

# **NSU Auditing Handbook**

**Part One: General and audit  
programme requirements**

**For National Screening Unit  
programmes**

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# 1 Introduction

The National Screening Unit (NSU) is committed to person-centred, safe screening assessments. We recognise audit as an essential monitoring function that supports effective programme stewardship with all screening providers. Principle 5 of the NSU Quality Framework seeks to ensure 'Screening programmes are monitored and evaluated on a regular basis'.

In 2019 NSU established a monitoring and evaluation framework. For a diagram of the framework, including the function of provider audit, see Appendix One.

The *NSU Auditing Handbook: Part One* and *Part Two* are prepared as components of the new quality assurance audit programme that the Designated Audit Agency (DAA) Group will deliver from early 2021.

The purpose of this handbook is to:

1. describe the requirements of the auditing process for all parties involved
2. ensure NSU supports programme governance and improvement processes within each programme.

We will update the two parts of the handbook periodically and in collaboration with the DAA Group.

Part One (this part) describes the responsibilities of the DAA Group and NSU and also general requirements of the NSU audit programme. Part Two provides programme-specific information that may change as each audit programme is evaluated.

If there is doubt as to how any interpretation or requirement specified within this handbook, the DAA Group will request written guidance on the matter from NSU.

## 1.1 NSU quality principles

Six core principles underpin the NSU Quality Framework. These principles provide a foundation for achieving the NSU's strategic vision of high-quality, equitable and accessible screening programmes.

1. The overall benefits of screening must outweigh the harm.
  - There should be regular review of the evidence on which the programmes are based.
  - There is transparency around significant decisions, major changes to screening programmes and serious adverse events.

2. National screening programmes are people centred.
  - Screening should be acceptable to individuals, whānau and the populations being screened.
  - Advisory groups include appropriate consumer representatives with experience of the condition(s) screened for and the health system.
  - Screening programmes are delivered in an ethically and culturally competent manner for New Zealand.
3. National screening programmes will achieve equitable access to screening and equitable outcomes for all population groups.
  - Screening programmes should incorporate the principles of the Treaty of Waitangi.
  - Solutions to access are focused on improving processes and adapting systems to meet the needs of individuals and under-screened populations.
4. Informed consent is a priority throughout the screening pathway.
  - Screening programmes should provide full information to people. This includes details on the benefits and harms of screening.
  - Screening programmes must address cultural and health literacy differences when providing information to support informed consent.
5. Screening programmes are monitored and evaluated on a regular basis.
  - Information systems should be set up to enable timely monitoring, audit and evaluation of screening programmes and providers.
6. National screening programmes are committed to continuous quality improvement in programme management and clinical service delivery.
  - Policy makers, providers and all those involved in screening programmes are accountable and responsible for maintaining capacity and capability in delivering screening programmes and services of the highest possible quality.

## 1.2 Updating the handbook online

This handbook will be updated periodically online to keep it accurate. For the latest version, please access or download the online handbook at <https://www.nsu.govt.nz>.

The *Ministry of Health Auditor Handbook* (Ministry of Health 2019) is a sector reference for this handbook. Where changes relevant to this handbook are made to the *Ministry of Health Auditor Handbook*, we will incorporate them into the *NSU Auditing Handbook* as required.

## 1.3 Additional reading

The DAA Group and screening service providers are expected to be familiar with legislative and regulatory requirements, accreditation information and good practice guidance along with the relevant screening programme documents. These include:

- NSU Quality Framework 2015
- BreastScreen Aotearoa National Policy and Quality Standards
- National Bowel Screening Programme Interim Quality Standards
- National Cervical Screening Programme Policies and Standards
- Universal Newborn Hearing Screening and Early Intervention Programme
- National Policy and Quality Standards
- Newborn Metabolic Screening Programme Policy Framework.

The NSU programme lead will inform screening providers and the DAA Group of any updates or changes made to these programme documents.

## 2 Definitions

Term	Definition
Audit	A systematic, independent, objective and documented evaluation or review of the provision of screening services and the extent to which the screening provider complies with standards and processes, based on audit criteria.
Audit cycle	A regular three-year rotation of audit events, starting with a verification event, followed by a surveillance event two months either side of the half-way point of 18 months and then a verification event three years from the initial verification event and so on.
Audit reporting template	A programme specific NSU document that the DAA Group completes as a record of the audit and submits electronically to NSU.
Clinical governance	A system that provides accountability for continuously improving the quality of services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.
Consumer, participant, kiritaki hauora	A person who uses, participates in or receives a screening assessment and service.
Consumer auditor	A member of the audit team who either is a user of the type of service being audited or is a family member or primary carer of such a person. In an audit of a provider for multiple services, someone who reflects the primary nature of the service is acceptable as a consumer auditor.
CAR	Corrective action request.
CAR closure	Final closure of a CAR after a subsequent surveillance audit reviews evidence that a provider has resolved the issue.
CAR follow-up	A provider's presentation of evidence to NSU programme manager or advisor to support its resolution of an issue raised in a CAR.
Critical risk	A risk requiring immediate planning for a corrective action and notification to NSU while the audit team is on site. An agreed action plan is to be documented and implemented to ensure participant safety within 24 hours and NSU must be notified in writing.
Designated auditing agency (DAA)	An auditing agency designated under section 32(1) of the Health and Disability Services (Safety) Act 2001.
Executive summary	A preview of the main points from the audit report. It is written in plain language and contains enough information for readers to familiarise themselves with the content of the full report. It should not contain information about anything that has occurred after the audit.
Evidence-based approach	The rational method for reaching reliable and reproducible audit conclusions in a systematic audit process. This may include sampling a subset of a population to provide a representative picture from which it is possible to confidently generalise conclusions.
HDC	Health and Disability Commissioner.
High risk	A risk requiring corrective action within one month, including documentation of an action plan with sign-off by the lead auditor within 48 hours and notification in writing to the NSU, in the interests of participant safety.



<b>Term</b>	<b>Definition</b>
Incidental sampling	Sampling required to gather enough information to form audit evidence and ensure the audit is reliable. Information from incidental sampling can supplement other information collected through various audit methodologies throughout the audit process.
Individual tracer	A tracer designed to 'trace' the experience of a person when participating in a screening assessment. It is a way to analyse the organisation's system of providing assessment or service where a service user's experience provides information about its level of conformance to the required standards. A person selected for a tracer will likely be a typical screening participant or someone of an age who is most likely to enable the best in-depth evaluation of the organisation's processes and practices such as the parent of a newborn.
Issue	An identifiable variation from accepted conformance to a standard.
Lead auditor	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 NSU. 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 AS/NZS ISO 19011.
Ministry	Ministry of Health.
Multi-site	Where the structure of the screening provider includes a central location where screening service is planned, controlled or managed along with a network of local offices, branches and services (sites) that carry out screening assessments. This may include mobile services.
Multi-site audit	A process carried out under a written, pre-negotiated agreement between a multi-site provider of NSU screening services and NSU, which establishes that an agreed percentage or number of the provider's premises or 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 no requirement to submit a multi-site audit plan to the NSU before the audit.
National Screening Unit (NSU)	The unit in the Ministry of Health's Population Health and Prevention directorate that is responsible for the safety, effectiveness and quality of organised screening programmes.
NSU programme audit lead	The programme role or roles assigned within NSU as audit lead and liaison including coordination of the programme audit between the DAA Group and the programme screening provider. The function may be assigned to any role within the NSU programme team so is not specific to a job title.
Observed audits undertaken by NSU staff	Process in which an official from the NSU observes the DAA Group conducting an audit, for the purpose of becoming familiar with the programme audit process. The presence of an observer must be agreed with DAA Group prior to the site visit.
Peer reviewer	A lead auditor qualified in quality management, 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 and properly documented and satisfy established quality requirements.

<b>Term</b>	<b>Definition</b>
Problem	An unacceptable deviation from accepted conformance to a standard.
Programme	One of the screening services offered to the New Zealand public.
Quality indicators	Measurable elements of service provision. Quality indicators relate to the desired outcome or performance of staff or services.
Readiness audit	An audit undertaken before NSU verifies a new screening service provider to provide the service.
Recommendation	The standard is being achieved. A recommendation is where the audit process has identified an opportunity to improve.
Sampling	An agreed number of interviews and file reviews based on the type of screening programme and number of staff and consumers using the screening pathway.
Scope	A document that describes the selected screening provider's services, sites and size of each service or programme provided for NSU that will be the subject of the audit.
Screening journey	The journey an individual from the eligible population experiences from receiving the screening invitation to reaching the end of the screening process.
Screening pathway	The clinical process steps to complete the screening assessment and action the outcome.
Screening provider	An organisation that operates a screening programme or provides services that are involved in a screening pathway.
Site visit	A visit by an auditor to a screening provider site to audit applicable standards or parts of standards. This includes verifying that each site has implemented generic policies, procedures and systems.
Standard	The minimum requirement for conformance, which is achieved when all indicators or criteria associated with it are met.
Surveillance audit	An audit that occurs half-way through an audit cycle with the focus on an agreed sub-set of standards to ensure quality management systems are maintained and that corrective action requests have been actioned and are effective.
Systems tracer	A tracer that looks at one system sampling across multiple parts of the organisation. Systems-based tracer methodology can be applied to programmes such as complaints or risk management systems.
Technical expert assessor (TEA)	An experienced health professional with a current annual practising certificate or equivalent and who has demonstrated knowledge, skills and experience related to the screening programme being audited.
Tracer methodology	The methodology involved in using a tracer to follow the actual screening experience of a participant who is receiving services at the time of the audit. Selection of a tracer should include a participant who has a complex journey through the screening process.
Transition plan	A plan that is developed when a provider is managing a change. It includes how information about the change is being communicated, how risks are mitigated and how any intended changes to the service (eg, changes to staff, policies and procedures) will be implemented.
Triangulation of evidence	A process of drawing information from three sources (interviews, observations and documentation) in order to gather reliable evidence.

<b>Term</b>	<b>Definition</b>
Verification audit	An audit that determines if a provider is conforming to the relevant screening programme's quality and performance standards. It is a full audit of the standards outlined in the audit scope (refer to the audit tool for the relevant programme).
Verification condition	A follow-up action required for a screening service to maintain its verification of conformance status.
Verification of evidence	The process an auditor follows to confirm their conclusions, which should involve triangulation of evidence wherever possible.



# ***General requirements***



# 3 Auditing principles

## 3.1 NSU programme audit approach

With each cycle of audit, NSU will work with the DAA Group to identify the focus points that the audit process will emphasise. The purpose of a focus point is to identify opportunities to achieve NSU or programme-wide quality improvement activity.

Audit will invariably identify areas for improvement. In addition, however, NSU wants to tap into the opportunity a regular audit cycle creates to highlight screening providers, staff and processes that demonstrate a commitment to high-quality, person-centred and safe screening assessments.

The screening provider is expected to evidence its commitment to continuous quality improvement in its quality plan.

## 3.2 Audit principles

The DAA Group and NSU require 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 to NSU audits.

- **Person focus:** Care, support and services meet the needs and preferences of participants consistent with currently accepted practice.  
Technical expert assessors will use their technical and clinical expertise to collect audit evidence directly from participants, relatives and providers and include a review of screening service received, considering both their screening journey and individual components of the screening process.
- **Outcomes focus:** Auditors must consider the context for service provision, acknowledging that outcomes can be achieved through various inputs, processes and outputs.
- **Systems and process focus:** Effective systems and processes are implemented to support the delivery of screening services.  
Auditors will determine, through the audit evidence they collect, that standards of screening services are not dependent on any one person, but rather on the systems and processes present.
- **Openness and transparency:** Information is effectively communicated throughout the audit process.  
Auditors ensure stakeholders involved in the audit process are fully informed.

# 4 The DAA Group responsibilities

The DAA Group must:

1. maintain third-party accreditation for its organisation
2. meet requirements of a New Zealand designated audit agency, as specified in the *Ministry of Health Auditor Handbook* (Ministry of Health 2019)
3. meet NSU contractual requirements, including those set out in this handbook
4. notify NSU immediately of any suspension or conditions imposed on DAA Group by a third-party accreditation body or Ministry of Health designation
5. notify NSU immediately of any inability to meet the contractual requirements.

## 4.1 Contract requirements

The DAA Group will:

1. follow IAF MD2:2007 for the transfer of information at the termination of the NSU screening programme contract
2. ensure screening providers are aware that the NSU or a recognised third-party accrediting body (ISQua) may accompany DAA Group auditors on any audit as part of their observation audit or witnessed audit, performance monitoring process, their accreditation or designation/re-designation process
3. maintain confidentiality for all information obtained or created during the performance of audit activities
4. provide the NSU with an annual audit schedule updated quarterly, starting on 1 July each year
5. report to NSU as contractually required
6. have a DAA Group NSU client manager to manage the audit programmes, liaise with the NSU programme leads/advisors and facilitate each audit with the service provider's nominated representatives.



## 4.2 Audit teams

The DAA Group is required to ensure each of its audit teams comprises competent lead auditors, and technical expert assessors with clinical or technical expertise as appropriate to the screening service and the nominated focus points of the audit.

## 4.3 Audit process

### Scheduling

The DAA Group audit process includes the scheduling of audits on an annual basis with a quarterly review in collaboration with each NSU programme team.

- Each NSU programme team will work in collaboration with the DAA Group to schedule audits on a three-yearly cycle and review this on a quarterly basis.
- Each NSU programme team may recommend the order in which service providers are scheduled for audit before the annual audit schedule is prepared.
- The scheduling process will consider priorities set by the NSU team, monitoring outcomes, identified issues, and geographical location and co-location.
- Other considerations include the location of auditors and technical expert assessors.

### Audit scope

Refer to the Part Two that describe the scope for specific programme audit requirements.

### Planning and preparation

- The DAA Group NSU client manager will plan and prepare for audit together with the relevant NSU programme audit lead(s) and the specific screening service provider representative(s).
- This work will include reaching agreement with NSU on focus points and specific standards for each programme at the start of the three-year audit cycle.

### Methodology

Any alteration to the audit methodology will be agreed with the NSU programme managers and screening service providers as relevant. For example, it might be necessary to conduct a remote audit due to a COVID-19 resurgence or another similar crisis.

## Two-stage audits

- The audit process will be in two stages, as Section 7 describes.
- Stage one is off site and stage two is on site.

## Audit reports

For information on the audit reports the DAA Group auditors provide, see:

- **Section 7.4** Audit outcome
- **Section 11** Audit reporting.

# 4.4 Management of conflict of interest

The DAA Group is required to:

1. appoint and use a committee for safeguarding impartiality, consistent with a process for managing conflicts of interest as set out in AS/NZS ISO/IEC 17021-1
2. ensure all auditors complete a conflict-of-interest declaration before every audit
3. have established processes to specifically manage conflicts of interest at an organisational level – noting that:
  - the DAA Group must not provide any consulting services to a screening programme service that is also receiving auditing services
  - individual auditors must not provide auditing services where they have provided consultancy or educational services within the last two years to the same provider
  - there must be a rotation of auditors.

# 5 NSU responsibilities

Each of the screening programmes has responsibilities in the audit process. This is because audit is a critical part of each programme's regular monitoring and evaluating activity.

For a diagram of the NSU generic audit process, see Appendix Two.

Each programme will appoint an NSU programme audit leads.

The NSU programme audit leads will:

- confirm the audit scope and focus point
- provide the audit team with relevant information before the audit begins
- sign off the final audit report
- after receiving the final report, follow up on action that providers must take
- agree the plan with the provider to address any audit critical and high-risk corrective action requests (CARs) within the timeframes
- regularly advise the programme leadership roles on progress with CARs
- recommend commendation identified through the audit as one or more exemplars of high-quality practice and performance
- at the conclusion of a full audit cycle with all screening providers, analyse high-level outcomes to identify trends or areas of interest to inform focus points in the next audit cycle or programme lead continuous quality improvement projects.

During the period of the first three-year cycle, NSU will work with the DAA Group to include a consumer auditor in the screening programme audit teams.

We see the role of a consumer auditor as invaluable because it enables the audit process to assess the quality of a screening service across the screening pathway based on the experience of a service participant. By adopting this approach, NSU will demonstrate a commitment to person-centred screening delivery.

In addition, individual tracers will be used as one of the standard audit methodologies to ensure the pathway for consumers is at the centre of the audit process.

Separately, the NSU programme leads will provide feedback to the DAA Group based on regular auditor reports and will review the audit schedule for each programme every year.

# 6 Relationships and communication

The DAA Group undertakes to develop professional working relationships with the NSU lead roles and managers and each of the screening programme service providers to enable clear communication and high-quality audit outcomes.

The DAA Group states a commitment to reflect the values of professionalism, partnership, passion, integrity, innovation and independence in all interactions with NSU staff and screening service providers.

The DAA Group commits to be open and honest, inclusive and collaborative in its communication throughout the audit process, including the preparation and planning stages as well as the on-site audit activity.

The DAA Group NSU client manager is the main point of contact for NSU programme managers and service providers on all programme-specific audit activity. The DAA Group NSU client manager also ensures technical expert assessors are recruited, trained and available for audit.

The NSU quality manager or delegate will be the primary liaison person and agreement relationship manager with the DAA Group.

The DAA Group will liaise with screening providers on matters specific to the screening programme and audit arrangements. This may include agreeing the schedule of audits or providing notification when a change to the date for a site visit is needed.

# ***Audit programme requirements***



# 7 NSU audit programme framework

The NSU audit programme provides a person-centred approach to quality and risk audit. All screening programme audits have similar person-centred quality requirements although unique screening programme elements are also incorporated into each programme audit.

Screening programmes have a three-year audit cycle. The DAA Group manages the NSU audit programme schedule in conjunction with the NSU screening programme managers. The three-year audit cycle typically includes a verification audit followed by a surveillance audit at mid-cycle. Following each verification audit, the relevant screening programme manager issues a conformance verification letter to the screening provider.

The conformance verification letter states any ongoing conditions arising from the audit process. An example of a condition is a requirement to provide progress reports at specified intervals before closure of a CAR in a subsequent surveillance audit. The conformance verification letter is not reissued following the mid-cycle surveillance audit unless the surveillance audit result signals an amendment is needed.

See Appendix One for a flow diagram showing the NSU corrective action request process.

## 7.1 Two-stage audit process for verification and readiness audits

All verification and readiness audits include a two-stage process.

### Self-assessment and document review

The first stage of the audit incorporates off-site activities, including a self-assessment and document review.

## Provider responsibilities

The provider will complete the self-assessment using the specific screening programme template available from the:

- NSU website
- DAA Group website
- DAA Group NSU client manager.

The provider will give the completed self-assessment, along with documents as requested for review or information, to the DAA Group six weeks before the on-site audit.

Where documents are requested for review as part of stage one, the provider will supply them electronically or allow electronic access to them.

The self-assessment and document review stage includes:

- identifying and providing policies and procedures (covering, for example, management systems and clinical systems)
- reviewing and providing prior relevant audit reports along with NSU and screening provider monitoring information.

The document review tool should help the screening service provider to prepare for the audit, and if required, to complete minor corrections or improvements to policies and procedures ahead of the on-site audit.

## DAA Group responsibilities

The purpose of the self-assessment and document review is to allow the DAA Group to collect enough verifiable information to contribute to the second stage of the audit.

The DAA Group is responsible for ensuring that, before a verification audit, each screening programme is provided with a self-assessment document based on the standards to be audited.

The DAA Group may provide, as required, one or more training sessions to guide screening providers on how to complete the self-assessment. It also will provide ongoing support as required throughout the audit cycle, to the extent that it can while maintaining audit independence.

The DAA Group will complete a review of the provider self-assessment and documentation before every verification audit. The audit team will use the review to help it to prepare for the audit, reducing the need to review policies and procedures while on site.

The DAA Group will request documents it requires for the review at least 40 working days before the scheduled on-site audit. The list of documents requested must match the document review reporting template available on the NSU website.



The lead auditor performing the on-site audit must complete the document review report. The DAA Group will then send the document review report to the provider using the document review reporting template at least 20 working days prior to the scheduled on-site audit.

The DAA Group is required to give the provider written feedback so it can remedy any issues before the on-site audit begins.

The DAA Group can supply members of the audit team with documents requested for review as part of stage one.

If stage one requires additional activities that are consistent with AS/NZS ISO/IEC 17021-1/17065, the DAA Group must communicate this requirement to the service provider in a timely manner.

The auditors at the on-site audit must review any documents that a provider changes between the document review and on-site audit.

If stage one identifies a significant number of non-conformities, the DAA Group will contact the NSU programme audit lead to discuss appropriate timing for the next stage. When conducting readiness audits, the DAA Group will document whether the policies reviewed are those of the current provider or the potential provider. Where the potential provider intends to implement its own policies or staffing, rather than following the approach of the current provider, it must have a transition plan and implementation timetable.

## On-site and remote audit (for all types of audit)

The second stage of the audit is an on-site audit.

The audit team is on site to undertake the audit, using the methodology and sampling of evidence that this section describes. The *NSU Audit Programme Handbook: Part Two* sets out the programme-specific requirements.

Remote auditing may occur in some situations. It may include accessing the screening service provider's electronic data to review quality and risk systems without the need for an on-site visit.

## 7.2 Length of audit

Deciding on the time required to conduct an on-site audit will take account of the following aspects (as applicable):

- the requirement that an auditor's day is a minimum of seven hours
- the size and complexity of the service under audit, including geographic spread between regional and outreach services from the primary service
- results of previous audits
- multi-site considerations
- requirements to meet the standards of auditing practice for the DAA Group
- use of technical expert assessors
- the requirement that time on site comprises at least 50 percent of the estimated total audit time.

For additional guidance on aspects of the length of audit that this handbook does not cover, see IAF MD5 *Mandatory Document for Duration of QMS and EMS Audits* (International Accreditation Forum 2009).

## 7.3 The NSU audit approach

The DAA Group will include all sites of the screening service provider in the scope of services when developing the audit plan. It will use a sampling methodology to develop the scope of audit for multi-site services and agreed with NSU as part of the multi-site service's preparation for audit.

Unless specified in the individual programme's sampling methodology, the audit will consider all sites, where possible, over the audit cycle (That is, sites that auditors do not visit at verification audit could be included at surveillance audit.)

The NSU audit programme will take a streamlined approach to all audits. The NSU audit programme framework process will focus on points of critical importance across the screening pathway.

### Evidence-based approach

When conducting audits against the screening programme standards, the DAA Group will 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.

## Sample size

The DAA Group will ensure all audits achieve an adequate sample size in the following way.

NSU will agree on the sampling method for each screening programme to ensure the number of interviews undertaken and files reviewed is representative. This may include an agreed ratio and an agreed time period to cover in the audit process.

Alternatively, where the sampling formula for any type of audit produces a number below five, the auditors will interview a minimum of five consumers and review their corresponding clinical records.

Where an auditor finds a non-conformity within the minimum sample, the audit will widen the sample sizes to verify whether the case is due to system or process failure, or a one-off anomaly.

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

Interviews with personnel (staff, management, contractors, visiting health professionals and advocates) will be part of the audit process.

Each screening programme will determine the minimum number of staff to be interviewed, in addition to interviews with management, consumers and visiting health professionals.

The sample must represent all roles of screening staff.

All audits will refer to any satisfaction survey (or equivalent) of participants, relatives and/or staff that the provider has undertaken, or someone has undertaken on behalf of the provider or funder, since the last audit. In referencing surveys, the audit team may include survey results and actions taken in response to them.

## Stratified sampling

Auditors will 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, in line with the relevant screening programme's sampling plan.

## Random sampling

With random selection of consumers, staff or documents (where any individual or document can be selected), the audit is less likely to be biased and auditors can accurately generalise their audit results. In every audit, auditors will select several 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.

## Incidental sampling

Auditors will base incidental sampling on the relevant screening programme's sampling methodology.

## Individual tracer methodology

An individual tracer follows the experience of the screening consumer. Selection of a tracer should include a consumer who is following a complex screening pathway as their experience shows how the provider's systems and processes support the quality of that consumer's screening experience. Complex screening services may encompass multidisciplinary interventions but do not need to be extensive.

To implement individual tracer methodology, an auditor must review both the chronology and the quality of assessment, support and service provision. They use the participant record as a roadmap to move through the service and follow the experience of the consumer, matching an audit of the continuum of service provision to a consumer's experience.

The purpose of an individual tracer methodology shifts the focus from written policies and procedures, examined in isolation, to the delivery of screening services. 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 methodology also gives the organisation a good opportunity to share examples of current practice.

Auditors must obtain the individual's verbal consent to participate in the tracer. If their verbal consent is not possible, then the tracer interview will not proceed.

Individuals may either have recently been or be currently participating in a screening assessment at a distinguishable stage across the screening pathway. The people selected at stages across the screening pathway are likely to have received services that test the programme and local systems and processes, including transfers within services or between services.

Individual tracer methodology will involve:

- reviewing the participant file
- observing service provision
- observing the environment and equipment use
- reviewing competencies of staff
- interviewing as many people as possible, including but not limited to the participant and the staff (nursing, medical, support) who have been directly involved in the delivery of the screening service.

Where practicable, the tracer will begin before the participant receives an invitation to screen.

The tracer description in the audit report will not include any identifiable information about an individual. Suitable samples for review of a participant's screening experience include, but are not limited to, a participant who has:

- been involved in a complex screening experience
- experienced a recent illness where pain or a complication resulted from the screening assessment, and may have required a public hospital admission
- provided feedback or made a complaint about their assessment and/or screening experience.

## 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 or facility. The process for undertaking systems-based tracers is similar across all systems being audited. Examples of systems-based tracers include infection prevention and control, and recruitment and retention management.

To complete a systems-based tracer, the auditor will look at a sample of the provider's process from start to finish to determine how well the system and the process used within the system meet the needs of the service and the participants in that service.

A key difference between a systems-based tracer and individual tracer lies in their focus and approach to sampling. 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. In contrast, the systems-based tracer looks at one system or programme, sampling across multiple parts of the organisation or service.

In undertaking a systems-based tracer, auditors must:

- review relevant documentation, such as policies, procedures, internal audits, incident reports, complaints, dashboard reporting and relevant monitoring
- conduct an interview or small focus group discussion with staff that are involved in management and delivery of the system. This usually includes both groups or committees with the system responsibility and staff who are directly involved in the system
- audit a sample of current participant records and undertake observation and informal interviews across the organisation, which they can use to test the implementation of the process or programme within the system.

## Interviewing

Auditors will use interviews to:

- gather new audit evidence
- corroborate audit evidence.

Auditors will interview at least some staff, participants and relatives individually rather than only in groups. Because of the lack of confidentiality in this situation, an individual may not disclose their true opinions.

Staff interviewed will include staff directly providing services. Interviews must not be limited to management or staff employed in a team leader or management capacity.

Auditors will apply the sampling methodology to interviewing that the *NSU Auditing Handbook: Part Two* describes. Note that they should make the sample large enough to ensure their conclusions are representative of the service they are auditing.

Auditors will use interviewing to corroborate information, such as how processes work and their effectiveness.

## Collecting audit evidence

Auditors will use work documents, such as checklists, audit sampling plans and forms, to record information, such as supporting evidence, audit findings and records of meetings and interviews. This approach supports a consistent standard of collecting the 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 will collect evidence using appropriate sampling methods, including but not limited to interviews, documentation and observations.

Before making audit findings, auditors will consider whether they have gathered enough relevant information. They must not use one-off events and unsubstantiated information as the sole basis for an audit finding. Instead, they will use such data as a prompt to collect more information in order to confirm or reject the initial information.

Where an auditor determines that an isolated event poses a serious risk of harm or potential harm to a participant, they must either:

- establish that the service in question has remedied the situation and the risk of reoccurrence is negligible, or
- further substantiate the risk and make an appropriate audit finding (see section 7.4.5) and agree on an action plan.

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

Auditors will strive to triangulate evidence as part of the corroboration process. In triangulating evidence, they must gather evidence from three sources using three of following four methods.

1. Interview consumers, relatives, personnel (managers, staff members), other health professionals (for example, a screening radiologist) and advocates.
2. Review documents and records, including but not limited to:
  - 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)
  - information for members of the public, consumers and other stakeholders (for example, pamphlets or admission brochures)
  - screening assessment clinical records
  - completed internal audits or assessments, progress reports, complaints, adverse events and accident records
  - other records (for example, personnel records; staff training records or minutes of meetings; consumer, relative and staff satisfaction surveys; complaints)
  - reports (for example, NSU monitoring incident reports, quality assurance or self-assessment reports)
  - 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 physical environment, reviewing practices, such as implementation of the Code of Health and Disability Services Consumers' Rights, and identifying any support that consumers need.
4. Collect data from other sources, such as data analysis reports, external reports and feedback (for example, complaints to the Health and Disability Commissioner (HDC)).

An exception to the requirement to have more than one source of evidence is when an auditor sights a document that confirms a service has met the requirement, such as a building warrant of fitness or a current operative evacuation scheme approved by the New Zealand Fire Service.

## 7.4 Audit outcome

### 7.4.1 Analysing audit evidence

Auditors will discuss findings with the whole audit team and evaluate evidence objectively to reach conclusions about the extent to which a provider has fulfilled its requirements. This includes evaluating the information collected to identify which information supports conformity and which does not.

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

- whether evidence supports the conclusion that a provider has achieved the criteria (sufficiency)
- whether evidence has identified deficiencies in systems, policies or processes
- whether evidence has identified deficiencies in the way a provider has implemented systems and processes
- trends within evidence
- causes of identified deficiencies, which auditors can use to identify the best standard or criterion to evidence the non-conformity against and to help providers to develop and agree on a corrective action plan
- risks and consequences of issues identified, using the risk assessment matrix (see section 7.4.3).

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 will be fair, balanced and free of bias.



## 7.4.2 Ratings

Auditors will determine their findings and allocate one of the following attainment levels for each criterion of the audit tool.

### **FA Fully Attained**

The service can clearly demonstrate implementation (practice evidence, training, records, visual evidence, etc) of the process, systems or structures in order to meet the required outcome of the criterion.

### **PA Partially Attained**

Either:

- evidence indicates implementation of an appropriate process (policy, procedure, guidelines, etc), system or structure without the required documentation, or
- a documented process (policy, procedure or guideline), system or structure is evident, but the organisation or service is unable to demonstrate implementation where this is required.

### **UA Unattained**

The organisation or service is unable to demonstrate appropriate processes, systems or structures to meet the required outcome of the criterion.

### **CM Commendation**

Having fully attained the criterion, the service can, in addition, clearly demonstrate a review process including analysis and reporting of findings, evidence of action taken based on those findings, and improvements to service provision and consumer safety, or satisfaction as a result of the review process.

The audit report will reflect findings and ratings at the time of the audit. This approach will ensure that subsequent audits will continue to monitor appropriate criteria.

In the audit report, auditors will:

1. explain why any criterion is '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. not rate as 'fully attained' any criterion that contains a corrective action planned for a future date. If the provider advises the DAA Group that it has completed a corrective action before the DAA Group has completed the audit or submitted the report, the grading remains 'partially attained' or 'unattained', and the risk rating (see section 7.4.3) will 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. award a rating for each criterion that reflects the lowest level of attainment achieved where multiple service categories are being audited for a single service provider or where multiple service areas provide the same service. For example, if one mobile unit achieves PA and another mobile unit at the same provider achieves FA for the same criterion, the rating awarded for this criterion will be PA

5. include audit evidence for a commendation rating that demonstrates one or more of the following criteria:
  - achievement beyond the expected full attainment
  - a review process has occurred, including analysis and reporting of findings
  - evidence shows the service has taken action based on findings and that action has improved its provision
  - consumer safety or consumer satisfaction has been measured as a result of the review process.

A commendation rating is for a system-wide improvement that affects or relates to a programme priority group, or the quality of the whole screening service instead of the individual participant or parts. It may be awarded if the service demonstrates one or more of the above conditions at subsequent or consecutive audits.

6. When a commendation has been awarded at a previous audit, the auditor will verify that the service continues to demonstrate the relevant criteria so that it maintains the previous commendation rating.
  - only change NSU audit programme framework attainment ratings within the period between the end of the on-site audit and the submission of the report where this relates to:
  - a building warrant of fitness or building code of compliance or a certificate of public use
  - New Zealand Fire Service approval of an evacuation scheme, or written approval of an exemption.

## 7.4.3 Risk assessment matrix

This risk management matrix will be used to determine the risk rating for any partially attained or unattained criterion, and the timeframe for the CAR.

		Likelihood				
		The likelihood of this occurring is <b>almost certain</b>	The likelihood of this occurring is <b>likely</b>	The likelihood of this occurring is <b>moderate</b>	The likelihood of this occurring is <b>unlikely</b>	The likelihood of this occurring is <b>rare</b>
Consequences	The consequences of not meeting these criteria would put consumers at <b>extreme risk of harm or actual harm is occurring</b>	Critical	Critical	High	Moderate	Low
	The consequences of not meeting these criteria would put consumers at <b>significant risk of harm</b>	Critical	High	Moderate	Low	Negligible
	The consequences of not meeting these criteria would put consumers at <b>moderate risk of harm</b>	High	Moderate	Moderate	Low	Negligible
	The consequences of not meeting these criteria would put consumers at <b>minimal risk of harm</b>	Moderate	Low	Low	Low	Negligible
	Risk of harm is <b>insignificant even if these criteria are not met</b>	Low	Low	Negligible	Negligible	Negligible

### Timeframe for implementing a corrective action plan

These timeframes for implementing a corrective action plan are a guide for lead auditors. The final decision on timeframe is for lead auditors to make, based on their professional judgement that takes account of the issue identified and the action required.

Implementation timeframes are from the day of audit.

	Corrective action plan	Implementation
Negligible	Not required	
Low	Within a month	Within 120 working days
Moderate	Within a month	Within 60 working days
High risk	Within 48 hours	Within 20 working days
Critical	Immediate	Within 48 hours

## 7.4.4 NSU corrective actions process

Audit teams will generate a CAR for each audit finding that results in a PA or UA rating. An audit finding resulting in CARs will:

- clearly define the extent of the problem (description, level of attainment and risk rating)
- provide a rationale for the finding
- describe expected outcomes
- define timeframes for these actions.

The service provider is responsible for developing the corrective action plan and implementing the corrective actions.

The NSU programme manager or delegate will review and accept corrective action plan and timeframe for completion. This approach will clearly identify the method and frequency of any reporting that is required. The conformance verification letter issued to the provider will include any reporting conditions relating to findings from the audit.

The NSU screening programme manager will monitor the provider's progress against the requirements and the agreed timeframes.

The closure of a CAR will be achieved following on-site review of evidence of resolution at the mid-cycle surveillance audit. Where a provider has ongoing issues with resolving a CAR, the DAA Group may be asked to undertake a one-off, additional on-site audit to verify the progress or completion of the corrective actions.

## 7.4.5 Managing critical and high-risk findings – corrective action follow-up process

When audit teams agree that an audit finding resulting in a PA or UA rating is of critical or high risk, the lead auditor will notify the DAA Group NSU client manager and/or the NSU programme manager by phone and will follow up by email as follows.

### Critical risk – notify before leaving the audit

- The NSU escalates the issue to the Clinical Director immediately.
- Agree an action plan to reduce or eliminate the risk within 24 hours.
- Agree what reporting is to occur, and who to report to, for the implementation of the plan.
- The provider reports to the NSU programme manager with evidence of action it has taken based on the plan.

## High risk – notify within 48 hours of completing the audit

- The NSU escalates the issue to the Clinical Director immediately.
- The provider sends an action plan to the NSU programme manager within one week of the audit.
- On agreement of the action plan, develop a monitoring plan.
- The provider reports with evidence of action it has taken based on the monitoring plan.

When a clinical safety issue is identified in the audit process, and to immediately address the issue, the screening programme will consider initiating an NSU programme lead clinical investigation team.

This team will work with the cooperation of the screening provider to identify causative factors, share learnings and prevent a recurrence of the issue. The audit team will complete the audit report and ensure the audit conclusions:

- clearly define the extent of the problem (description, level of attainment and risk rating)
- provide a rationale for the finding
- describe expected outcomes.

# 8 Audit teams

## 8.1 DAA Group NSU client manager

The DAA Group NSU client manager is responsible for forming the audit team.

They agree on the requirements for each audit together with the relevant NSU programme advisor and the provider of the specific screening programme service.

The DAA Group NSU client manager works closely with the delegated lead auditor to prepare each audit event.

While their roles and responsibilities are not limited to the following, the DAA Group NSU client manager will:

1. confirm the membership of the audit team is appropriate to the type of audit it is conducting
2. ensure the audit is conducted in accordance with DAA Group policies and procedures and consistent with AS/NZS ISO 19011
3. ensure each team member has completed a conflict-of-interest declaration
4. confirm audit arrangements with providers, as specified by AS/NZS ISO 19011
5. contact the NSU programme relationship managers. This contact will include but is not limited to:
  - notifying the managers of the intended date of the audit
  - asking them to provide the DAA Group with any relevant information that may contribute to the audit process.

Where issues exist for one or more of the screening facilities, it may be necessary to include them in the sampling plan (if applicable).

## 8.2 Audit team requirements

The following requirements apply to every DAA Group audit team.

The expertise in the audit team must reflect the characteristics of the screening service and its users.

Every audit team must include a qualified and experienced lead auditor.

Where audits require technical expert assessors, the level of expertise will meet the specific requirements of the screening programme. One team member may be both the lead auditor and a technical expert assessor.

The audit team must have a working knowledge of the provider's current contracts to ensure it considers the relevance of contracted requirements as part of the verification audit process.

Each screening programme will define its own minimum audit team requirements.

## 8.3 Lead auditor

The DAA Group NSU client manager will coordinate the audit together with the lead auditor. While their roles and responsibilities are not limited to the following, the lead auditor must:

1. confirm the membership of the audit team is appropriate to the type of audit it is conducting
2. ensure the audit is conducted in line with DAA Group policies and procedures and consistent with AS/NZS ISO 19011
3. confirm audit arrangements with providers, as specified by AS/NZS ISO 19011
4. review provider information, such as:
  - self-assessment and document review
  - last audit, where applicable
  - any surveillance or other audit event since the last audit
  - programme monitoring reports or other assessments undertaken by third parties
  - progress reports
  - accreditation or audits undertaken by third parties as available.

The lead auditor also:

1. chairs the opening and closing meetings with the screening service and maintains a record of these
2. ensures the opening and closing meetings conform with the requirements of AS/NZS ISO/IEC 17021-1/17065 and AS/NZS ISO 19011 and include a discussion with the provider about the audit objectives
3. ensures the audit team substantiates and validates information it has gathered before using it as audit evidence
4. ensures the provider receives a copy of the audit findings and corrective action required at the closing meeting. They also forward a copy of the corrective actions report generated on site to the NSU programme relationship manager within 24 hours if it contains any critical or high-risk findings

5. ensures the provider has obtained consumers' verbal consent for the audit team to interview them
6. notifies the DAA Group NSU client manager and/or NSU programme manager about the progress of an audit where the audit has identified a high or critical risk
7. coordinates the audit team and is a resource to the team (see AS/NZS ISO 19011), for example in helping to validate information collected
8. is the central point of contact for the provider throughout the on-site audit, liaising with them as appropriate to ensure openness and transparency throughout (see AS/NZS ISO 19011)
9. reviews the full audit report before it is peer reviewed, and reviews the report before it is submitted to the NSU
10. provides any feedback on audit team performance to the DAA Group.

## 8.4 Technical expert assessor

A technical expert assessor (TEA) is an experienced health professional who has a current annual practising certificate or equivalent, along with demonstrated knowledge, skills and experience related to the screening programme being audited. The DAA Group will train the TEA to perform this role.

TEAs must be included in verification audits for each of the screening programme services.

In some cases, the TEA can provide advice remotely.

A technical expert assessor will:

1. have demonstrated knowledge and skills related to, and recent experience of, working within the screening service being audited
2. have capability to reach an informed opinion on the appropriateness of the services of the screening service being audited
3. be able to identify trends in relation to service delivery
4. complete a conflict-of-interest declaration.



## 8.5 Consumer auditors

A consumer auditor, when included in the audit team, is expected to:

- be involved in planning and preparing methods of service user participation in the audit and in evaluating the need for independent support for service users
- participate as a full audit team member
- focus on the experience of people who use the services
- be included in key meetings with the organisation, management, staff and consumers
- facilitate meetings and interviews with service users and consumer groups
- interview service users independently and work under the direction of the lead auditor when completing any other aspects of the audit
- 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
- be trained in auditing principles, the use of the approved standards and audit tools as a member of the audit team
- have the following knowledge, skills and attributes:
  - knowledge of the legislative and regulatory requirements for the service being audited
  - understanding of continuous improvement concepts, methodologies and planning processes
  - understanding of quality management systems
  - ability to communicate effectively in writing or orally or to use alternative communication systems with all parties involved in the audit process.

When a consumer auditor is included in the audit team, the team will comprise a minimum of two members: either a consumer auditor and a combined role of lead auditor/technical expert assessor; or a combined role of lead auditor/consumer auditor and a technical expert assessor.

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 specific purpose. Given the scope of their role, the consumer auditor will not review clinical information, for example:

- medical specialist letters
- medical records
- medication records.

They may view personal plans, for example:

- informed consent forms
- information about services in conjunction with service user interviews.

# 9 Types of audits

## 9.1 NSU verification audit

<b>Definition</b>	The purpose of the NSU programme audit is to determine if a provider is conforming to the relevant screening programme's quality and performance standards. A verification audit is a full audit of defined standards as they apply to the provider's screening service (refer to the relevant programme's audit tool).
<b>Applies to</b>	The audit applies to all screening providers that provide a screening service in New Zealand.
<b>Scope</b>	The audit should meet defined relevant requirements of the individual programme's standard using the NSU audit programme approach. Refer to Part Two for each programme-specific section for individual programme scope.
<b>Provider roles and responsibilities</b>	A screening provider must: <ul style="list-style-type: none"> <li>• demonstrate that the verification of conformance remains current</li> <li>• report to the NSU screening programme a risk or issue that compromises the status of the audit outcome.</li> </ul>
<b>DAA Group roles and responsibilities</b>	The DAA Group must: <ul style="list-style-type: none"> <li>• notify the relevant NSU programme relationship manager, at least 20 days prior to audit, of the intention to audit and detail all services to be audited</li> <li>• where the relevant NSU programme manager specifies contractually or quality-related issues to consider at audit, notify the provider of this requirement seven working days before the audit</li> <li>• submit the audit report at least 20 working days before the expiry date on the provider's verification of conformance letter</li> <li>• ensure the provider receives a copy of the final audit report</li> <li>• hold records of the audit in the form of auditor notes, which will be maintained to two audit cycles.</li> </ul>
<b>Outcome</b>	The audit will verify that the screening service conforms to the programme standards and according to the audit scope. A verification of conformance letter is sent to the screening provider. This letter will include an expiry date. All providers must have one surveillance audit two months either side of the mid-point of this period unless: <ul style="list-style-type: none"> <li>• significant shortfalls are identified following an inspection or issues-based audit</li> <li>• a condition of the letter of verification requires an additional surveillance audit.</li> </ul>

## 9.2 Surveillance audit

<b>Definition</b>	<p>A surveillance audit is undertaken two months either side of the mid-point of the provider’s verification cycle to assure the NSU that the provider continues to meet relevant standards.</p> <p>The focus of the audit is on the quality management systems concerned with delivery of a specific service, as well as on reviewing criteria not fully attained at the previous audit.</p> <p>Surveillance audits provide assurance to the screening programme that the provider is making progress on the verification audit correction action(s) or CARs.</p>
<b>Applies to</b>	<p>The audit applies to all screening providers that provide a screening service in New Zealand.</p>
<b>Scope</b>	<p>The audit should meet all relevant requirements of the specific screening programme.</p> <p>See Part Two specific programme requirements for the list of criteria matched to standards that are required for surveillance audits.</p>
<b>DAA Group roles and responsibilities</b>	<p>The DAA Group must:</p> <ul style="list-style-type: none"> <li>▪ notify the NSU of the intended date of the surveillance audit at least three months before the audit (as part of providing quarterly notifications to the NSU of upcoming surveillance audits)</li> <li>▪ when requested, provide any additional documentation and evidence</li> <li>▪ ensure the provider receives a copy of the final audit report</li> </ul> <p><b>Audit activity</b></p> <ul style="list-style-type: none"> <li>▪ undertake a surveillance audit where this is a condition of verification of conformance</li> <li>▪ conduct a surveillance no more than two months either side of the date on the verification of conformance letter, unless it has NSU approval for a changed timeframe</li> <li>▪ submit the audit report electronically within 20 working days of completing the audit</li> <li>▪ widen the scope of the surveillance audit to include any aspect of the relevant programme standards if any areas of non-conformity (actual or potential) have been identified. The reason to widen the scope will be as a result of the audit process (for example, 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).</li> </ul>
<b>Outcome</b>	<p>Following a surveillance audit, either:</p> <ul style="list-style-type: none"> <li>• the most recently issued verification of conformance letter may not change, or</li> <li>• a new or amended letter may be issued in response to the audit result.</li> </ul>

## 9.3 Readiness audit

<b>Definition</b>	<p>A readiness assessment audit is either:</p> <ul style="list-style-type: none"> <li>• a programme-initiated audit of a prospective provider's preparedness to start a new screening service, or</li> <li>• on behalf of a prospective owner if a current service is under a purchase agreement to fulfil programme due diligence.</li> </ul>
<b>Applies to</b>	<p>The audit applies to a prospective provider.</p>
<b>Scope</b>	<ul style="list-style-type: none"> <li>• The audit should include an interview with the prospective provider (or contact person) to establish it is prepared to deliver a screening service (see Appendix One).</li> <li>• The audit report should include interview guidance and report on evidence related to the standards criteria.</li> <li>• The audit should assess the current facility against selected or all relevant standards.</li> <li>• Where a quality improvement activity is planned but not completed, such as the plans of the prospective provider for training or recruitment, the audit should award a PA.</li> </ul>
<b>Provider roles and responsibilities</b>	<p>The prospective provider must:</p> <ul style="list-style-type: none"> <li>• apply for and have completed a signed declaration. If an audit fee applies, it must also pay the prescribed fee to NSU</li> <li>• as applicable, provide a certificate of incorporation (or other relevant legal documentation of a business entity) to NSU.</li> </ul> <p>A prospective provider must:</p> <ul style="list-style-type: none"> <li>• participate with the DAA Group to undertake the readiness audit</li> <li>• reflect the outcome of the audit in the transition plan</li> <li>• participate with the DAA Group to undertake the readiness audit.</li> </ul>
<b>DAA Group roles and responsibilities</b>	<p>The DAA Group will not undertake a readiness audit without documented approval from NSU.</p> <p>The DAA Group must:</p> <ul style="list-style-type: none"> <li>• submit the audit report to NSU within 20 working days of the audit (see section 7)</li> <li>• ensure the NSU programme and prospective provider receives a copy of the final audit report.</li> </ul>
<b>Outcome</b>	<p>Approval to proceed with purchase or contract is supported.</p> <p>A verification audit is performed within a year.</p> <p>The prospective provider transition plan will be updated to consider the outcome of the readiness audit.</p> <p>The current provider is responsible for any improvement actions identified by the readiness audit until the settlement or transfer to the new provider has occurred.</p>

## 9.4 Extension audit

<b>Definition</b>	<p>The purpose of an extension audit is to establish the level of preparedness of an existing provider to provide a new or reconfigured screening service.</p> <p>The DAA Group will not undertake an extension audit without documented approval from NSU.</p> <p>Providers must liaise directly with NSU before engaging the DAA Group, as an audit may not be required or NSU may approve a combined audit where another audit activity is imminent.</p>
<b>Applies to</b>	<p>The audit applies to a screening provider that is:</p> <ul style="list-style-type: none"> <li>• applying to add another screening service to its existing screening service</li> <li>• applying to change the configuration of existing services (eg, adding new screening technology or increasing the capacity of an existing screening service)</li> <li>• adding a new building as an extension to an existing site or for a building that is not currently providing screening services on a new site.</li> </ul>
<b>Scope</b>	<p>The audit should include an:</p> <ul style="list-style-type: none"> <li>• interview with the provider (or contact person)</li> <li>• audit against the agreed programme standards.</li> </ul> <p>Where an activity is planned but not completed (eg, planned training or a delayed start date for a key role), auditors should award a PA.</p> <p>Each programme defines the standards that must be rated as fully attained before the change to the service or occupation of the building. For more information, see Part Two for the Programme Specific Requirements.</p>
<b>Provider roles and responsibilities</b>	<p>The provider must notify NSU of any planned reconfiguration or increase in capacity before implementing it, giving enough notice to complete an extension audit.</p> <p>Where NSU has determined an audit is required, it will engage the DAA Group to undertake the extension audit.</p> <p>Where a new premise is involved in the extension audit process, the timing of the audit steps must allow for an assessment of the new building as close to the completion of the build as possible. This is to allow the auditors to accurately assess the provider's preparedness to provide the new or reconfigured service in the new building and support a planned occupancy. The NSU may delay an audit if the construction is still substantially unfinished.</p> <p>The screening provider will, on request, provide any additional documentation, including where relevant:</p> <ul style="list-style-type: none"> <li>• a copy of a current building warrant of fitness (or a certificate of public use for a new site) or written advice from the relevant local authority confirming one is not required for a service currently certified</li> <li>• 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.</li> </ul>

<b>DAA Group roles and responsibilities</b>	<p>The DAA Group will:</p> <ul style="list-style-type: none"> <li>• notify the relevant NSU programme manager, at least 10 days before the audit, of the intention to audit the provider</li> <li>• rate criteria as PA where planned activities are not yet completed</li> <li>• submit the audit report at least eight working days before the date the screening provider intends to begin service delivery</li> <li>• ensure the provider receives a copy of the final audit report.</li> </ul>
<b>Outcome</b>	<p>The new or reconfigured service will be verified as conforming to the programme standards and according to the audit scope.</p> <p>For a new site, a verification of conformance to minimal standards will be issued for one year, with a verification audit to follow 12 months later.</p> <p>A new or amended verification will be developed in response to the findings with progress reporting requirements to the screening programme.</p>

## 9.5 Remote/virtual audit

<b>Definition</b>	<p>An audit performed from a remote location using information and communication technology, such as Zoom or Webex, to perform virtual tours of a facility, conduct face-to-face interviews and access the provider's computer systems.</p> <p>A remote or virtual audit may be required due to the location of a service provider or external factors, such as a pandemic response, to assure NSU the provider continues to meet all relevant standards.</p>
<b>Applies to</b>	<p>The audit applies to services scheduled for an audit.</p> <p>It may apply to services in remote locations at any time.</p>
<b>Scope</b>	<p>The audit should meet all relevant requirements of the specific screening programme.</p>
<b>DAA Group roles and responsibilities</b>	<p>The DAA Group must:</p> <ul style="list-style-type: none"> <li>• follow accepted best-practice virtual audit guidelines</li> <li>• follow the usual audit timelines</li> <li>• ensure the provider receives a copy of the final audit report</li> </ul> <p><b>Audit activity</b></p> <ul style="list-style-type: none"> <li>• undertake a remote audit where this is a condition of the verification process</li> <li>• submit the audit report electronically within 20 working days of completing the audit</li> <li>• widen the scope of the remote audit to include any aspect of the relevant programme standards if the audit has identified any areas of non-conformity (actual or potential). This will be as a result of the virtual audit process (eg, as a result of observation while conducting a virtual tour of the service or in the review of clinical files, or in interviews with staff, consumers or relatives).</li> </ul>
<b>Outcome</b>	<p>For a virtual verification audit, a verification of conformance letter will be issued in response to the audit result.</p> <p>For a virtual surveillance audit, the most recently issued verification of conformance letter may not change or a new or amended letter may be issued in response to the audit result.</p>

# 10 General requirements for the audit process

The following audit requirements apply to all service provider types. For information on a specific service provider type, also refer to the section on that type in the *NSU Auditing Handbook: Part Two*.

## 10.1 Cultural considerations

Planning for the three-year cycle schedule for each programme will consider what cultural components to incorporate into screening provider audits. The DAA Group will be do this in conjunction with screening programme leaders.

## 10.2 Combining audits

A combined audit involves completing two or more audits at the same time.

A readiness audit cannot be combined with any other audit because the prospective provider commissions the readiness assessment whereas NSU commissions all other types of audit.

When completing two audits at the same time, the DAA Group can submit one audit report that covers the scopes of both audits.

Where services have changed (for example, through the addition of another site, or an increase in capacity or reconfiguration of a service) and are being verified as part of a routine audit, the DAA Group can include information about the changes in the general overview section of the audit reporting template.



## 10.3 Auditing against specific conditions

### Ad hoc NSU or screening programme requirements

When a screening provider has a condition added to its verification of conformance letter as a result of an NSU requirement, the NSU requires the service provider to submit evidence as part of programme monitoring.

NSU will inform the DAA Group of any conditions added to a verification of conformance letter that apply to a screening provider. The DAA Group will audit according to the conditions at the next scheduled audit.

### Requirements from previous non-conformities

When conducting an on-site audit, the DAA Group will audit all conditions on the existing verification of conformance letter. Where a condition has been generated as a result of a corrective action, the DAA Group will audit the specified criterion and not only the completion of the corrective action. This requirement also applies to any conditions that the NSU has monitored through progress reporting.

## 10.4 Include relevant information

When conducting audits against each of the screening programme standards, the DAA Group will 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 regulation notices).

# 11 Audit reporting

The DAA Group undertakes an audit for the purpose of providing the Group Manager and Clinical Director-of NSU with an audit report that NSU leadership roles can use to determine whether a screening provider meets the required standards and/or contract requirements.

Audit reports submitted to the NSU will use the DAA Group NSU audit reporting template.

## Audit evidence

They must present evidence that is competent, sufficient, relevant and reliable.

For evidence to be **valid**, it will:

- be collected by appropriately skilled and experienced members of the audit team (that is, qualified lead auditors and technical expert assessors with clinical expertise matched to the service being audited, as appropriate)
- come from an adequate sampling methodology
- demonstrate **corroboration** of evidence, triangulated wherever possible, from a variety of reliable sources
- include evidence from documented records **and** interviews with stakeholders that can be substantiated.

Where a provider meets standards or contract requirements, reports will summarise each standard or section. Each summary will set out evidence that is:

- **sufficient**, meaning it will provide detailed information with relevant and quantified examples
- **relevant**, meaning it will:
  - demonstrate the relationship between actual and expected outcomes
  - be consistent
- **reliable**, meaning it will:
  - report attainment ratings against each standard or contract requirement and criterion that is not rated as fully attained or where there is a continuous improvement
  - report risk ratings against each standard or contract requirement and criterion within the scope of the audit when not fully attained
  - be proofread, peer reviewed and endorsed by the lead auditor, before the DAA Group submits it to the NSU.

## 11.1 DAA Group audit report writing guideline

The DAA Group provides its contracted auditors and technical expert assessors with the DAA Group report writing guideline, which sets out best-practice requirements.

## 11.2 Documented evidence

The audit team will document evidence in the audit tools that the DAA Group provides it with. It will describe the evidence in enough detail to support the report findings.

## 11.3 Submission of the NSU audit report

The DAA Group will submit every audit report electronically to NSU.

Before submitting the audit report to the NSU, the DAA Group will ensure that:

1. the service provider has had an opportunity to comment on the draft report. The DAA Group will clearly document any disagreement between the DAA Group 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 lead auditor and a peer reviewer have reviewed the report and the lead auditor has endorsed it following peer review
5. the report is complete
6. the service audited has received the report.

### Timeframes

The DAA Group must submit NSU audit reports within 20 working days of the audit team's last site visit.

It must negotiate any request for an exemption from these timeframes directly with the NSU programme manager on a case-by-case basis.

## Supporting documents

Records of all audits must be available to the NSU on request, if it needs these for further review or information.

If NSU programme managers ask the DAA Group to submit the required evidence, the DAA Group must submit this evidence within five working days.

## 11.4 NSU report review and action process

Each programme within the NSU audit programme will have a documented, unambiguous process to manage audit outcomes.

Each programme will ensure the screening provider reports on progress against corrective actions within the agreed timelines and will actively engage the screening provider on a delayed or unsatisfactory response.

Each programme team is responsible for escalating non-compliance with reporting timelines to the programme manager.

The screening programme leaders are responsible for overseeing the audit programme outcomes, to identify common themes and introduce programme-wide improvements as required. The programme may consult with advisory groups on matters arising from audit.

## Support to NSU teams

The DAA Group will provide initial training, as required, to help NSU programme staff manage the corrective action process.

The DAA Group NSU client manager or lead auditor will provide telephone support to NSU staff, as required.

# 12 Progress reporting

Written progress reports apply to any provider whose verification of conformance letter contains a condition for progress reporting or monitoring.

Each programme will prepare the audit reporting template, frequency and details necessary to effectively monitor progress with the corrective actions.

Each NSU programme lead is responsible for monitoring the progress reporting.

# References

International Accreditation Forum. 2009. *Mandatory Document for Duration of QMS and EMS Audits*. IAF MD5. International Accreditation Forum.

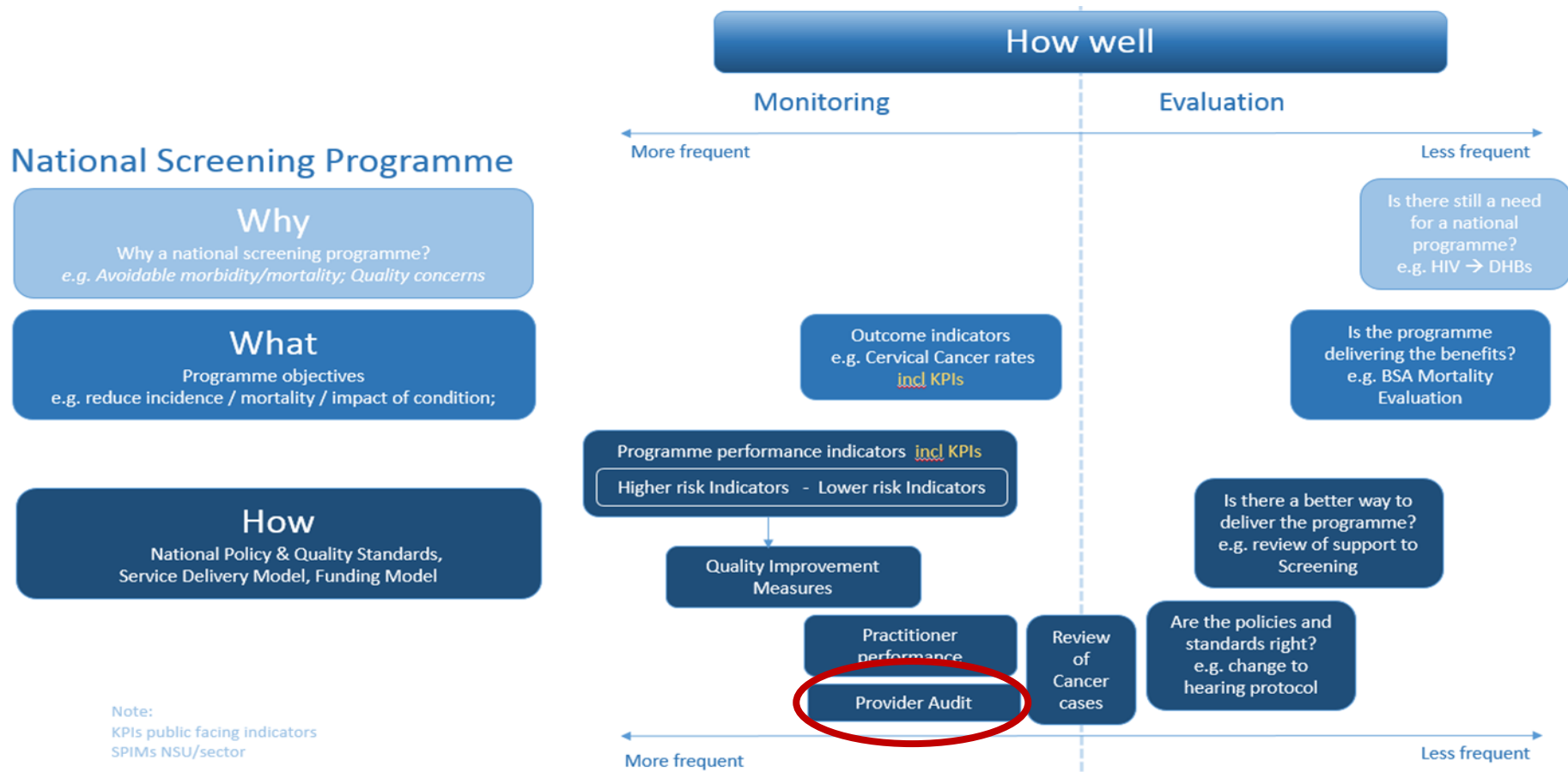
Ministry of Health. 2019. *Designated Auditing Agency Handbook: Ministry of Health Auditor Handbook (revised 2019)*. Wellington: Ministry of Health.

# ***Appendices***



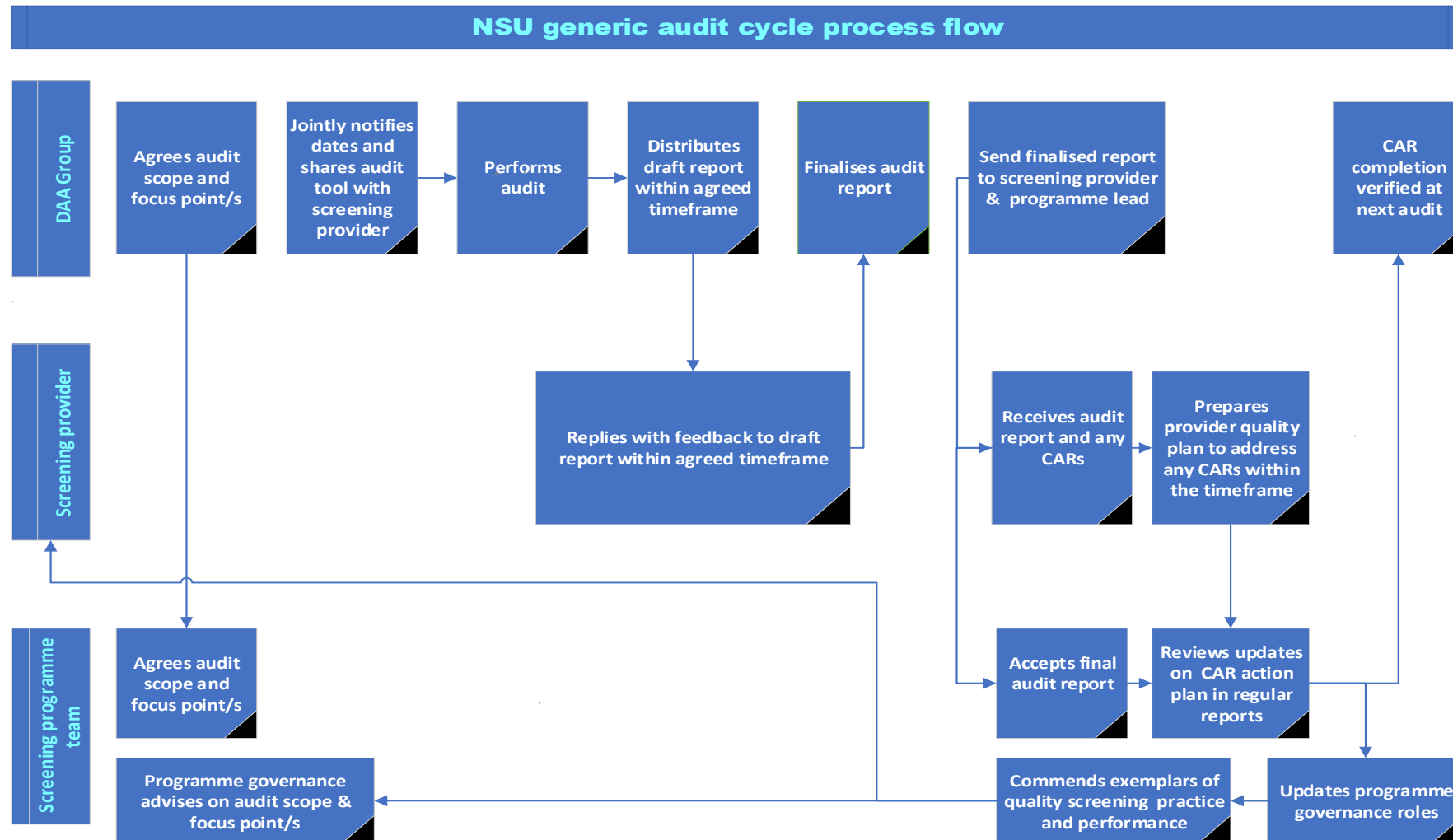


# Appendix One: NSU monitoring and evaluation framework



Note: BSA = BreastScreen Aotearoa; DHBs = district health boards; KPIs = key performance indicators.

# Appendix Two: NSU generic audit process



Note: CAR = corrective action request.

# Appendix Three: Readiness audit – the interview with the prospective provider

Whenever a screening service changes ownership, auditors undertake a readiness audit. Through this process, they establish:

- how well the prospective provider is prepared to provide a screening service
- that the prospective provider understands the screening service standards
- 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). It is preferable this person is available for the on-site audit; if they are not, then an off-site interview is acceptable.

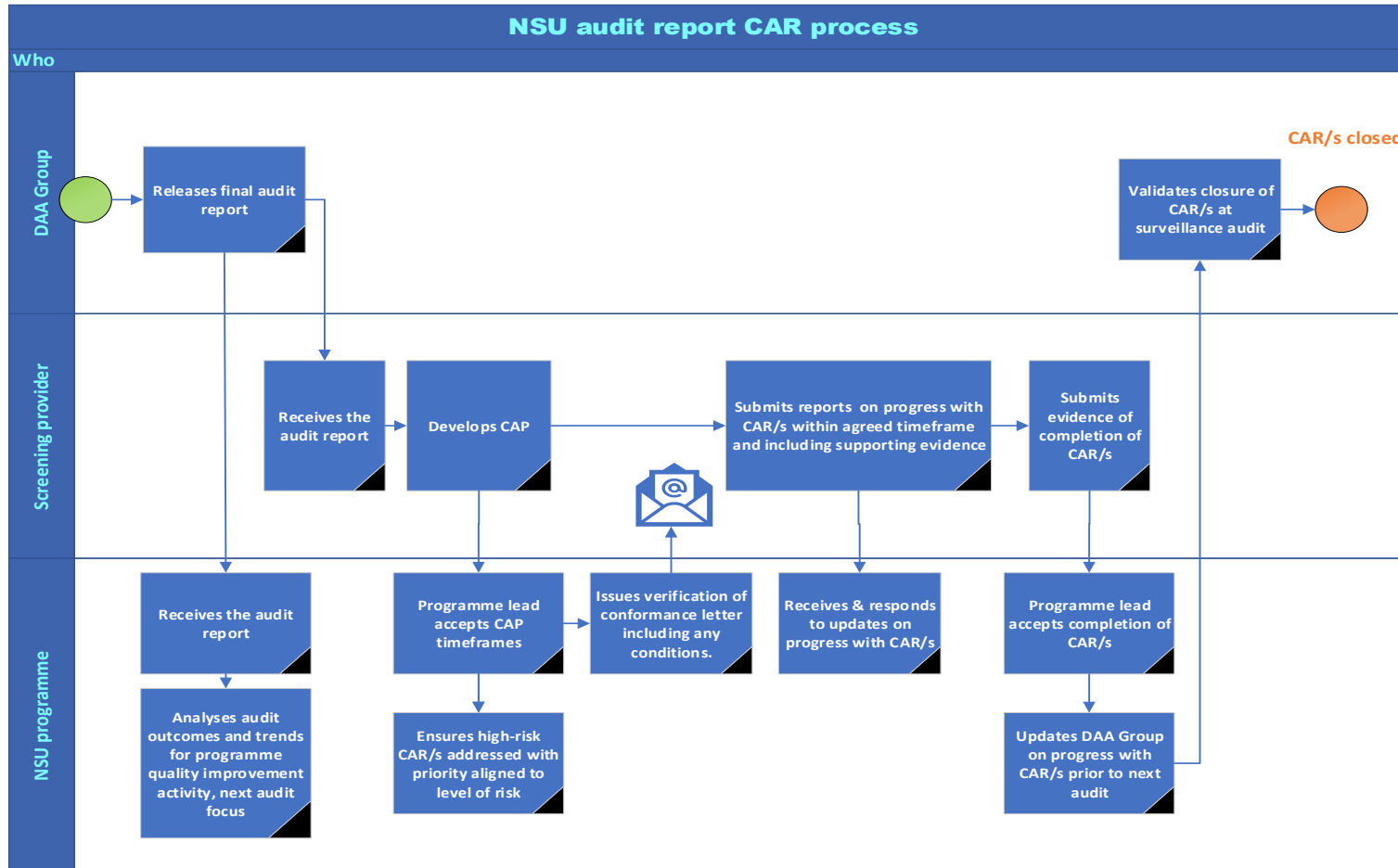
During the interview, the auditor will determine whether the prospective provider meets all the following criteria.

- The prospective provider knows and understands the consumer rights that it must uphold.
- The prospective provider has an established organisational structure (governance and management) and a predetermined lead-in time.
- The prospective provider has identified any changes to key personnel (involving governance, organisational and financial management, clinical management and team leader levels) that will occur after taking ownership of the service and has confirmed management and workforce full-time equivalent (FTE) at the time the service begins.
- The prospective provider has developed a transition plan with timelines, if required, allowing a timeframe for implementation.
- Where it is planning changes within the service that may affect the service's capacity to meet the requirements of the screening standards and 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.
- There are no legislative compliance issues (for example, concerning health and safety, employment or the local body) that could affect the service.
- The prospective provider will produce an annual quality plan and has established quality management systems including schedules for internal audit, changes and continuity.

- The prospective provider has a policy on staff skill mix, including contractual obligations and acuity of consumers within the service.
- The prospective provider has established plans for service management, such as determining who will cover when rostered staff are absent and managing staff changes.
- 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 programme standards.

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

# Appendix Four: NSU corrective action request process



Note: CAP = corrective action plan; CAR = corrective action request.