National Screening Unit

Incident Management
Contents

Contents ......................................................................................................................... 2
Overview ......................................................................................................................... 4
  Purpose ......................................................................................................................... 4
  Audience ....................................................................................................................... 4
  Background ................................................................................................................... 4
  Definition ....................................................................................................................... 4
  Principles ....................................................................................................................... 4
  Standards ...................................................................................................................... 4
  Definitions ................................................................................................................... 5
Introduction ................................................................................................................... 6
  Background ................................................................................................................... 6
  Purpose ......................................................................................................................... 6
  Purpose cnt. ................................................................................................................... 7
  Scope ............................................................................................................................ 7
  Responsibility for National Screening Programme Incidents ...................................... 7
  Responsibilities of Service Provider ........................................................................... 7
  Key responsibilities of NSU ....................................................................................... 8
  Responsibilities of Quality and Equity Team .............................................................. 8
Incident Management Process Diagram ........................................................................ 9
Cycle of Improvement .................................................................................................... 10
  Introduction .................................................................................................................. 10
  Definition ...................................................................................................................... 10
  Plan ................................................................................................................................ 10
  Check ........................................................................................................................... 10
  Act .................................................................................................................................. 10
  Identification ................................................................................................................ 11
Stage 1 Plan .................................................................................................................... 12
  Incident Identification ................................................................................................. 12
  Notifying the NSU ........................................................................................................ 12
  Select an investigation team ...................................................................................... 12
  Plan the investigation ................................................................................................. 13
  Systems failure check ............................................................................................... 14
  Prioritisation ................................................................................................................ 15
  Severity Assessment Code scoring process ............................................................... 15
  Possible outcomes of the preliminary investigation ................................................ 15
  Reporting ...................................................................................................................... 16
Stage 2 Do (Detailed Investigation) .................................................................................. 17
  Determine the sequence of events .............................................................................. 17
  Identify the causal factors ......................................................................................... 17
  Identify the root cause ............................................................................................... 17
  The outcome ............................................................................................................... 18
Stage 3 Check .................................................................................................................. 19
  Develop the corrective action plan ............................................................................ 19
  Report .......................................................................................................................... 19
  NSU Report ................................................................................................................ 20
Stage 4 Act ....................................................................................................................... 21
  Implementation ........................................................................................................... 21
  Evaluate effectiveness of actions ............................................................................. 21
  Lessons learned ......................................................................................................... 21
Communications Strategy ................................................................................................ 22
  Actions ......................................................................................................................... 22
Appendix ........................................................................................................................ 24

National Screening Unit – Incident Management
20th December 2010
Appendix One – NSU Incident Notification Template............................24
Appendix Two – NSU Incident Investigation Report Template...............25
Appendix Three – Specific Examples ..................................................27
Appendix four - NSU Incident Assessment Criteria Matrix .................28
Appendix five - Severity Assessment Code (SAC) Matrix Step 1 -Consequences Table (Revised) Version 1.0 ..........................29
Overview

Purpose
The purpose of this document is to clarify the National Screening Unit (NSU) Incident Management policy. It details the internal processes and procedures for managing the occurrence of incidents across all Screening Programmes managed by NSU.

Audience
The intended audience of this document is NSU staff members; it provides instructions and guidance to ensure effective Incident Management.

Background
The NSU Incident Management policy and process is based on the National Policy for the Management of Healthcare Incidents and the Cancer Screening Managing Serious and Sentinel Incidents Policy.

Definition
An incident is an event or circumstance which could have, or did, result in unintended or unnecessary harm to a person or programme, and / or a complaint, loss or damage.

Principles
The principles behind the NSU Incident Management policy follow those documented in the National Policy for the Management of Healthcare. They include:

- Transparency and openness
- Openness of incident reporting
- Systems focus not individuals.
- Emphasis on learning and improvement
- Obligation to act
- Accountability
- Fairness
- Appropriate prioritization of action
- National Consistency
- Local commitment and action but with a national overview

Standards
The NSU Incident Management process requires staff to ensure that:

- All incidents related to the provision of NSU screening services that may have a potential impact are recorded in the Incident Management system (JIRA)
- All Incidents are allocated a ‘severity’ rating
- Normal screening programme services are restored as quickly as possible with minimum disruption
- Records related to Incidents are maintained to support this process and the ongoing management and monitoring of the screening programmes
- Incident escalation / transfer is based on the impact to a particular programme, service or provider
- Q&E will monitor and track the status of Incidents on behalf of NSU
Definitions

Complaint
Is an expression of dissatisfaction by a complainant? In many instances, complaints are incidents that have occurred in a health or disability service, but that have been reported by a consumer, carer or family member, service user or resident.

Incident
Is an event or circumstance which could have, or did, result in unintended or unnecessary harm to a person and/or a complaint, loss or damage.

Incident management
Is a systematic process for identifying, notifying, prioritizing, investigating and managing the outcomes of an incident and acting to prevent recurrence.

Investigation
Is defined as a searching inquiry in order to ascertain facts.

Issue
An issue is an “event” or obstacle which makes it difficult to achieve a desired goal, objective or purpose. It refers to a situation, condition, or problem that is yet unresolved.

JiRa
Is the software used by NSU to log, document and track all details of the incident including resolution.

Notification
Is the process of reporting an incident or near miss.

National Screening Unit (NSU)
Manages the National Screening Programmes and is a business unit within the Ministry of Health.

Providers
Providers also known as Service Providers operate screening services as contracted on behalf on the National Screening Unit (NSU).

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

Sentinel incident
A sentinel incident is an incident that signals something serious has occurred and warrants in-depth investigation. There is opportunity for either actual or potential serious harm to occur.
Introduction

Background

The National Screening Unit (NSU) was established in 2001 to deliver safe, effective and equitable screening programmes nationwide. The NSU’s vision is to achieve ‘high quality, equitable and accessible national screening programmes’.

The work of the NSU focuses on the achievement of five strategic objectives:
- Increase awareness and access
- Deliver equitable screening services
- Demonstrates sector leadership and enhance relationships
- Improve delivery standards and quality
- Build information and knowledge.

A successful screening programme requires a coordinated approach that includes:
- clear roles and responsibilities and lines of accountability
- high quality equitable service provision
- effective monitoring of defined policy and quality standards
- timely availability, and appropriate integration, of screening, diagnostic, treatment and follow-up services
- high levels of programme enrolment and participation for all ethnic groups.

Purpose

The purpose of the NSU Incident management document is to make it clear in the process required to manage national screening related incidents and to provide clarity on the roles and responsibilities between the:

- Ministry NSU staff that are responsible for the national leadership, purchase, contract and performance management of national screening programmes
  and,
- Screening Providers who deliver the actual Screening health service to the public.

The National Screening Unit (NSU) is responsible for the purchasing and contract and performance management of the following screening/quality improvement programmes:

1. **BreastScreen Aotearoa (BSA)**
   Offers two yearly screening mammograms to eligible women (aged 45 - 69) for the early detection of Breast Cancer

2. **National Cervical Screening Programme (NCSP)**
   Offers three yearly cervical smears to women aged 20 – 69 years to detect abnormal changes to cells on the cervix.
Purpose cnt..

3. **Antenatal HIV Screening Programme (AHIV)**
   Offers HIV screening to pregnant women to reduce the chances of HIV being passed to the baby.

4. **Newborn Metabolic Screening Programme (NMSP)**
   Offers screening of newborn babies for certain metabolic disorders.

5. **Universal Newborn Hearing Screening and Early Intervention Programme (UNHSEIP)**
   Offers screening of newborn babies to detect moderate or more severe hearing loss.

6. **Antenatal Screening for Down Syndrome and other conditions**

   **Quality Improvement Measures (ASDSQIM)**
   Offers access to screening for those women who choose to have antenatal screening for Down Syndrome and other conditions.

**Screening Service Providers**

National Screening Programmes are delivered by a large number of Screening Service Providers across the six national screening programmes, from health promotion to treatment.

**Scope**

This guidance is aimed at all staff working within the NSU and the Service Providers who may be involved in identifying and/or managing incidents.

**Responsibility for National Screening Programme Incidents**

Incident Management is everyone’s responsibility within the health and disability sector.

Effective incident management requires a whole of organisation approach with clear points of accountability for reporting and feedback lines at all levels of the organisation. This incorporates individual roles and responsibilities and those of organisations and the NSU.

Under this policy the following specific responsibilities are assumed.

All staff are responsible for:

- notifying all incidents they identify
- participating in the investigation of incidents as required
- participating in the implementation of recommendations made
- encouraging colleagues to notify incidents that have been identified.
- working safely to minimize the occurrence of incidents.

**Responsibilities of Service Provider**

- Identify the incident
- Select investigation team based on prioritisation
- Plan the investigation
- Determine sequence of events
- Identify causal factors
- Complete a root cause analysis (RCA)
- Complete report template
- Implement action plan
- Evaluate effectiveness of action
- Provide feedback and/or education to consumer and/or staff
- Submit final report to NSU SMT.

**Key responsibilities of NSU**

**Performance Manager and Programme Leader**

Work in partnership with the Service Provider and manage the process to ensure that:
- incident is logged
- necessary stakeholders are included in the investigation
- reassess severity and rating of incident
- review corrective action

**Senior Management Team**

- Reviews incident report and recommendations
- Signs off and approves incident closure
- Ensures that appropriate correct action has been taken and risks mitigated

**Responsibilities of Quality and Equity Team**

- Ensure that the incident is logged
- Present incident to SMT
- Follow-up on progress
- Consider systemic failure
- Support the investigation team
- Log final report and outcomes
Incident Management Process Diagram

National Screening Unit

Performance Manager
Programme Leader logs incident and assigns severity rating. Notifies those identified by severity rating. Start Communication plan.

Performance Manager
Programme Leader updates Incident record. Consider if 3rd party involvement is required through consultation with those identified by severity rating.

Reassess severity rating and updates incident record

Performance Manager
Programme Leader updates Incident record and those identified in severity matrix.

Performance Manager
Programme Leader updates Incident record and those identified in severity matrix.

Senior Management Team reviews actions and incident report and recommendations. Signs off and approves incident closure.

Communications Strategy

With Pull of
Update the NSU on progress

Update the NSU on preliminary investigation results

Notify the NSU within 48hrs of identification

Agree on investigation team

Update the NSU on progress

Communicate incident closure to screening provider

Ensure the NSU is kept abreast at all stages of action plan progress

Evaluate effectiveness of actions

Implement the action plan

Complete Report Template appendix 2

Develop the corrective action plan

Notify NSU of root cause

Corrective action plan provided to NSU for approval to proceed

Identify the incident’s causal factors

Complete a root cause analysis

Determine the sequence of events

Plan the investigation

Select an investigation team assessment matrix appendix 4

Identify the incident

Provider of Screening Provision

Version A
20th December 2010
Cycle of Improvement

Introduction
As part of the development of the corrective action plan. Incidents/issues provide the opportunity for improvement to be implemented. The cycle of improvement tool provides the mechanism to do this.

Definition
The cycle of improvement is made up of four repeated stages and is the recommended methodology for continuous Quality Improvement.

Plan
Define the question that you want to answered, including what you would expect the outcome to be. Cover why, what, when, where and how, and the measures that will be used to determine success.

Do
Ensure all baseline data and information has been collated. Implement plan.

Check
Work with the key stakeholders to determine whether or not the issue/incident has been resolved.

Act
Decide on any further actions required, and provide education and training to prevent reoccurrence.
**Identification**

**Provider Identification**

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

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

**NSU Identification**

Issues that may lead to an incident 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 incidents that may occur. This document will give you some examples and guidance on how an incident will be managed, but cannot categorically list all issues that will become an incident.

It is a requirement of all Screening service providers to report all incidents to the NSU.

It is the NSU’s responsibility to ensure that all incidents are managed appropriately and centrally logged to prevent the likelihood of recurrence.
Stage 1 Plan

**Incident Identification**

Once an incident is identified, it is important to determine the severity of the incident 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 within the screening service.

As part of identifying the incident, gather and log the following information.

- Describe the incident or area of concern.
- How was the incident identified or discovered?
- When was the notification received (e.g., time etc.)?
- Which other departments/agencies/services are involved?
- Why this incident warrants in-depth investigation?
- Notify those directly involved in the incident of the proposed investigation.
- Who else needs to be notified, who by, and about what?
- Identify who will lead the investigation? (What specialist skills/knowledge does the investigation leader need to bring to the investigation team?)
- Nominate a lead investigator
- Identify who has the mandate to approve the investigation? (Name, designation, date, etc.)

**Notifying the NSU**

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

The template must be completed within 48 hours of the incident and sent to the provider designated NSU Programme Leader and/or Performance Manager.

The NSU Performance Manager logs the incident in JiRa and assigns a severity rating and communicates as appropriate as identified in matrix in Appendix 4.

**Select an investigation team**

Bring together a team of appropriate people to ensure all relevant parties are represented. Establish an investigation Team Leader. The NSU representative must be one of the team members if it is determined that they need to be involved.

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

- The Service Manager
- The Clinical Advisor
- The NSU representative (if involved)
- Appropriate specialist team members, eg. physicist, nurse, radiologist, colposcopist, etc.

The team should be established within 72 hours of the incident being identified.
The team may require access to:
- Independent expertise in the screening programme
- Communications advice
- Legal advice
- Human resources advice
- Counselling advice.

Plan the investigation

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

The purpose of collecting information at this stage is to:
- Secure information to ensure it is available for use during the investigation
- Describe the incident, including the sequence of incidents 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 incident.

The quality of the screening service should not be compromised, or additional people 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.

Questions that the preliminary investigation should investigate:
- **What is the problem?**
  - Is it an isolated incident or has it happened before?
  - How was the problem identified?
  - What evidence is available so far?
- **What is the scale of the problem?**
  - When the problem was first identified?
  - How long has it been going on?
  - Are any people 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?**
Systems failure check

Incident Decision Tree to confirm systems failure

START HERE

Deliberate Harm Test

Physical/Mental Health Test

Forensic Test

Substitution Test

Incidents are investigated using a systems approach within the context of a Just Culture. The purpose is to identify and rectify systems failures to improve patient safety. This algorithm should only be used when clarification is required to confirm an intentionally unsafe act which includes the following:
1. A criminal act
2. The use of illicit drugs or alcohol
3. A deliberate unsafe act
4. Deliberate patient harm.

"System Failure: A system failure is a fault, breakdown or dysfunction within an organisation’s methods, processes or infrastructure.

Clarification required about whether or not the incident involves an intentionally unsafe act

- Consult HR re: further management
- Advise employee of right to support/representation
- Offer referral to Employee Assistance Programme
- Highlight any systems issues identified

- Consult HR re: further management
- Consider in conjunction with HR advice
  - Refer to Occupational Health and Safety Services
  - Adjustment to duties or sick leave
  - Refer to Employee Assistance Programme
  - Advise employee of right to support/representation
  - Highlight any systems issues identified

- Consult HR re: further management
  - Competency training
  - Supervision
  - Adjustment to duties
  - Refer to Employee Assistance Programme
  - Advise employee of right to support/representation
  - Highlight any systems issues identified

- Consult HR re: further management
  - Advice employee of right to support/representation
  - Consider in conjunction with HR advice
  - Refer to disciplinary/legislative body
  - Adjustment to duties
  - Refer to Occupational Health and Safety Service
  - Disciplinary process
  - Highlight any systems issues identified
Prioritisation

All incidents must be prioritised to ensure that the appropriate action is taken on each incident. Prioritisation involves the standardised, objective measure of severity of each incident or near miss.

The Severity Assessment Code (SAC) is the method to be used by any person who has identified an incident, to prioritise that incident.

The score must be ascertained by rating the consequence of the incident and its likelihood of recurrence. While there is necessarily a level of subjectivity / judgment involved in this assessment the SAC provides a means by which to prioritise actions. The SAC must be determined on an incident at least twice, by different people, to ensure greater reliability of the score.

Each incident is assessed for the actual consequence and the potential consequence. The potential consequence is the worst case scenario for the incident being assessed. All ‘actual’ SAC 1 and SAC 2 incidents must be notified immediately to the person responsible for the management of the organisation and then to the NSU.

It should be noted that the SAC score is also of value for incidents that did not actually result in any harm or a poor outcome, such as near misses, sometimes called close calls. This is a valuable feature, as near misses generally occur more frequently than actual incidents and provide an opportunity to improve the system without having had to experience a poor consequence.

Incidents that have been allocated a SAC 1 or SAC 2 score based on the potential consequence of the incident must also be notified to the organisation’s central repository. Investigation of potential SAC 1 and SAC 2 incidents may occur at the discretion of the health and disability service, in accordance with other priorities.

Severity Assessment Code scoring process

The SAC score must be applied to all incidents. The SAC matrix is the method by which the SAC score is derived (appendix five). The four SAC process steps are:

Step 1: Determine the consequence of the incident using the definitions provided
Step 2: Determine the likelihood of recurrence of this incident using the definitions provided. This analysis will require knowledge of the facility or health service in which the incident occurred
Step 3: Allocate a SAC score to the incident using the SAC matrix
Step 4: Determine the appropriate action to be taken using the table provided.

Actual and potential SAC 1 and SAC 2 incidents may be recorded separately in the health and disability service’s central data base.

Possible outcomes of the preliminary 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 providers Programme Leader/Performance Manager, at the NSU, who will analyse the incident with clinical input 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 incident 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 reviewed in more detail in the ‘Stage 3. Check’ section of this document.
## Stage 2 Do (Detailed Investigation)

### 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 team.

### 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.

### Identify the root cause

Root causes are the most basic events or conditions that, if eliminated or identified, would reduce the possibility of the incident 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 incident has occurred.

**Moderate or Minor Incident**

If the incident is confirmed as a moderate or minor incident, the investigation team will prepare a report using the template in Appendix Two.

The report should be sent to the NSU Programme Leader/Performance Manager, who will log and update the appropriate people in the NSU, as per the severity matrix provided in appendix 4.

**Major or Serious Incident**

If the investigation has confirmed that a serious or sentinel incident 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 incident.

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:

- Programme Manager/Leader (NSU)
- Manager, Quality & Equity (NSU)
- NSU Senior Management Team
- Programme Clinical Advisor
- Director General of Health/National Director National Health Board/
  Director National Services Purchasing

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 incident or problem.
  - Summary of root causes if known.
  - Summary of actions taken.

- Section 2: Introduction and background.
  - A brief description of the incident 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 incident, including chronology and responses to the incident.
- Brief descriptions and results of the analyses that were conducted, e.g., 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 (e.g., 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.

NSU Report
The report needs to be forwarded to SMT, for approval of the corrective action plan
Feedback of approval or comments to report writer
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.

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 incident.

The incident will normally be closed when all the consequences of the incident 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 incident.

Lessons learned

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

- Identifying the problem
- Preventing a recurrence
- Managing the incident 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 incident, it may be appropriate to incorporate a communications strategy. The investigation team is 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 participants who are directly affected by the incident
- 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 incident. The investigation team will need to agree on the appropriate communications strategy.

1. Set up a database of all people affected (names, addresses, date of birth, and GP) and check it for accuracy.

2. Decide what action to take for those who have been affected. This may include:
   - Recalling for additional screening or assessment
   - Providing access to support and advice from staff.

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 public.

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. (if required)
   - 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 those directly affected. This must be done at the same time that GPs are informed about the problem and before those directly affected are informed.

6. Write to those directly affected.
   - Send by courier or registered mail.
   - Ask them 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 those directly affected can access support from health professionals or their GP. If they are asked to confirm by telephone, it is preferable to have the phones manned by appropriately qualified staff (e.g., nurses, counsellors). If the numbers of affected people allow, it may be preferable for the first contact to be by telephone by appropriately qualified staff.

7. Brief the staff directly 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.


9. Provide a briefing for the Minister of Health, the Director of Health, and the DHB Chief Executive.
Appendix

Appendix One – NSU Incident Notification Template

The Incident Notification Template should be completed when advising NSU of an incident. Send it to the Provider Performance Manager, within 48 hours 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?)

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>By Who</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix Two – NSU Incident Investigation Report Template

Use the following template when reporting on a NSU incident investigation.

The report should:
- Set out the reasons for why the matter was investigated
- Describe what happened (the incident 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 incident 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:
- NSU Senior Management Team
- Director General of Health / Director, National Services Purchasing (if deemed required by the NSU).

For each incident the investigation team will need to determine whether the report is required to be sent to individuals affected by the incident or other parties, eg. DHB, HDC.
NSU Incident Investigation Report

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

2. Introduction and background.
   - A brief description of the incident 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 incident, including chronology and responses to the incident.
   - 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.
## Appendix Three – Specific Examples

Specific examples of potential Serious Incidents in National Screening programmes

<table>
<thead>
<tr>
<th>Programme/ Unit</th>
<th>Categories of Serious incident</th>
<th>Programme specific examples of POTENTIAL serious incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antenatal &amp; Newborn</td>
<td>Screening Pathway</td>
<td>Outstanding Second Samples from LMC midwife for the Newborn Metabolic Screening Programme (NMSP)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Any cases of error in antenatal diagnosis</td>
</tr>
<tr>
<td>BSA</td>
<td>Intervention/treatment delays</td>
<td>Increased in death/mortality rates due to delayed treatment</td>
</tr>
<tr>
<td></td>
<td>Leading to serious harm in a single patient or potential harm to several patients</td>
<td>Increased severity of size, type and extent of the cancer prior to treatment</td>
</tr>
<tr>
<td></td>
<td>Reporting lead times too long for appropriate clinical action to be taken</td>
<td>Failure to start appropriate treatment within an acceptable time frame</td>
</tr>
<tr>
<td>NCSP</td>
<td>Screening Pathway</td>
<td>Equipment failure</td>
</tr>
<tr>
<td></td>
<td><strong>Histology Misdiagnosis</strong></td>
<td>Lack of Clinical expertise</td>
</tr>
<tr>
<td></td>
<td>Failure to report abnormal result</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Affected person not identified</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Failure to follow the correct screening protocol/procedure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Recording of incorrect test results in outcomes</td>
<td></td>
</tr>
<tr>
<td>Information Systems</td>
<td><strong>Register</strong></td>
<td>Server back up/transfer of data issues leading to loss of patient episodes</td>
</tr>
<tr>
<td></td>
<td>Inappropriate access and use of the National Register at local screening programme level</td>
<td></td>
</tr>
<tr>
<td></td>
<td>IT failure leading to loss of patient data</td>
<td></td>
</tr>
</tbody>
</table>
## Appendix four - NSU Incident Assessment Criteria Matrix

<table>
<thead>
<tr>
<th>NSU Incident Severity (JiRa Priority)</th>
<th>NSU Consultation &amp; Decision Makers</th>
<th>NSU Incident Assessment Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Serious Incident (P1)</strong></td>
<td>• Director National Purchasing</td>
<td>• Screening pathway process, action or lack of action results in operational failure, impacting on delivery of multiple services or resulting in sentinel incident</td>
</tr>
<tr>
<td></td>
<td>• Group Manager NSU</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Chief Advisor Screening</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Quality &amp; Equity Manager</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Programme Manager</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Clinical Advisor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Media Advisor</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Major Incident (P2)</strong></td>
<td>• Group Manager NSU</td>
<td>• Incidents that require external 3rd party investigation or review</td>
</tr>
<tr>
<td></td>
<td>• Chief Advisor Screening</td>
<td>• Programme register(s) failure leading to disruption of service for more than 8hrs</td>
</tr>
<tr>
<td></td>
<td>• NSU Senior Management Team</td>
<td>• Significant ongoing disruption to a key provider service</td>
</tr>
<tr>
<td></td>
<td>• Quality &amp; Equity Manager</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Programme Manager</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Clinical Advisor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Programme Leader</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Media Advisor</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Moderate Incident (P3)</strong></td>
<td>• Programme Manager</td>
<td>• Incidents that require investigation</td>
</tr>
<tr>
<td></td>
<td>• Clinical Advisor</td>
<td>• Complaints received into NCSP-R which require referral</td>
</tr>
<tr>
<td></td>
<td>• Programme Leader</td>
<td>• Partial technology failure leading to disruption of service for more than 24hrs</td>
</tr>
<tr>
<td></td>
<td>• Quality &amp; Equity Manager</td>
<td>• Disruption to a key service or recommendations requiring action within 3mths</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Minor Incident (P4)</strong></td>
<td>• Clinical Advisor as appropriate</td>
<td>• Incidents that can be resolved at first contact without 3rd party involvement</td>
</tr>
<tr>
<td></td>
<td>• Programme Leader</td>
<td>• Complaints received into NCSP-R which require no referral</td>
</tr>
<tr>
<td></td>
<td>• Performance Manager</td>
<td>• Data requests requiring NKG approval</td>
</tr>
<tr>
<td></td>
<td>• Programme/Team</td>
<td>• Isolated impact on technical infrastructure, not affecting service delivery capability</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Appendix five - Severity Assessment Code (SAC) Matrix

#### Step 1 - Consequences Table

(Revised) Version 1.0

<table>
<thead>
<tr>
<th>Clinical Consequence</th>
<th>Corporate Consequence</th>
<th>Analyze all incidents against ACTUAL and POTENTIAL outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Serious</strong></td>
<td><strong>Major</strong></td>
<td><strong>Moderate</strong></td>
</tr>
</tbody>
</table>
| Unexpected patient(s) death resulting from the process of health care, which is unrelated to the expected outcome of a patient's management | Major permanent disability or loss of function (sensory, motor, physiologic or psychological) unrelated to the natural course of the illness and differing from the expected outcome of patient management | Permanent reduction in bodily functioning (sensory, motor, physiologic or psychological) unrelated to the natural course of the illness and differing from the expected outcome of patient management | An Increased level of care including:  
  - Review and evaluation  
  - Additional investigations  
  - Referral to another clinician | No injury or increased level of care or length of stay |
| Or any of the following events:  
  - Inpatient suicide  
  - Wrong patient, wrong site or wrong invasive procedure, wrong implant event  
  - Retained equipment / sward sst requiring surgical removal  
  - Misadministration of radioactive materials  
  - Patient/ infant abduction / discharge to the wrong family  
  - Any investigation commenced by police related to patient abuse (e.g. rape)  
  - Blood transfusion resulting in haemolysis | Or any of the following:  
  - Suicide of an outpatient known to the mental health service within 7 days of contact with the service  
  - Unauthorised leave of a mental health patient with an assessed high risk of serious harm to self or others  
  - Unauthorised leave of Special Patient  
  - Threatened or actual physical or verbal assault of patient or staff requiring police intervention | Or any of the following:  
  - Increased length of stay as a result of the incident  
  - Surgical or other intervention required as a result of the incident  
  - Patient at risk, absent against medical advice | |
| Staff, contactor, visitor:  
  Death(s) of staff member  
  contactor or visitor | Staff, contactor, visitor:  
  Permanent disability or loss of function to staff member, contactor or visitor; requires major additional medical or surgical intervention | Staff, contactor, visitor:  
  Staff member, contactor or visitor requires extended treatment | Staff, contactor, visitor:  
  Staff member or contractor requires short term treatment only with no lost time or restricted duties. Visitor requires short term treatment | Staff, contactor, visitor: Minimal injury to staff member, contactor or visitor; first aid required |
| Services: Non delivery of a key service; loss of Certification / accreditation status | Services: Significant ongoing disruption to a key service; Certification awarded for 2 years or less / recommendations requiring action within 6 weeks | Services: Disruption to service; Certification recommendations requiring action within 3 months | Services: Minimal disruption to low impact on Certification / accreditation status | |
| Finances: Cost overrun or reduction in revenue; the lower of >$3M or > 10% | Finances: Cost overrun or reduction in revenue; the lower of >$2M or > 7-10% | Finances: Cost overrun or reduction in revenue; the lower of >1.5M or > 4-7% | Finances: Cost overrun or reduction in revenue; the lower of >$1.5M or > 2-4% | |
| Environment: Toxic release off-site with detrimental effect; Fire requiring evacuation | Environment: Off-site release with no detrimental effects or fire that grows larger than an incipient stage | Environment: Off-site release contained with outside assistance or fire at incipient stage or less | Environment: Off-site release contained without outside assistance | |

The dot point lists provided above relate mostly to secondary and tertiary care. Primary care and other health and disability services must assess the consequence of the incident using the descriptors provided.
### STEP 2 – Likelihood Table

<table>
<thead>
<tr>
<th>PROBABILITY CATEGORIES</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certain</td>
<td>Is expected to occur again either immediately or within a short period of time (likely to occur at least once in the next 3 months)</td>
</tr>
<tr>
<td>Almost certain</td>
<td>Will probably occur at least once in the next 4-12 months</td>
</tr>
<tr>
<td>Likely</td>
<td>Is expected to occur within the next 1 to 2 years</td>
</tr>
<tr>
<td>Unlikely</td>
<td>Event may occur at some time in the next 2 to 5 years</td>
</tr>
<tr>
<td>Highly unlikely</td>
<td>Unlikely to recur – may occur only in exceptional circumstances i.e. 6+ years</td>
</tr>
</tbody>
</table>

### STEP 4 – Action Required Table

<table>
<thead>
<tr>
<th>ACTION REQUIRED FOR ‘ACTUAL’ INCIDENT RATING</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Extreme risk – Immediate action required – A Root Cause Analysis (RCA) investigation must be completed within 70 calendar days. Reportable Event Brief (REB) must be forwarded to the national central agency</td>
</tr>
<tr>
<td>2</td>
<td>High risk – senior management attention needed – Notification to the national central agency and a detailed investigation must be completed within 70 calendar days</td>
</tr>
<tr>
<td>3</td>
<td>Medium risk – All incident forms to be reviewed, review in common incident types may be most appropriate to develop a common action plan. Responsibility for management of these incidents must be assigned.</td>
</tr>
<tr>
<td>4</td>
<td>Low risk – manage through team level review and improvement procedures.</td>
</tr>
</tbody>
</table>

Incidents rating a SAC of 3 or 4 may also be reported to the national central agency if the incident is considered by the organisation’s senior manager to represent potential risk of serious harm, that should be widely known.

### STEP 3 – SAC Matrix

<table>
<thead>
<tr>
<th>CONSEQUENCE</th>
<th>Serious</th>
<th>Major</th>
<th>Moderate</th>
<th>Minor</th>
<th>Minimal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certain</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Almost certain</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Likely</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Unlikely</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Highly unlikely</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>