



Data Systems  
and Processes  
Audit Manual

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- **Introduction**

This manual documents the process for the Data Systems and Process Audit of BreastScreen Aotearoa (BSA) Lead Providers. The purpose of this manual is to ensure a consistent approach to the BSA Data Systems and Process Audit process.

It is intended that this manual is used in conjunction with the BSA Audit Plan and BSA Audit Framework. Information already contained in these documents is not duplicated in the Data Systems and Process Audit Manual.

The author of this manual would like to acknowledge support provided by BreastScreen Australia staff.

- **Purpose of Data Systems and Process Audit**

The purpose of the Data Systems and Process Audit is to:

- Assess whether the Lead Provider data management protocols and procedures comply with data management standards and procedures referred to in the BSA Data Management Manual and other related documents.
- Ensure Lead Providers can accurately monitor their screening provision and track quality improvement measures

- **Objectives of Data Systems and Process Audit**

The objective of the Data Systems and Process Audit is to:

- examine the data management systems and procedures in use
- evaluate the accuracy, completeness, security, timeliness and accessibility of data
- review consistency of data management, analysis and reporting procedures
- provide a report identifying issues that require immediate action or areas where improvement is required. The report will also identify those areas that are assessed as meeting data standards
- recommend any changes required to ensure the currency, integrity and security of data

- **Scope of Data Systems and Process Audit**

The scope of the Data Systems and Process Audit is to:

- review overall data management and training
- assess the accuracy, completeness, security, timeliness and accessibility of data
- evaluate the overall quality of information produced
- undertake specific data checks to enable the verification of the above points

- **Roles and Responsibilities for the Data Systems and Process Audit**

The roles and responsibilities for the parties involved in the Data Systems and Process Audit is documented in the BSA Audit Workbook and BSA Audit Plan.

- **Data Systems and Process Audit Process**

The Data Systems and Process Audit process is comprised of the following steps.

- **Preparation Prior to Data Systems and Process Audit**

20 working days before the Data Systems and Process Audit:

- National Screening Unit (NSU) notifies the Lead Provider, including:
  - a) Date of Data Systems and Process Audit
  - b) Data Systems and Process Audit team details

10 working days prior to the Data Systems and Process Audit:

- Lead Provider will provide the NSU (to send to the Data Systems and Process Audit team) with the following documentation
  - a) LP Configuration (Sites, site addresses, assessment & screening days, mobile schedule and screening volumes)
  - b) Staff List
  - c) Copy of all paper data collection forms
  - d) Copy of all letters generated by the system
  - e) Copy of IS User Manual / Data Manual
  - f) Quality Management System Manual
  - g) Table of contents for Procedures Manuals

- **Pre-Data Systems and Process Audit Meeting**

- On the first day of the Data Systems and Process Audit, the Data Systems and Process Auditor will meet with the Lead Provider Programme Manager and Data Manager with an agenda that includes:
  - Background to the Data Systems and Process Audit
  - Objective of the Data Systems and Process Audit
  - The Data Systems and Process Audit process and any questions
  - Review any existing issues specific to the Lead Provider
  - The reporting process and timeframe
  - Confirm the Data Systems and Process Audit timetable
- Any concerns or considerations raised by the Lead Provider will be noted for inclusion in the Data Systems and Process Audit Report.

- Conduct the Data Systems and Process Audit
  - The Data Systems and Process Audit will involve:
    - ◇ Interview personnel including:
      - Management and internal users
      - Data entry staff and supervisors
      - Information systems personnel
      - External users, such as hospitals, where applicable and if time permits
    - ◇ Review documents including:
      - information system requirements and specifications
      - user and training manuals
      - forms and instructions
      - client records
      - problem and change records
      - other relevant material
    - ◇ Performing specific data check of hardcopy and electronic information. For each major screening site, the Data Systems and Process Auditor will randomly select women's files from the following categories.
      - Five women screened who were returned to routine rescreening
      - Five women referred to assessment who were returned to routine rescreening
      - Five women referred to assessment who had a benign open biopsy
      - Five women referred to assessment who are diagnosed with cancer
      - Five women referred to assessment, diagnosed with cancer and who have received treatment

The Lead Provider will be asked to obtain the files, and the Data Systems and Process Auditor will then check the contents of the files against the information system.
    - ◇ Inspect all locations where files and IT equipment is stored
    - ◇ Record findings including:
      - Compliance being either
        - Non Compliance (NC)
        - Partial Compliance (PC)
        - Compliance (C)
      - Risk Assessment where "NC" or "PC" compliance is recorded. Valid values are:
        - Low (L)
        - Medium (M)
        - High (H)

- Post-Data Systems and Process Audit Meeting
  - On the final day of the Data Systems and Process Audit, the Data Systems and Process Auditor will meet with the Lead Provider Programme Manager and Data Manager to review issues, risks and improvement suggestions identified during the Data Systems and Process Audit. This will include:
    - ◊ Review of all issues identified
    - ◊ Review of any remedial action already taken by the Lead Provider
    - ◊ If the Data Systems and Process Auditor considers the remedial action to be insufficient to address the issue then this will also be noted in the report
  - Any concerns or considerations raised by the Lead Provider will be included in the Data Systems and Process Audit Report.
  - The Lead Provider Manager and Data Manager will have the opportunity to review a draft of the Data Systems and Process Audit Report for any factual errors.
  
- Complete the Data Systems and Process Audit Report

10 working days after the Data Systems and Process Audit:

- The Lead Auditor will present an audit report to the NSU that includes the findings from the Data Systems and Process Audit
- Any issues identified will be noted in the report.
- Any remedial action completed by a Lead Provider will also be noted in the report.
- Any issues identified during the validation of the Quantitative Report are included in the report.
- Ownership of the Data Systems and Process Audit Report is retained by the NSU.

20 working days after the Data Systems and Process Audit:

- The external audit provider will send the draft audit report, including the findings from the Data Systems and Process Audit, to the Lead Provider to review for factual inaccuracies
- The provider will have 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 perspective.
- If the provider believes there are any inaccuracies in the draft report then this must be supported with reasons and factual evidence.

Once complete the external audit contractor will send the audit report to the Lead Provider.

- **Areas Covered By Data Systems and Process Audit**

A summary of the areas to be covered by the Data Systems and Process Audit is presented below. The audit will assess the provider's compliance against the Data Management Manual and the National Policies and Quality Standards. A detailed Data Systems and Process Audit Checklist is presented in Appendix A: Data Systems and Process Audit Checklist.

- **Management and Training**

- ◇ Organisation roles and responsibilities in relation to data management and interaction with internal and external users
- ◇ Training with regard to:
  - the provision of training to all staff, including availability and frequency of training programs, and qualifications and experience of trainers
  - the availability and use of procedures manuals for all stages of data handling
  - the availability of and use of other relevant documents including the Data Management Manual
  - the routine assessment of adherence of procedures
  - procedures for the management of errors/problems including follow-up action

- **Quality of Data Capture Process**

- ◇ Data flow procedures and practices, both manual and automated
- ◇ System performance relative to requirements and expectations
- ◇ Systems security including:
  - Security policies and procedures
  - Responsibility for oversight and review of security policies and procedures
  - Security internal and external to the Lead Provider
  - External access to records
  - Management of external access to records
  - Security logs
  - Security clearance levels
  - Password security
  - Back-ups and their location
- ◇ Data storage including:
  - location and availability of paper records
  - efficiency and accuracy of records management
  - records tracking and retrieval
  - adequacy of paper records
  - links between paper and computer records
- ◇ Data currency and accuracy including:
  - accuracy of source data
  - checks at all stages of data processing, including at source
  - validation of data once it has passed in-built quality checks (i.e. Operator error)

- error log including feedback and follow-up action
  - levels of data handling and timeliness of data entry
  - back-up procedures
  - procedures for managing data inconsistencies such as items varying between documents, either for the same episodes or between episodes, and checks to ensure that the reader's report relates to the correct client or that a particular case is not read twice by the same reader
  - procedures for identifying and managing missing data
- Quality of Output
    - ◇ Links between process and outputs
    - ◇ Data disposal methods
    - ◇ Analytical methods
    - ◇ Request procedures including responsibility for approving requests, producing output and checking output
  - Compliance with the NSU Quality Plan
    - ◇ Documentation of roles
    - ◇ Processes documented
    - ◇ Compliance of Lead Provider Forms
    - ◇ Monthly check of manual records
    - ◇ Information system Change Management
    - ◇ NZHIS Compliance script process
    - ◇ Data submission Control Report
  - NZHIS Data Collection Process
    - ◇ Data submission process and roles
    - ◇ Lead Provider and NZHIS database synchronisation
  - Compliance with the BSA National Policy & Quality Standards (NPQS)
  - Specific Data Checks
    - ◇ The Data Systems and Process Auditor will select data items to assess consistency and accuracy in the calculation of some of the measures in the Quantitative Report provided by the Lead Provider
  - Review of Specific Issues
    - ◇ Legislative requirements, including compliance with the Privacy Act and associated principles
    - ◇ Expected system changes

## Appendix A: Data Systems and Process Audit Checklist

Item Number	Check	Ref	Comments	Compliance (NC/PC/C)
<b>Data Management</b>				
1	<p><b>Organisation Roles</b></p> <p>Are there clearly documented roles and responsibilities stating the authority and interrelationship for all those who manage, perform or verify work affecting screening data, particularly the role of the Data Manager as per NPQS 39?</p>	NPQS 39		
2	<p><b>Availability of Programme Documents</b></p> <p>Do all staff who manage, perform or verify work affecting screening data have access to all relevant procedures manuals and Program documents, including the standards documents and the Data Management Manual?</p> <p><b>What is the process for distributing updated documents and retrieving obsolete document versions?</b></p> <p><b>What is the process for training staff when new/updated documents are distributed?</b></p>	NPQS 12		
<b>Procedures</b>				

Item Number	Check	Ref	Comments	Compliance (NC/PC/C)
3	<p><b>Coverage of Procedures</b></p> <p>Written policies &amp; procedures exist for:</p> <ul style="list-style-type: none"> <li>- Privacy (NPQS 9)</li> <li>- Complaints</li> <li>- Confidentiality policy and procedure</li> <li>- Staff confidentiality declaration</li> <li>- Security of hard copy</li> <li>- File Tracking</li> <li>- Roles &amp; responsibility for each step of the screening pathway</li> <li>- Information system procedure manual</li> <li>- Data entry protocol</li> <li>- Ethnicity Data Protocol</li> <li>- Risk management protocol</li> <li>- Adverse/sentinel events reporting procedure</li> <li>- Film hanging and reading procedures</li> <li>- Consensus procedure</li> <li>- Re-Screening procedure</li> <li>- Extended assessment procedure</li> <li>- Procedure for ensuring timely and accurate notification of screening results</li> <li>- Procedure for ensuring timely and accurate notification of assessment results</li> <li>- Procedure for women with mammographic abnormalities</li> <li>- Consent (NPQS 5.1)</li> <li>- Transfer of women (NPQS 17)</li> <li>- Outcome of screening – failure or refusal to assessment (NPQS 24.4)</li> <li>- No further active recall (NPQS 31)</li> </ul>	NPQS 5.1, 9, 12, 17, 24.4 & 31		

Item Number	Check	Ref	Comments	Compliance (NC/PC/C)
4	<b>Currency and Accuracy</b> Are each of the procedures complete current and accurate? Evidence of good version control Evidence of management review	NPQS 12		
5	<b>Use of Forms</b> Are all forms used by the procedures clearly noted within the procedure with the role and responsibility of those affected clearly noted? <ul style="list-style-type: none"> <li>- Easy to follow form layout</li> <li>- Form matches data entry screens?</li> <li>- Forms adhere to consent protocol (NPQS 5.1)</li> </ul>	NPQS 5.1		
6	<b>Coverage of Minimum Data Set</b> Do the procedures, forms and data management system cover all aspects of the Data Management Manual?	DMM3		
7	<b>System Coverage</b> Does the computer system documentation cover all system functions?	NPQS 11.2		
8	<b>Adherence to Procedures</b> Are there measures in place to ensure adherence to data management procedures? (Auditors to do spot checks)	NPQS 12		

Item Number	Check	Ref	Comments	Compliance (NC/PC/C)
9	<p><b>Errors/Problems</b></p> <p>Do all staff who manage, perform or verify work affecting screening data follow procedures for the management and follow-up of errors/problems.</p>	NPQS 12		
<b>Failsafe Mechanisms</b>				
10	<p><b>Recording Results</b></p> <p>The reading of the screening mammogram shall occur in such a manner as to maximise detection of any mammographic abnormality that could be cancer.</p> <ul style="list-style-type: none"> <li>- The reading radiologist should have access to all available information when interpreting mammograms, which includes any symptoms, previous breast surgery and hormone replacement therapy</li> <li>- films are read independently by two radiologists.</li> <li>- The Hangfilm process is failsafe</li> </ul> <p>NOTE: The IT system should ensure that the second radiologist is reading in a true independent manner and cannot view or alter the results entered by the first reader</p>	NPQS 23.13		
<b>Security</b>				

Item Number	Check	Ref	Comments	Compliance (NC/PC/C)
11	<p><b>Security of Data</b></p> <p>Are there policies and procedures that provide a sufficient level of security over the data, both electronic and hard copy at all times?</p> <p><b>Is an electronic audit trail maintained for all changes to data in the information system? Can this audit trail information be queried?</b></p> <p><b>Is audit trail analysed on a regular basis?</b></p> <p><b>Documented procedures to identify and address issues?</b></p>	NPQS 11		
12	<p><b>Review of Security Procedures</b></p> <p>Is there a procedure that facilitates the review of security policies and procedures?</p>	NPQS 11		
13	<p><b>Personnel Responsible</b></p> <p>Are there policies and procedures which clearly define which personnel are responsible for the implementation, adherence to and review of security</p>	NPQS 11		
14	<p><b>Security Mechanisms</b></p> <p>Are there policies and procedures that cover the establishment and maintenance and use of security clearance levels and passwords?</p>	NPQS 11		
15	<p><b>External Access</b></p> <p>Are there procedures for managing external access to electronic and hard copy records, e.g. Access by hospital staff?</p>	NPQS 11		

Item Number	Check	Ref	Comments	Compliance (NC/PC/C)
16	<b>Back-up and Recovery</b> Are there documented backup and recovery procedures for all systems affecting the data?	NPQS 11		
17	<b>Location of Backups</b> Is there a procedure that covers the storage of backups, both on and off site?	NPQS 11		
18	<b>Archiving</b> Are there procedures for the archiving of electronic and hard copy records?	NPQS 11		
<b>File Storage</b>				

Item Number	Check	Ref	Comments	Compliance (NC/PC/C)
19	<p><b>Security of Files</b></p> <p>Women's personal information and data about women is collected, stored, accessed and destroyed to a standard that complies with the Health Information Privacy Code 1994</p> <p>Access to clinical records (both in use or in storage) is limited to those with authorisation</p> <p>Identifiable names, lists and files are not on display in public areas</p> <p><b>Inspect all locations where files and IT equipment is stored.</b></p>	NPQS 9.1		
20	<p><b>Files Removed from Premises</b></p> <p>Are there procedures that provide for the security of hard copy files if they are leaving Program premises for any reason?</p>	DMM Chapter 2 NPQS 23.14		
21	<p><b>Data Disposal</b></p> <p>Are there procedures in place which provide guidance as to how data is to be disposed of and under what circumstances?</p>	DMM Chapter 2		
<b>Data Accuracy</b>				

Item Number	Check	Ref	Comments	Compliance (NC/PC/C)
22	<p><b>Accuracy Checking</b></p> <p>The BreastScreen Aotearoa Provider will ensure that captured data is accurate and complete before use</p> <ul style="list-style-type: none"> <li>- Staff involved in data entry (including the interpretation and recording of clinical screening, analysis/treatment notes) are adequately trained and supported in the process</li> <li>- Non-clinical staff members involved in data entry are not permitted to interpret data but are to be given adequate training in the reading of data provided by the clinicians and to subsequently enter it into the IS system</li> <li>- Clinicians are responsible for recording their own screening and assessment data (either directly into the computer system or as a paper record) and for its accuracy and completeness. If the computer recording system does not allow sufficient detail to be recorded, then a paper record must supplement this</li> </ul>	NPQS 10 and NPQS 11		
23	<p><b>Matching Records</b></p> <p>Are there procedures in place which ensure that existing paper records and clients are accurately matched to avoid duplication?</p>	NPQS 11.2		

Item Number	Check	Ref	Comments	Compliance (NC/PC/C)
24	<p><b>Links with Computer Records</b></p> <p>Are there procedures in place to ensure ongoing checking of data accuracy, from source data through the data processing stage?</p> <p>Is the random selection of files pulled complete and accurate?</p> <p>Specifically check each files contains:</p> <ul style="list-style-type: none"> <li>- Electronic matches hardcopy</li> <li>- Correct Films</li> <li>- Correct ethnicity (NPQS 11.3)</li> <li>- Written consent obtained (NPQS 5.1)</li> <li>- Letters to the women and GP (NPQS 23.13)</li> <li>- Correct Outcome</li> </ul>	NPQS 10.1 & NPQS 11.2		
25	<p><b>Quality Assurance</b></p> <p>Are there procedures in place which provide for the validation of data once it has been processed and has passed in-built quality checks?</p> <p><b>Who is responsible for ensuring data quality?</b></p> <p><b>Is there a procedure/process for the resolution of data quality problems?</b></p>	NPQS 11.1c & NPQS 11.2		

Item Number	Check	Ref	Comments	Compliance (NC/PC/C)
26	<p><b>Data Inconsistencies</b></p> <p>Are there procedures in place which provide guidance on how data inconsistencies are to be managed e.g. Parts of the same record having conflicting information, or items varying between documents either for the same episode or between episodes?</p>	DMM Chapter 2		
27	<p><b>Inconsistencies of Process</b></p> <p>Are there procedures in place which provide a check that inconsistencies of process have not occurred, e.g. Checks to ensure that the readers report relates to the correct client or that the reader has not read the same case twice?</p>	NPQS 11.2		
28	<p><b>Error Logs</b></p> <p>Are there procedures in place to ensure that an error log for data entry is maintained and used, including for feedback and follow-up action?</p>	NPQS 11.1		
29	<p><b>Back-ups</b></p> <p>Are there procedures in place to ensure retrievals from back-ups are accurate and complete?</p>	DMM Chapter 2		
<b>Data Completeness</b>				

Item Number	Check	Ref	Comments	Compliance (NC/PC/C)
30	<b>Completeness of Source Data</b> Are there procedures that relate to the review of the completeness of source data?	NPQS 10.1		
<b>Timeliness</b>				
31	<b>Missing Data</b> Are there procedures in place for follow-up of missing data?	NPQS 11.2 & NPQS 11.3		
32	<b>Timeliness of Source Data</b> Are there procedures that set out requirements in relation to the timeliness of completion of source data through all stages including follow-up data?	NPQS 11.2 & NPQS 11.3		
33	<b>Timeliness of Data Entry</b> Are there procedures that set out requirements in relation to the timeliness of data entry?	NPQS 11.2 & NPQS 11.3 & NPQS 30.2		
34	<b>Timeliness of Data Flow</b> Are there procedures that set out requirements in relating to the timeliness of data flow?	NPQS 11.2 & NPQS 11.3		

Item Number	Check	Ref	Comments	Compliance (NC/PC/C)
35	<p><b>Timeliness of Reports</b></p> <p>Are there procedures that set out requirements in relation to the timeliness of data extraction and standard report production?</p> <p><b>Are appropriate management reports produced?</b></p> <p><b>Evidence that reports are understood and used?</b></p> <p><b>Are corrective actions identified and implemented?</b></p>			
<b>Quality of Output</b>				
36	<p><b>Data Field Definitions</b></p> <p>Is documentation of data field definitions readily available? This includes the mapping of any Lead Provider specific fields and definitions to the DMM.</p>			
37	<p><b>Report Specification</b></p> <p>Are standard reports, including NPQS requirements, adequately defined, specified and documented</p>	NPQS 11.2		
38	<p><b>Links between Process and Outputs</b></p> <p>Are there procedures in place to ensure that the outputs generated accurately represent the requested information?</p>	NPQS 11.3		
39	<p><b>Analytical Methods</b></p> <p>Are there procedures in place to ensure that the extraction and manipulation of data for analytical purposes is valid and accurate?</p>			

Item Number	Check	Ref	Comments	Compliance (NC/PC/C)
40	<b>Requests for Output</b> Are there procedures that cover requests for reports, including responsibility for producing output and checking output?	NPQS 11.4		
<b>Compliance with the NSU Data Quality Plan</b>				
41	<b>Roles Documented</b> Are there clearly documented roles and responsibilities for each Data Quality Plan process?	BSA DQP		
42	<b>Process Documented</b> Is the operational process clearly documented for each Data Quality Plan process?	BSA DQP		
43	<b>Monthly Check of Manual Records</b> Have the required number of manual patient files been pulled for each site and checked against database records? Has this been completed on a required regular basis? Have Audit Check Reports been sent to the NSU after each Audit check?	BSA DQP		
<b>NZHS Data Collection Process</b>				

Item Number	Check	Ref	Comments	Compliance (NC/PC/C)
44	<b>Data Submission Process and Roles</b> Are the extract data submission calculations documented? Is the process clearly documented with clear roles and responsibilities?	BSA DQP		
45	<b>LP and NZHIS Database Synchronisation</b> Is there a process in place to delete NZHIS records if a key field in a record is modified E.g. if a NHI is merged to a different NHI value the existing record in NZHIS should be deleted and the records resent with the updated NHI.	BSA DQP		