificate of Public Use • 1.4.7 – Approved Fire Evacuation Plan. Where a change to the current plan is required, the provider can evidence that an application has been lodged with the New Zealand Fire Service. In addition, a plan is in place to undertake a trial evacuation at the time of audit • 1.4.7 – an appropriate 'call system' is in place • 1.4.2 – appropriate equipment and amenities are in place • 1.4.2 – the audit evidences that the physical environment minimises harm to residents • 1.2.8 – a documented process that addresses staffing implications and staff recruitment (where required) is, at a minimum, under way at the time of audit.
Provider roles and responsibilities	The provider must: • notify the Ministry of any planned reconfiguration or increase in capacity before implementation • submit an application, signed declaration, prescribed fee and self-assessment (refer to the relevant forms on the HealthCERT website) to HealthCERT • where HealthCERT has determined an audit is required, engage a DAA to undertake the partial provisional audit.

DAA roles and responsibilities	The DAA must: • notify the relevant DHB portfolio manager, at least 10 days prior to audit, of the intention to audit where the provider holds or has applied to hold a contract for services • notify the Ministry's National Services Purchasing, National Health Board, at least 20 days before the audit, of the intention to audit where the provider holds or has applied to hold a contract for disability services • submit the audit report at least eight working days prior to the date the provider intends to commence service delivery • when requested, provide any additional documentation, including where relevant a copy of a current building warrant of fitness (or a certificate of public use in respect of a new site) or written advice from the relevant local authority confirming one is not required for a service currently certified; and a copy of the New Zealand Fire Service's approval of an evacuation scheme or the Fire Service's notification that a scheme will not be approved until after occupation • ensure the provider receives a copy of the final audit report.
Outcome	Additional service type / reconfiguration: The new or reconfigured service will be added to the current certificate (the period of certification will remain unchanged). New site: A certificate will be issued for one year. Surveillance audit may be required (unannounced for aged care and residential psychiatric). Schedule: A new or amended schedule will be developed in response to the findings with progress reporting requirements.
Note specific to Occupational Rights Agreements	A certified provider with Occupational Rights Agreement (ORA) units may request a reconfiguration to provide rest home or hospital-level services in the units. However, such a 'change in use' of parts of a facility may mean that the provider no longer meets the Fire Department requirements and so does not have approval for its fire evacuation plan. If this change of use has happened since the Building Warrant of Fitness (BWOF) was issued, that BWOF will not show that the local authority has acknowledged the 'change of use' and granted an exemption or indicated the possible need for a new BWOF to be issued. In such cases, therefore, the provider needs to ensure that the local authority has assessed the pre-existing BWOF and has granted an exemption until a new BWOF is issued. During a partial provisional audit, auditors then check that a current BWOF is in place and that a fire evacuation scheme has been approved before the provider can use the apartments/studios for hospital or rest home levels of service. Providers are obliged to comply with legislation (HDSS 1.4.2.). Legislation relevant to reconfiguring ORA units includes the Building Act 2004 and the requirements of regulation 3 of the Building Regulations 2002 (ie, the Building Code in Schedule 1).

8.3 Certification audit

Definition	A certification audit is undertaken to determine if a provider is meeting the relevant service standards.
Applies to	The audit applies to: • all providers providing a health or disability service required to be certified under the Act.
Scope	The audit should meet all relevant requirements of the HDSS NZS 8134:2008 using a streamlined audit approach. See Appendix 1 for the list of criteria matched to Standards.
Provider roles and responsibilities	A certified provider must: • ensure that the certification remains current • submit an application, signed declaration and prescribed fee to HealthCERT.
DAA roles and responsibilities	The DAA must: • notify the relevant DHB portfolio manager, at least 20 days prior to audit, of the intention to audit where the provider holds or has applied to hold a contract for services • notify the Ministry's National Services Purchasing, National Health Board, at least 20 days before the audit, of the intention to audit where the provider holds or has applied to hold a contract for disability services • where the relevant DHB or Ministry's Disability Services specifies contractually related issues to be considered at audit, notify the provider of this requirement seven working days prior to audit • undertake the audit no more than three months prior to the expiry of the provider's certificate, unless it has HealthCERT's prior agreement to a different arrangement • submit the audit report at least 20 working days prior to the expiration date on the provider's certificate (refer to 10.4.1) • provide any additional documentation and evidence, including where relevant a copy of a current building warrant of fitness or written advice from the relevant local authority confirming one is not required for a service currently certified; and a copy of the New Zealand Fire Service's approval of an evacuation scheme • ensure the provider receives a copy of the final audit report. Note: For residential disability providers, the audit team must witness medication administration and meal preparation/management.
Outcome	A period of certification for up to five years may be provided (section 29(1) of the Act). All providers are required to have one surveillance audit at the mid-point of this period unless: • an additional surveillance audit is required as a result of information disclosed in the provider surveillance declaration, or • significant shortfalls are identified following an inspection or issues-based audit, or • a condition of certification is the submission of a mid-point surveillance declaration (eg, residential disability – intellectual, physical, sensory). Providers must submit an annual declaration to their DAA by the end of each calendar year for every year in which they have not had any audits (refer to the HealthCERT website for the relevant form).

8.4 Surveillance audit

Definition	A surveillance audit is undertaken part-way through a service provider's period of certification to assure the Ministry that the provider continues to meet all relevant standards. The focus of the audit is on service delivery and review of criteria not fully attained at the previous audit. All surveillance audits carried out as part of aged care residential audits must be unannounced; they are termed spot audits.
Applies to	The audit applies to: • affected providers providing a health or disability service that is certified under the Act.
Scope	The audit should meet all relevant requirements of the HDSS NZS 8134:2008 using a streamlined audit approach. See Appendix 2 for the list of criteria matched to Standards that are required for surveillance audits.
DAA roles and responsibilities	The DAA must: **Notification** • notify the Ministry of the intended date of the unannounced surveillance audit at least three months prior to the audit (as part of provision of quarterly notifications to the Ministry of upcoming unannounced surveillance audits) • notify the relevant DHB portfolio manager, at least 20 days prior to audit, of the intention to audit where the provider holds or has applied to hold a contract for services • notify the Ministry's National Services Purchasing, National Health Board, at least 20 days before the audit, of the intention to audit where the provider holds or has applied to hold a contract for disability services • where the relevant DHB or Ministry's National Services Purchasing, National Health Board specifies contractually related issues to be considered at audit, notify the provider of this requirement seven working days prior to audit (unless it is an unannounced surveillance) • when requested, provide any additional documentation and evidence, including where relevant a copy of a current building warrant of fitness or written advice from the relevant local authority confirming one is not required for a service currently certified; and a copy of the New Zealand Fire Service's approval of an evacuation scheme • ensure the provider receives a copy of the final audit report **Audit activity** • undertake an unannounced surveillance audit where this is a condition of certification • for announced audits, conduct a surveillance no more than six weeks prior to the date on the schedule, unless it has the Ministry of Health's approval for a different timeframe • for unannounced audits, undertake the audit unannounced within three months on either side of the surveillance audit due date • submit the audit report electronically within 20 working days of completing the audit • widen the scope of the surveillance audit to include any aspect of the HDSS if any areas of non-conformity (actual or potential) have been identified as a result of the audit process (eg, as a result of observation while conducting a tour of the service or in the review of clinical files, or in interviews with staff, consumers or relatives).
Outcome	The period of certification does not change. However, a new or amended schedule may be issued in response to the audit result. Note: A provider proposing a reconfiguration of services at the time of a surveillance audit may also be required to undergo a partial provisional audit.

9 General requirements for the audit process

The following audit requirements apply to all service types. For information on a specific service type, refer to the relevant section on that service type **in addition** to this section.

9.1 Combining audits

A combined audit involves completing two audits (eg, certification and partial provisional audit or surveillance and partial provisional audit) at the same time.

A provisional audit cannot be combined with any other audit because the provisional audit is commissioned by the prospective provider whereas any other audit is commissioned by the current provider.

Where it is completing two audits at the same time, the DAA can submit one audit report that covers both of them. The report must have:

1. the 'type of audit' field completed correctly
2. evidence that clearly describes each audit under subheadings for the relevant criteria
3. specific information relating to each audit type included in the general overview section of the report template
4. findings and corrective actions clearly related to the relevant audit type.

Note: Where services have changed (for example, through an increase in capacity or reconfiguration) and are being verified as part of a routine audit, the DAA can just include information about the changes in the general overview section of the report template.

9.2 Auditing against conditions on a certificate

9.2.1 Ministry inspection

Where a service has conditions added to its certificate as a result of a Ministry inspection, the Ministry requires the service provider to submit evidence as part of monitoring requirements directly to the Ministry or to the DHB for aged care providers. The Ministry notifies the DAA of any conditions added to a certificate applying to any of its clients, and the DAA shall audit against these conditions at the next conducted audit.

9.2.2 Requirements from previous non-conformities

When conducting an on-site audit, the DAA shall audit all conditions on the existing certificate. Where a condition has been generated as a result of a corrective action, the DAA shall audit the HDSS standard and **not** merely the completion of the corrective action. This requirement also applies to any conditions that the DAA has monitored through progress reporting.

For example, where an assessment issue has been identified at a prior audit and a finding against HDSS NZS 8134.1.3.4.2. has been made, the DAA shall audit the full requirements of HDSS NZS 8134.1.3.4.2 across the service at the surveillance audit.

9.3 Include relevant information

When conducting audits against HDSS, the DAA shall include all relevant information. This includes (but is not limited to) HDC complaints, police investigations, coroner's inquests, issues based audits and any other notifications, eg, public health.

9.4 Evidence-based auditing

When conducting audits against the HDSS, the DAA shall consider all consumers' experiences of services as an important part of the triangulation of evidence. Principles of sampling apply to the review of documents as well as to interviews and observations.

9.4.1 Sample size

Designated auditing agencies shall ensure an adequate sample size for all audits as follows. The formulae are to be applied to each service type of a certified provider. For example, in aged care, formulae are applied to the number of rest home, dementia, hospital and psychogeriatric beds.

1. The minimum sample of clinical files and consumer interviews shall be the square root of the number of consumers (rounded to the upper whole number) for all certification audits and 0.6 times the square root of the number of consumers for surveillance audits.[11] Alternatively, where the sampling formula for any type of audit produces a number less than five, a minimum of five consumers shall be interviewed and their corresponding clinical files reviewed. Relatives shall be included in the minimum sampling requirements for consumer interviews. Note: Relative and consumer interviews are to be stratified in the audit evidence.

2. At least one tracer for each service type shall be undertaken to review a consumer's care experience using tracer methodology, for example, rest home, dementia, hospital and psychogeriatric beds. See section 9.4.5 for additional information.

3. Auditors shall interview **every** consumer, staff member or relative who specifically requests to be interviewed.

4. In determining the minimum number of medication records to be reviewed as part of the audit, DAAs shall double the number of consumer files reviewed.

5. Where an auditor finds a non-conformity within the minimum sample, sample sizes shall be widened in order to verify whether the case is one of system or process failure, or a one-off anomaly.

[11] See DHB-specific audit processes in section 15 for sampling requirements in DHBs.

6. Auditors shall not allow the service to pre-select samples for them. This requirement applies to samples of staff, consumers and clinical files.

7. Where HealthCERT approval is not required for a multi-site audit plan and the service is spread over a number of sites, or includes a number of specialties or subspecialties, DAAs shall sample in such a manner that it includes each site, specialty or subspecialty. The sample shall represent a minimum of 10 percent of data available in each group.

8. Personnel (staff, management, contractors, visiting health professionals and advocates) shall be interviewed as part of the audit process, as follows.

    a. In determining the minimum number of staff to be interviewed in addition to management, consumers and visiting health professionals, apply the square root rule.

    b. The sample shall represent all shifts and roles of staff, which may mean the sample is larger than that produced by the square root rule. (Note that this requirement may be achieved by interviewing staff working on a day or afternoon shift who also work night shifts as part of rotating duties or relief duties.)

    c. Where possible, interview at least one medical clinician from each service in all audited hospitals.

    d. Ask any visiting advocates present on the day of audit (eg, Age Concern, Grey Power or HDC advocates) whether they wish to be interviewed. Where there is a regular consumer advocate associated with a service, an auditor shall formally ask this person whether they wish to be interviewed (either on site or via a telephone interview prior to the audit).

9. All audits shall include reference to any satisfaction survey (or equivalent) of consumers, relatives and/or staff undertaken by the provider, or on behalf of the provider or funder, since the last certification or surveillance audit. In referencing surveys, the audit team shall include results and actions taken in response to survey results.

9.4.2 Stratified sampling

Auditors shall identify relevant subgroups as part of their sampling methodology in order to consider the different characteristics of the population that the audited service is catering for.

Examples of relevant subgroups for a provider may include consumers:

1. with a particular presentation – for example, impaired cognitive function, behavioural symptoms or a medical condition requiring a specific treatment
2. receiving a specific kind of care – for example, wound care, terminal care, respite care
3. people under 65 years of age receiving YPD services in an aged care environment.

Examples of staff subgroups are:

1. registered nursing staff
2. health care assistants / support workers
3. administrative staff
4. full-time staff
5. part-time or casual staff
6. staff who work night shifts

7. direct staff
8. supervisory staff
9. management staff.

Note: Stratification (including sampling numbers) of residents, families, staff and files is reported in STD 1.3.3.

9.4.3 Random sampling

Random selection of consumers, staff or documents (where any individual or document is as likely to be chosen as the next) reduces the likelihood of bias and allows for accurate generalisation of audit results. In every audit, DAAs shall randomly select a number of clinical files through random sampling in addition to stratified sampling.

On site, auditors are expected to choose consumers and staff for interview as randomly as possible.

9.4.4 Incidental sampling

In incidental sampling, an auditor selects the sample based on the collection of evidence from whomever or whatever comes along (eg, through informal talks with consumers on a tour of the facility). Auditors shall not use incidental sampling as the principal form of evidence collection, although the use of incidental sampling can supplement other information collected throughout the audit process.

9.4.5 Individual tracer methodology

An individual tracer follows the actual care experience of the consumer who is receiving care or treatment at the time of the audit. Selection of a tracer should include a consumer who is receiving complex care and treatment as their experience shows how the provider's systems and processes support the care they receive.

Complex care may encompass multidisciplinary interventions but does not need to be extreme.

Individual tracer methodology requires an auditor to review both chronology and the quality of assessment, care/support and service provision. The consumer record is used as a roadmap to move through the service and follows the experience of the consumer allowing an audit of the continuum of care matched to a consumer's experience of service provision.

Individual tracer methodology changes the focus from written policies and procedures, examined in isolation, to the delivery of care. It enables a form of observation and assessment in which the auditor looks for trends that might point to potential issues at the system level within an organisation. The organisation also has a good opportunity to share examples of current practice.

Auditors must get individuals' verbal consent for their participation where possible.

Individuals shall be current residents or patients who have recently been or are receiving multiple or complex services. In choosing someone receiving more complex care, they are likely to have received services that test the systems and processes of the organisation including transfers within services or between services.

Individual tracer methodology shall involve a review of the consumer file, observation of care, observation of the medication process, observation of the environment and equipment use, review of competencies of staff and interviews with as many people as possible, including but not limited to the consumer and the staff (nursing, medical, support) who have been directly involved in the delivery of services to the consumer. Each tracer should commence in the area where the patient or resident is currently located (particularly for DHB).

Individual tracer samples shall be reported in Standard 3.3 (Service Provision Requirements) and evidenced throughout the HDSS to demonstrate triangulation of evidence.

Note: No identifiable information about an individual shall be included in the tracer description in the audit report.

The following are two examples of how tracer methodology might be used.

1. If a consumer in a residential service has recently experienced a chest infection, the audit would include review of the assessment undertaken when the consumer became unwell, medical care prescribed and delivered, short-term care planning and documentation of the delivery of care in progress records and on observation charts, along with a record of the care experience as recounted by the consumer (and/or their relatives) and staff. Findings are also then matched to relevant policies and procedures.
2. An audit tracing a consumer requiring wound care would include a review of the wound assessment process, care plan, progress of wound healing, liaison between health professionals (for example, wound care nurse and doctor) and management of the consumer's diet, and an interview with the consumer and staff. Findings are also then matched to wound care policies and procedures.

Suitable samples for review of a consumer's care experience include but are not limited to a consumer:

1. who has been involved in an incident or accident
2. who has experienced a recent illness where pain or a complication was a feature
3. in a residential service requiring public hospital admission following a change in their condition
4. receiving palliative care
5. receiving care other than an aged care service type within an aged care setting (for example, respite, palliative or residential disability physical care)
6. is or has recently been involved in an activity or work programme within a residential disability service.

9.4.6 Systems-based tracer methodology

A systems-based tracer is used to audit a process, programme or system across an organisation to determine how well it functions in relation to relevant Standards across an organisation/ facility. The process for undertaking systems-based tracers is similar irrespective of the system being audited. Examples of systems-based tracers include infection prevention and control, and medication management.

To complete a systems-based tracer, the auditor will look at a sample of consumers' care experience to determine how well the system and processes used within the system have responded. A key difference between a systems-based tracer and individual tracer is that the individual tracer looks at multiple systems and processes in relation to the individual and then extends sampling beyond that individual tracer based on the findings from that tracer. The systems-based tracer looks at one system or programme sampling across multiple consumers. Systems-based tracer methodology can be applied to programmes such as falls management or the deteriorating patient.

The process for undertaking systems-based tracers requires:

- a review of relevant documentation such as policies, procedures, internal audits, incident reports, complaints, dashboard reporting and individual tracer results
- an interview or small focus group discussion with staff that are involved in management and delivery of the programme or system. This usually includes direct care staff
- audit of a sample of current consumer records, observation and informal interviews across the organisation which can be used to test the implementation of the process or programme within the system
- analysis that results in the determination of the relevance, reliability, sufficiency and validity of evidence gathered to form audit findings
- audit findings that create clear linkages to relevant Standards
- providing feedback on the findings and analysis to senior and middle management staff.

Requirements of audits to include systems-based tracers are currently required in DHB audits.

Refer to Section 15.2.2 for more information about DHB systems-based tracers including reporting requirements.

9.4.7 Interviewing

Auditors shall use interviews to:

1. gather new audit evidence
2. corroborate audit evidence.

Interviewing of staff, consumers and relatives shall not take place solely in groups.[12] In such a situation an individual may not disclose his or her true opinions, due to the lack of confidentiality.

Interviewing of staff shall include staff directly providing services. It shall not be isolated to management or staff employed in a team leader or management capacity.

Auditors shall apply sampling methodology to interviewing as described in section 9.3.1 above. Note that they should make the sample of a sufficient size to ensure their conclusions are representative of the service they are auditing.

[12] However, staff may be interviewed in pairs or with a support person. Where staff are interviewed together, they should be of the same level (for example, both caregivers or both registered nurses, neither at the managerial level).

Auditors shall use interviewing to corroborate information such as how processes work and their effectiveness. The DAA shall ensure that, when interviewing, auditors:

1. obtain permission from interviewee(s) prior to conducting the interview
2. conduct interviews in an appropriate environment that provides for adequate privacy
3. reduce barriers to effective communication (for example, do not use jargon, and take into account hearing impairments or specific cultural requirements)
4. introduce themselves to the interviewee(s) before beginning the interview
5. explain the purpose of the interview to the interviewee
6. explain that the interview is confidential and that what the interviewee says will not be referenced in a way that could identify them
7. seek permission to take notes
8. start the interview using a standard set of questions[13]
9. use a balance of open and closed questions
10. validate their understanding by summarising information or reflecting it back to the interviewee
11. end the interview by allowing the interviewee to ask any questions or make comments that may not have been covered within the interview.

9.4.7 Relatives

Certification and re-certification audits shall gather information from a sample of relatives, through either an interview or a survey conducted by the DAA. The DAA shall ensure:

1. relatives are interviewed individually or as a family, either in person or in a telephone interview
2. focus group interviewing represents no more than 10 percent of the sample of consumers and relatives
3. where a DAA undertakes a survey of relatives, the survey is posted or emailed to all relatives at least two weeks prior to a certification or re-certification audit. If posted, the survey shall include a pre-paid envelope for the return of the survey.

Unannounced surveillance audits shall include incidental sampling of relatives. This means that DAAs shall ask relatives visiting the service on the day or days of the surveillance audit if they are willing to be interviewed as part of the audit process. Note that if a sufficient sample has been obtained, not all relatives need be asked.

Where relatives are not interviewed as part of the audit process, the audit report shall clearly state the reason why relatives have not been interviewed.

[13] The DAA is responsible for developing questions unless otherwise notified by the Ministry.

9.4.8 Collection of audit evidence

Auditors shall use work documents such as checklists, audit sampling plans and forms for recording information such as supporting evidence, audit findings and records of meetings and interviews to support a consistent standard of collection of information that will form audit evidence.

AS/NZS ISO 19011 defines audit evidence as 'records, statements of fact or other information which are relevant to the audit criteria and verifiable'.

Auditors shall collect evidence using appropriate sampling methods, including but not limited to interviews, documentation and observations.

Auditors shall consider the sufficiency and relevance of the information gathered prior to making audit findings. They shall not use one-off events and unsubstantiated information as the sole basis for an audit finding, but shall use such data as a prompt to collect more information in order to corroborate or repudiate the initial information.

Where an auditor determines that an isolated event posed a serious risk of harm or potential harm to a consumer, they are required to determine that the service in question has remedied the situation and the risk of reoccurrence is negligible, or to further substantiate the risk and make an appropriate audit finding (see section 10.3 on reporting critical and high risks) and agree on an action plan.

Auditors are required to triangulate evidence where possible and at a minimum corroborate each piece of evidence they cite, to increase the reliability of their findings. The corroboration process shall include substantiation from at least two sources.

Auditors shall strive to triangulate evidence as part of the corroboration process. Triangulation requires evidence to be gathered from three sources, by using the following three strategies.

1. Interview consumers, relatives, personnel (managers, staff members), other health professionals (for example, a doctor, a clinical specialist, an allied health professional, Needs Assessment and Service Coordination organisation) and advocates (for example, Age Concern, Grey Power, HDC).
2. Review documents including but not limited to:
    a. plans, policies, procedures, manuals and work instructions (for example, a service's quality and risk management plan, annual plan, clinical policies and procedures, cleaning procedures and infection control manual)
    b. information for consumers and other stakeholders (for example, pamphlets or admission brochures)
    c. clinical records (for example, nursing, medical, allied health, medicines, wound care, completed assessments, progress, complaints, incident and accident records)
    d. other records (for example, personnel records, staff training records or minutes of meetings, consumer, relative and staff satisfaction surveys, complaints)
    e. reports (for example, incident reports, quality assurance or self-assessment reports)
    f. forms (for example, data collection forms used as assessment tools).

3. Observe the process. Observation allows the auditor to review practices in the service on the day of audit, including (but not limited to) assessing elements of the living environment and physical environment; reviewing practices such as activity programmes and the presentation, sufficiency and appropriateness of meals; and identifying any support required by consumers.

The only exception to the requirement for more than one source of evidence is an auditor's sighting of the building warrant of fitness and current operative evacuation scheme approved by the New Zealand Fire Service.

9.4.9 Requirements for electrical testing

Electrical testing needs to be part of a residential facility's safety activities. The Electricity Act 1992, the Health and Safety in Employment Act 1992 and Occupational Safety and Health regulations put the duty of care on both the employer and the employee to ensure the safety of all people using the facility, as with any other work premises.

Testing must be in accordance with Australian and New Zealand Standard AS/NZS 3760 or, for medical equipment, AS/NZS 3551. Standard AS/NZS 3760 specifies the frequency of testing required according to these circumstances.

9.5 Analysis of audit evidence

Auditors shall discuss findings with the whole audit team and **evaluate** evidence objectively to reach conclusions that determine the extent to which requirements have been fulfilled. This includes the evaluation of information collected to identify information that supports conformity and information that does not.

When undertaking an analysis of evidence, the audit team shall determine:

1. whether evidence supports the achievement of criteria (sufficiency)
2. whether evidence has identified deficiencies in systems, policies or processes
3. whether evidence has identified deficiencies in the implementation of systems and processes
4. trends within evidence
5. causes of identified deficiencies, to allow auditors to determine the best Standard or criterion to evidence the non-conformity against and to assist providers to develop and agree on a corrective action plan
6. risks and consequences of issues identified (using the HDSS risk matrix).

Reported evidence must include a narrative that reflects the relationship between:

- evidence collected specific to the Standard
- evaluation of that evidence
- how criteria have contributed to the level of achievement awarded to the Standard.

Conclusions shall be fair, balanced and free of bias.

9.6 Ratings

The audit report shall reflect findings and ratings at the time of the audit. This will ensure that appropriate criteria will be further monitored at subsequent audits. Levels of attainment at criterion and Standard level are defined in HDSS NZS 8134:2008 under 'Audit Framework'.

Auditors shall ensure that they:

1. record in the report an explanation of the reason for any criterion being 'not applicable' to the service being audited
2. document audit evidence for each criterion and Standard in a way that meets the reporting requirements set out in this handbook
3. do not rate as 'fully attained' (FA) any criterion that contains a corrective action planned for a future date. If the client advises the DAA that it has completed a corrective action before the DAA has completed the audit or submitted the report, the grading remains 'partially attained' (PA) or 'unattained' (UA), and the risk rating shall remain as it was determined at the time of the on-site audit. The report may reflect that action has been taken, and the impact of this action on the risk level may be contained in the report commentary
4. where they award a 'continuous improvement' (CI) rating, include audit evidence that demonstrates all of the following:
    a. achievement beyond the expected full attainment
    b. a review process has occurred, including analysis and reporting of findings
    c. evidence of action taken based on findings and improvement to service provision
    d. consumer safety or consumer satisfaction has been measured as a result of the review process

    Note: a CI may be awarded at any audit provided the above conditions are met together with the relevant interpretation of attainment levels of the HDSS NZS 8134:2008 Audit Framework. This may occur at subsequent or consecutive audits.
5. where they are auditing multiple service categories for a single service provider or where multiple wards or service areas provide the same service, award a rating for each criterion that reflects the lowest level of attainment achieved. For example, if:
    a. one medical ward achieves a PA for the same criterion for which another medical ward at the same provider achieves a FA, the rating awarded for this criterion shall be a PA
    b. a rest home service achieves a PA for the same criterion for which the hospital service at the same provider achieves a FA, the rating awarded for this criterion shall be a PA.

Only the following HDSS attainment ratings may be changed within the period between the end of the on-site audit and the submission of the report:

1. NZS 8134.0:2008 1.4.2.1 where this relates to building warrant of fitness or code of conformity
2. NZS 8134.0:2008 1.4.7.3 New Zealand Fire Service approval of an evacuation scheme, or written approval of an exemption.

9.7 Corrective actions

Audit teams shall generate a corrective action request for each audit finding resulting in a PA or UA rating. Audit conclusions resulting in corrective action requests shall:

1. clearly define the extent of the issue (description, level of attainment and risk rating)
2. provide a rationale for the finding
3. describe expected outcomes
4. describe actions to be taken that have been developed by the service provider and approved by the DAA (or alternatively, developed by the DAA and agreed by the service provider) in a corrective action plan. Corrective action planning shall be undertaken in consultation with a DHB portfolio manager or the Ministry's National Services Purchasing, if required actions directly influence a service contract held with a DHB or the Ministry
5. define timeframes for these actions
6. define the method and frequency of reporting to be made against progress.

The service provider is responsible for developing the action plan and implementing the corrective actions. Where a condition on a service provider's certification schedule requires a written progress report to be submitted, the entity responsible for monitoring the provider's progress against corrective actions is stated. A DAA may also undertake on-site auditing to verify progress/completion. (For details on requirements for progress reporting, see section 12.)

10 Audit reporting

The purpose of a DAA undertaking an audit is to provide the Director-General of Health (the Director-General) with an audit report to allow the Director-General to determine if the provider meets the required standards.

Audit reports submitted to the Ministry shall use the Ministry audit reporting template and present evidence that is competent, sufficient, relevant and reliable.

In order for evidence to be:

1. **valid**, it shall:
    a. be collected by appropriately skilled and experienced members of the audit team (that is, technical experts, qualified lead auditors and auditors with clinical expertise matched to the service being audited, as appropriate)
    b. be derived from an adequate sampling methodology (see section 9.3)
    c. demonstrate **corroboration** of evidence, triangulated wherever possible, from a variety of reliable sources
    d. include evidence from documented records **and** interviews with stakeholders that can be substantiated
2. **sufficient**, it shall:
    a. provide detailed information with relevant and quantified examples
3. **relevant**, it shall:
    a. demonstrate the relationship between actual and expected outcomes
    b. be consistent
4. **reliable**, it shall:
    a. report attainment ratings against each Standard and criterion not rated fully attained or where there is a continuous improvement
    b. report risk ratings against each Standard and criterion within the scope of the audit
    c. be proofread, peer reviewed, and endorsed by the lead auditor, before it is submitted to the Ministry.

10.1 Audit report writing guideline

The *Audit Report Writing Guide*, a Ministry guideline for DAAs on preparing audit reports, is available online at: www.health.govt.nz/publication/audit-report-writing-guide.

10.2 Documented evidence

The following minimum standards are required when documenting evidence.

1. Evidence is reported against attainment ratings for all HDSS NZS 8134:2008 at Standards level and for any criterion that is not rated fully attained.

2. Evidence is reported against risk ratings (as specified by HDSS NZS 8134:2008).

3. Evidence reported as unattained, partial attainment, or continuous improvement must be reported at criterion level against the most relevant criterion. This evidence does not need to be repeated at the Standard level as it can be referred to in the Standard level reporting along with the impact of this evidence on the Standard itself.

4. Fully attained (FA) criteria do not need to have evidence reported at criterion level. FA must be populated against the criterion.

5. Audit evidence must not be repeated across Standards and criteria. Place evidence where it is most relevant. Auditors must refrain from issuing non-conformities across multiple criteria or Standards that identify the same issue based on the same evidence as this overstates evidence.

6. All tracer reporting should follow the same format when reporting at Standard level. This requires three paragraphs of two sentences each:

   - why the patient or issue within the system was selected. The severity and frequency of the potential issue or reason for focus
   - how and where the evidence was obtained
   - findings of conformance and non-conformance with any cross referencing to any other Standards or criteria.

   Refer to the HealthCERT auditor resource web-page for an example of tracer evidence.

   Individual tracer evidence must be reported against 1.3.3 and evidenced throughout the HDSS to demonstrate triangulation of evidence. Note that auditors should use field notes, taken whilst auditing a tracer case, to help in documenting information that then forms evidence. The evidence reported must reflect the analysis of this information and relationship of any tracer findings to the service which is then supported by supplementary sampling. This is a necessary step to ensure auditors can state what relevance the tracer findings have at both an individual and aggregated level. Note there should not be detailed reporting of tracer cases that could lead to the identification of the individual. Tracers are used as an example where no detail about the person is required in the report itself.

7. Evidence is quantified (how representative the evidence is, eg, x sampled out of total x or general statement of sample size) and the source of the evidence is stated (eg, in a sample of consumers interviewed).

8. Evidence sources are referenced and do not include any self-assessments that have not been verified or undertaken by an authorised third party.

9. Evidence clearly distinguishes differing service categories and service areas (for example, a dementia unit within a rest home or an acute medical unit within a medical service) where evidence has been collected.

10. Evidence of the involvement of consumer auditors where part of an audit team is traceable in the audit report. This requires the activities undertaken by the consumer auditor to be documented. For example, the consumer auditor interviewed XX residents.
11. Evidence is written in the past tense unless the statement will hold true after completion of the audit in which case it can be written in present tense. Evidence does not include statements of intent.
12. The lead auditor / team leader reviews reports, and they are peer reviewed before they are submitted to the Ministry.

10.3 Reporting of critical and high risks

The lead auditor / team leader or DAA shall report to HealthCERT in writing, within 24 hours of the audit's completion, any services where the level of risk is assessed as critical, according to the HDSS risk matrix.

The lead auditor / team leader or DAA shall report to HealthCERT in writing, within 24 hours of the audit's completion, any services where the level of risk is assessed as high across multiple criteria, posing an increased level of risk that the Ministry should be aware of immediately.

Where a service holds a service contract with a DHB and a DAA identifies critical or high-risk issues, the DAA shall ensure the DHB is aware of the proposed corrective actions required to address risks by forwarding a copy of the corrective actions report to the DHB within 24 hours of the on-site audit's completion.

10.4 Submission of the Ministry of Health audit report

Every audit report shall be submitted electronically to HealthCERT within the Ministry of Health and, in the case of service providers who hold contracts with a DHB, copied to the relevant DHB (unless the DHB states otherwise).

Before submitting the audit report to the Ministry, the DAA shall ensure that:

1. the service provider has had an opportunity to comment on the draft report. The DAA shall clearly document any disagreement between the DAA and provider on the content
2. every mandatory field has been completed (including the executive summary)
3. finding statements and corrective action requests are completed and appropriate to the level of attainment and risk determined
4. the report has been reviewed by the lead auditor / team leader and a peer reviewer, and endorsed by the lead auditor / team leader following peer review
5. the report is complete
6. the report has been received by the service audited.

10.4.1 Timeframes

Certification audit reports are to be submitted whichever is the earlier time of: within 20 working days of the last site visit undertaken; or no less than 20 working days before the certificate expiry date. All other audit reports are to be submitted within 20 working days of the last site visit undertaken.

Any request for an exemption from these timeframes must be negotiated directly with the Ministry on a case-by-case basis.

In the case of multi-site providers, the total number of audits shall be completed within 20 working days (or such other time agreed with the Ministry in advance, and in writing) of the first audit.

10.4.2 Supporting documents

If the content of the audit reporting template is inadequate or incomplete and Ministry advisors need to seek further clarification, HealthCERT will ask the DAA to submit the required evidence. The DAA shall submit this evidence within two working days, in one of the following ways.

1. Upload it against the relevant audit case in PRMS; please also send an e-mail to advise that it is there.
2. Email it to certification@moh.govt.nz or the HealthCERT advisor requesting the information.
3. Send it to HealthCERT, Ministry of Health, PO Box 5013, Wellington.
4. Deliver it to HealthCERT, Ministry of Health, Level 2, 1 The Terrace, Wellington.

Additional evidence that may be required and must be provided on request includes but is not limited to:

1. document reviews
2. audit plans and correspondence between the DAA and provider relevant to the audit
3. conflict-of-interest declarations for each member of the audit team
4. opening and closing meeting records
5. audit field notes, tools, checklists or workbooks completed by individual auditors
6. interview records
7. auditor notes
8. reports written by technical experts or technical expert assessors
9. surveys undertaken by the DAA in respect of the audit.

10.5 Incomplete or inadequate reports

If audit reports present conflicting, incomplete or insufficient supporting evidence, the chief executive officer of the DAA will be notified and the report returned via PRMS to the DAA for correction and re-submission.

HealthCERT advisors review and check the accuracy of the audit report. If any alteration to the audit content is needed, the DAA is contacted and is then responsible for making changes, in consultation with the provider. The timeframe for re-submitting an audit report will be determined on a case-by-case basis but will not be longer than five working days from request.

Where the Ministry has to repeatedly request additional evidence or clarification, or the re-submission of reports, and the DAA has been provided with ample opportunities to rectify the issues but has failed to, the Ministry will treat this as a performance issue and notify the appropriate third-party accrediting body. The Ministry may choose to terminate designation of the DAA.

11 Published audit information

11.1 Published summaries

The intent of publishing audit information is to provide:

- consumers and their families with information about a service with which they can make more informed choices among care options
- the wider public with a snapshot of how a health care provider is performing in relation to the New Zealand Health and Disability Service Standards.

Published summaries will be increasingly available on PRMS for all provider types. The same principles apply to all summaries for publication.

Published audit summaries will be generated by the PRMS. Information for publication will be extracted electronically from the completed audit reporting template. This includes:

- the premise name (or registered address), service type, DHB (where applicable), DAA and certification period
- the executive summary
- finding statements
- corrective action requests
- timeframes for completing corrective action requests.

Published summaries are consumer focused. As the majority of information is extracted from the executive summary, the DAA shall ensure it:

- reviews the current published certification summary on the website when completing a general overview for a surveillance audit. This will ensure information is not repeated (for example, capacity where there are no changes)
- is consistent with the intent of the summary
- considers the reader – for many readers, this report is their first introduction to the provider
- keeps within the set word limits
- follows the Ministry of Health's *Audit Report Writing Guide*.

The general overview, as the section published for all audit types, shall:

- be grouped in 'themes' where possible – for example, 'care planning, documentation and policy development' rather than 'eight partial attainments were identified'
- be written in plain language, without technical terms and abbreviations such as 'Medico Douglas' and 'tertiary-level ACC WSMP'
- give individualised information on the provider – for example, 'The service has completed a number of building renovations since the previous audit …'

- summarise the improvements – for example, 'Improvements made since the last audit include embedding policies and procedures and educating staff on them, and implementing a varied activities programme'
- summarise the shortfalls – for example, 'The audit found one area that requires improvement, related to the safe labelling and storage of chemicals'
- provide a factual narrative – for example, 'Visual inspection of the facility provided evidence that the facility is clean, adequately heated/ventilated and is well maintained'. Avoid vague or value-laden statements such as 'meandering streams', 'picturesque rural views' or 'well-respected' facility.

The table below sets out the word limit and the information that is to be published for each type of audit.

Audit type and word limit	What is published
Certification Maximum of 1400 words	The full executive summary (ie, all sections of the executive summary), the Ministry of Health's conformity summary (ie, 'traffic lights') Finding statements Corrective action requests and timeframes to remedy Progress as corrective actions are amended in the PRMS Corrective Action Monitoring
Surveillance Maximum of 200 words	General overview section The Ministry of Health's conformity summary (ie, 'traffic lights') The overview should comment on changes since the last audit that specifically address areas of non-conformity. Aspects of bed capacity already recorded on website summary at certification need not be repeated in the general overview. Finding statements Corrective action requests and timeframes to remedy Progress as corrective actions are amended in the PRMS Corrective Action Monitoring
Provisional Maximum of 200 words	General overview section This overview should comment on the current level of conformity and the prospective provider's level of preparedness.
Partial provisional Maximum of 200 words	General overview section This overview should comment on the intent of this audit (ie, addition of service or new location), the current level of conformity and, if this audit concerns a new unoccupied site, the prospective provider's level of preparedness; or if the focus is on a reconfiguration or increased capacity, the areas of non-conformity are identified.

Note: Not all providers currently have published audit summaries. Publication of all audit summaries will be progressively implemented throughout 2013 and 2014.

11.2 Publication of full audit reports

Full audit reports for aged care services will be published on the Ministry's website. These reports will be redacted in line with requirements of the Official Information Act 1982 and the Privacy Act 1993. This process will include removing commercially sensitive information; information subject to an obligation of confidence; personal information (including personal health information); and information relating to official investigations or judicial proceedings that are or will be in progress.

11.3 Exception process

If the provider does not wish to have the new summary published, the Ministry will contact the provider directly and discuss their specific concerns. If a satisfactory agreement cannot be reached and the Ministry considers the summary to be factual, the Ministry will give 15 working days' notice of its intention to publish the summary.

If the provider takes action to prevent the publication of the summary, the Ministry will publish a statement to the effect that the provider has requested a summary not be published.

11.4 Publication of addendums

An addendum is an addition to the certification information that is published on the Ministry's website.

The following information can be published as an addendum to the certification audit information:

1. a summary of any audit or inspection conducted by either a DHB (or its representative agency) or the Ministry that has resulted in audit findings substantiating a complaint about the health service provider that has been received
2. a website link to any HDC report naming a health service provider as being in breach of the HDC Code of Rights.

An addendum will be published in chronological order so that the most recent information is readily retrievable.

Addendum information will remain published (that is, will remain online) for seven years.

12 Progress reporting

Written progress reports apply to any certified provider whose schedule contains a condition for progress reporting or monitoring.

12.1 Procedure – all services where progress is required to be monitored by a DAA

Where a condition on a certified provider's schedule requires **'a written progress report to be submitted to the Director-General of Health by a designated auditing agency'**, the responsibility for monitoring the provider's progress lies with the DAA.

The DAA shall ensure the Director-General receives the written progress report by the date specified on the provider's schedule. It shall then assess the progress report to determine if any non-conformity has been corrected since the last audit.

The DAA shall provide to the Ministry on request: all progress reports written by the provider; the documented review of progress by the DAA; and correspondence between the provider and DAA.

The DAA is required to complete the PRMS Corrective Action Monitoring (CAM) case to report to the Ministry on a service provider's progress against all criteria that were not fully attained at audit.

The DAA is required to use the PRMS 'Review by Ministry' notification in the CAM case to report:

1. that a service provider is making inadequate progress, irrespective of the risk rating as it appears in the audit report
2. all criteria and Standards audited as high or critical risk
3. a service provider's progress against Standards or criteria rated unattained, regardless of the associated risk rating
4. a service provider's progress against HDSS 1.2.8.1 (service provider levels and skill mixes) irrespective of the risk level as it appears in the audit report.

DAAs should attach supporting information when requesting a review by the Ministry.

If a review is not required, then the DAA may choose 'Reporting Complete'.

DAAs shall report new information received from providers into the PRMS within five working days of receiving it.

Where the Ministry becomes aware of a particular issue with a provider (for example, a consumer complaint or DHB or HDC Office concerns) and the issue relates to criteria identified within a scheduled progress report, it may contact the DAA for information.

13 Unannounced surveillance audits

Surveillance audits can be announced or unannounced (spot) depending on the requirements on the schedule to the certificate.

Where a surveillance audit is announced, the DAA undertaking the audit notifies the provider ahead of the audit and agrees a date to undertake the audit. The DAA will also liaise with the provider when developing the audit plan and audit schedule.

Where the surveillance audit is an unannounced (spot) audit, the DAA will not contact the provider prior to the audit.

If the manager of a service to be audited (or their deputy or other designated temporary manager) is not present on the day of audit and the auditors are unable to access all necessary documentation to verify information, the auditors shall determine the criteria partially attained.

In the following instances the auditor shall contact the manager the next day and obtain the information that the auditor needs to make a determination where:

1. an up-to-date complaints register does not contain all complaints because the manager is holding a separate file on a current complaint under investigation for confidentiality reasons (HDSS 1.1.13.3)
2. records of ongoing education for staff are held in human resources files that are not accessible to staff working on the day of the audit (HDSS 1.2.7.5).

If the usual health professional or clinical manager responsible for a clinical service is not available on the day of an unannounced audit, the auditor shall arrange and conduct a phone interview with that person in order to obtain sufficient evidence before determining achievement of criteria relevant to the role of the health professional or clinical manager.

14 Aged residential care (rest home and hospital geriatric) – specific audit process requirements

Note: The requirements below are **in addition** to the general requirements outlined in section 9.

HDSS audits are integrated with audits under the Age Related Residential Care (ARRC) service agreement and/or Aged Residential Hospital Specialised Services (ARHSS) service agreement.

Any other service kind being concurrently provided at an aged residential care service, for example physical disability must be audited clearly distinguishing the service kind in sampling and reporting.

14.1 Funder involvement in aged residential care audits

At least 20 days prior to each audit, the DAA is required to contact the relevant DHB or Health of Older Persons Portfolio Manager and NSP where applicable (funder), in accordance with the process below. The funder will provide any relevant information to the DAA to support its audit planning. Additionally, the funder will notify the DAA if it wishes a funder representative to attend all or part of the audit. The DAA shall get agreement from the provider where the funder wishes to attend any part of the audit.

When notifying the funder of an upcoming audit, please include the:

- premise name
- names of the audit team members
- date of audit
- type of audit.

After a DAA has undertaken an audit, its audit report will not be considered final until the funders and the Ministry (HealthCERT) have reviewed the report for completeness. If the funder or HealthCERT requests follow-up on a specific issue relating to a provider (prior to the audit), the DAA must address this issue clearly in the body of the audit report. The DAA must submit the audit report within the required timeframes (see details for each type of audit in section 8) to HealthCERT via the PRMS.

Note: The funder will view the report via the PRMS.

14.2 Document review

The DAA must complete a document review before every on-site certification audit. The auditors should use the review to help them to prepare for the audit, reducing the need to review policies and procedures while on site. The review should assist the provider in preparing for the audit and allow it the opportunity to make minor corrections or improvements to policies and procedures if required.

1. The DAA must request documents required for the review at least 30 working days before the scheduled on-site audit. The list of documents requested must match the document review reporting template available on the Ministry website.
2. The lead auditor or second auditor appointed to the team performing the on-site audit must complete the document review.
3. The DAA must send the report to the provider using the document review reporting template (available on the Ministry website) at least 20 working days prior to the scheduled on-site audit.
4. The provider may use information from the document review report to make changes to policies and procedures often associated with minor non-conformity.
5. Any documents that a provider changes between the document review and on-site audit must be reviewed by the auditors at the on-site audit.

14.3 Safe and appropriate environment checklist

Providers should be encouraged to complete a safe and appropriate environment checklist as part of their preparation for a certification audit. Auditors should refer to the provider's completed checklist at the on-site audit.

1. The DAA must ensure the provider receives a copy of the safe and appropriate environment checklist available on the Ministry website at least 20 working days before the scheduled on-site audit, together with instructions for its completion.
2. The audit team must request a copy of the completed checklist and refer to it while completing the on-site audit.

14.4 On-site audit

1. Auditors must refer to the document review completed before the on-site audit so that they do not request documents for review when they have already been reviewed, which is unnecessary unless a point of clarification or verification is required.
2. Auditors must request and refer to the safe and appropriate environmental checklist where a provider has completed one in preparation for the on-site audit. Auditors should use this checklist to help them audit standards within NZS 8134.1.4:2008. Use of this checklist does not negate the need for a tour of the service.
3. When on site, auditors shall refer to section 14.9Occupational Right Agreement (ORA).[14]

[14] ORA is also known as Care Suites, Licence to Occupy (LTO) and Rent to Occupy (RTO).

14.5 Sampling

Where possible, interview at least one general practitioner providing services to the consumers of the audited services[15] in all audited aged residential care services.[16]

Auditors must undertake a minimum of one tracer for each service type. In addition, where there is a dementia care or psychogeriatric care service, or physical disability, they must undertake a tracer for each of these services that applies.

In determining sample size, auditors shall consider each service type (see section 9.4).

14.6 Progress reporting procedure – for aged residential care services

Where a condition on a certified provider's schedule requires **'a written progress report to be submitted to the Director-General of Health by your district health board'**, the responsibility for monitoring the provider's progress lies with the DHB.

Note: The DAA shall still determine the corrective actions required, identify risk levels and set timeframes for action within the audit process. The DHB will request and approve the corrective action plan and monitor progress against the corrective action plan, including entering progress information into the PRMS.

14.7 DHB owned / operated aged care services

Where a DHB owns an aged care facility or a multi-service facility that includes aged care service provision, a general overview of the aged care service is required for publication. The DAA shall audit these services in accordance with the integrated audit process for those services holding a contract with a district health board to provide aged residential care services and it shall ensure the information relevant to the aged care service is recorded separately from the other services. Use headings within each Standard and Criterion of the audit report and ensure equivalent audit evidence is reported for the aged residential care service as it would be otherwise reported if audited with its own certificate.

Where the aged residential care service is audited separately from the DHB provider audit, the DAA will monitor progress unless otherwise specified as a condition on the certificate schedule.

[15] A telephone interview is acceptable if the GP is not be at the facility on the day(s) of the audit. Note that if the GP declines to be interviewed, this must be recorded in the audit report and shall not affect the level of attainment awarded for any criterion.

[16] Certification and surveillance audits. This requirement does not apply to disability services.

14.8 interRAI requirements

From 1 July 2015, aged residential care facilities are obligated to use the interRAI Long Term Care Facilities (LTCF) assessment to inform their care planning. Auditors undertaking certification and surveillance audits against the HDSS should consider how the interRAI LTCF is being used to inform assessment and care planning.

interRAI is an international collaborative that has a suite of validated comprehensive clinical assessment instruments. The interRAI Long-Term Care Facilities Assessment (interRAI LTCF) provides a standardised comprehensive instrument to assess and evaluate the needs, strengths and preferences of residents receiving long term residential care.

Registered nurses are required to meet annual obligations to maintain their competency and are randomly selected for quality review and endorsement of their competency status.

The interRAI LTCF should be used as a generalised assessment which is first completed within 21 days of admission as part of meeting ARRC obligations. For long term care planning, the interRAI LTCF should be done first before other assessments as additional assessments may not be necessary. Some assessments previously done in aged residential care homes will be redundant when using interRAI LTCF as the interRAI assessment outcomes are validated against standard assessments (eg, Mini-Mental Score). More in-depth assessments may be required where a specific need has been identified by a screener (eg, pain scale). Where other assessments are undertaken, the results should be recorded in the comments sections in the Minimum Data Set (MDS) before the interRAI assessment is closed by the assessor.

The interRAI LTCF assessment process includes direct interviewing of the resident, their primary support person (if available), observation of the resident, communication with other members of the care team and a review of available documents including medical records.

The assessment triggers Clinical Assessment Protocols (CAPs). CAPs identify areas where there is the possibility of resolving the problem, where there is a higher than expected risk of decline and where there is an increased potential for improvement. CAPs are used to inform care planning. The registered nurse uses their clinical judgement to determine which CAPs will be included in the care plan. Where the clinical decision is not to include any CAP in the care plan, this decision must be recorded on the Assessment Summary. Care in response to CAPs is in addition to standard care needs that have been identified by the assessment, irrespective of CAPs.

In conjunction with triggered CAPs, Outcome Measures, calculated automatically, evaluate and provide measures of the current clinical status. Outcome Measures include the ADL Hierarchy Scale- measure of disability; ADL Short and Long Form Scales (the level of performance in activities of daily living), Aggressive Behaviour Scales; CHESS – Changes in health, end-stage disease, signs and symptoms (medical instability); Cognitive Performance Scale; Communication Scale; Depression Rating Scale; Pain Scale; Pressure Ulcer Risk and Body Mass Index. The lower the score, the lower the level of disability or risk for the resident level of disability or risk to the resident.

The following reports will assist auditors in determining how an interRAI LTCF assessment has been completed and used to inform care planning. These are:

- Assessment Summary (page 22 of the LTC MDS report)
- MDS Comments
- Client Summary Report – triggered CAPs and Outcome Scores
- Care Plan.

As part of the interRAI system, there is resident level and integrated reporting available. The Residents Listing Assessments Due report and Wound Management Report may provide useful information to inform audits. Other reports such as the CAP trending by resident report and the weight and BMI by resident report may also be useful to identify change in resident status.

For more information refer to the interRAI LTCF Handbook for NZ use: www.centraltas.co.nz/LinkClick.aspx?fileticket=PPlwltvnla4%3D&tabid=259&mid=933.

14.8.1 Auditing requirements

The following areas should be considered when auditing the following HDSS.

Standard	interRAI area of relevance
1.2.3 (Quality and Risk Management Systems)	Policies and procedures updated to include appropriate reference to interRAI LTCF. Also review any integrated reporting used by the facility that helps inform quality improvement.
1.2.7 (Human Resource Management)	Sufficient number of RNs interRAI competent (endorsed) meeting the annual obligations for maintaining competency).
1.2.9 (Consumer Information Management Systems)	Information is accurately entered into the notes to the assessment on Momentum (the interRAI software programme). This includes entering other assessments results that have been clinically indicated in the comments section in the Minimum Data Set (MDS). The Assessment Summary will indicate the clinical decisions regarding the inclusion of CAPs and Outcome scores and other identified needs that will be addressed in the care plan.
1.3.4 (Assessment)	Effective from 1 July 2015, All new residents admitted have an interRAI assessment completed or is in progress. The first interRAI LTCF assessment (from admission) must be completed within 21 days of admission. It should include the review of any previous interRAI assessments (LTCF or Home Care) noted in the comments to the assessment. interRAI LTCF is being used as the generalised assessment with other assessments being undertaken as clinically indicated (or as per the aged residential care facilities policies). Ensure cultural needs have been identified and recorded into the comments of the LTCF and the need for cultural needs to be care planned is identified on the Assessment Summary. The interRAI LTCF assessment process is being followed (ie, the assessment information is referenced to the identified Assessment Reference Date (ARD) and the related look back periods. reference to interviews with the resident, their family and other health professionals and review of relevant documentation is included in the notes to the assessment). The interRAI LTCF assessment results are discussed with the resident (as recorded on the care plan or in resident progress notes).

Standard	interRAI area of relevance
1.3.5 (Planning)	The interRAI Assessment, Assessment Summary which includes triggered CAPs, Outcome Scores and the needs identified by the Registered Nurses clinical judgement informs the care plan. The following reports have been reviewed by the RN as part of the planning process: • Assessment Summary (page 22 of the LTC MDS report) • MDS Comments • Client Summary Report (CAPs and Outcome Scores) • Care Plan.
1.3.8 (Evaluation)	Reassessments are completed using the interRAI LTCF within the last six months. (Effective from January 1, 2016) Effective from July 1, 2015, All significant health status change reassessments have been completed using interRAI LTCF. Review any resident level trending reports that have been used to inform the evaluation and reassessment process.

14.9 Hospital-level care in Occupational Right Agreement units

Where an aged residential care service includes the provision of hospital level services with Occupational Rights Agreements (ORAs), the audit report shall include specific reference to ORA services. Reporting shall include how services meet the relevant criteria of the Age Related Residential Care (ARRC) services agreement that relate to ORA services and include commentary in the following Standards and Criteria:

- HDSS 1.2.7 and 1.2.7.3
- HDSS 1.2.8 and 1.2.8.1
- HDSS 1.4.7 and 1.4.7.1; 1.4.7.2; 1.4.7.7.

Note: The audit should include determining that each resident's needs are being met within the environment in which they live. Auditors should focus on the safety of residents who may be receiving rest home level care and hospital-level care in ORA units. Consider the following issues in particular:

- it would not be safe for an ORA unit to be isolated from the care unit and in a separate building without 24-hour care staff. ORA units should preferably be adjacent to the care facility and within the same footprint
- there should be enough staff to meet the needs of all residents, with priority given to the care of hospital-level residents
- there should be at least two care staff at all times in all areas of the ORA units, which may be in addition to the requirements of the ARRC agreement
- the registered nurse on duty should be able to call on more staff if the residents' acuity levels change
- if a staff member from another area of the facility is 'on call' to assist in the ORA units, that staff member should not be leaving the area they normally work in shortstaffed when they are called away
- care staff hours reviewed at audit should be for care only and no other duties
- responses to call bells and sensor mat alerts should be in line with the provider's policy and the HDSS, and should be monitored frequently

- care staff should be available to assist with ORA residents' meals in addition to the staff available in the dining room. Additional staff may be needed or meals could be served at different times
- registered nurse coverage should be adequate to fulfil all the duties expected under the ARRC agreement
- if CCTV monitoring is used, it should not replace staff in a hospital care ORA environment.

14.9.1 Notifying DHBs

When undertaking an audit to verify that ORA units are suitable for aged care services, the DAA needs to notify the relevant DHB. The DHB can then give feedback to the DAA and Ministry about any relevant concerns.

14.10 Charges

There are instances where providers charge subsidised residents extra for services that are additional to services covered by the Age-Related Residential Care (ARRC) agreement. Auditors should check these service charges comply with clauses A13, A14 and D13 of the ARRC agreement and any attachments to the agreement specific to ORA and reporting as appropriate under HDSS 1.1.10 and HDSS 1.3.1.

Further information is available at: www.dhbsharedservices.health.nz/Site/Health-of-Older-People-/Default.aspx

14.11 Auditor guidance specific to dementia services

When auditing aged residential services against HDSS NZS 8134:2008 the audit team shall consider the purpose of Specialist dementia services and consider the safe environment and therapeutic care needs of residents with dementia. See www.health.govt.nz/publication/new-zealand-framework-dementia-care

Consumer rights

1.1.10: All residents have an appointed Enduring Power of Attorney, where an EPOA is not in place the provider is supporting actions to have one appointed.

Organisational management

1.2.1 and 1.2.2: The service organisation philosophy and strategic plan reflect a person/family-centred approach to all services.
1.2.7: All staff have completed dementia training as set out in the ARRC agreement.

Continuum of service delivery

1.3.1: Specialist referral to the service is confirmed; EPOA has consented for the resident to be admitted.
1.3.5: Resident files reviewed for behaviour management plans including triggers and interventions for behaviours.

1.3.7: A holistic 24/7 approach to activities is available and includes aspects of the resident's life and past routines.
1.3.13: Nutritional needs are met and include the availability of snack food available 24/7.

Safe and appropriate environment

1.4.2: The environment design should provide safe areas that encourage purposeful walking; this includes easy access to a safe outdoor area. For more information reference Appendix H of SNZ HB 8134.5:2005.
1.4.7: The services emergency plan considers the special needs of people with dementia in an emergency.

14.12 Auditor guidance specific to young physically disabled people

Although important to all people receiving health and disability service, when auditing aged residential services against HCSS NZS 8134:2008 that include physical disability services subject to certification, the audit team should pay particular attention to the following:

Consumer rights

1.1.3: Young people with disabilities are able to maintain their personal, gender, sexual, cultural, religious and spiritual identity.
1.1.9: Language and communication needs and use of alternative information and communication methods are available and used where applicable.
1.1.12: The service is responsive to young people with disabilities accessing the community, resources, facilities and mainstream supports such as education, public transport and primary health care services in the community. The service promotes access to family and friends.

Organisational management

1.2.1 and 1.2.2: The service organisation philosophy and strategic plan reflect a person/family centred approach.
1.2.7: All staff participate in continuing education relevant to physical disability and young people with physical disabilities.

Quality and risk management systems

1.2.3: Young people with disabilities have input into quality improvements to the service. Satisfaction with choices, decision making, access to technology, aids, equipment and services contribute to quality data collected by the service.

Continuum of service delivery

1.3.5: Support plans are person centred, developed with the person and includes wellbeing, community participation, meeting physical needs and health needs where the service has a role to play.
1.3.7: Young people with disabilities are able to participate in a range of education, recreation, leisure, cultural and community events consistent with their interests and preferences.
1.3.12: The service facilitates young people with disabilities wishing to self-medicate.

Safe and appropriate environment

1.4.2: Sufficient equipment is available (personal equipment is not used for other residents). The facility is accessible to meet the mobility and equipment needs of people receiving services.
1.4.5: The facility includes places where young people with disabilities can find privacy within communal spaces. There is consideration of compatibility with residents.
1.4.7: The services emergency plan considers the special needs of young people with disabilities in an emergency.

15 District health boards – specific audit process requirements

Note: The requirements below are **in addition** to the general requirements outlined in section 9. Certification requirements are described separately to surveillance requirements. Requirements that are the same for certification as surveillance are more fully described in the certification section.

15.1 Certification audits

15.1.1 DHB self-assessment

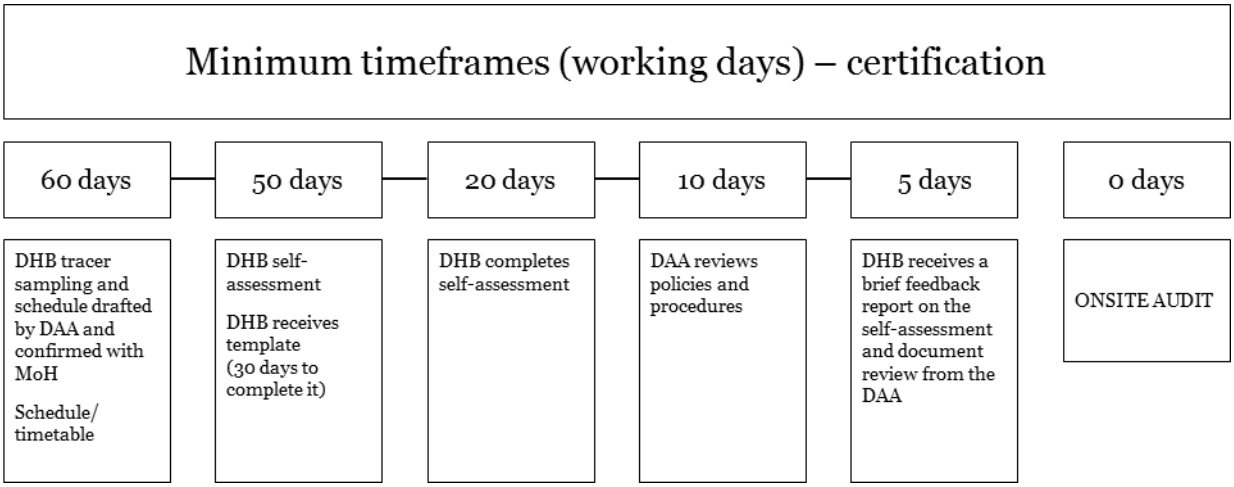
The DHB self-assessment process is designed to reduce the audit activity required at the on-site audit and take into full consideration internal and external audit activities, benchmarking and quality monitoring that occurs in DHBs. For example, it is not necessary to re-audit a kitchen or laundry service that has been externally audited and for which a third party is managing corrective actions.

At least 50 days before an audit the DAA shall request the DHB to complete a self-assessment using the self-assessment template (available from the Ministry website). The DHB has 30 days (4 weeks) to complete the self-assessment.

At least 20 working days before an audit, the DAA must receive the completed self-assessment from the DHB for review. The lead auditor, and/or other auditors delegated by the lead auditor that are part of the on-site audit team, must undertake the review.

At least 10 working days before a certification audit, the DAA must arrange to view DHB policies and procedures.

At least five working days before the audit, the DAA must provide the DHB with a brief report that comments on the self-assessment and review of policies and procedures.



15.1.2 Scheduling

The DAA must submit timetable and sampling plan for an audit to the Ministry no later than 60 working days before an audit. The sampling plan shall include a list of speciality and clinical areas, bed numbers in wards and units where services are provided 24/7 across the DHB. The timetable shall include individual and system-based tracer numbers.

HealthCERT will give approval when the DAA has met all requirements for the timetable, audit team and sampling plan.

15.1.3 Timetable

The timetable should include the names of auditors and technical expert assessors that will be present at the audit. The DAA has a responsibility to update HealthCERT in relation to any changes to the audit timetable, particularly where they involve a change in team membership, start time, completion time or site changes. Note that changes to an approved timetable will require re-approval by HealthCERT.

The timetable is to be sufficiently detailed to provide a clear understanding of:

- start and finish times for each day
- auditor team meetings
- time (and auditor/s) allocated to each service, including auditor activity to be completed – for example, 'staff interviews (3), file review (2), medication chart review (4)'
- travel time between sites if relevant
- scheduled interviews with key personnel such as Chief Operating Officer (or Chief Executive Officer), Director of Nursing, Chief Medical Officer, After Hours Manager
- any technical experts and/or technical expert assessors involved, including which auditor they are working with
- any trainee auditor involved and the auditor supporting them. The provider is notified (and agrees to) trainee auditors attending the audit. There shall be no more than one trainee auditor on any audit. The DHB is not to incur any additional cost in having a trainee auditor participate in an audit.

15.1.4 Auditor selection

The DAA must ensure that in addition to requirements set out in section 6, the audit team members meet the role description requirements for the lead auditor in Appendix 4 and auditor in Appendix 6.

15.1.5 Technical expert assessor selection

Technical expert assessors will be part of the audit team for DHB certification audits. The technical expert assessors will undertake tracers in their clinical specialty area. Technical expert assessors must work within the role description for a technical expert assessor (see Appendix 5).

The auditors and technical expert assessors will work as part of the audit team. The Ministry will allocate technical expert assessors to audits from its register of technical expert assessors.

Note: Once allocated to an audit, the DAA is responsible for arranging all travel, accommodation and other disbursements for technical expert assessors. Technical expert assessors are paid by their current employer and no costs other than disbursements can be passed on to the DHB being audited.

15.2 Certification sampling

15.2.1 Sampling plan

The DAA shall base each sampling plan on resourced bed numbers and staffing levels as determined by the provider. It is acknowledged actual sample sizes may show marginal variance, auditors will need to recalculate them on day one of the audit based on actual patient numbers.

Contracted staff shall be included in sample size where outsourced services are evidenced (eg, Spotless Catering) and there is no current independent audit report available for that service.

The methodology to determine the sample size is as follows:

- clinical files: tracer files and in addition a minimum of the square root of the **total** number of inpatients in that clinical area/ward. Note that where a sample is widened in response to non-conformities, the sampling is in addition to the minimum sampling requirement
- medication charts: tracer files and clinical file samples
- individual tracer sampling requirements have been developed for each DHB. The tracer requirements are available from HealthCERT
- staff interviews: staff identified within the tracer samples plus clinical leaders and service managers within each clinical and non-clinical service necessary to obtain and triangulate evidence
- patient and relative interviews: within the context of the tracers identified and additional incidental sampling within wards and departments which should at a minimum equate to 0.6 square root of the total sample of clinical files

When stratifying large services, it is acceptable for auditors to take a 'sensible' approach to maximise the effectiveness of auditor time on site. (For example, where it is apparent there are like services, such as two general surgical wards, the audit can be undertaken in full in one ward.) However, auditors are to visit tertiary and secondary clinical services and/or regional services and clearly delineate them on the sampling plan provided to HealthCERT.

15.2.2 Tracer sampling

Sampling includes individual tracers and systems-based tracers.

1. Individual tracers must concentrate on the journey of a consumer through the hospital system with a particular focus on risk points (eg, handovers and transfer of care between units).

2. A minimum of one individual tracer per service type is required.

3. Auditors and technical expert assessors should jointly choose individual tracers following a brief tour of a clinical area in discussion with the clinical team or unit manager. The team leader, or unit manager on the auditor's behalf, must gain consent before the tracer begins. Verbal consent is acceptable.

4. Auditors shall choose individual tracers that represent complexity in either the consumer's clinical presentation or their journey through a hospital system. Examples of consumers suited to this methodology are a:
   - patient with limited mobility who uses oxygen or has cognitive impairment
   - patient who has had multiple hospital admissions
   - surgical patient whose recovery included a stay in the intensive care or a high dependency unit
   - medical patient who has been transferred from a cardiac care unit
   - child who has been admitted from the emergency department, is nearing discharge and will receive specialist district nursing services upon discharge
   - baby that has been through both maternity and neonatal services.

   It is important to coordinate tracer selection with the lead auditor to avoid overlap of visits to various services or units as much as possible.

   In DHBs with multiple sites, individual tracers shall include patients who move between locations and services.

   See section 9.4.5 for additional information on individual tracer methodology.

5. Two systems-based tracers will be completed at the certification audit.

   a. **Medication management:** Auditors look at a sample of consumers who are receiving a high-risk medicine, or for which close monitoring is needed, or evaluate the introduction of a new medication or medication practice, for example, pain relief. This will include reviewing staff education specific to the medication, patient education, medication management processes, evaluation of the continuity of the process (prescribing, dispensing, administration and monitoring) and evaluation of medication reconciliation across the continuum. The tracer should begin with an interview with at least one member of pharmacy/medication committee. Interviews as part of the tracer process should include ward staff (doctors, nurses, educators, patient and pharmacist).

      The completion of this tracer should take no more than half an auditor day to complete. Report findings from the medication management tracer in Standard 1.3.12.

b. **Infection prevention and control:** Auditors choose a high-risk consumer group or an outbreak event as the basis for reviewing the planning, implementation and evaluation of the infection prevention and control programme. The tracer should begin with an interview with at least one member of the infection control committee and review of desktop information before moving to the relevant clinical areas.

   The completion of this tracer should take no more than half an auditor day to complete. Report findings from the infection prevention and control tracer in Standard 3.2 or Standard 3.5 (as appropriate).

15.2.3 Incidental sampling

Incidental sampling is required to ensure sufficient information is gathered to form audit evidence and ensure the audit is reliable.

1. Incidental sampling of files must include informed consent, observation records, progress notes and medication charts. The simplest way to do this is to take the square root of the number of patients in a clinical area to create an additional sample. Sampling should commence in the clinical area where the tracer is being undertaken and applied to other clinical areas based on that patient's journey. This means that auditors will work across multiple clinical areas throughout the audit process.

   Incidental sampling must also include patient and relative interviews to determine their satisfaction with services and the DHB's conformity with consumer rights standards.

   Auditors shall use several approaches to gain patient, family and whānau perspectives. The approaches shall include in-depth interviews related to the tracer, informal interviews with patients, family and whānau (in addition to tracers), interviews with staff who hold positions specific to patient or family and whānau liaison, and review of satisfaction survey results and complaint information.

   An interview with the general practitioner liaison staff member, should also be undertaken to gather information about entry and exit from services (including discharge planning and transfer of information).

   Note: Incidental sampling can be undertaken consecutively with patient and systems-based tracers. Auditors must conduct additional sampling throughout the audit process to ensure conformity with the Standards. This includes but is not limited to the review of information held at ward level, service level and organisational level, such as quality monitoring records, minutes of meetings, patient satisfaction survey results and complaints information, staff training opportunities, orientation to clinical areas and staffing/roster issues.

2. Where issues arise in tracers or incidental sampling as described above, auditors should take a wider sample specific to the particular issue to establish whether the finding is a single incident or a systemic issue. Auditors should ensure their sample is sufficient and that this is in addition to the planned incidental sampling.

15.2.4 Staff interviews

Auditors shall record the exact number of staff interviews by designation in their field notes; for example, 'Medicine – Senior Medial Officer x2; Charge Nurse Manager x5'.

Where group discussions are part of auditors' introduction to the service, these do not contribute to the tally of the total number of staff interviewed; instead, they are to be recorded within evidence against Standards.

The following do not constitute interviews in terms of sampling requirements:

- informal conversations
- clarification of file layout and process
- database familiarisation with staff.

15.3 Using self-assessments

When reviewing the self-assessment, the DAA will determine what information provided requires validation. Independent reports and third party audits do not require validation.

Where validation of the self-assessment is required, the DAA should take a sampling approach considering:

- information submitted with the self-assessment that provides evidence to support narrative conclusions in the report
- reviewing information submitted with the self-assessment to determine whether it is sufficient to demonstrate conformance
- interviewing the quality manager or delegated person responsible for completion and submission of the self-assessment
- on-site auditing of areas identified in the self-assessment as being partially attained or not attained
- on-site auditing of areas identified in the self-assessment as having insufficient supporting evidence where an interview with the quality manager has not clarified concerns
- on-site auditing of a small sample from the self-assessment to determine validity of findings where it has not been possible to validate this by reviewing supporting evidence.

Note that on-site sampling can be included within incidental sampling undertaken with tracer activity.

15.4 Daily meetings

The lead auditor shall hold a daily meeting with a DHB representative, at which they offer a concise summary of audit activities undertaken to date. The lead auditor shall make general comments on significant issues arising, note any specific positive findings and emphasise trends that could lead to partial attainment ratings. The lead auditor shall give the DHB the opportunity to provide information that may have been missed and schedule time for more extensive discussion or review and review the agenda for the day ahead.

Prior to the briefing meeting, the lead auditor shall ensure the audit team has had an opportunity to discuss their findings to date. This discussion can cover whether issues identified that are likely to be systemic or isolated.

15.5 Audit reporting

The draft audit report will be peer reviewed and proof read before it is given to the DHB. The DAA shall give DHBs at least 10 working days to complete their review of the draft audit report. Refer to section 11.1 for guidance. Corrections should include corrections of fact as well as requests for change where audit evidence is inaccurate.

15.6 Progress reporting

DHBs are responsible for managing progress monitoring in conjunction with the Ministry. There is no requirement for DAAs to participate in this process.

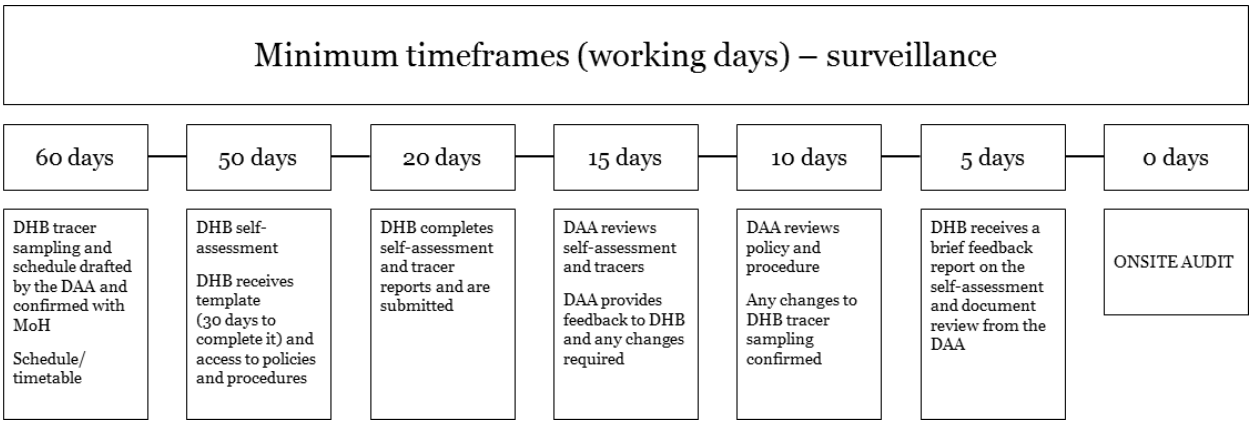
15.7 Surveillance audits

15.7.1 DHB self-assessment

The self-assessment for surveillance audit will include an update to the self-assessment completed for the certification audit.

DHBs have the option of undertaking individual tracers in the lead up to the surveillance audit. Where this occurs tracer results are also reported as part of the self-assessment process. Only any new or changed policies and procedures should be reviewed. Note that viewing may be arranged via remote access to the DHB server.

At least five working days before the audit, the DAA must provide the DHB with a brief report that comments on the self-assessment and review of policies and procedures.



15.7.2 Scheduling

As for certification audits. In addition, the DAA should refer to the CAMS report available within the PRMS.

15.7.3 Timetable

As for certification audits.

15.7.4 Auditor selection

As for certification audits.

15.7.5 Technical expert assessor selection

The Ministry will decide on a case-by-case basis whether one or more technical experts are required for a surveillance audit. Where required, the process is the same as for certification audits.

15.8 Surveillance sampling

15.8.1 Sampling plans

As for certification audits.

15.8.2 Tracer sampling

The extent of the requirement of the DAA to undertake individual tracers is dependent on the DHBs decision to complete individual tracers as part of its self-assessment process.

For each DHB surveillance audit, the DAA will always undertake one maternity tracer and one mental health tracer (dependent on these service types being within the scope of the audit).

Where a DHB has not completed individual tracers as part of its self-assessment, one individual tracer for each service type will be undertaken by the DAA.

Where a DHB has completed individual tracers, the DAA will not complete individual tracers for the service types that the DHB has completed individual tracers unless approved by HealthCERT.

The individual tracer process is the same as for certification audits.

1. Four systems-based tracers should be completed at surveillance audits.
    a. **Medication management:** As for certification audits.
    b. **Infection prevention and control:** As for certification audits.
    c. **Deteriorating patients:** Auditors review the system used by the DHB to recognise and respond to clinical deterioration in acute care settings. This will include an interview or focus group meeting with the patient at risk team (or equivalent) and gathering information about the early warning system (or equivalent), how it is implemented including weekends and after hours; and how it is monitored. Documents to be reviewed include incident reporting, internal audits or other quality monitoring. In addition to sampling across the organisation, it is recommended that a sample of patients to review as part of the audit is obtained through patients identified as being at risk from the afterhours report, patients in the High Dependency Unit, patients discharged from the High Dependency Unit, patients in Intensive Care Unit, patients discharged from the Intensive Care Unit, patients admitted to the Medical or Surgical Assessment Units as this will ensure the sample will include patients who have deteriorated or are at high risk of deterioration. In addition to the review of clinical files, the systems-based tracer

activity includes interview of patients or relatives (where possible), educators and direct care staff (doctors, nurses, allied health professionals).

Note:

- The system for management of the deteriorating patient should include adults and paediatrics; and any satellite/regional hospitals.
- The completion of this tracer should have one auditor day assigned.
- It is not necessary to go to the emergency department to complete this tracer.

Report findings from the deteriorating patient tracer in Standard 1.3.8; and additionally in other standards and criteria as relevant.

d. **Falls prevention:** Auditors review the falls prevention programme used by the DHB. This will include consideration of governance structures and systems for the prevention and management of falls and how patients are screened or assessed and strategies implemented including patient education and disclosure (treatment injury).

e. Review of documents includes incident reporting, risk assessments, education, reporting and monitoring consistent with Health Quality and Safety Commission guidelines and requirements.[17] Audit activities in a sample of wards and units should include implementation of risk assessment and care planning processes and observation of the environment essential in preventing falls. In addition to the review of clinical files and observation in clinical areas, the systems-based tracer activity includes interview of patients or relatives (where possible), educators and direct care staff (doctors, nurses, allied health professionals).

The completion of this tracer should take no more than half an auditor day to complete.

Report findings from the falls prevention tracer in Standard 1.3.4; and additionally in other standards and criteria as relevant.

Note that the system-based tracer sampling is part of the timetable which must be approved by HealthCERT.

15.8.3 Incidental sampling

As for certification audits. If applying a square root rule for determining the size of the incidental sample, auditors may apply 0.6 the square root if this will result in a sufficient sample.

15.8.4 Staff interviews

As for certification audits.

[17] www.hqsc.govt.nz/our-programmes/reducing-harm-from-falls/

15.9 Validating self-assessments including individual tracers completed by DHBs

As for certification audits.

In addition, the validation of individual tracers undertaken by DHBs shall include:

- review of the individual tracer report to ensure it includes all required fields of the template
- on-site review of the actions taken in response to the individual tracer where it has identified opportunities for improvement
- on-site interview of a sample of staff that either undertook or participated in the tracer process.

Note that where the DAA determines an individual tracer cannot reliably be used to supplement on-site audit activities following its review of the individual tracer report, the DAA will provide notification of this to HealthCERT and the DHB prior to completing the on-site audit. HealthCERT will review the individual tracer information provided and will either work with the DHB to ensure another tracer is undertaken prior to the audit or approve additional individual tracers to be undertaken on-site by the DAA.

15.10 Daily meetings

As for certification audits.

15.11 Audit reporting

As for certification audits.

15.12 Progress reporting

As for certification audits.

16 Residential disability – specific audit process requirements

This section applies to residential disability services excluding residential disability – psychiatric. For residential disability – psychiatric, see section 17 and Appendix 7.

Note: The requirements below are **in addition** to the general requirements outlined in section 9.

16.1 Interpretation

Guidance has been developed for auditors to ensure they take into consideration the service type, scope and complexity when auditing residential disability services. See Appendix 7 for this guidance.

16.2 Audit preparation

16.2.1 Contacting National Services Purchasing, Ministry of Health

At least 20 days prior to each audit, the DAA must contact National Services Purchasing, National Health Board, Ministry of Health. National Services Purchasing will provide any relevant information to the DAA to support its audit planning.

16.2.2 Developing the sampling plan

The DAA develops the sampling plan in consultation with the provider, HealthCERT, who will liaise with the National Quality Group, National Health Board, Ministry of Health to ensure the sample is appropriate. Where psychiatric services form part of the provider's certified services, HealthCERT will also consult the relevant DHB portfolio manager.

The DAA must forward its proposed sampling plan to HealthCERT no less than 20 working days and no more than three months before the audit. Where the provider changes the configuration or location of premises after the sample has been agreed, it may be necessary to audit these premises in addition to the agreed sample.

The DAA notifies the provider of the facilities to be audited only when sending the audit plan to the provider. The DAA may discuss the following with the provider:

- the number of facilities for audit
- the number of facilities for a site visit as part of the audit process
- the methodology – see sections 16.2.4 and 16.4.1 below.

The total number of audits shall be completed within 20 working days (or as agreed in writing with the Ministry) and submitted within 20 working days of the last audit.

Specific requirements are that:

- where multiple sites are included within one certificate, the period of certification will be based on the lowest level of achievement obtained by the provider for any one site
- for 'respite only' services, the audit team must conduct the audit while residents are in attendance.

16.2.3 Sampling – multiple sites

A multi-site provider will be eligible for site sampling where the provider demonstrates a centralised management structure that includes:

1. system documentation and systems changes
2. management review
3. complaints
4. evaluation of corrective actions
5. internal audit and self-assessment planning and evaluation of results
6. service user assessment.

16.2.4 Sampling – number of homes for certification

For certification audits the minimum number of homes audited will equate to no fewer than ($y = \sqrt{x}$) rounded to the upper whole number unless otherwise agreed with HealthCERT.

The calculation will be made separately based on service variation (for example youth or adult services) and service complexity (for example challenging behaviours). Then select homes based on:

1. significant variations in the size of the service and number of service users
2. complexity of the service provider and variance within the service kind
3. geographical location – for example, grouped within DHB localities or similar (eg, regional management structure of a national organisation)
4. homes where issues related to service delivery have been identified
5. ensuring the sample includes homes that were not audited at the last certification audit or were not visited as part of a developmental evaluation within the last certification period.

Note: This approach should not significantly increase the overall sample size for the audit; rather, rotate the sample.

16.2.5 Sampling – interviews and record review

Sample sizes for interviews and record reviews are managed as set out in section 9. In the case of disability services, an auditor may interview the Needs Assessment and Service Coordination organisation (NASC).

The DAA shall also record the number of interviews and records to be reviewed, in the sampling plan it submits to HealthCERT before the on-site audit.

Note: For residential disability houses subject to certification with 5 or fewer residents, all files are sampled.

16.3 Publication

Audit summaries and corrective actions shall not identify homes (or individual sites) specifically.

Note: No information will be published at the mid-point of certification unless an on-site surveillance audit has been undertaken.

16.4 Surveillance audits

Providers who offer combined services (eg, aged residential care and residential disability (psychiatric) or mental health services) and residential disability are subject to surveillance audit requirements.

Residential disability providers who offer intellectual, physical or sensory services are not automatically subject to an on-site surveillance audit unless this is a condition of certification.

Where HealthCERT identifies the need for an on-site surveillance audit, and specifies a future date, the DAA will undertake an on-site visit within 30 working days of that date.

16.4.1 Sampling methodology – surveillance audits

For surveillance audits, the minimum number of homes evaluated will equate to no fewer than $(0.6(y = \sqrt{x}))$ rounded to the upper whole number.

16.5 Surveillance monitoring

Residential disability providers who offer intellectual, physical or sensory services and do not have an on-site surveillance audit as a condition of certification are subject to the surveillance monitoring and reporting requirements described below.

16.5.1 Provider responsibilities for surveillance monitoring

The provider is responsible for meeting all conditions of certification. This includes submitting a provider surveillance declaration to the DAA (it can download this form from the Ministry's website) by the mid-point of surveillance together with a copy of a corrective action progress report and most recent developmental evaluation report.

Note: The provider is responsible for ensuring the developmental evaluator has received a copy of the certification audit report and any onward progress monitoring.

16.5.2 DAA responsibilities for surveillance monitoring

The DAA is responsible for:

1. ensuring the provider submits all necessary information to the DAA on the dates due. This must include the developmental evaluation report where one is available and any progress reports
2. reviewing the submitted declaration and associated information
3. contacting the developmental evaluator if more information is required following discussion with the provider, review of the developmental evaluation report and any progress reports
4. submitting a surveillance report to the PRMS within 20 working days of receiving the provider surveillance declaration
5. providing HealthCERT with additional information, including all documents and the declaration the provider submitted to the DAA, if HealthCERT requests it. Note HealthCERT is likely to make this request where the DAA recommends an on-site surveillance audit.

17 Residential disability – psychiatric

This section applies to residential disability – psychiatric and any community-based mental health providers subject to certification requirements.

Note: The certification process for residential disability – psychiatric and community-based mental health providers subject to certification requirements is undergoing a change process. As a result, DHBs may issue information in relation to additional audit activities that are a clip-on to the certification audit process where audit activities are outside the scope of a residential disability service that is subject to certification.

Note: The requirements below are **in addition** to the general requirements outlined in section 9.

Integrated audits

HDSS audits are integrated with audits under the Tier 1, 2 and 3 Mental Health Service Specifications that apply to residential services. Visit www.nsfl.health.govt.nz/apps/nsfl.nsf/pagesmh/498 for specific information

17.1 Audit preparation

17.1.1 Contacting the DHB

At least 20 days prior to each audit, the DAA must contact the relevant DHB or Mental Health Portfolio Manager in accordance with the process below. The DHB will provide any relevant information to the DAA to support its audit planning. Additionally, the DHB will notify the DAA if it wishes a DHB representative to attend all or part of the audit. The DAA shall get agreement from the provider where the DHB wishes to attend any part of the audit.

When notifying the DHB of an upcoming audit, please include the:

- premise name
- names of the audit team members
- date of audit
- type of audit.

After the DAA has undertaken an audit, its audit report will not be considered final until the DHB and the Ministry (HealthCERT) have reviewed the report for completeness. If the DHB or HealthCERT requests follow-up on a specific issue relating to a provider (prior to the audit), the DAA must address this issue clearly in the body of the audit report. The DAA must submit the audit report within the required timeframe (see details of each type of audit in section 8) to HealthCERT via the PRMS.

Note: The DHB will view the report via the PRMS.

17.1.2 Preparation to include relevant service specifications

The DAA shall include relevant service specifications from the Nationwide Service Framework and any DHB provider specific specifications in audit tools it develops to ensure capture of contractually relevant requirements within the integrated audit process.

17.1.3 Sampling plan

Follow the sampling plan requirements as set out for residential disability services in section 16.

17.2 On-site audit

Within the integrated audit process, the DAA shall thoroughly audit the following areas within the Tier 1 Mental Health and Addiction Services Service Specification and related Tier 2 and Tier 3 Service Specifications which include residential services:

- services will be responsive
- Māori Health
- Pacific Health
- key inputs
- service links.

Note: Audit reporting templates will not have cross-references which means the DAA auditors need to be explicit within their reporting as to contractual aspects.

17.2.1 Relapse prevention

When auditing residential disability – psychiatric or mental health services against HDSS NZS 8134:1.3.5.4, note that in the case of people who have been consumers of mental health services for two years or more, the Ministry focuses on relapse prevention planning through DHB accountability processes. As such, it requires DAAs to pay particular attention to relapse prevention planning in their audits. A relapse prevention plan is defined by the Ministry as follows:

> Relapse prevention plans identify early relapse warning signs of clients. The plan identifies what the client can do for themselves and what the service will do to support the client. Ideally, each plan will be developed with involvement of clinicians, clients and their significant others. The plan represents an agreement and ownership between parties. Each plan will have varying degrees of complexity depending on the individual. Each client will know of (and ideally have a copy of) their plan.

17.3 Progress reporting procedure

Where a condition on a certified provider's schedule requires **'a written progress report to be submitted to the Director-General of Health by your district health board'**, the responsibility for monitoring the provider's progress lies with the DHB.

Note: The DAA shall still determine the corrective actions required, identify risk levels and set timeframes for action within the audit process. The DHB will request and approve the corrective action plan and monitor progress against the corrective action plan including entering progress information into the PRMS CAMs.

17.4 Unannounced surveillance audits

As in some residential disability (psychiatric) services it may be more likely that a full service will be away on a day trip or holiday, the DAA should ask providers to submit to it, at least three months prior to the notice period, any dates that create a direct conflict within the six-month window in which an unannounced surveillance audit may take place.

Note: For multi-site providers with a head office or regional office, the unannounced audit should commence at that site.

Appendix 1: Streamlined audit criteria certification audits

The audit should meet all relevant requirements of the HDSS NZS 8134:2008.

		Rest home and hospital care – geriatric services	Residential disability	Residential disability – psychiatric	DHB including mental health	Specialist (eg, private surgical, hospice, maternity)
1.1	**Consumer rights**					
Std 1.1.1	Consumer rights during service delivery	1.1.1.1	1.1.1.1	1.1.1.1	1.1.1.1	1.1.1.1
Std 1.1.2	Consumer rights during service delivery	1.1.2.3 1.1.2.4	1.1.2.3 1.1.2.4	1.1.2.3 1.1.2.4	1.1.2.3 1.1.2.4	1.1.2.3 1.1.2.4
Std 1.1.3	Independence, personal privacy, dignity and respect	1.1.3.1 1.1.3.2 1.1.3.6 1.1.3.7	1.1.3.1 1.1.3.2 1.1.3.6 1.1.3.7	1.1.3.1 1.1.3.2 1.1.3.6 1.1.3.7	1.1.3.1 1.1.3.2 1.1.3.6 1.1.3.7	1.1.3.1 1.1.3.2 1.1.3.6 1.1.3.7
Std 1.1.4	Recognition of Māori values and beliefs	1.1.4.2 1.1.4.3 1.1.4.5	1.1.4.2 1.1.4.3 1.1.4.5	1.1.4.2 1.1.4.3 1.1.4.5 1.1.4.7	1.1.4.2 1.1.4.3 1.1.4.5	1.1.4.2 1.1.4.3 1.1.4.5
Std 1.1.5	Recognition of Pacific values and beliefs			1.1.5.1 1.1.5.2	1.1.5.1 1.1.5.2	
Std 1.1.6	Recognition and respect of the individual's culture, values and beliefs	1.1.6.2	1.1.6.2	1.1.6.2	1.1.6.2	1.1.6.2
Std 1.1.7	Discrimination	1.1.7.3	1.1.7.3	1.1.7.2 1.1.7.3 1.1.7.4 1.1.7.5	1.1.7.2 1.1.7.3 1.1.7.4 1.1.7.5	1.1.7.3
Std 1.1.8	Good practice	1.1.8.1	1.1.8.1	1.1.8.1	1.1.8.1	1.1.8.1
Std 1.1.9	Communication	1.1.9.1 1.1.9.4	1.1.9.1 1.1.9.4	1.1.9.1 1.1.9.4	1.1.9.1 1.1.9.4	1.1.9.1 1.1.9.4
Std 1.1.10	Informed consent	1.1.10.2 1.1.10.4 1.1.10.7	1.1.10.2 1.1.10.4 1.1.10.7	1.1.10.2 1.1.10.4 1.1.10.7	1.1.10.2 1.1.10.4 1.1.10.7 1.1.10.8 1.1.10.9	1.1.10.2 1.1.10.4 1.1.10.7 1.1.10.8 1.1.10.9
Std 1.1.11	Advocacy and support	1.1.11.1	1.1.11.1	1.1.11.1	1.1.11.1	1.1.11.1
Std 1.1.12	Links with family/whānau and other community resources	1.1.12.1 1.1.12.2	1.1.12.1 1.1.12.2	1.1.12.1 1.1.12.2	1.1.12.1 1.1.12.2	1.1.12.1 1.1.12.2
Std 1.1.13	Complaints management	1.1.13.1 1.1.13.3	1.1.13.1 1.1.13.3	1.1.13.1 1.1.13.3	1.1.13.1 1.1.13.3	1.1.13.1 1.1.13.3

		Rest home and hospital care – geriatric services	Residential disability	Residential disability – psychiatric	DHB including mental health	Specialist (eg, private surgical, hospice, maternity)
1.2	**Organisational management**					
Std 1.2.1	Governance	1.2.1.1 1.2.1.3	1.2.1.1 1.2.1.3	1.2.1.1 1.2.1.3	1.2.1.1 1.2.1.3	1.2.1.1 1.2.1.3
Std 1.2.2	Service management	1.2.2.1	1.2.2.1	1.2.2.1	1.2.2.1	1.2.2.1
Std 1.2.3	Quality and risk management systems	1.2.3.1 1.2.3.3 1.2.3.4 1.2.3.5 1.2.3.6 1.2.3.7 1.2.3.8 1.2.3.9	1.2.3.1 1.2.3.3 1.2.3.4 1.2.3.5 1.2.3.6 1.2.3.7 1.2.3.8 1.2.3.9	1.2.3.1 1.2.3.3 1.2.3.4 1.2.3.5 1.2.3.6 1.2.3.7 1.2.3.8 1.2.3.9	1.2.3.1 1.2.3.3 1.2.3.4 1.2.3.5 1.2.3.6 1.2.3.7 1.2.3.8 1.2.3.9	1.2.3.1 1.2.3.3 1.2.3.4 1.2.3.5 1.2.3.6 1.2.3.7 1.2.3.8 1.2.3.9
Std 1.2.4	Adverse event reporting	1.2.4.2 1.2.4.3	1.2.4.2 1.2.4.3	1.2.4.2 1.2.4.3	1.2.4.2 1.2.4.3	1.2.4.2 1.2.4.3
Std 1.2.5	Consumer participation			1.2.5.1 1.2.5.2 1.2.5.3 1.2.5.4 1.2.5.5	1.2.5.1 1.2.5.2 1.2.5.3 1.2.5.4 1.2.5.5	
Std 1.2.6	Family/whānau participation			1.2.6.1 1.2.6.2 1.2.6.3	1.2.6.1 1.2.6.2 1.2.6.3	
Std 1.2.7	Human resource management	1.2.7.2 1.2.7.3 1.2.7.4 1.2.7.5	1.2.7.2 1.2.7.3 1.2.7.4 1.2.7.5	1.2.7.2 1.2.7.3 1.2.7.4 1.2.7.5	1.2.7.2 1.2.7.3 1.2.7.4 1.2.7.5	1.2.7.2 1.2.7.3 1.2.7.4 1.2.7.5
Std 1.2.8	Service provider availability	1.2.8.1	1.2.8.1	1.2.8.1	1.2.8.1	1.2.8.1
Std 1.2.9	Consumer information management systems	1.2.9.1 1.2.9.7 1.2.9.9 1.2.9.10	1.2.9.1 1.2.9.7 1.2.9.9 1.2.9.10	1.2.9.1 1.2.9.7 1.2.9.9 1.2.9.10	1.2.9.1 1.2.9.7 1.2.9.9 1.2.9.10	1.2.9.1 1.2.9.7 1.2.9.9 1.2.9.10
1.3	**Continuum of service delivery**					
Std 1.3.1	Entry to services	1.3.1.4	1.3.1.4	1.3.1.4 1.3.1.5	1.3.1.4 1.3.1.5	1.3.1.4 1.3.1.5
Std 1.3.2	Declining referral/entry to services	1.3.2.2	1.3.2.2	1.3.2.2	1.3.2.2	1.3.2.2
Std 1.3.3	Service provision requirements	1.3.3.1 1.3.3.3 1.3.3.4	1.3.3.1 1.3.3.3 1.3.3.4	1.3.3.1 1.3.3.3 1.3.3.4 1.3.3.5 1.3.3.6	1.3.3.1 1.3.3.3 1.3.3.4 1.3.3.5 1.3.3.6	1.3.3.1 1.3.3.3 1.3.3.4
Std 1.3.4	Assessment	1.3.4.2	1.3.4.2	1.3.4.2 1.3.4.5	1.3.4.2 1.3.4.5	1.3.4.2
Std 1.3.5	Planning	1.3.5.2 1.3.5.3	1.3.5.2 1.3.5.3	1.3.5.2 1.3.5.3 1.3.5.4	1.3.5.2 1.3.5.3 1.3.5.4	1.3.5.2 1.3.5.3
Std 1.3.6	Service delivery/interventions	1.3.6.1	1.3.6.1	1.3.6.1 1.3.6.3 1.3.6.5	1.3.6.1	1.3.6.1
Std 1.3.7	Planned activities	1.3.7.1	1.3.7.1	1.3.7.1	1.3.7.1	1.3.7.1
Std 1.3.8	Evaluation	1.3.8.2 1.3.8.3	1.3.8.2 1.3.8.3	1.3.8.2 1.3.8.3 1.3.8.4	1.3.8.2 1.3.8.3 1.3.8.4	1.3.8.2 1.3.8.3
Std 1.3.9	Referral to other health and disability services (internal and external)	1.3.9.1	1.3.9.1	1.3.9.1	1.3.9.1	1.3.9.1
Std 1.3.10	Transition, exit, discharge or transfer	1.3.10.2	1.3.10.2	1.3.10.2	1.3.10.2	1.3.10.2

		Rest home and hospital care – geriatric services	Residential disability	Residential disability – psychiatric	DHB including mental health	Specialist (eg, private surgical, hospice, maternity)
Std 1.3.11	Use of electroconvulsive therapy (ECT)				1.3.11.1 1.3.11.2 1.3.11.3 1.3.11.4	
Std 1.3.12	Medicine management	1.3.12.1 1.3.12.3 1.3.12.5 1.3.12.6	1.3.12.1 1.3.12.3 1.3.12.5 1.3.12.6	1.3.12.1 1.3.12.3 1.3.12.5 1.3.12.6 1.3.12.7	1.3.12.1 1.3.12.3 1.3.12.5 1.3.12.6 1.3.12.7	1.3.12.1 1.3.12.3 1.3.12.5 1.3.12.6
Std 1.3.13	Nutrition, safe food and fluid management	1.3.13.1 1.3.13.2 1.3.13.5	1.3.13.1 1.3.13.2 1.3.13.5	1.3.13.1 1.3.13.2 1.3.13.5	1.3.13.1 1.3.13.2 1.3.13.5	1.3.13.1 1.3.13.2 1.3.13.5
1.4	**Safe and appropriate environment**					
Std 1.4.1	Management of waste and hazardous substances	1.4.1.1 1.4.1.6	1.4.1.1 1.4.1.6	1.4.1.1 1.4.1.6	1.4.1.1 1.4.1.6	1.4.1.1 1.4.1.6
Std 1.4.2	Facility specifications	1.4.2.1 1.4.2.4 1.4.2.6	1.4.2.1 1.4.2.4 1.4.2.6	1.4.2.1 1.4.2.4 1.4.2.6	1.4.2.1 1.4.2.4 1.4.2.6	1.4.2.1 1.4.2.4 1.4.2.6
Std 1.4.3	Toilet, shower and bathing facilities	1.4.3.1	1.4.3.1	1.4.3.1	1.4.3.1	1.4.3.1
Std 1.4.4	Personal space/bed areas	1.4.4.1	1.4.4.1	1.4.4.1	1.4.4.1	1.4.4.1
Std 1.4.5	Communal areas for entertainment, recreation and dining	1.4.5.1	1.4.5.1	1.4.5.1	1.4.5.1	1.4.5.1
Std 1.4.6	Cleaning and laundry services	1.4.6.2 1.4.6.3	1.4.6.2 1.4.6.3	1.4.6.2 1.4.6.3	1.4.6.2 1.4.6.3	1.4.6.2 1.4.6.3
Std 1.4.7	Essential emergency and security systems	1.4.7.1 1.4.7.3 1.4.7.4 1.4.7.5 1.4.7.6	1.4.7.1 1.4.7.3 1.4.7.4 1.4.7.5 1.4.7.6	1.4.7.1 1.4.7.3 1.4.7.4 1.4.7.5 1.4.7.6	1.4.7.1 1.4.7.3 1.4.7.4 1.4.7.5 1.4.7.6	1.4.7.1 1.4.7.3 1.4.7.4 1.4.7.5 1.4.7.6
Std 1.4.8	Natural light, ventilation and heating	1.4.8.1 1.4.8.2	1.4.8.1 1.4.8.2	1.4.8.1 1.4.8.2	1.4.8.1 1.4.8.2	1.4.8.1 1.4.8.2
2	**Restraint minimisation and safe practice**					
Std 2.1.1	Restraint minimisation	2.1.1.4	2.1.1.4	2.1.1.4	2.1.1.4	2.1.1.4
Std 2.2.1	Restraint approval and processes	2.2.1.1	2.2.1.1	2.2.1.1	2.2.1.1	2.2.1.1
Std 2.2.2	Assessment	2.2.2.1	2.2.2.1	2.2.2.1	2.2.2.1	2.2.2.1
Std 2.2.3	Safe restraint use	2.2.3.2 2.2.3.4 2.2.3.5	2.2.3.2 2.2.3.4 2.2.3.5	2.2.3.2 2.2.3.4 2.2.3.5	2.2.3.2 2.2.3.4 2.2.3.5	2.2.3.2 2.2.3.4 2.2.3.5
Std 2.2.4	Evaluation	2.2.4.1 2.2.4.2	2.2.4.1 2.2.4.2	2.2.4.1 2.2.4.2	2.2.4.1 2.2.4.2	2.2.4.1 2.2.4.2
Std 2.2.5	Restraint monitoring and quality review	2.2.5.1	2.2.5.1	2.2.5.1	2.2.5.1	2.2.5.1
Std 2.3.1	Safe seclusion use* *Residential disability – ID only		2.3.1.1 2.3.1.2 2.3.1.3 2.3.1.4 2.3.1.5		2.3.1.1 2.3.1.2 2.3.1.3 2.3.1.4 2.3.1.5	
Std 2.3.2	Approved seclusion* rooms *Residential disability – ID only		2.3.2.1 2.3.2.2 2.3.2.3 2.3.2.4		2.3.2.1 2.3.2.2 2.3.2.3 2.3.2.4	

		Rest home and hospital care – geriatric services	Residential disability	Residential disability – psychiatric	DHB including mental health	Specialist (eg, private surgical, hospice, maternity)
3	**Infection prevention and control**					
Std 3.1	Infection control management	3.1.1 3.1.3 3.1.9	3.1.1 3.1.3 3.1.9	3.1.1 3.1.3 3.1.9	3.1.1 3.1.3 3.1.9	3.1.1 3.1.3 3.1.9
Std 3.2	Implementing the infection control programme	3.2.1	3.2.1	3.2.1	3.2.1	3.2.1
Std 3.3	Policies and procedures	3.3.1	3.3.1	3.3.1	3.3.1	3.3.1
Std 3.4	Education	3.4.1 3.4.5	3.4.1 3.4.5	3.4.1 3.4.5	3.4.1 3.4.5	3.4.1 3.4.5
Std 3.5	Surveillance	3.5.1 3.5.7	3.5.1 3.5.7	3.5.1 3.5.7	3.5.1 3.5.7	3.5.1 3.5.7
Std 3.6	Antimicrobial				3.6.1 3.6.4	3.6.1 3.6.4
Total		**101**	**110**	**128**	**141**	**106**

Note: * And ID services.

Appendix 2: Streamlined audit standards surveillance audits

A surveillance audit for all providers other than District Health Boards should include the following Standards.

1.1 Consumer rights	
Std 1.1.9	Communication
Std 1.1.13	Complaints management
1.2 Organisational management	
Std 1.2.1	Governance
Std 1.2.3	Quality and risk management systems
Std 1.2.4	Adverse event reporting
Std 1.2.7	Human resource management
Std 1.2.8	Service provider availability
1.3 Continuum of service delivery	
Std 1.3.3	Service provision requirements
Std 1.3.6	Service delivery/interventions
Std 1.3.7	Planned activities
Std 1.3.8	Evaluation
Std 1.3.12	Medicine management
Std 1.3.13	Nutrition, safe food and fluid management
Mental health only	
Std 1.3.5	Planning
Std 1.3.10	Transition
1.4 Safe and appropriate environment	
Std 1.4.2	Facility specifications (confirmation building warrant of fitness if applicable)
Std 1.4.7	Essential emergency and security systems (if any alterations to building since last audit and date of last fire drill)
2 Restraint minimisation and safe practice	
Std 2.1.1	Restraint minimisation
3 Infection prevention and control	
Std 3.5	Surveillance

Additionally it should include **all partially attained and unattained criteria and Standards identified at the previous audit** (see section 9.2).

A surveillance audit for District Health Boards should include the following Standards.

1.1 Consumer rights	
Std 1.1.10	Informed consent
Std 1.1.13	Complaints management
1.2 Organisational management	
Std 1.2.3	Quality and risk management systems
Std 1.2.4	Adverse event reporting
Std 1.2.8	Service provider availability
1.3 Continuum of service delivery	
Std 1.3.3	Service provision requirements
Std 1.3.4	Assessment
Std 1.3.6	Service delivery/interventions
Std 1.3.8	Evaluation
Std 1.3.10	Transition, exit, discharge, or transfer
Std 1.3.12	Medicine management
Mental health only	
Std 1.3.5	Planning
1.4 Safe and appropriate environment	
Std 1.4.2	Facility specifications (confirmation building warrant of fitness if applicable)
Std 1.4.7	Essential emergency and security systems (if any alterations to building since last audit and date of last fire drill)
2 Restraint minimisation and safe practice	
Std 2.1.1	Restraint minimisation
3 Infection prevention and control	
Std 3.5	Surveillance

Appendix 3: Provisional or partial provisional audit – the interview with the prospective provider

Whenever a rest home or hospital service (geriatric care) changes ownership, auditors undertake a provisional audit. Through this process they establish:

- how well prepared the prospective provider is to provide a health and disability service
- the extent to which the existing provider conformed to requirements before the service changed ownership.

A necessary part of this process is to interview the prospective provider (or contact person). If this person is not present for the full audit then an off-site interview is acceptable. During the interview, the auditor shall determine whether the prospective provider meets all of the following Standards/criteria.

- The prospective provider knows and understands the consumer rights that it must adhere to (1.1.2).
- The prospective provider has an established organisational structure (governance and management) and a predetermined lead-in time. It has identified any changes to key personnel (involving governance, organisational management, clinical management and team leader level) that will occur after taking ownership of the service, and has confirmed management and registered nurse full-time equivalent staff (FTE) (1.2.1, 1.2.8).
- The prospective provider has developed a transition plan with timelines, if required, allowing timeframe for implementation (1.2.1).
- Where it is planning changes within the service that may affect the service's capacity to meet the requirements of the Health and Disability Services Standards, the prospective provider is aware of the issues and taking steps to ensure it will continue to meet those requirements.
- Any plans for environmental changes to the service comply with legal requirements (1.4.2).
- There are no legislative compliance issues (for example, concerning health and safety, employment, local body) that could affect the service (1.2.4).
- The prospective provider will produce an annual quality plan and has established quality management systems including schedules for internal audit, changes and continuity (1.2.3).
- The prospective provider has a policy regarding staff skill mix, including contractual obligations and acuity of consumers within the service (1.2.8).
- The prospective provider has established plans for service management, such as determining who will cover when rostered staff are absent and managing staff changes (1.2.2).
- Where it is changing existing operational (management and clinical) policies or procedures, the prospective provider has ensured the changes will meet the requirements of the Health and Disability Services Standards (1.2.3).

The provisional audit report must include evidence of the prospective provider's preparedness against each of the above criteria.

Appendix 4: Role description – lead auditor, DHB audits

Introduction

The lead auditor requires a thorough understanding of the relationship between the Health and Disability Services Standards, district health board systems, services and outcomes and how risk is managed in a complex environment.

The lead auditor has expert skills in identifying potential risk points and facilitates effective, constructive and collegial communication with the audit team and DHB leadership.

The lead auditor provides leadership and direction of the audit team and is responsible for applying systems analysis skills and inductive reasoning skills to determine the degree of conformity with HDSS and the functionality of care delivery systems across the DHB.

The lead auditor also undertakes audit activities as set out in the audit schedule.

This description outlines specific requirements for lead auditors working within DHBs that are **in addition** to those outlined in the *Designated Auditing Agency Handbook*.

Functions

There is one allocated lead auditor for each DHB audit. The role is not a shared role as other members of the audit team must be senior auditors and/or technical experts or technical expert assessors who require minimal supervision.

The lead auditor for DHBs is approved for DHB audits by the Ministry.

Note: The following list of functions is not exhaustive but is aimed to assist the lead auditor / team leader to better understand their role in relationship to DHB audits.

Working with the audit team

Ensures auditors and technical experts or technical expert assessors:

- are conversant with results from stage one of the audit
- work collaboratively to collect audit evidence
- undertake all tasks and activities in accordance with the audit schedule
- flag any emerging issues with the lead auditor at the earliest opportunity.

Stage one of the audit

- Is responsible for requesting and analysing self-assessment report and associated data. Note the analysis cannot be delegated to administration or support staff.
- Is responsible for disseminating relevant information to the audit team from stage one. Note: If the lead auditor allocates any analysis of the self-assessment to members of the audit team, the lead auditor must ensure their own analysis takes into consideration the relevance of the whole in addition to that of the parts.

Stage two of the audit

- Actively uses information and knowledge gained from stage one to verify findings from the self-assessment using a sampling methodology.
- Tests systems through the audit process that have been identified as high-risk areas.
- Determines the extent to which evidence is indicative of system-wide non-conformities.
- Engages auditees and the audit team in interactive dialogues in order to identify the nature of issues and their relevance to the Standards.

Qualifications and experience

Holds an audit qualification and health professional qualification with a current annual practising certificate or holds an audit qualification and health management or business management postgraduate degree, and in addition has:

- at least four years' quality auditor experience
- proven ability and at least two years' experience working in a lead auditor role across a number of health or disability support services
- proven experience in supervising and managing a team of audit professionals ranging in size from 8 to 16 people
- previous experience working in a district health board in a fourth tier or higher management position within the last six years, or has previous experience working across complex health systems – in addition to any audit activities (as determined and approved by the Ministry) within in the last six years
- demonstrated **current** knowledge of district health board systems and processes.

Appendix 5: Role description – technical expert assessor, DHB audits

Introduction

Technical expert assessors have a vital role as part of the audit team for certification audits. The effectiveness and credibility of the audit process is highly reliant on the competence, professionalism and integrity of health professionals who have specialist relevant and current knowledge of district health board systems and current practice in delivery of services.

Functions

- Provides advice to qualified quality auditors based on their specific knowledge and expertise.
- Conducts an assessment of technical competence of service delivery within specific clinical settings using tracer methodology (individual and systems).
- Provides information to quality auditors who can then use this information to form part of the audit evidence required to objectively determine the extent to which standards and associated criteria have been fulfilled.
- Has clinical expertise in the area in which they will be acting as a technical expert/assessor.

Stage one of the audit

- Receives the results of stage one via a briefing prior to the on-site audit.

Stage two of the audit

- Accompanies the auditor on a tour of the ward or department.
- Discusses observations from the tour of the ward or department with the auditor.
- Provides advice to the auditor on request.
- In completing individual tracers:
  - assists in identifying a suitable patient for tracer through discussion with nurse in charge
  - ensures verbal consent has been obtained for individual tracers
  - begins the tracer in the ward in which the patient resides
  - reviews care processes by reviewing records, interviews and observations. One of the records reviewed is the clinical file (hard copy and electronic), including progress notes, consent forms, procedure records, laboratory records, observation records, medication records (ideally done with a staff member familiar with the patient concerned)

- determines what other wards and departments need to be visited in response to the review of the clinical file and ensures this information is communicated to the auditor who will schedule onward appointments
- alerts the auditor to any concerns found through reviewing the notes
- interviews a selection of staff currently providing care (in the ward) with a focus on care delivery
- interviews the patient (and/or family), which may be in conjunction with a consumer auditor
- makes observations in the ward (eg, handover, patient movements)
- as they identify issues, reports findings to the auditor to allow the auditor to respond to these
- may undertake some interviews together with the auditor
- moves to clinical areas where the patient was before the current ward/department
- interviews staff in relation to the systems and processes, using the patient as an example
- focuses on risk points such as handovers between services
- continues to move progressively back in time to the point of admission (but does not need to go to outpatient services, radiology or laboratory services unless an issue was identified or the nature of the procedure requires a review of the process)
- takes field notes that they then provide to the auditor at the completion of the tracer
- when the tracer is completed, talks with the auditor to discuss findings.

Qualifications and experience

- Holds a health professional qualification with a current annual practising certificate.
- Is a current employee of a district health board working in a senior leadership position with a clinically active role (equivalent middle management or above).
- Has participated in clinical audit, quality improvement initiatives, service reviews or other equivalent activities.

Attributes

- Possesses sound judgement and analytical skills.
- Has knowledge of quality management principles.
- Is able to obtain and assess information objectively.
- Has good time management skills.
- Is able to work under pressure.
- Has strong interviewing skills.

Training

Technical expert assessors will successfully complete a Ministry of Health training programme to ensure they: have a basic understanding of the Health and Disability Services Standards and the audit process; and can competently assess service delivery within their specialty area using tracer methodology.

Conflict of interest

Technical expert assessors must be free from any conflict of interest.[18] As such, they cannot be current employees of the DHB being audited or provide expert advice to that DHB.

Note: Technical expert assessors complete workbooks which they then provide to quality auditors along with verbal handovers or advice at the end of the audit. However, they are **not** required to contribute to the writing of the audit report.

[18] Interest in respect of employment means current employment or any position held up to two years previously.

Appendix 6: Role description – quality auditor, DHB audits

Introduction

Quality auditors have a vital role as part of the audit team for certification audits. The effectiveness and credibility of the audit process rely heavily on the competence, professionalism and integrity of quality auditors who can work alongside technical experts and technical expert assessors.

Quality auditors need a thorough understanding of the relationship between the Health and Disability Services Standards, district health board systems, services and outcomes and how risk is managed in a complex environment.

General requirements of auditors in relation to the principles and code of conduct they must follow are outlined in the *Designated Auditing Agency Handbook*. This description outlines additional, specific requirements.

Functions

Note: The following list of functions is not exhaustive but is aimed to assist auditors in better understanding their role in relationship to the technical expert or technical expert assessor.

Working with technical experts and technical expert assessors

- Receives advice from technical experts and technical expert assessors and synthesises this information to objectively determine the extent to which Standards and associated criteria have been fulfilled.
- Helps to select a consumer suitable for the tracer. Note the selection process should be undertaken in the clinical area following the tour of this area.
- Supports technical experts and technical expert assessors to assess the technical competence of service delivery within specific clinical settings, using tracer methodology.
- Ensures technical experts and technical expert assessors complete the tracer process including sampling and interviewing across clinical areas relevant to the consumer selected for the tracer.
- Ensures technical experts and technical expert assessors keep to time allocated.
- Facilitates discussions with the technical experts and technical expert assessor to tease out issues, determining their relevance to the Standards and where additional information or focus is required.

- Receives completed workbooks and takes a verbal handover from technical experts and technical expert assessors, ensuring they have gathered all the information auditors need to use as part of audit evidence and to write the audit report. Note that once technical experts and technical expert assessors have left the on-site audit, they may not be available for further comment or advice and do not directly contribute to the writing of the audit report.

Stage one of the audit

- Is conversant with the results from stage one of the audit process.

Stage two of the audit

- Leads introductions in clinical areas outlining the activities and time expectations of being in the clinical area for both the auditor and technical expert or technical expert assessor.
- Jointly undertakes a short tour of the clinical area with the technical expert or technical expert assessor and DHB staff member to observe interactions between staff and patients, other staff, the availability and location of equipment, respect for privacy and confidentiality of information and general risk management (eg, standard precautions in place, isolation, use of equipment). Note: The tour should not take an inspection approach.
- Ensures that the manager or person in charge has asked for verbal consent from the consumer chosen as the tracer.
- Facilitates meetings and interviews with the technical expert.
- Takes notes at all meetings and interviews, where the auditor and the technical expert or technical expert assessor are present.
- Asks any additional questions at meetings and interviews following the questions the technical expert or technical expert assessor asks (eg, orientation programme, ongoing training, annual competencies).
- Works alongside the technical expert or technical expert assessor to undertake incidental sampling and additional sampling to validate findings of the technical expert or technical expert assessor from the tracer review and assist in determining the nature of non-conformities (isolated anomaly, specific to the clinical area, service specific, or across the district health board).
- Undertakes medication file audits in addition to the tracer sample.
- Undertakes an audit of a sample of informed consent (including surgical or procedural consents, for example, resuscitation status).
- Follows up on risk areas that the technical expert or technical expert assessor identified, to determine the extent to which risks are systemic across the district health board.
- Undertakes additional interviewing as indicated to validate findings or determine conformity with a Standard not directly captured through the tracer process. Note: This may or may not be done in conjunction with the technical expert or technical expert assessor.
- Undertakes informal interviews with consumers of services. Note: The technical expert or technical expert assessor will conduct a formal interview with the consumer who has consented to be part of the tracer process and that interview does not need to include the auditor.
- Follows up on and reviews any policies or procedures in response to findings that are inconsistent with the findings from stage one of the audit (including the DHB self-assessment).

- Reviews quality data that are from the ward or clinical area and are not otherwise reviewed in stage one of the audit.
- Reviews the roster of the ward or clinical area.
- Observes a partial handover between shifts. Note: The auditor is likely to do this in conjunction with the technical expert assessor or technical expert.
- Before leaving a clinical area, thanks the manager or person in charge of the service, providing them with a short debrief of findings (both positive and negative). Where there are negative findings, manages this information sensitively and does not present it as a definitive finding, given further information will be collected across other service areas which may or may not be relevant to the findings in a specific clinical area.
- Completes own field notes.
- Undertakes a critical appraisal of information collected and determines the sufficiency of evidence and how the evaluation of this evidence will be reflected in the audit report, ensuring that it is applicable to the district health board at the level of clinical area, service, facility or the district health board as a whole.
- Completes audit reporting as directed by the lead auditor.

Qualifications and experience

- Holds an audit qualification and health professional qualification with a current annual practising certificate as outlined in the *Designated Auditing Agency Handbook*.
- Has at least two years' quality auditor experience and is qualified as a quality auditor.
- Has previous experience working in a district health board and **current** knowledge of district health board systems and processes.

Appendix 7: Guidance for auditing residential disability services

When auditing residential disability services against HDSS NZS 8134:2008, the audit team shall consider the philosophy of these services within the context of the audit.

Note that HealthCERT accepts the following interpretations of the HDSS.

1.1.2 Consumer rights during service delivery: The Code of Rights and Advocacy Services information should be readily available in a public place (for example, lounge bookshelf), and not publicly displayed on walls.

1.1.9 Communication: Staff may or may not wear name badges. Where they do not wear name badges, other methods of staff identification should be identified during audit.

1.1.10 Informed consent: Policies should reflect the provider's process around managing advance directives within the residential disability setting.

1.3.12 Medicines management: The audit team must witness medication administration as part of the audit process.

1.4.2 Code of compliance / building warrant of fitness (BWOF): Where the property is exempt from needing a BWOF as defined in the Building Act 2004,[19] the audit report should expressly identify this exemption. It is expected that appropriate maintenance processes will be evident.

1.4.3 Hot water temperatures: Refer to local body bylaws to ensure hot water temperatures meet requirements. Evidence must reflect the mechanisms in place to monitor and maintain an acceptable water temperature in sanitary fittings.

1.4.3.5 Toilets and showers have clear distinguishable identification: As the house is the consumer's home, it is acceptable to rate this criterion as not applicable.

1.4.7.3 Approved evacuation plan: Where there is no requirement for an approved plan under the Fire Safety and Evacuation of Buildings Regulations 2006, it is expected the provider will have a documented procedure in place, with evidence that evacuations are practised at regular intervals.

[19] Department of Building and Housing: Determination 2006/92.

Infection prevention and control auditing guidance

The following points offer general guidance.

- In a small service, a 'committee' can be one person assigned to be responsible for activities that a committee would usually undertake in a larger setting.
- In a large service with multiple sites, a committee can be a central committee that is responsible for multiple sites.
- The level of detail within an infection prevention and control programme should be tailored to the size, scope, complexity and risk. Auditors shall take this requirement into full consideration when completing their audit. For example, residential disability homes should comply with food safety tips as published by the New Zealand Food Safety Authority for 'food safety at home' and should monitor fridge temperatures, rather than complying with the food safety requirements for a commercial kitchen.

Specific guidance for infection prevention and control

The following specific guidance on meeting NZS 8134.3:2008 is provided for residential disability services against specific criteria.

Reference	Guidance
1.1	Includes identification of staff responsible for the programme, whether it is a large provider with an overarching committee or a designated staff member with appropriate knowledge.
1.2	Includes a documented escalation process to ensure notification of serious infections both within the organisation and as may be required through regulation or legislation.
1.3	An infection control programme or series of policies to form an infection control programme: • outlines orientation and training of staff to build their familiarity with policies and procedures and their ability to follow them • outlines policies and procedures (standard precautions, body fluid spills, outbreaks, food safety; cleaning; incontinence products and equipment) • defines roles and responsibilities of managers and supervisors; role of support staff; and role of the doctor, including the doctor attending unwell consumers and prescribing medications • documents responsibility for identifying, supplying, cleaning and maintenance of, any equipment • ensures there is focused surveillance of serious infections likely to impact on other consumers • defines a serious infection • monitors and reports serious infections and outbreaks appropriately (eg, within the quality management programme and at least annually and in accordance with legislated requirements) • specifies review dates.
1.4	Content of programme meets current accepted practice for residential disability and the organisation's needs and has been authorised by management.
1.5	May be managed through a recognised primary health care service or a memorandum of understanding with DHB infectious disease physician, Infection Control Team, laboratory or another organisation that has access to an infection control specialist.
1.7	A large provider with multiple sites may have an overarching committee whereas a smaller facility may not.
1.9	There is a process for restricting visitors that are unwell (could be covered within a brochure). Information may also be in outbreak policy and human resources policies.

Reference	Guidance
2.1	There is a staff member in each facility who takes responsibility for the implementation of the infection control programme in that facility and has access to expert advice when required (eg, registered nurse, general practitioner, DHB Infection Control Team).
2.3	Infection control training to update a designated person within the organisation or contracted to the organisation can be evidenced as occurring at least once every two years.
2.4	Sufficient information is available to determine infections have been identified and treated appropriately. This may be through the quality management system (QMS) monitoring or by receiving information from the doctor, such as documentation of doctor management (monitored by the doctor) which resolves infections in a timely manner. If the service does not hold records of diagnostic tests, it should be verified that the doctor does.
3.2	Hand hygiene policy and transmission-based precautions may be defined within standard precautions policy. Transmission-based precautions may also be defined within outbreak management policy. Antimicrobial usage is not always applicable if there are processes for the doctor or laboratory to manage. Disinfection, sterilisation and reusable devices may not all be applicable. Single-use items may not be applicable. Renovations and construction may be included in a principle within the infection control programme to consult with appropriate experts if undertaking renovations and construction.
4.1	May be covered within orientation training and ongoing, at least two yearly.
4.2	As for 4.1 above.
4.3	May be covered within infection control programme review.
4.4	All training records are maintained.
4.5	Consumer education information, including how it was/is delivered and is reviewed. It may also include: outbreak management; food hygiene (if there is communal food preparation and cooking); hand hygiene; and continence management. Records may be held in consumer files.
5.1	The infection control programme should clearly state what surveillance includes. Surveillance should be appropriate to the size and complexity of the organisation. The process does not need to be complex or limited only to infections subject to cross-infection.
5.2	Policy may state as undertaken by doctor or doctors. Can rate as fully attained if this can be confirmed.
5.3	As delegated in roles and responsibilities and as per reporting process within QMS.
5.7	Should be evident within QMS reporting.
5.8	As per communications with the doctor or doctors (may not necessarily be in writing) or infection control expert within or contracted to the organisation.