National Cervical Screening Programme
Audit Framework
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1. Introduction and Background

The National Cervical Screening Programme (NCSP) is New Zealand’s nationally organised cervical screening programme.

The programme aims to reduce the incidence of and mortality from cervical cancer by detecting pre-cancerous changes of the cervix in early stages when early treatment provides a better health outcome. In order to be successful in meeting its aim, the NCSP must ensure that the services delivered are of the highest possible quality. Monitoring and audit, as part of a continuous quality improvement cycle, are therefore integral to the success of the programme. The NCSP must also ensure that it is appropriately expending funds on the purchase of services to the Programme.

Audit can be seen as a systematic evaluation of processes and outcomes against agreed standards and policies. Such an evaluation will be based on fact finding, rather than fault finding.

Where a Service Provider has an Agreement for the Provision of Cervical Screening Services (through the National Screening Unit of the Ministry of Health), there will be contractual obligations to participate in audit and monitoring activities. This framework is subject to those contractual provisions. Examples of contractual provisions are annexed as Appendix 6.

This audit framework (this ‘framework’) is designed to provide an outline of the process that will be followed for routine compliance audits issue based audits and follow-up audits associated with the NCSP.

There are a number of different types of services provided in the NCSP. These services include:

- health promotion services
- smear-taking services
- laboratory services
- colposcopy services
- NCSP Regional Services.

This framework is also subject to applicable legislative provisions. Examples of legislative provisions are annexed as Appendix 7 to this framework. This framework will be subject to any legislative changes.

This framework is not intended to apply in the following circumstances:

- financial audits conducted by HealthPAC, a division of Ministry of Health
- audit of Invasive Cervical Cancers
- audit of professional standards or clinical practice outside that detailed in the NCSP Standards and related contractual documentation. If matters indicating concern arise that are beyond the scope of the NCSP auditors referral may be made to the appropriate College or professional body for further investigation
- where any legislative provision provides for any audit, evaluation or monitoring activities and we conduct our audit, evaluation or monitoring activities under those legislative provisions
• where individuals or organisations provide services not directly contracted for by the National Screening Unit (NSU).
2. Purpose, Principles and Expectations

2.1 Purpose

The goal of the NCSP is to reduce the incidence of, and mortality from, cervical cancer among New Zealand women. To achieve this goal all services within the screening programme need to be of the highest quality. To ensure that service provision meets these expectations, a range of audit, monitoring and evaluation activities are required. The performance of the NCSP and of the providers to the NCSP will be audited, monitored and evaluated on an ongoing basis by the NSU and/or its agents.

2.2 Principles

Auditing acts as a catalyst for continuous quality improvement and provides better information for decision-making. In doing so audit improves efficiency and effectiveness contributing to a better service and funding relationship. Auditing identifies gaps to be bridged between required service delivery levels and quality and actual performance.

It is important to ensure that the NCSP Providers’ actual service delivery conforms to that contracted for and reported on. An audit verifies this by observing the facts as displayed by service related records and confirmed by other parties where appropriate. Another function of the audit is to improve the quality, both of the services provided and the associated knowledge base for planning, contracting and performance monitoring purposes in the future.

2.3 Aims

The aims of audit are to:

- ensure that Providers maintain a high quality service for women participating in the screening programme
- promote continuous quality improvement by taking a continuous improvement approach
- ensure that the outcomes of all services are safe, effective, accessible, equitable and efficient\(^1\) to women thereby maximising opportunities for uptake and continued participation
- complement and support the Provider’s management functions and emphasise the developmental and educational potential of the role
- provide the audited Provider with an opportunity to improve their level of conformity with specified requirements
- assess and document the relevant risks resulting from any deviations in compliance and a mechanism/process of addressing these
- identify and recognise good performance of the providers

• meet regulatory requirements – the NSU (as representative of the Ministry of Health) is required under the New Zealand Public Health and Disability Act 2000 to monitor the performance of Crown Funding Agreements (and in particular sections 9 and 10 of that Act)
• comply with the audit objectives and principles of the Ministry of Health described in Audit and Monitoring: Guidance for DHBs (2001).

2.4 Expectations

All parties will act with courtesy and respect during the audit process.

2.4.1 National Screening Unit (Funder)

In undertaking audit activities the NSU and its agents/contractors are expected to:
• advise providers of the intended audit process
• conduct on-site visits in a manner that minimises disruption and with the appropriate sensitivity to the rights of staff, clients and others seen in the course of a visit
• access such records and information as are necessary and permitted by the relevant Agreement, including records and information held by sub-contractors to the Provider and recommend timeframes for meeting the requirements
• use the audit programme to provide feedback on the Provider’s performance during the audit or later in the formal report
• identify and report on compliance and or non-compliance with contractual and legislative requirements by any Provider
• identify and report on any recommendations for the improvement of service provisions by the Provider
• comply with relevant contractual and legal provisions
• acknowledge and observe tikanga and kawa of Māori services which include, eg, pōwhiri, karakia and poroporoaki.

2.4.2 Provider

In a routine compliance audit the Provider is expected to:
• provide all relevant information and prompt responses to relevant queries
• address any reported non-compliance within agreed timeframes
• comply with relevant contractual and legal provisions.
2.5 Confidentiality

Confidentiality will be preserved throughout the audit. Subject to the Official Information Act 1982 the detailed results of all audits will be confidential to the Provider, the NSU and its agent. Detailed audit findings and service recommendation reports will not routinely be publicly available.

The steps taken to maintain the confidentiality of information will comply with the requirements of the Official Information Act 1982 the Privacy Act 1993 and the Health Information Privacy Code 1994. Information will be released pursuant to the Official Information Act where the Act deems it necessary.

No information, which identifies individual women, will be included in any audit or service recommendation reports and any confirmation with other parties will remain confidential. Details relating to these provisions are contained in Appendix 5. Where Providers collect client information they need to ensure that clients are aware that audit is one of the purposes for which information is collected, ie, by listing audit among the purposes that are presented when information is collected.

2.6 Rules of audit

In deference to privacy and confidentiality of personal information, the audit will proceed on the basis that the information the National Screening Unit’s auditor requires will come from the least sensitive source first.
3. Definitions

3.1 Audit

Audit involves the systematic evaluation of the extent to which contracted service Providers (and their sub-contracted Providers) meet agreed standards and processes. Therefore, it identifies any gaps between requirements and performance.

There are three levels of audit anticipated for the National Cervical Screening Programme:
- routine compliance audit
- issue-based audit
- follow-up audit.

3.2 Routine compliance audit

A routine compliance audit is conducted to assess the level of compliance with the National Screening Unit’s contractual requirements. A flow chart of the expected course of the routine compliance audit is shown in Appendix 1.

The routine compliance audits will involve measuring and documenting performance against the requirements of all contractually related documentation and any relevant legislation.

Any routine compliance audit of a NCSP Provider will be specific to the type of services provided and therefore specific audit plans, tools, etc will be customised according to the type of service provided.

3.3 Issue-based audit

An issue-based audit is an audit focusing on specific issues or problems (Appendix 2). The issues may arise from either the routine compliance audit process or other information received by the National Screening Unit, for example from the quantitative monitoring process, audit of invasive cervical cancers or other sources.

Issues leading to this type of audit may include addressing:
- irregularities in service provision or documentation
- significant variation in performance between Providers
- cases of concern as reported from other sources that warrant further investigation
- consistent failure to meet or deviation in performance of national targets
- apparent deviation in compliance with the requirements of the quality standards as specified in the contract
- specific issues arising from invasive cervical cancer audits or other NCSP evaluations.
A more detailed description of issue-based audit is contained in Appendix 2.

Issues based audits will be conducted in compliance with contractual provisions – extracts from Provider Agreements are annexed at Appendix 6.

3.4 Follow-up audits

Follow-up audits are to review specifically identified areas of non-compliance and to confirm that the necessary requirements to address such non-compliance are in place. Ongoing periodic audits outside of the routine compliance audits may be needed for the funder, or designated agency, to be assured that the specific issues investigated are being rectified by the Provider.

Follow up audits will be conducted in compliance with contractual provisions – extracts from Provider Agreements are annexed at Appendix 6.

3.5 Auditor

An auditor is a person who has demonstrated the ability to perform all or part of a management system audit either alone or as a member of a team.

3.6 Lead auditor

A Lead Auditor is a person who has demonstrated the competencies to manage an audit team and co-ordinate all aspects of a complete management system audit.

Note: For the purposes of this audit framework, the terms Auditor and Lead Auditor refer to persons who conduct management system audit and not financial audits.


3.7 Auditee

The auditee is the Provider who is audited (refer definition of Provider below).

3.8 Provider(s)

The term Provider refers to those organisations or individuals providing services under NSU Agreements (‘Agreements’) for cytology and/or histology services, colposcopy services, smear taking, regional services and health promotion services for the NCSP.
4. **Scope of NCSP Provider Audit**

4.1 **Scope of audit**

The NSU may audit any services for which it contracts with a Service Provider as part of the National Cervical Screening Programme of the Ministry of Health.

The NCSP Provider Agreements have various provisions. Each Provider should refer to that specific Agreement for the applicable clause.

The Agreement between the National Screening Unit and the Provider specifies the services to be delivered. It should be noted that the NCSP Agreements encompass specific documents as part of the Agreement, eg, the Interim Operational Policy and Quality Standards of October 2000 (the Interim Standards), NCSP Monitoring Plan, etc. In these instances audit will include the full scope of all such contractual requirements.

The objective of the audit is to establish:

a) that the delivery of contracted NCSP services meets the contractual and legislative requirements

b) this may include for instance ascertaining that the services delivered also meet, where relevant, the:
   i. Code of Health and Disability Services Consumers’ Rights: 1994
   ii. Health Information Privacy Code: 1994
   iii. Operational Policy and Quality Standards: October 2000
   iv. cultural safety of the population served
   v. identified needs of consumers and their whanau (including confidentiality, privacy etc)
   vi. service specification in the Agreement
   vii. appropriate professional standards and codes.

c) The audit may also review the:
   i. needs of the population
   ii. accuracy of performance reports against the Agreement
   iii. documented policies and procedures; and clinical records
   iv. health education/ promotion resources.
4.2 Records and materials to be audited and their relation to providers

During the audit visit the auditors may conduct a review of the Provider’s records, which are relevant to the provision of services as described in the Agreement between the Ministry of Health and the Provider, to ascertain that the contracted services have been performed as reported, and that the records have been maintained in a businesslike and professional manner.

Any records, including those of sub-contractors, which relate to the service being audited may be requested, viewed and discussed as part of an audit. This may include information that is made available to women, letters and communications with women and/or health professionals and others, and/or all written material held on files. This may require a printout of any relevant electronic records. The latter may need to be viewed in situ where it is not practical to print them out e.g. large registers.

Any equipment or health education/promotion resource may be subject to verification and inspection by the auditors. Verification of quality accreditation processes may also be sought.

Where patient records are to be viewed, this will be done in accordance with the Health Act 1956, the Privacy Act 1993 and the Health Information Privacy Code 1994, and may also involve section 22G of the Health Act 1956. A Provider may also request that a Provider representative attend at the time of inspection of such records.

The patient records will remain on site and any information taken off site will not contain personal information that could identify a patient.

See section 2.5 on confidentiality and Appendix 7 for details of related legislative requirements.
5. **Routine Compliance Audit Processes**

Compliance audit processes include:
- notice of audit to the Provider
- auditor selection
- preparation of an audit plan and tool specific to each compliance audit
- audit visits including briefing and debriefing meetings
- preparation of audit reports
- follow up as required.

5.1 **Audit team**

The audit team may include but is not limited to:
- lead assessor/auditor
- clinical/technical experts
- consumer representatives.

The NSU will establish a National Register of Approved Auditors, who may be contracted to, or employed by the NSU for conducting routine, issue-based and/or follow-up audits. These Auditors will be qualified professionals, specialist individuals or representatives of organisations, who are knowledgeable about screening programmes.

Auditors will be selected by the NSU for the National Register either through a call for nominations process or via a direct approach by the NSU. Due to the small size of New Zealand the NSU aims to include overseas auditors to ensure international input to the audit process to assist with maintaining objectivity and avoiding any conflict of interest.

Auditors will be selected for each Provider audit on the basis of skills, related qualifications, recent training and experience, availability and appropriateness for specific Providers/services (including Māori and Pacific Providers). Auditors must be senior clinical, management or other specialists in their field with a sound knowledge of and/or experience in national screening programmes.

The range of audit activities required for the NCSP requires personnel with a range of skills and expertise. Different auditors may need to be contracted for the different components of each audit. The composition of the audit team will depend on the type of audit being conducted.

A team of auditors will conduct each NCSP Provider routine compliance audit. Examples of the areas of expertise which may be represented on a routine compliance audit team include Lead Assessor/Auditor, pathologists, cytotechnologists, gynaecologists, smear takers, data management auditors, cultural auditors, administration and management auditors, public health specialists, health promotion specialists, consumers.
Auditors conducting routine compliance audits will be required to be familiar with the terms of this Audit Framework and comply with confidentiality/privacy policies and code of conduct obligations.

5.2 Conflicts of interest

Due to the relatively small size of New Zealand, conflicts of interest may occur. Without limiting the circumstances which might give rise to a conflict or potential conflict of interest may include, for example if an auditor, or an auditor’s spouse, or someone within the auditor’s immediate family:

- holds shares or a position of responsibility (eg, Board member) with the Provider being audited
- is employed by the Provider being audited
- holds shares, or is in a position of responsibility with an organisation which holds a cervical screening subcontract with the NCSP Provider being audited
- personally stands to gain in any way from a determination or decision by any member of the audit team in respect of the Provider being audited.

Then, this will be deemed to be a conflict of interest.

All identified conflicts of interest will be taken into account during the selection of auditors. An auditor with a conflict of interest will not be deemed appropriate for that particular audit unless both the National Screening Unit and the Provider agree, due to extenuating circumstances.

All auditors will be required to declare any potential conflicts of interest at the time of registering on the National Register of Approved Auditors and advise the National Screening Unit of any changes in circumstance whilst being named on that register.

The Provider will notify the National Screening Unit of any perceived conflict of interest of the appointed auditor within five working days of notification of the proposed audit team. In addition to conflict of interest, a Provider may have other reasons for objecting to an auditor.

Any objection should clearly set out the grounds for objection. A dialogue will ensue between the National Screening Unit and the Provider with a view to either confirming the original selection or selecting a replacement auditor. The National Screening Unit will endeavour to meet all objections within reason but retains the right to appoint either the auditor nominated or a replacement auditor(s) of its choice if the National Screening Unit and the Provider cannot reach agreement.
5.3 Auditor’s approach

Once the audit team for each Provider compliance audit have been confirmed it will:

- carry out their work in a professional and competent manner with minimal disruption to Providers
- act in an ethical manner at all times in accordance with the Auditor’s Code of Conduct (refer Appendix 4)
- prepare audit reports in a timely manner
- collect evidence and, where appropriate, document non-conformity with specified requirements
- use the information gained of the Provider’s business solely for the preparation of the audit report, unless the Provider/s give their express permission for other uses.
- recommend actions necessary for the Provider/s to align their service delivery with the contractual requirement(s)
- maintain confidentiality of information, audit processes and conclusions
- adhere to the health and safety and other organisational protocols of the provider.

The Provider has the right to be present while the auditors are on its premises. Audit staff will carry suitable identification that will be shown to members of the Provider organisation on request.

5.4 Frequency of audit

The National Screening Unit will determine the frequency of routine compliance audits for each Provider type. It is expected that a routine compliance audit of each type of service will be undertaken at least once every three years.

5.5 Training of auditors

The National Screening Unit will ensure all persons registered on the National Register of Approved Auditors will undergo audit training. At least one member of each audit team will have undergone formal audit training as determined by the NSU prior to participation in the audit process.
5.6 Audit plan

An Audit Plan is a management document for the National Screening Unit, the audit team and the Provider concerned. An audit plan will be prepared specific to each proposed compliance audit.

The plan will include the following:

- an overview of the audit process to be followed for that particular audit
- scope of the audit
- date and time of audit
- date of completion of audit report
- an outline of the general information resources to be viewed
- information to Providers of their right to make formal comments on reports and follow-up processes
- details of which staff must be available on the specified day(s) to meet with the members of the audit team and to provide information and assistance as required.

5.7 Audit tool

An audit tool will also be provided to the auditors and Providers. This document will provide a guide to auditors and Providers by itemising the specific National Screening Unit requirements that are to be audited. It will allow for an assessment of the level to which requirements are met along with supporting evidence and any comments. The tool may be varied according to the audit being undertaken but the main focus of each routine compliance audit will be to highlight the ability of the Provider to meet the relevant contractual requirements. The tool will be used to document both qualitative and quantitative evidence of conformity/non-conformity with specified requirements.

5.8 Notice to the provider

For routine compliance audits the National Screening Unit (or its agents) will initially contact the Provider by telephone to advise them of the audit and the preferred date for the visit(s). A letter of notification of routine compliance audit will follow this. The letter will contain:

- names and qualifications of the auditors and timeframe for objections
- an outline of the audit process
- a copy of the audit plan and audit tool
- timetable for the audit
- a copy of this framework
- details of the service(s) or components of service to be audited
- when the site visit (detailed below) will be carried out.
Auditors will endeavour not to unduly disrupt the normal operations of the Provider. To achieve this the NSU (or its agents) will attempt to arrange visits at times that are convenient to the Provider. *At least 20 working days’ notice* is to be given regarding the suggested date of the site visit. This time frame is able to be reduced by agreement between the National Screening Unit, the auditor(s) and the Provider. A suitable day(s) for the site visit will be agreed by the National Screening Unit, the auditor(s) and the Provider within 10 working days’ notification of the site visit. If agreement cannot be reached on suitable day(s) then the National Screening Unit shall state the day(s) on which the auditor(s) will attend for audit and shall give 10 working days’ notice to the Provider of this date(s) and the site visit shall occur on that date.

### 5.9 Site visit

Each routine compliance audit of an NCSP Provider will include a site visit to all sites operated directly by the Provider or under sub-contract by another Provider (where this is applicable).

The time required for site visits will depend on the size of the Provider operations, the number and location of sites to be visited. Site visits will vary in length depending on the nature of the audit and the depth to which the National Screening Unit has elected to take any particular audit.

The format and timetable for the visit(s) will be documented in advance of the visit in the Audit Plan and this shall be provided to the Provider. The Audit Plan and the Audit Tool will be provided to the Provider before the commencement of the site visit.

The audit team will ensure that the audit process takes place with minimal disruption to the day-to-day operations of the provider.

It will be imperative to leave some free time during each site visit for the audit team to meet or to ensure all their queries have been addressed.

Time will also be allowed for:

- an initial briefing and a closing debriefing as detailed below
- the audit team to meet by themselves at the end of each visit to discuss their findings, come to some decisions and agree on issues for inclusion in the audit report
- the audit team to meet with the key service staff at the close of each site visit to provide initial feedback.

During the site visit the auditor(s) will compare information and documentation against contractual requirements. The auditor(s) will assess whether or not the way in which the service is delivered meets, exceeds, partially meets or fails to meet requirements. To do this the auditor(s) will:

- at the commencement of the site visit, hold a brief meeting with all relevant staff – this allows two-way briefing both of the auditor and of the staff concerning the scope and objectives of audit, the audit processes, the estimated time and date of the closing debriefing meeting and answering any queries
- examine written policies and service specific records, slides and files etc
• observe service delivery and any associated facilities, where appropriate
• conduct private interviews with relevant and key staff, and obtain confirmation from other parties. Where appropriate service clients, relatives/whanau of service client’s or the client’s nominated persons may also be interviewed or surveyed. Any such interviews/surveys will be conducted in a manner that ensures confidentiality
• document matters found, recording both qualitative and quantitative evidence to support items assessed as not conforming to requirements
• hold a debriefing meeting with key staff to discuss the facts as found/observed during the site visit. These facts will subsequently be documented in the Audit Report.

5.10 Information to be provided before the site visit

The auditor(s) may require specific information and or a completed questionnaire to be provided by the Provider prior to the site visit. The detail of the information required, the date by which it is required, and the format for it to be supplied in will be included in the Audit Plan.

5.11 Obtaining the views of consumers and other parties

The success of organised screening programmes is dependent on the highest possible quality of service to ensure optimal cancer detection rates coupled with a high uptake and continued participation by eligible women.

To adequately audit all aspects of the cervical screening programme varying degrees of feedback may be required from eligible women, women who have participated, Primary Care Providers, related service Providers or others to ascertain appropriateness and acceptability of the services delivered. The scope, process and appropriateness of such feedback will be determined by the NSU during the development of the routine compliance audit plan and tool.

Techniques used to gather the necessary information may include surveys, individual questionnaires, personal interviews or focus groups. This aspect of information gathering may occur prior to, during and/or following the site visit.

Any contact with service consumers will be undertaken in compliance with the relevant privacy legislation and will always identify the source of the inquiry as the NSU, explain the role of the NSU, outline the audit process and be clear that this is a routine audit and should not be construed as a lack of confidence in the Provider. This may be undertaken in conjunction with or following a routine compliance audit activity.

Refer Appendix 5 for detail of confidentiality and confirmation with other parties.
5.12 Audit report

The Audit Report will be supplied in draft format (the draft report) to the Provider approximately 15 working days after completion of the site visit. This report will:

- identify the auditor and auditee
- detail the scope and objectives of the audit
- emphasise areas of good performance
- detail the facts as found during the audit. This will be reported against each of the criteria or standards in the audit tool
- detail any service component that is judged not to be meeting requirements together with a description of the evidence that was used to make this judgement
- highlight issues to be addressed, being clear about which are significant and which are of lesser importance
- summarise the findings of any information gathered from consumers or other parties.

The report may include recommendations related to the specific issues identified as significant.

The Provider will be given the opportunity to comment in writing on factual inaccuracies of the audit (if any) as recorded in the draft report, to both the auditor(s) and the NSU and to discuss these comments with the Auditors and the NSU. The Provider will have at least 10 working days to respond to the draft report and will focus solely on inaccuracies and not comment on the findings or recommendations themselves from any other perspective. If the Provider believes there are any inaccuracies in the draft Report, then this must be supported with reasons and factual evidence. The Provider may also be invited to give further evidence or explanation on areas of disagreement separately to the NSU.

After receiving the Provider’s comments on the accuracy of the draft report the audit team has a further 10 working days to make any appropriate changes following the Provider’s comments and shall then forward the Audit Report to the NSU and the Provider.

Both the Audit Report and any separate comments/reports relating to perceived inaccuracies will be discussed between the NSU and the Provider during the follow-up process detailed below. Any issues arising can be discussed with the NSU and the audit team at the NSU’s discretion.

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2 Note – this may be some time following a site visit if any subsequent surveys or questionnaires from consumers or other parties are required.

3 This timeframe may vary in special circumstances.
5.13 Follow-up process

The nature of the follow-up processes following a routine compliance audit will depend on each particular audit situation. Follow-up may be initiated on the receipt of the Audit Reports from the audit team documenting the facts as found and the auditor’s recommendations/suggestions (if any). The NSU will contact the Provider to discuss the Audit Report. Five possible courses of action are described below. Any of these could arise following a routine compliance audit and these relate to decreasing levels of compliance with contractual requirements.

1. Where the report indicates that the Provider’s service delivery shows a high level of compliance with contractual requirements the NSU may acknowledge this in a congratulatory letter and require no further action.

2. If minor changes are required the NSU will contact the Provider to discuss the Audit Report and issues and recommendations contained in that report including their implications for both the NSU and the Provider. Both parties will be able to acknowledge what is working well and to negotiate any action recommended/suggested to address identified issues.

3. Where more significant changes are required the level of follow-up work will increase to include:
   - negotiations between the NSU and the Provider about the changes highlighted in the reports and how the Provider will go about addressing needs
   - the Provider developing a plan for the implementation of negotiated changes within an agreed timeframe, these changes may include Provider's suggested solutions to problems with the concurrence of the NSU
   - the Provider self-certifying that the recommendations are accepted and will be implemented within a stated timeframe, this may also include submission of revised written policies and be the subject of one or more verification visits
   - the NSU will discuss with the Provider and then determine an appropriate mechanism to monitor performance against all negotiated strategies to achieve compliance and timeframes.

4. Where the routine compliance audit has raised issues of potentially serious concern, eg, serious discrepancies between the services required to be delivered and those actually delivered, these will initially be discussed during the follow-up process. If the matter cannot be resolved at this point then a preliminary issue-based audit will begin. For further details on issue-based audits refer to Appendix 2.

5. In the rare event of the routine compliance audit identifying areas of significant clinical risk, fraudulent practice or serious breaches of contract conditions then a formal issue-based audit will be initiated (this may occur immediately or at some later time). For further details on issue-based audits refer to Appendix 2.

At any time during the audit process and this follow up process the NSU may proceed immediately to exercise any of its contractual rights.
Appendix 1: Overview of National Cervical Screening Programme Provider Compliance Audit

START
Providers routine compliance

Auditor selected from panel and audit plan/tool provided

Provider selected and telephoned, date may be revised

Letter of notice sent advising preferred date and audit team

Provider Objection

Possibly New auditor(s) and/or new dates

No objections

Audit proceeds

All information available on site

No objections

Audit proceeds

All information available on site

No objections

Audit proceeds

All information available on site

Provider selected and telephoned, date maybe revised

Letter of notice sent advising preferred date and audit team

Provider Objection

Possibly New auditor(s) and/or new dates

No objections

Audit proceeds

All information available on site

No objections

Audit proceeds

All information available on site

NSU/Provider agree any changes & implementation

Process complete

NSU/Provider agree any changes & implementation

Process complete

NSU/Provider agree any changes & implementation

Process complete

No serious matters found

No serious matters found

No serious matters found

No serious matters found

Potentially serious matters found

Potentially serious matters found

Potentially serious matters found

Potentially serious matters found

Fraud, breaches of contract

Rare event

Rare event

Rare event

Rare event

Police/legal process

Formal issue-based audit

Preliminary and/or formal issue-based audit

Preliminary and/or formal issue-based audit

Preliminary and/or formal issue-based audit

Preliminary and/or formal issue-based audit

Findings reports/inaccuracy check & service recommendations reports to MoH Provider

Confirmation with other parties

Findings reports/inaccuracy check & service recommendations reports to MoH Provider

Confirmation with other parties

Findings reports/inaccuracy check & service recommendations reports to MoH Provider

Confirmation with other parties

Findings reports/inaccuracy check & service recommendations reports to MoH Provider

Confirmation with other parties
Appendix 2: Issue-based Audits

An issue-based audit may be carried out where the NSU has reason to seek clarification or further information with respect to services provided.

Issue-based audits may be either:
- preliminary and/or
- formal.

Issue-based audits will proceed in accordance with the contractual provisions relating to audit (as relevant to each individual Provider).

A2.1 Preliminary issue-based audit

A preliminary issue-based audit may be carried out where the NSU has reason to seek clarification or further information with respect to contracted services. The most likely reasons for a preliminary issue-based audit to be carried out are:

- where a routine audit suggests that there is a discrepancy between services which have been contracted for and/or are reported by the Provider as performed, and those actually delivered
- where information, has been received by the NSU (which may include information from routine monitoring data and/or a complaint that in the discretion of the NSU is considered serious), which indicate a probability that aspects of the Provider’s provision of services are unsatisfactory.

The process and procedure for a preliminary issue-based audit will be much the same as that for routine compliance audits. The time frames of advance notice specified for a routine audit may be reduced to the period specified in the relevant agreement. A preliminary issue-based audit will have an in-depth focus on specific issues in contrast to the broader overview of the routine audit. The Provider will be advised that a preliminary issue-based audit will be conducted.

In the unlikely event that an audit has raised issues of clinical safety or risk, suspected fraud or breaches of contract these may initially be discussed during the follow-up process. If the matter cannot be resolved at this point then a formal issue-based audit will begin.

A2.2 Formal issue-based audit

The NSU may determine to commence a formal issue-based audit if it is in receipt of information (from any source) that indicates a reasonable likelihood of issues of clinical safety or risk, suspected fraud or breaches of contract.

A routine compliance audit or a preliminary issue-based audit may also produce information that indicates that it is necessary to conduct a formal issue-based audit. A decision to move to a formal issue-based audit may be made by the NSU during or after either a routine compliance audit or a preliminary issue-based audit.

The Provider and any agent will be formally advised when a routine compliance audit or a preliminary issue-based audit becomes a formal investigation. This notification may be given orally but will be confirmed in writing within two working days.
A2.2.1 Procedures
The relevant Agreement terms will be followed when formal issues-based audits occur.

In some cases the procedures used in a formal issue-based audit may follow the normal process for a criminal investigation, ie, there may be police and/or legal involvement if the audit is being conducted as a result of suspicion of serious fraudulent practice.

A2.2.2 Advance notice
Where a formal issue-based audit is to be conducted, advance notice of visits may be reduced or in some cases not given at all. Notice will not be provided where NSU has good reason to believe that providing such notice may frustrate the formal investigation. Every effort will be made not to disrupt the normal operation of the Provider. If the Provider so wishes he or she will be allowed a period of up to 60 minutes to arrange for a representative to be present while records are viewed and/or copied. During this 60-minute period the NSU agent may remain on the Provider’s premises but will not commence the investigation.

A2.2.3 Records
Auditors may request access to any records held by a Provider. This could include booking records, administration records, correspondence, patient files and other documentation or records. This could include hard copy or computerised records.

The NSU and/or its agent will treat sensitive information carefully and ensure that it is stored in appropriate secure facilities and that only personnel who are required to use the information have access to it.

Should records be required for use as evidence in court, adequate provisions exist for the suppression of any sensitive information.

In the rare circumstances where Police require records for evidence in a potential court case, these will be taken under a search warrant. As original records are required for court proceedings, Police practice is to remove these records and to leave copies for the Provider’s continued use.

The steps taken to maintain the confidentiality of consumer information will comply with the requirements of any relevant legislation including sections of the Health Act 1956, the Privacy Act 1993 and the Health Information Privacy Code 1994 and as described in Section 2.5 and Appendix 3 of this document. The provisions of the Official Information Act 1982 and all subsequent amendments also apply. Computerised medical records may be viewed and printed/copied for services nominated by NSU. This will be done on the same basis as handwritten records.

At the end of an investigation copies will be returned to the claimant or destroyed in line with the Provider’s wishes, after all parties agree that no further action is contemplated.
Appendix 3: Confidentiality and the Privacy Act 1993, Health Information Privacy Code (HIPC) 1994 and the Health Act 1956

The Privacy Act enabled codes to be issued to cover specified classes of information and or activities. The HIPC applies in the health sector. The code applies to health information about identifiable individuals.

There are 12 rules (called principles in the Privacy Act) relating to privacy issues associated with health information. A brief summary of some of the relevant rules is shown below. It is expected that you will be fully familiar with your obligations under the Privacy Act 1993 and the HIPC.

Pursuant to section 7 of the Privacy Act the Principles (and therefore the Rules) are subject to other legislation.

Rule 3: Collection of health information from an individual’s representative

Health agencies are required to make individuals aware of a number of factors including the purpose for which the information is collected and the intended recipients of the information. Where Providers collect client information, audit should be listed among the purposes at the time of collection as audit is among the purposes for which client information can be used – see also Rule 10 below.

Rule 10: Limits on the use of health information

Health information obtained in connection with one purpose must not use the information for any other purpose unless ‘the purpose for which the information is used is directly related to the purpose in connection with which the information was obtained: …’. When Providers collect client information, audit should have been listed among the purposes for which client information will be used – see also Rule 3 above.

Rule 11: Disclosure of health information

Pursuant to Rule 11 a health agency holding health information must not disclose the information unless the disclosure of the information is one of the purposes in connection with which the information was obtained.

The Code’s commentary states that a health agency may disclose health information for a directly related purpose such as ‘peer review and quality audit’. The provisions of the Health Act override this section of the Privacy Act.

Privacy Act section 46.
Overriding Provisions of the Health Act 1956

All of these Rules are subject to provisions of other legislation, including the following:

Sections 22C to 22I and Part 4A of the Health Act; briefly, these sections cover: definition of health information, disclosure of health information, the duty to provide health information, communication of information for diagnostic and other purposes, inspection of records, anonymous health information and offence to retain health information (refer to Appendix 7 for selected extracts of this Act).

Under these provisions the NSU can access service Providers’ relevant personal information records (eg, relevant medical records) in the course of an audit for the purposes of verifying that the contracted services have been provided as paid for by the NSU.

References
1 Privacy Act 1993.
Appendix 4: Auditors’ Code of Conduct

Auditors will be required to work to the following code of conduct (based on that used by the Quality Society of Australasia (QSA)).

1) To act professionally, accurately and in an unbiased manner.
2) Not to represent conflicting or competing interests.
3) To disclose to any client or employer any relationships that may influence his or her judgement or the exercise of his or her professional duties.
4) Not to discuss or disclose any identifiable information relating to or accessed during an audit, unless specifically approved by the NSU or required by law or authorised in writing by the auditee, auditing organisation or any other affected party.
5) Not to accept any inducement, commission, gift or any other benefit from auditee organisations, their employees or any interested party, in return for making decisions or judgements that may be of advantage to the individual or organisation offering the inducement, nor knowingly allow colleagues to do so.
6) Not intentionally communicate false or misleading information that may compromise the integrity of any audit.
7) To co-operate fully with an inquiry in the event of any alleged breach of this code.
Appendix 5: Confirmation with Other Parties

A5.1 How and why
The auditors may wish to confirm with other parties that the services reported match those delivered and/or that the required contractual and quality standards were met. This will occur as part of any audit process or where the records indicate a need to confirm items with the other parties concerned. This confirmation may take several forms, it could be:

- written correspondence with the other parties,
- verbal confirmation (by phone or in person), or
- visits to other parties.

A5.2 Visits to other parties
All approaches to other parties will be handled with care and sensitivity. Inquiries of other parties will be made at reasonable times by agreement with the other party. The audit will not be discussed with the other party except to explain the process in general terms and how the other party came to be identified.

When another party is approached, the auditors will show identification and explain the role of NSU and the auditors. The other party will be asked to answer questions regarding the claimed service delivery and advised that they will not be identifiable in any way in the audit reports.

It is in the interests of the Provider, the NSU and other parties to ensure this part of the process is handled with care to ensure integrity of the process is maintained and other parties wishes and needs are respected.

A5.3 Confidentiality
Confidentiality will be preserved throughout the confirmation discussions with other parties. As described elsewhere in this document (subject to the Official Information Act) the results of any audit will be confidential to the Provider and NSU.

The steps taken to maintain the confidentiality of consumer information will comply with the requirements of the Privacy Act 1993 and the Health Information Privacy Code 1994.

A5.4 Summary
In following up any matters with other parties every care will be taken to:

- explain the purpose of the inquiries
- identify the auditors
- clarify any other party’s rights and the issues
- respect other party’s rights at all times
- clarify that the process seeks only to confirm delivery of the specified services
- maintain confidentiality of consumer information.
Appendix 6: Audit Clauses with Providers

Please refer to your agreement terms as these clauses are indicative only. Other contractual clauses may also have application in addition to the following clauses:

Audit clause from Health Promotion Services Agreement

12.1 You and your permitted sub-contractors must allow us and our authorised agents, access on 24 hours’ notice to:
   (a) your premises;
   (b) all premises where the Records are kept; and
   (c) staff, sub-contractors or other people used by you in providing the Services and allow us to interview any staff, subcontractors and the people you supply Services to (and their families) for the purposes of carrying out an audit of your performance and compliance with this agreement.

12.2 Our right to audit under this clause continues after this agreement ends but only to the extent that it is relevant to the period during which this agreement exists.

Audit clause from Colposcopy and NCSP Regional Offices Agreement

12.1 You and your permitted sub-contractors must allow us and our authorised agents, access on 24 hours’ notice to:
   (d) all records related to provision of the Services;
   (e) your premises;
   (f) all premises where the Records are kept; and
   (g) staff, sub-contractors or other people used by you in providing the Services and allow us to interview any staff, subcontractors and the people you supply Services to (and their families) for the purposes of carrying out an audit of your performance and compliance with this agreement.

12.2 Without limiting any other audit activity we may conduct we may:
   (a) access Confidential Information above any service user (subject to any applicable law); and
   (b) observe the provision or delivery of the Services.

12.3 Our right to audit under this clause continues after this Agreement ends but only to the extent that it is relevant to the period during which this Agreement exists.
Audit clause from Laboratory Services Agreement

The whole of Section I of the Agreement is applicable to the audit process. The following is the clause referring to Notice of Audit.

2.4 We will give you 10 Business Days’ prior written notice of our intention to carry out an Audit, except where we have reasonable grounds to believe that:

(a) there has been a material breach of the Agreement; or

(b) a delay of 10 Business Days would unreasonably prejudice the integrity of the Audit; or

(c) a delay of 10 Business Days would unreasonably prejudice the interests of any Eligible person

in which case a reduced notice period may be given which is reasonable in the circumstances (and may include less than 24 hours notice in some circumstances). This notice will include the identity of the person or persons we intend to appoint as Auditors and their qualifications, if any.

Audit clause from ISP (smear-taker) Agreement

12.1 You and your permitted sub-contractors must allow us and our authorised agents, access on 24 hours’ notice to:

(h) your premises;

(i) all premises where the Records are kept; and

(j) staff, sub-contractors or other people used by you in providing the Services and allow us to interview any staff, subcontractors and the people you supply Services to (and their families) for the purposes of carrying out an audit of your performance and compliance with this agreement.

12.2 Our right to audit under this clause continues after this agreement ends but only to the extent that it is relevant to the period during which this agreement exists.
Appendix 7: Extracts from Relevant Legislation

Health Act 1956

Section 22C

(1) Any person (being an agency that provides services or arranges the provision of services) may disclose health information –

(a) if that information –

(i) is required by any person specified in subsection (2) of this section; ...

(2) The persons and purposes referred to in subsection (1) (a) of this section are as follows:

... 

(g) Any employee of the Ministry of Health, for the purposes of –

(i) Administering the Health Act or the Hospitals Act 1957; or

(ii) Compiling statistics for health purposes.

Section 22G – Inspection of records

(1) In this section, provider means a person who has claimed payment for services from 1 or more of the following:

(a) the Ministry of Health:

(b) a district health board:

(c) the Health Funding Authority or a person authorised by the Health Funding Authority to make payments:

(d) a hospital and health service:

(e) a Crown health enterprise:

(f) an area health board:

(g) a hospital board:

(h) the Department of Health.

(2) Every provider must, forthwith after a request by the Director-General or the chief executive of a district health board or of Health Benefits Limited, make available any records of the provider that relate to the services concerned for inspection –

(a) by a person authorised in writing by the Director-General or the chief executive of the district health board or Health Benefits Limited, (as the case may be) for this purpose, being a person who holds a professional qualification relevant to the services provided by the provider or any other person the Director-General or the chief executive considers appropriate; and

(b) for the purposes of verifying the claim for payment.

(3) Any person authorised in accordance with subsection (2) of this section to inspect the records of a provider may copy or take notes of those records for the purposes of the inspection.
Part 4A National Cervical Screening Programme

Please refer to: http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes

The purpose of this Part is:
(a) to reduce the incidence and mortality rate of cervical cancer by providing for the continuation of the NCSP; and
(b) to facilitate the operation and evaluation of that national cervical screening programme by:
   (i) enabling access to information and specimens by the persons operating the programme; and
   (ii) enabling access to information and specimens by screening programme evaluators appointed to evaluate that programme.

The Health and Disability Services (Safety) Act 2001

This Act is to promote the safe provision of health and disability services to the public and enable the establishment of consistent and reasonable standards for providing health and disability services to the public safely. Parts of this Act come into force on 1 July 2002. The sections relating to implementation of service standards and auditing will be applicable from 1 July 2002. Provisions relating to enforcement (including inspection and monitoring of Providers) will come into effect from 1 October 2002.