

Cancer Screening Managing Serious and Sentinel Events

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Introduction

These guidelines outline the best practice for managing serious and sentinel events in the Cancer Screening Programmes – BreastScreen Aotearoa (BSA) and the National Cervical Screening Programme (NCSP).

The process is based on Standards New Zealand ‘Sentinel Events Workbook’ (SNZ HB 8152:2001) and the Ministry of Health’s ‘Reportable Events Guidelines’.

Providers identify most incidents in a screening programme. This can happen through a number of means, including:

- A specific event that gives rise to concern
- Routine quality control by staff
- Quality assurance activities
- Staff concerns
- A complaint (eg. from the Health and Disability Commissioner, Registration Boards, or the patient directly)
- Media interest.

Issues may also be identified during external audits or data assessment undertaken by the National Screening Unit (NSU).

There are a number of important reasons for reporting incidents in the screening Programmes. These include:

- Quality improvement
- Learning from errors
- Sharing fixes with other providers
- Public reporting responsibility.

Unfortunately the NSU cannot develop a definitive list of serious or sentinel events that may occur. This document will give you some examples and guidance on how an event will be managed, but cannot categorically list all issues that will become an event.

Remember: It is a requirement to report all incidents to the NSU.

Definitions

Serious event

A serious event is one that may significantly compromise screening, and/or assessment activities, and/or outcomes, and/or be an event for which a facility fails to take appropriate corrective action in a timely manner.

The characteristics of a serious event could include:

- A system failure resulting in a reduction in the quality of service
- Significant deviation from the organisation's usual process
- The potential to result in significant harm
- An event that must be reported to regulatory bodies under statute
- An event that needs to be reported to the organisation's insurance carrier
- The potential for adverse media attention.

Sentinel event

A sentinel event is an event that signals something serious has occurred and warrants in-depth investigation. It will commonly reflect system and process deficiencies, and may result in actual or potential harm.

The characteristics of a sentinel event include:

- Major systems failure
- Multiple teams, departments or services involved
- The potential for serious adverse media attention
- The potential to seriously undermine public confidence
- When a group of consumers have potentially suffered harm.

Examples

Serious or sentinel events may include but are not limited to:

- Failure to inform
- Failure to reinvite a woman for her screen or smear
- Failure to inform a woman and her GP of a significant symptom and appropriate action
- Employment of personnel who do not have the required skills as outlined in BSA's National Policy & Quality Standards (NPQS) or NCSP's Operational Policy & Quality Standards (OPQS)
- Accidents or near misses
- An event that results in a missed or delayed cancer diagnosis
- An event that causes missed or delayed treatment once disease is identified
- Infections/notifiable diseases
- Serious breaches of confidentiality
- Other reportable serious events and/or sentinel events as indicated by legislation, regulation, professional practice standards, and contracts.

Specific BSA examples may include:

- Failure to recall a woman with an identified mammographic abnormality to assessment
- Failure of mammographic equipment resulting in need to re-medicate women
- Failure to send mammography reports in a timely manner.

Specific NCSP examples may include:

- Failure to assess and treat a woman with a high grade abnormality by colposcopy
- False negative cytology
- Failure to be screened or to be screened regularly.

**Process for
Managing
Events**

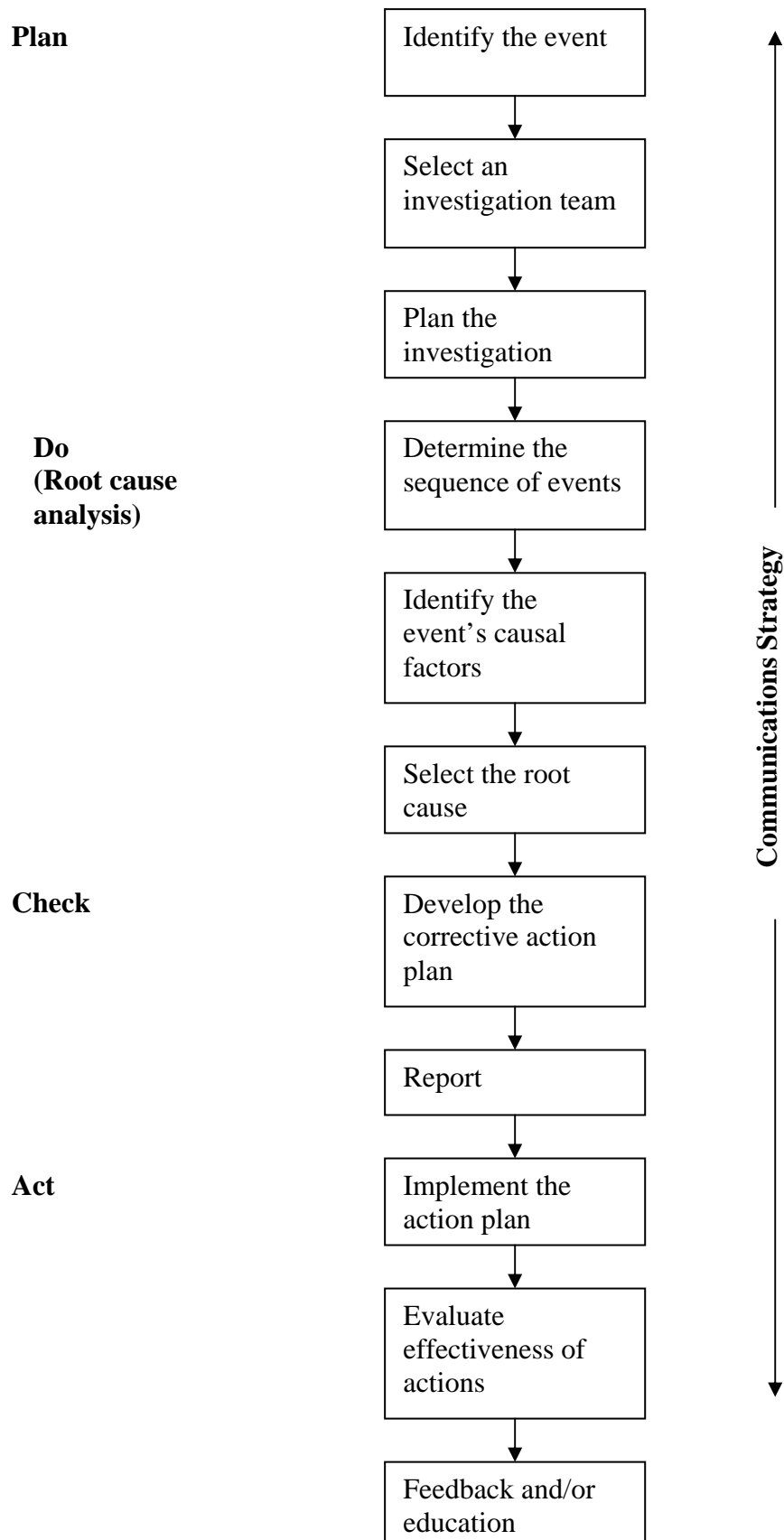
There are four stages involved in identifying and managing an event.

1. Plan
2. Do (root cause analysis)
3. Check
4. Act

We will look at all of these stages in detail in the rest of this document. We also discuss when it may be appropriate to have a communications strategy and what that may include.

Overview of the Process

Your organisation is responsible for the investigation and reporting to NSU. NSU will provide support during the process as required.



Stage 1. Plan

Identify the Event

Once you become aware of an incident, it is important to determine the significance of the event and whether an in-depth investigation is needed.

The initial investigation aims to establish as quickly as possible whether or not there is a problem.

As part of identifying the event, gather the following information.

1. Describe the event or area of concern.
 2. How was the event identified or discovered? When was the notification received (eg. time etc.)?
 3. Which other departments/agencies/services are involved?
 4. Why this event warrants in-depth investigation?
 5. Notify those directly involved in the event of the proposed investigation.
 6. Who else needs to be notified, who by, and about what?
 7. Who will lead the investigation? (What specialist skills/knowledge does the investigation leader need to bring to the investigation team?)
 8. Who has approved the investigation? (Name, designation, date, etc.)
-

Notifying the NSU

The NSU must be notified about the event. An incident notification template has been provided in Appendix One.

The template must be completed within three working days of the incident and sent to the Manager, Quality Assurance at the NSU.

The Manager, Quality Assurance will determine which staff members in the NSU need to be advised of the event. The NSU will then determine whether they need to be involved in the investigation.

Note: The NSU may contract another person or organisation to look into the event on their behalf.

Select an investigation team

Bring together a team of people who have an intimate knowledge of the 'normal process'. In most cases a special team will need to be assembled to ensure all relevant parties are represented. Ideally, the investigation team should consist of three to four people, as well as the investigation leader. The NSU representative must be one of the team members if it is determined that they need to be involved.

The investigation leader (and the NSU representative if involved) will decide what expertise is needed on the team, and identify who fits the role. The NSU retains the right to appoint the team members of its choice if the NSU and the investigation leader cannot agree.

Membership of the team will depend on the nature of the incident but is likely to include:

- The Lead Provider Manager or Service Manager
- The Clinical Director
- The NSU representative (if involved)
- Relevant specialist team members, eg. physicist, nurse, radiologist, colposcopist, etc.

The team should be established within five working days of the event being identified.

It may also be useful for the team to have access to:

- Independent expertise in the screening programme
- Communications advice
- Legal advice
- Human resources advice
- Counselling advice.

Plan the investigation

Collect facts, knowledge, and physical items related to the event as soon as possible.

The purpose of collecting information at this stage is to:

- Secure information to ensure it is available for use during the investigation
- Describe the event, including the sequence of events leading up to the incident
- Organise the information
- Provide initial direction to the investigation team
- Identify relevant policies and procedures
- Identify what information is required to be collected about the event.

Information is best collected as soon as possible after the event has occurred. It is also useful to use a numbering or referencing system for tracking information easily.

Some of the questions that the initial investigation will try to answer include:

- What is the problem?
 - Is it an isolated event or has it happened before?
 - How was the problem identified?
 - What evidence is available so far?
- What is the scale of the problem?
 - When was the problem first identified?
 - How long has it been going on?
 - Are any women directly affected? If so, estimate how many.
 - Does it affect any staff?
 - What are the possible causes of the problem? Is there a failure of equipment, procedures, diagnostic interpretation, IT systems, or an individual?
- What has been done about the problem so far?
 - Is it still a problem?
 - If yes, is it safe to continue the service?
 - Has the service been stopped by the Provider? If yes, what are the implications?
 - Are there any immediate implications for other services in the screening programme?
 - Are any other agencies involved, such as ACC or the Health and Disability Commission?
 - Is the problem public knowledge? If so, how has that happened?
- What will we do next?

Note: The quality of the screening service should not be compromised, or additional women put at risk while the suspected incident is being investigated. If there is a possibility that there has been a serious service failure, the NSU will consider whether it is safe to continue the screening service while investigations are in progress. However, this would be a very uncommon event.

Possible outcomes of the initial investigation

1. Incident is low risk and easily resolved or already resolved.
 - The investigation team will prepare a report that:
 - Sets out the reasons for why the matter was investigated
 - Records the methodology used in the initial investigation
 - States that the incident is low risk and is easily resolved or has already been resolved (include actions taken)
 - Reassures staff in the screening service.
 - The report should be sent to the Manager, Quality Assurance at the NSU, who will analyse the incident with the Programme's Clinical Leader and draw out generic lessons learned, as well as specific lessons for the service.
 - NSU staff will widely disseminate the lessons learned to providers, with quality improvement suggestions.

2. Problem still suspected, further investigation needed.
 - The investigation team will continue with a more detailed investigation, as outlined in the next stage.
 3. Problem confirmed.
 - The investigation team will continue with a more detailed investigation and plan, as outlined in the next stages.
-

Reporting

A reporting template has been included in Appendix Two that provides prompts for the information required.

The report summarises the investigation and should cover:

- What happened (the event description and chronology)
- Why it happened (the causal factors and the root cause)
- What can be done to prevent a recurrence (the proposed corrective action)
- Any action already taken.

The report is discussed in more detail in the ‘Stage 3. Check’ section of this document.

Note: An incident that is identified as low risk and resolved may not need to include sections 5, 6 and 7 of the reporting template.

Stage 2. Do (root cause analysis)

Determine the sequence of events The investigation team now conducts a detailed investigation to determine the sequence of events. This is usually in much greater detail than the initial collection of information conducted by the investigation leader and the NSU representative.

Further investigation is likely to include one or more of the following.

BSA	NCSP
A review of: <ul style="list-style-type: none"> • Equipment fault reporting and quality control procedures • Previous screening mammograms • Assessment cases • Call and recall procedures • Pathology cases • Surgical procedures • MDM arrangements 	A review of: <ul style="list-style-type: none"> • Equipment fault reporting and quality control procedures • Current and previous case history and potential case review • Statistical analysis for individual/unit performance • Interpretation/diagnostic deficiencies in education, CME, CPD, etc. • MDM arrangements • Treatment procedures
Continued analysis of data on past performance	Continued analysis of data on past performance
Collection and analysis of further performance data	Collection and analysis of further performance data

Identify the causal factors Once the sequence of events has been identified, the investigation team should try to identify the causal factors.

Examples of causal factors include the following components:

- People/person/injured party.
 - Personal.
 - History.
- Task.
 - Availability and use of protocols.

- Individual (staff).
 - Skills and knowledge.
 - Human factors.
- Team.
 - Verbal and written communication.
 - Leadership/responsibility.
- Work environment.
 - Administration.
 - Workload.
 - Staffing.
- Organisational and management factors.
 - Policy, standards, and goals.
 - Safety culture.
- DHB.
 - Economic and regulatory context.
 - Inter-provider context.
- National.
 - Legislation and regulations.
 - Standards.

Select the root cause

Root causes are the most basic events or conditions that, if eliminated or identified, would reduce the possibility of the event and its consequences recurring.

The investigation team should be confident that they have adequately analysed the contributing factors to determine the actual root cause(s).

Root causes may include:

- Errors
- Omissions
- System deficiencies
- Inadequate competencies
- Non-adherence to policies, procedures, protocols, or work instructions
- Poor communication or documentation
- Inadequate facilities or equipment
- Inadequate skill mix or availability of the health care team
- Managerial inaction.

More than one root cause may be identified, so the investigation team should prioritise the solutions for each root cause.

When developing proposed solutions, consider both the positive and negative impacts on any:

- Interlinking processes within the whole system
 - Identical processes in different sections or services.
-

The outcome The investigation team must come to the conclusion that the investigation has either:

- Identified that the incident is low risk and easily resolved or already resolved (include actions taken) or
- Confirmed that a serious or sentinel event has occurred.

Low risk

If the incident is confirmed as low risk, the investigation team will prepare a report using the template in Appendix Two.

The report should be sent to the Manager, Quality Assurance at the NSU, who will disseminate it to appropriate people in the NSU.

Serious or sentinel event

If the investigation has confirmed that a serious or sentinel event has occurred, the investigation team should continue to the next stage.

If the incident is a serious service failure, the investigation team should decide whether urgent action is needed to remove an individual or equipment from the process or service.

Safety is of paramount importance. All steps should be taken to remove or minimise the risk of harm.

Stage 3. Check

Develop the corrective action plan

At this stage, the investigation team needs to generate a plan to address the root causes that either directly or indirectly contributed to the event.

The action plan should:

- List the root causes
- List the actions to address the root causes
- Identify who is responsible for implementing the action(s)
- Identify the timeframe for implementation and completion of any requirements or actions
- Identify any resource requirements
- Record evidence of completion (including measures for ongoing monitoring where required)
- Have actions formally signed-off as they are completed
- Identify the date to evaluate the effectiveness of the action plan and who will evaluate it.

Report

The investigation team needs to prepare a report using the template in Appendix Two.

The report will be provided to the following people:

- Manager, Cancer Screening (NSU)
- Manager, Quality Assurance (NSU)
- NSU Senior Leadership Team
- Director General of Health / Deputy Director General Health & Disability National Services Directorate (if deemed required by the NSU).

For each incident the investigation team will need to determine whether the report should also be sent to individuals affected by the incident or other bodies, eg. DHB, HDC.

The report should include the following sections.

- Section 1: Summary (do last).
 - State the event or problem.
 - Summary of root causes if known.
 - Summary of actions taken.

- Section 2: Introduction and background.
 - A brief description of the event and its results.
 - A brief introduction of the team conducting the investigation.
 - A description of the scope of the investigation, purpose, timeframes, methodologies used, who was involved, and the findings. Include whether an independent view has been provided or expert advice sought.
 - How many people were impacted or harmed, and the consequences.

- Section 3: Analysis and findings.
 - Factual description of the event, including chronology and responses to the event.
 - Brief descriptions and results of the analyses that were conducted, eg. summary of issues based audit, previous audits, or relevant investigations.
 - Root cause(s) identified and rationale for selecting the root cause.
 - Summarise key issues and options considered for action. Consider standards, training, and monitoring requirements.
 - Include risk of harm ongoing or elsewhere, and public/political view if relevant.

- Section 4: Conclusions and actions.
 - Summarise conclusions and proposed and/or implemented corrective actions. Match solutions with root cause(s) to which they apply – who, what, when.
 - Plans for evaluating the effectiveness of corrective actions, eliminating, minimising, and isolating the root cause.

- Section 5: Learning points.
 - Pass on the knowledge. List the learning points that need to be passed on to appropriate staff, either through formal training, or through some other means (eg. individual feedback, coaching, etc.).

- Section 6: Residual risk(s).
 - Where the root causes are not addressed, or there is an outstanding risk, identify the following:
 - Likelihood of recurrence
 - Consequences of recurrence
 - Control effectiveness if recommended actions are taken
 - Acceptability of the residual risk

- Section 7: Attachments.
 - List all attachments and references to the report. This may include, but is not limited to, relevant documents relating to the incident (if appropriate), flow charts, existing or new policies, and external standards.
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Stage 4. Act

Implementation The investigation team needs to finalise and implement the action plan.

The following steps should be taken.

- Plan implementation of the corrective actions.
 - How will the results be communicated?
 - Which policies and procedures need to be reviewed?
 - What training is required?
 - What ongoing monitoring needs to be established?
 - Are there any other areas of improvement?
 - Pilot actions.
 - Do you need to test or pilot the solutions?
 - Test the effectiveness of the change.
 - Did the solution achieve the desired outcome in the pilot?
 - Implement the recommended action.
 - Ensure that all relevant personnel are aware that the recommended action has been implemented.
-

Evaluate effectiveness of actions

At the evaluation date, the investigation team should evaluate the changes or solutions specified within the action plan to determine the level of implementation and effectiveness. All groups of staff should be allowed to be involved in the evaluation.

The evaluation will ensure that:

- The root cause(s) have been addressed
- The likelihood of recurrences has been reduced or eliminated
- Lessons have been learnt and communicated
- Ongoing education and monitoring have been implemented
- Identified barriers to change have been removed.

The investigation team should then decide when to formally close the event.

The event will normally be closed when all the consequences of the event have been identified and arrangements for dealing with them are in place and operating effectively. If these arrangements are ongoing, the investigation team must make sure that appropriate reporting arrangements are in place before closing the event.

Lessons learned There may be lessons for the wider Programme or other screening programmes in:

- Identifying the problem
- Preventing a recurrence
- Managing the event and dealing with the consequences
- Educational activities.

The NSU is responsible for sharing lessons learned across the Programme and will prepare a report for national distribution.

Communications Strategy

Incidents may occur that have a wide impact on the screening programme.

As part of the process for managing the event, it may be appropriate to incorporate a communications strategy. The investigation team are responsible for communications, although they should use a designated communications or media person to help them.

The investigation team should consider whether a communications strategy is required at each stage of the process.

The focus of the communications strategy is to:

- Care for women who are directly affected by the event
- Minimise anxiety
- Maintain confidence in the screening programme as a whole.

If the investigation team decides to implement a communications strategy, staff working in the programme and GPs must be kept well informed and adequately supported, so that they are able to answer questions from women. There must also be arrangements for answering queries from the media and the general public.

Actions

Following are a list of actions that may be appropriate depending on the circumstances of the event. The investigation team will need to agree on the appropriate communications strategy.

1. Set up a database of all women affected (names, addresses, date of birth, and GP) and check it for accuracy.
2. Decide what action to take for women who have been affected. This may include:
 - Recalling women for additional screening or assessment
 - Providing access to support and advice from nurses.
3. Prepare for the consequences of each action.
 - Consider setting up an 0800 help line.
 - Make arrangements to deal with queries from the media and the general public.
 - Brief Providers who may get an increased number of queries from worried women.

Note: It won't always be necessary to set up a help line. If the investigation team is confident that all women directly affected have been contacted and have been offered the opportunity to discuss their concerns with an appropriate health professional, then setting up a general help line may generate unnecessary anxiety amongst other women.

4. Carefully consider the wording to be used in any communications, including any legal implications and issues of confidentiality.
 - Be informative about what has happened and why.
 - Describe what will happen next and the likely timeframes.
 - Put the incident into the context of the screening programme as a whole.
 - Consider responses to likely questions.
 - Provide information on sources of further information and advice.
 - Be accurate, truthful, and consistent.

5. Inform GPs.
 - Send a letter explaining the problem, the steps being taken to deal with it, and the likely timeframes.
 - Copies should be sent to practice managers and practice nurses.
 - Where possible, send letters by fax or email rather than by post.
 - Consider inviting GPs for a briefing session.

Note: Specific information about individual patients and the actions proposed should be sent to the GPs of women directly affected. This must be done at the same time that GPs are informed about the problem and before the women are informed.

6. Write to women directly affected.
 - Send by courier or registered mail.
 - Ask the women to confirm receipt of the letter either by telephone or by a pre-paid, self-addressed envelope and return slip.
 - Include any relevant leaflets about the programme.

Note: The letter should be delivered during the working week so the women can access support from health professionals or their GP. If the women are asked to confirm by telephone, it is preferable to have the phones manned by appropriately qualified staff (eg. nurses, counsellors). If the numbers of affected women allow, it may be preferable for the first contact to be by telephone by appropriately qualified staff.

7. Brief the staff involved.
 - Hold face-to-face briefings with staff in the screening programme.
 - Hold face-to-face briefings with staff such as pathologists, surgeons, and nurses, who may have to deal with an urgent and increased workload.
 - Provide a general briefing note to other staff, outlining the problem and the action being taken.
 8. Prepare a press briefing.
 9. Provide a briefing for the Minister of Health, the Director of Health, and the DHB Chief Executive.
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Appendix One – Cancer Screening Incident Notification Template

The Incident Notification Template should be completed when advising NSU of an incident. Send it to the Manager, Quality Assurance (NSU), within three working days of the incident.

Incident Investigation and Notification Plan

(State Issue/Complaint)

- 1. Description of incident or area of concern** (Include dates)
- 2. How was incident discovered / notified?**
- 3. Which other organisations are involved?**
- 4. Why does the incident warrant further investigation?**
- 5. Who is involved in the investigation?**
- 6. Who else needs to be notified of the incident?** (By whom and what do they need to know?)
- 7. Investigation Plan** (Update ongoing – who is doing what?)

Date	Action	By Who	Status

Appendix Two – Cancer Screening Incident Investigation Report Template

Use the following template when reporting on a cancer screening incident investigation.

The report should:

- *Set out the reasons for why the matter was investigated*
- *Describe what happened (the event description and chronology)*
- *Identify why it happened (the causal factors and the root cause)*
- *Outline what can be done to prevent a recurrence (the proposed corrective action)*
- *State any actions already taken to resolve the issue*
- *Reassure staff in the screening service.*

Note: If the initial investigation identifies that the event is low risk and is easily resolved, or has already been resolved, the report may not need to include sections 5, 6 and 7.

The report will be provided to:

- *Manager, Cancer Screening (NSU)*
- *Manager, Quality Assurance (NSU)*
- *NSU Senior Leadership Team*
- *Director General of Health / Deputy Director General Health & Disability National Services Directorate (if deemed required by the NSU).*

For each incident the investigation team will need to determine whether the report should also be sent to individuals affected by the incident or other bodies, eg. DHB, HDC.

Cancer Screening Incident Investigation Report

1. Summary (do last).
 - State the event or problem.
 - Summary of root causes if known.
 - Summary of actions taken.

2. Introduction and background.
 - A brief description of the event and its results.
 - A brief introduction of the team conducting the investigation.
 - A description of the scope of the investigation, purpose, timeframes, methodologies used, who was involved, and the findings. Include whether an independent view has been provided or expert advice sought.
 - How many people were impacted or harmed, and the consequences.

3. Analysis and findings.
 - Factual description of the event, including chronology and responses to the event.
 - Brief description and results of the analyses that were conducted, eg. summary of issues based audit, previous audits, or relevant investigations.
 - Root cause(s) identified and rationale for selecting the root cause.
 - Summarise key issues and options considered for action. Consider standards, training, and monitoring requirements.
 - Include risk of harm ongoing or elsewhere, and public/political view if relevant.

4. Conclusion and actions.
 - Summarise conclusions and proposed and/or implemented corrective actions. Match solutions with root cause(s) to which they apply – who, what, when.
 - Plans for evaluating the effectiveness of corrective actions, eliminating, minimising, and isolating the root cause.

5. Learning points.
 - Pass on the knowledge. List the learning points that need to be passed on to appropriate staff, either through formal training, or through some other means (eg. individual feedback, coaching, etc.).

6. Residual risk(s).
 - Where the root causes are not addressed, or there is an outstanding risk, identify the following:
 - Likelihood of consequence
 - Consequences of recurrence
 - Control effectiveness if recommended actions are taken
 - Acceptability of the residual risk.

7. Attachments/appendices.

- List all attachments and references to the report. This may include, but is not limited to, relevant documents relating to the incident (if appropriate), flow charts, existing or new policies, and external standards.