**Quality Manual**

|  |  |
| --- | --- |
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1. **General Information**

The Neuropathology Department is part of the NMSK and Neurosciences Division of North Bristol NHS Trust (NBT). The NMSK & Neurosciences Division has managerial responsibility for:

* Major Trauma Centre
* Orthopaedic Trauma
* Elective Orthopaedics
* Spinal Orthopaedics
* Rheumatology
* Centre for Enablement
* Chronic Pain
* Neurosurgery
* Neurology
* Stroke
* Neuropsychiatry
* Neuropsychology
* Neurorehabilitation
* Neurophysiology
* Neuropathology
* Bristol Speech & Language Therapy Research Unit.

The Trust’s Establishment Order can be found at:

<http://www.legislation.gov.uk/uksi/1999/625/contents/made>

This outlines the legal entity of the nature and functions of the Trust. A copy of this documentation is also stored on QPulse (NP/EX/GUIDE/003).

**Location**

The Neuropathology Department is situated in the Pathology Sciences Building on the Southmead Hospital site. The laboratory and reporting rooms for Neuropathology are on level 1 and the office is located on level 0 of this building. This is a purpose-built laboratory, and other pathology departments also occupy this building.

Address for Correspondence:

Neuropathology Department

Pathology Sciences Building

Southmead Hospital

Southmead Way

Bristol

BS10 5NB

Tel: 0117 4142400/42401/42402

**Range of Services:**

North Bristol NHS Trust provides a wide range of teaching hospital services to the population of North Bristol, North Somerset & South Gloucestershire. In addition, specialist & regional services are provided to patients from a wider area of southwest England and south Wales. The Trust has approximately 1,500 beds and treats around 47,000 elective inpatients, 45,000 emergencies and 81,000 outpatients per year.

The services provided are: -

* Diagnosis of biopsies from the central nervous system (CNS) using histology, cytology and electron microscopy (EM)
* Samples for intraoperative brain surgery procedures are analysed using cytological and rapid frozen section techniques
* Diagnosis of muscle biopsies using histochemistry and electron microscopy
* Diagnosis of biopsies from the peripheral nervous system (PNS) using histochemistry and electron microscopy
* Diagnosis of autopsy specimens from the CNS
* Forensic examination of autopsy specimens from the CNS
* The Neuropathology Department also takes part in scientific research where this has been agreed by the North Bristol NHS Trust and appropriately funded.

Additional information on the services offered by the department is provided in the **Neuropathology Department Users Handbook NP-QM-POL-002**. This can be obtained from the department.

Quality and patient care are at the heart of our mission. To substantiate this, it is our policy to seek accreditation and certification through third party assessment. Currently the laboratory is accredited with the United Kingdom Accreditation Service (UKAS) to the British Standards Institute Publication BS EN ISO 15189

**Hours of Business: 8:00 am to 5:00 pm - Monday to Friday.**

**The Quality Manual**

The Quality Manager is responsible to the Laboratory Manager and the Consultant Head of Neuropathology for the creation and control of the quality manual, using the standard procedure for the formatting, creation and control of documents within the department NP-QM-SOP-003. The quality manual describes the quality management system and is cross-referenced to other documents.

The quality system of North Bristol NHS Trust Neuropathology Service consists of:

* The quality manual and quality policy – this gives the overall intention and direction of the laboratory.
* Quality objectives and indicators – this enables the intentions of the quality policy to be fulfilled
* The quality, management, technical and training procedures and policies – these detail the activities required to carry out the intentions of the quality system and give practical ways of how they are translated into actions.
* Binders containing procedures and records.
* There are a collection of records that provide evidence of day to day compliance. These include:
	+ Minutes of meetings
	+ QPulse
	+ Forms and records relating to QMS and to diagnostic cases
	+ Worksheets
	+ Internal quality assurance record
	+ Validation and verification records
	+ Personnel competency records
	+ External quality assurance scheme participation record
	+ Reports from external bodies
	+ Records of actual & potential nonconformities that include the immediate, corrective and preventive actions planned, implemented, and evaluated with respect to their contribution to continual improvement of the pre-examination, examination and post-examination processes and the quality system.

The Quality System is compiled to meet the needs & requirements of service users and to conform to the international standard **BS EN ISO 15189**, and the Quality Policy of the NMSK Division and the North Bristol NHS Trust.

***The policies described in the quality manual, together with*** ***all the standard operating procedures contained within the department’s manuals are mandatory in the Neuropathology Laboratory.***

***Changes are only to be implemented using the processes set out in the document control system.*** The Neuropathology Policy set out below is also available as a separate document NP-QM-FM-019*.*

**Neuropathology Quality Policy**

The Neuropathology Department at North Bristol NHS Trust provides a neurohistology service to the Trust and to the wider healthcare community, mainly in the south-west of the UK, and aims to supply: (1) clinicians with diagnostic data that benefits the treatment of their patients; (2) appropriate authorities with autopsy neurohistology information to help establish cause of death; and (3) the neurosciences community in general with additional knowledge that may be of benefit to future patients. The reported information should be reliable and be available within an appropriate time-scale, and any uncertainties should be clearly stated in accordance with clinical need and appropriate professional standards.

The services provided are: -

* Diagnosis of biopsies from the central nervous system (CNS) using histology, cytology and electron microscopy (EM), and samples for intra-operative brain surgery procedures are analysed using cytological and rapid frozen section techniques
* Diagnosis of muscle biopsies and biopsies from the peripheral nervous system (PNS) using histochemistry and EM
* Diagnosis of autopsy specimens from the CNS
* Forensic examination of autopsy specimens from the CNS
* The Neuropathology Department also takes part in scientific research where this has been agreed by the North Bristol NHS Trust and appropriately funded.

The policies described in the quality manual, together with all the standard operating procedures (SOPs) contained within the department’s manuals are mandatory in the Neuropathology Laboratory.

The Quality Policy is implemented by having: -

* A Quality System in place that integrates all procedures and processes, and ensures continual quality improvement by: setting and achieving quality objectives; monitoring and reacting to users’ needs; ensuring continuing compliance with **BS EN ISO 15189** international standard
* Commitment to health and safety of all staff and visitors, delivered by systems of safe working practice, with appropriate monitoring, which comply with legislation on health and safety and environmental protection legislation
* Commitment to professional standards of practice
* Personnel with appropriate authority, training and resources to undertake their duties effectively
* Appropriate collection, preservation, transport, preparation, identification, and storage of specimens, with documentation that is adequate for its purpose
* Checks to ensure that all specimens are accompanied by appropriate documentation containing evidence of any necessary consent provided by the patient or next-of-kin, and that the Department is vigilant in ensuring the limits and instructions of the consent are complied with
* Reliable system of laboratory work with checks in place to identify and control systematic and random errors, and appropriate validation & verification of procedures
* Turnaround times within appropriate limits to meet clinical needs
* Information reported clearly, and supported by appropriate communication with clinicians, with procedures to ensure confidentiality
* Annual reviews to determine the continued effectiveness and suitability of the quality policy.
* A copy of this quality policy issued to all personnel, with a verbal explanation of its content and opportunity to ask questions, so that all personnel are familiar with the quality policy.

Signed by Date

**Organisation and Management**

The following charts illustrate organisation and staffing structure within North Bristol Trust, the NMSK Division and the Neuropathology Department.

Fig 1 illustrates the organisational structure of the Neuropathology Department.

**Fig 1: Organisational structure Neuropathology**

**Specialist Registrar**

Vacancy

**Consultant Neuropathologists**

Dr Kathryn Urankar

Prof Kathreena Kurian

Dr Jillian Davis

**Neuropathology Laboratory Director**

Professor Kathreena Kurian (70% NHS, 30% University)

**Laboratory Manager**

**Medical secretaries**

Allison Finnie

Layla Nasrawi

**General Manager, NMSK**

Andrew Clark

**Clinical Director, NMSK**

Harsha Gunawardena

**North Bristol NHS Trust Board**

**Quality Manager** – Masuma Jahen

**Training Officer**– Rebecca Woodward

**Biomedical Scientist** – Acacia Nickle-Taylor, Bethan Benham, Megan Bull

**Trainee Biomedical Scientist –** Amber Morgan

**Associate Practitioner** – Katherine Ashley

**Roles and Responsibilities**

Professor Kathreena Kurian is the Laboratory Director and is responsible for the overall direction of the Neuropathology service. She is accountable to the NMSK General Manager and the NMSK Clinical Director.

A Divisional Accountant and assistants supports the NMSK Division and are managerially responsible to the Director of Finance.

A Divisional HR Manager supports NMSK Division and is managerially responsible to the HR Director.

**Key Responsibilities and Current Post Holders within the Neuropathology Department:**

**Laboratory Director: Professor Kathreena Kurian**

Professor Kurian directs and is responsible for the overall service offered and for the training of the medical staff and is assisted in these functions by the following members of staff and their respective roles:

|  |  |
| --- | --- |
| **Position** |  |
| Laboratory Director | Professor Kathreena Kurian |
| Consultant Neuropathologist | Dr Kathryn Urankar |
| Consultant Neuropathologist | Dr Kathreena Kurian |
| Specialist Registrar  | Vacant |
| Laboratory Manager  |  |
| Quality Manager | Masuma Jahen |
| Training Officer  | Rebecca Woodward |
| **Senior BMS**Responsible for histochemistry, main laboratory on a rotational basis | Rebecca WoodwardMasuma Jahen |
| Biomedical ScientistRotation through laboratory | Bethan Benham, Acacia Taylor-Nickle, Megan Bull |
| Trainee Biomedical Scientist | Amber Morgan |
| Associate Practitioner | Katherine Ashley |
| Medical Secretaries | Allison Finnie |
| Health and Safety Officer | Katherine Ashley  |
| Fire Warden | Bethan Benham |
| COSHH and Risk Assessments | Rebecca Woodward |
| Manual Handling Lead | Katherine Ashley |
| HTA Coordinator | Katherine Ashley |
| EROS requisitioners | Katherine AshleyAllison Finnie |
| EROS Authorisers | Rebecca Woodward |

**Laboratory Director**

The laboratory shall be directed by a person or persons with the competence and delegated responsibility for the services provided.

The responsibilities of the laboratory director shall include professional, scientific, consultative or advisory, organisation, administrative and education matters relevant to the services offered by the laboratory.

The laboratory director may delegate selected duties and/or responsibilities to qualified personnel; however, the laboratory director shall maintain the ultimate responsibility for the overall operation and administration of the laboratory.

The laboratory director (or the designates for delegated duties) shall have the necessary competence, authority and resources in order to fulfil the requirements.

|  |  |
| --- | --- |
| **Duties of Laboratory Director** | **Delegated Action?** |
| Provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities | Laboratory manager |
| Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required; | Done in conjunction with Laboratory manager |
| Ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users | Laboratory manager |
| Ensure the implementation of the quality policy | Quality Manager |
| Implement a safe laboratory environment in compliance with good practice and applicable requirements | In conjunction with Laboratory manager |
| Serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate |  |
| Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results; |  |
| Select and monitor laboratory suppliers | Laboratory Manager |
| Select referral laboratories and monitor the quality of their service | In conjunction with Laboratory Manager |
| Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organisation | Training Officer |
| Define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services | Laboratory Manager |
| Monitor all work performed in the laboratory to determine that clinically relevant information is being generated |  |
| Address any complaint, request or suggestion from staff and/or users of laboratory services  | Laboratory Manager |
| Design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable | In conjunction with Laboratory Manager |
| Plan and direct research and development, where appropriate |  |

**Quality Management System**

**Introduction**

The Quality Management System consists of the Quality Manual, together with meetings, processes, documents and records, as described below.
The Quality System is compiled to meet the requirements of international standard **BS EN ISO 15189** and to comply with the Quality Policy of the NMSK Sciences Division and the North Bristol NHS Trust.

The Quality Manager is responsible for the implementation, maintenance, function and effectiveness of the Quality Management System, and the delegation of the tasks required as appropriate.

All documents comprising the Quality Management System are held on QPulse to which all Neuropathology staff has access.

**The Quality Documents**

This comprises of SOPs, methods, forms and report templates for the internal audit programme, internal quality assurance record, external quality assurance schemes, the incident record and collation of users’ opinions on the service. This comprises the core documentation for the use and maintenance of the Quality Management System. These documents are located in QPulse.

**The Management Documents**

These comprise SOPs for the management of staff, resources and records. In addition, SOPs for the reporting process, with details of internal audit of reporting, are included. These documents are located in QPulse.

**The Technical Documents**

These comprise of SOPs and methods for all laboratory processes. These are located as hard copies in laboratory areas and in QPulse.

**The Training Documents**

These comprise details of all pre-registration and post-registration training for Biomedical Scientists, and training for Medical Laboratory Assistants and Medical Secretaries. It also explains the Clinical staff training regime.

**The Quality Incident Record**

The trust has an Accident and Incident Management System (DATIX) for documenting adverse patient incidents, and health and safety incidents or accidents. The report form for this system is available to use on-line on the trust intranet; the system sends reports to the selected department manager, and to the Trust’s Clinical Risk Management or Health and Safety management teams as appropriate. In addition, the Department has a Corrective and Preventive Action record, which is used to record all adverse events, any user complaints, and to monitor the implementation of corrective action plans.

**Controlled Forms and Methods**

Controlled forms and methods are stored on QPulse.

These forms or methods are referred to in the appropriate standard operating procedures or policies.

**Assessment of User Satisfaction, Needs and Complaints.**

The Neuropathology Department has close links to its users, and receives very few complaints. Action to resolve complaints is given very high priority. Every effort is made to respond to users’ needs, for example requests to expedite work on a patient’s specimen. Complaints are dealt with by following North Bristol NHS Trusts complaints procedure CG20, which can be located on the trusts intranet page. All complaints will be logged using our internal complaints procedure.

The Neuropathologists participate in multi-disciplinary team meetings, which are held weekly, to discuss cases, and this provides an additional forum for users to express satisfaction or complaint.
In addition to the excellent informal communications with our users a regular questionnaire is distributed, and results of this are analysed and reported to the Annual Management Review*.*
The Quality Manager is responsible to the Department’s management for coordinating awareness of the needs and requirements of users.

**The Internal Audit Programme for Laboratory Processes.**

Horizontal audits of pre examination, examination and post examination processes are carried out, as described in the quality procedures manual, and the results and any subsequent recommendations and action plans are recorded. Vertical audits are carried out on one of each type of specimen received each month, as described in the quality procedures manual, and the results and any subsequent recommendations and action plans are recorded. Management and training activities are audited, as is the Quality Management System. Audit results are reported to the Consultant Head of Department and Laboratory Manager and are presented at the bimonthly departmental meetings, with appropriate immediate, corrective & preventive actions, both implemented and planned, as recorded.

**Quality Management Reviews**

The standing agenda for the Quality Management Review can be found as NP-MGT-FM-001; this is the minimum agenda for the review.

**Department Meetings**

These bimonthly meetings include discussion of turnaround times for all specimen types, which are monitored using the Laboratory Information Management System WinPath.
Any failure to meet targets is analysed, and action plans are made as required. The Quality Manager reports to the Laboratory Manager and presents quality issues to the department at the bi-monthly department meetings and laboratory meetings; the minutes of these meetings are sent to the Divisional General Manager. The Laboratory Manager also communicates quality issues to the MSK & Neurosciences Division Risk meetings for inclusion in the Risk register if appropriate.

There are also monthly laboratory team meetings with a set agenda.

Minutes from laboratory and departmental meetings are stored on QPulse.

**Quality Objectives**

The Quality Manager is responsible to the laboratory management for the effective communication and implementation of the quality objectives and plans set by them. The bi-monthly department meetings and the annual Quality Management Review are all key events in setting quality objectives and for planning their implementation. Quality objectives may also be set in response to a particular incident or problem. The audit programme is used to assess the implementation of quality objectives.

**Quality Indicators**

The Quality Manager will measure and record the following quality indicators:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Quality Indicator** | **Method of Measure** | **Objective** | **Duration** | **Action if not achieved** |
| ISO Compliance | Audits, quality reviews, quality system.  | Maintain ISO compliance | Maintain compliance throughout 2023 | Would lose accreditation. |
| Document Control | Review date for documents on Q-Pulse.  | To review all expired documents within 3 months of review date | Monthly discussed at laboratory meeting | To do RCA and action plan |
| User Satisfaction | User survey, complaints, feedback | 70% of answers at satisfied or better for user survey. CAPA formulated for questions that have 30% or higher as not satisfied or less. 90% of complaints responded in timeframe set out in SOP | Annual user survey – discussed at AMR. Complaints analysed bi-monthly and discussed at departmental meetings. | Complaints – as per complaints procedure.User survey – do RCA and plan action |
| Turn Around Time | Turn around times of main specimen types – PM, biopsy, muscle, CSF, EM | Achieve TATs as per RCPath guidelines; 80% of cases within 65 days (autopsy), within 8 days (biopsy), within 11 days (muscle), within 7 days (CSF), 80% of cases within 6 weeks (EM) | Bi-monthly – discuss at departmental meetings | To do RCA and action plan |
| Number of CAPAs | CAPA spreadsheet. Trend analysis carried out for process problems and raised and discussed in AMR and lab meetings. | 80% CAPAs implemented or planned within 3 months. Ensure effectiveness check is carried out within specified time frame | Monthly – discussed at laboratory and departmental meetings | Must have follow up actions assigned if not within timescales. Re-audit. |
| EQA Performance | NEQAS scheme results | Mean result for EQA scheme for each quarter to be at least satisfactory in 75% of cases | Bi-monthly – discussed at laboratory and departmental meetings | To do RCA and action plan |
| Training Meetings | Training meetings  | 80% of training meetings should have taken place within one month of being scheduled for each month. | Bi-Monthly – discuss at departmental meetings | RCA |
| Competency Assessments  | Competency Assessments | 80% of competency assessments should be up to date at annual appraisal and all should be reviewed for each staff member at every training meeting. | Annual (appraisal) and bi-Monthly – discuss at departmental meetings | RCA |
| Environmental Monitoring | Temperature, airflow, xylene and formalin monitoring | To monitor levels to keep within safe limits | Monthly  | Immediate action must be taken. |
| Neuropathologist Quality Feedback | Neuropathologist Quality Feedback forms | Ensure that 100% of feedback received since last laboratory meeting is given to laboratory at laboratory meetings | Monthly | To do RCA and action plan |
| Targeted Laboratory Objective for Continuous Improvement | Project Immunohistochemical Staining (IHC) library  | 5 antibodies added to IHC library per month that outline specific staining patterns as well as supporting information for all antibodies in staining repertoire. | Monthly discussed at laboratory meetings | To do RCA and action plan  |

**Procedures for the Control of Documents, Records and Clinical Materials.**

These are described below.

**Document Preparation and Control**

All documentation for the department is prepared on the networked computers within the department, and all electronic data is stored in a dedicated Neuropathology partition of a shared Trust file-server, or on QPulse. Data security is maintained by having access to this partition limited to authorised Trust IT-system users who are members of one of this Department’s user groups. Other Trust IT-users are denied access to this data. All user accounts are password protected, and are managed through the Trust’s IT Department.

Data security and back-up of these records is described in NP-MGT-SOP-010.

There is a Document Control SOP NP-QM-SOP-003 describing:

* The creation of new SOP documents and manuals using the department’s document control template.
* The processes for reviewing and creating new versions of existing procedures.
* Using QPulse to manage the collection of controlled documentation (SOPs, manuals, method sheet and forms) and to facilitate the review process.

**Document System**

**Quality
Manual**

**Quality
Procedures
Manual**

**Management
Procedures
Manual**

**Training Manual**

**Technical
Procedures
manual**

**Quality System
Standard Operating
Procedures**

**Management
Standard
Operating
Procedures**

**Technical
methods and forms**

**Technical
Standard
Operating
Procedures**

**Management
methods and forms**

**Training
Standard
Operating
Procedures**

**Quality methods
and forms**

**Training
methods and forms**

**Quality Records**

Quality records are kept for 30 years; current documents are stored in the main laboratory or office. The entire laboratory and office is a secure area. Records and their indexes that have been inspected by UKAS are archived in box files in the Pathology stores and kept for a minimum of 8 years. Documents from August 2021 onwards are now scanned and stored on the Neuropathology folder on the N: Drive (Neuropathology> Laboratory> Scanned Documents). Quality records include EQA reports, internal audit reports, the user satisfaction survey, the incident log, quality management review minutes & summaries, departmental meeting minutes, quality improvement plans, and records of completed quality actions.

The quality system documents are stored on QPulse.

**Process Records**

Process records of the pre-examination, examination, and post-examination processes are entered onto Winpath which has been designed to manage this data.

A paper worksheet for each autopsy specimen is printed from QPulse (NP-LAB-FM-070). These are filed in reverse date order in labelled binders and are kept for 30 years in the laboratory or store.

There is an MS-Excel file [N:\Neuropathology>SharedResources OperatingProcedures>ControlledForms>On-line Forms >Autopsy Management] recording examination process status of autopsy specimens; this file is password protected.

Information on the fate of autopsy specimens is entered in the patient records on Winpath, as described in NP-MGT-SOP-004*.* WinPath indexes records by laboratory number. The security of these records is described in the standard operating procedure NP-MGT-SOP-010.

Receipts for autopsy specimens that have been returned to originating pathologists or the next-of-kin via undertakers are indexed in specimen acquisition order and are stored in the medical secretaries’ office and form part of the quality record for control of clinical material.

A paper worksheet for each day’s biopsies is printed from information stored on WinPath. These are kept in reverse date order for one year in a document box located on the shelves in the laboratory.

Paper request sheets for additional work on specimens are kept in reverse date order for one year in a file located on the shelves in the laboratory (hand written forms, information transferred from these to WinPath).

From Jan 2011 onwards – all paper biopsy request forms, including CSF, muscle and nerve biopsies, are filed numerically by laboratory number after being scanned and saved in N\NeuroPathology\Report Archive\BIOPSY REQUEST FORMS\BIOPSY REQUEST FORMS yyyy.  All paperwork relating to requests for neuropathological examination of autopsy specimens is scanned and stored in a subfolder alongside the electronic archived copy of the main report - N:\NeuroPathology\LIMS\AutopsyReports\yyyy.  See NP/QM/SOP/004.

All worksheets and request sheets are shredded prior to disposal.

The most recent specimen request forms and paper copies of reports are stored in the secretaries’ office, in specimen acquisition order, for 1 year in labelled files and boxes. Older documents are archived on the N:\Neuropathology\ReportArchive.

Paper process records for all specimens received before 1988 have been retained and are archived as described in NP-QM-SOP-004*.*

**Control of Clinical Material**

There are standard operating procedures that describe the control of clinical material.

* The identification and indexing of clinical material is described in
NP-LAB-SOP-001*.*
* The retention, storage, retrieval, and disposal of clinical material are described in NP-LAB-SOP-008.
* The transport of clinical material is described in NP-LAB-SOP-009.

**The additional control measures for clinical material suspected to be infected with TSE are described in detail in NP-LAB-SOP-020*.***

**Clinical material is stored in four ways: - in formalin fixative in labelled containers, in labelled paraffin embedded tissue blocks, on labelled slides or frozen in cryogenic tubes in an 80°C freezer; the methods follow processes designed to ensure the validity of repeat or additional examinations, as described in NP-LAB-SOP-008*.***

**The policies and procedures described above for the retention of clinical materials comply with the Human Tissue Act and BS EN ISO:15189.**

**Personnel**

The Neuropathology Department is led by the Consultant Head of Department (Laboratory Director).

Medical staffing of the Department consists of three Consultant Neuropathologists (including the Consultant Head of Department). One of these posts is part-NHS / part-University of Bristol, another is part time NHS. In additional there is a vacant Specialty Senior Registrar post.

The scientific staffing consists of six HCPC-registered Biomedical Scientists (one Laboratory manager, two seniors, one part-time trainee biomedical scientist, three biomedical scientists). The department also employs a part-time Biomedical Associate Practitioner.

The department office is staffed by medical secretaries.

**Specialist Roles**

In addition to performing the varied scientific activities necessary for the provision of a diagnostic neuropathology service, the most senior members of the laboratory staff have additional specialist roles as described below.

The Laboratory Manager has full responsibility for the operational management of the laboratory and secretarial services. The Laboratory manager is managerially accountable to the Trust’s NMSK Sciences Divisional General Manager and professionally accountable to the Consultant Head of Neuropathology.
In this role she is responsible for ensuring that the department is maintaining an effective and responsive Quality System that meets the standards required to meet the needs of users and to conform to **BS EN ISO 15189**. Other roles include: non-medical personnel management; overseeing mandatory and professional education / training, and continuing professional development for non-medical staff; and health & safety lead for the Department. The laboratory manager also communicates quality issues to NMSK for inclusion on the Risk Register, if appropriate.

The **Laboratory Manager/Quality Manager** has day-to-day responsibility for implementing and maintaining the Neuropathology Department’s quality system to meet to the international standard BS EN ISO 15189. This includes the following activities:

* + regularly reviewing policies and procedures in all sections of the Department with the authority to propose or implement appropriate changes to Neuropathology quality management system
	+ responsibility for writing and reviewing the Department’s Quality Manual, and to supervise, and participate in, the production of policies, protocols and standard operating procedures
	+ managing Neuropathology’s section of QPulse
	+ coordinating NEQAS external quality assurance scheme activity, and defining and maintaining internal quality control standards
	+ monitoring the Department’s quality indicators, and implementing and analysing a range of audit activities to regularly assess the performance of all aspects of the Department’s work
* managing the Department’s adverse incident log, reporting all adverse incidents and non-conformities to the Consultant Head of Neuropathology, immediately if patient safety may be compromised
* coordinating awareness of the needs and requirements of users of the Neuropathology service
* reporting all matters arising from the management of the quality system to department meetings and the Annual Management Review

The **Training Officer** has day-to-day responsibility to provide professional development programmes for laboratory staff and oversees the assessment of competence for staff working in the laboratory and office areas. This includes the following activities:

* Reviewing the training documents held as part of the Quality Management System
* Ensuring competency assessments are completed by staff working in the laboratory and office areas
* Monitoring frequency of competency assessments
* Holding training meetings
* Supporting continuing professional development for relevant team members
* Provide information to the Laboratory Manager on competence and professional development of the team.
* Deputise for the Laboratory Manager, as appropriate.

**Personnel Management**

The trust has policies and procedures in place for

* Recruitment and selection
* Orientation and induction
* Job descriptions and contracts
* Staff records
* Staff annual joint review (appraisal)
* Staff training, education and personal development
* Grievance procedures and disciplinary action
* Data protection policy
* Information Governance policy

These policies and procedures are located via links on the trust intranet page.

In addition the department has its own personnel management standard operating procedure NP/MGT/POL/001 supplementing the Trust’s documentation, and maintains further personnel records to supplement those held by the personnel department. The systems in place conform to **BS EN ISO 15189**

**Code(s) of Conduct**

All employees, including Temporary Staff, Students, Volunteers and Locums, working in the NHS are bound by a legal duty of confidence to protect personal information they may come into contact with during the course of their work. This is not just a requirement of their contractual responsibilities but also a requirement within the EU General Data Protection Regulation 2016 and the Data Protection Act 2018 and, in addition, for health and other professionals through their own professions Code(s) of Conduct.

For further information refer to North Bristol Trust’s policy for Code of Conduct (IMT IG04)

<https://link.nbt.nhs.uk/Interact/Pages/Content/Document.aspx?id=3659&SearchId=0>

Confidentiality, information governance and fraud are also covered in the Trust induction.

There are arrangements in place to minimise potential conflicts of interest that may arise from activities that the laboratory could be engaged in, that could influence its technical judgement. These policies are described in the trust policy Declarations of Interest Policy NBT (CO10) which each member of staff has access to and is available on the Trust intranet and is part of corporate induction. These policies should be referred to if a situation where a potential conflict of interest arises. All staff are made aware of these policies, and comply with the standards set, to ensure that the department is not involved in any activities which could affect the integrity of the laboratory.

**Communication**

The Trust provides an intranet system, which also allows access to the internet and e-mail. Individual Trust IT user accounts are available for all staff. This system provides a wide range of information on trust wide and national issues including policy and procedures. The intranet home page has a link to a searchable telephone directory for the trust’s internal telephone system. There is also a weekly update from our Chief executive known as ‘Maria’s mid-week message’ that is e-mailed to all trust staff.

In addition, there is also a monthly Neurosciences newsletter.

The trust provides a telephone system.

**Staff Meetings**

All laboratory personnel participate in monthly laboratory meetings, chaired by the Laboratory Manager. Minutes of previous meetings are distributed via QPulse.

All medical personnel, a secretary, and senior scientific personnel participate in bi-monthly departmental meetings, the agenda for which includes review of quality issues such as turnaround statistics. The minutes for these meetings are available to all personnel in the department on QPulse. These meetings are part of the management review process.

**Staff Training and Education**

The training and education programme for the Department is described in the **training manuals** NP-TR-POL-001, NP-TR-POL-002 and NP-TR-POL-003, and are designed to meet the guidelines of the Health Professions Council and the Institute of Biomedical Science, and conform to **BS EN ISO 15189.**

Trainee staff have a designated mentor/supervisor, and have regular training reviews with the department’s training officer.

There are resources for training and education that conform to **BS EN ISO 15189.**

Records of education and training are kept in individual’s training folders.

**Premises and Environment**

The Neuropathology Department is housed on two floors in the Pathology Sciences Building, alongside all other Pathology specialities. Access to the Department is controlled both during and outside of working hours. Security of the premises is described in NP-MGT-SOP-009.

**Level 0 houses: -**

* The secretaries’ office (shared with Cellular Pathology departmental secretaries), with filing for clinical and secretarial documents
* The staff’s rest room and locker room
* The slide archive (shared with Cellular Pathology Department)
* The Neuropathology brain archive, with appropriate extraction facilities and security

**Level 1 houses:-**

**The main laboratory, with:**

* lockable storage for small quantities of inflammable substances, acids and toxic substances
* appropriate extraction facilities
* a Class 1 containment hood for all work involving unfixed samples
* separate bays for incompatible work processes

**The Cut Up Room containing:**

* a dissection table having downdraft fume extraction facilities
* storage for autopsy specimens undergoing fixation
* Band saw

**The Store Room containing:**

* consumables stocks

**-80°C Freezer Room containing:**

* -80 freezer for Neuropathology specimens
* -80 freezer for Tumour bank

**The Undercroft Storage Room**

* The block and slide archive (shared with Cellular Pathology Department

There are locked disposal bins for clinical waste located in the waste store on level 1.

There is an external locked store for inflammable substances situated outside the building on level 1 (access via waste store).

There is a locked cage containing liquid nitrogen outside the building on level 1 (access via waste store).

Main General Pathology Stores is also located on level 1 where some Neuropathology stock is located.

The Department currently houses 10 years of the block and slide archive on site in the pathology Sciences Building on level 0. The remainder of the archive is stored with CellNass.

**Health and Safety**

All the standard operating procedures for the laboratory indicate best practice with respect to health and safety and other appropriate legislation and Trust policy. All Trust policies are available on the Trust Intranet and relevant Health and Safety policies are available in the laboratory office.

Appropriate personal protective equipment is provided and there are standard operating procedures in place for its use.

If the department receives specimens from suspect TSE cases, the specific health and safety procedures for this are set out in NP-LAB-SOP-020.

The health and safety of visitors to the department is ensured by familiarising them with the layout of the premises, the location of emergency exits, the procedure in event of a fire or alarm, and the availability and use of personal protective equipment. A copy of the controlled form NP-MGT-FM-016 is issued to visitors to supplement the personal advice they receive on arrival at the department. See NP-LAB-POL-001.

General health and safety provisions are given in the Health and Safety SOP
NP-LAB-POL-001 and additional specific instructions in the individual SOPs and method sheets, including NP-LAB-SOP-016, NP-LAB-SOP-014, and NP-LAB-SOP-017. This documentation, together with the appropriate records and risk assessments, is stored in the main laboratory office.

**Equipment**

All items of capital equipment are maintained on service contracts, and service records are held in the department. The Trust holds an inventory of all capital equipment. The Neuropathology department has a programme for the phased replacement of its capital equipment.

The department has appropriate systems and records for:

* Monitoring the performance of all temperature-controlled equipment
* Monitoring the performance of all extraction equipment.
* Training in the correct and safe use of all equipment.

Verifying the performance characteristics of equipment following validation by the manufacturer

**Materials**

All reagents, kits and consumables are purchased from approved and monitored suppliers, as described in NP-MGT-SOP-014. The suppliers are listed in the spreadsheet NP-MGT-FM-017.

Management of reagents is detailed in NP-LAB-SOP-015.

**Information Technology**

The Neuropathology Department IT workgroup has its own dedicated fileserver for the storage and distribution of departmental data. The server has a disc array operating under RAID-5 to protect against hard disc failure. In addition, there is an automated tape back-up facility.

The system is connected to the Trust-wide IT network and runs in a Microsoft Windows environment. The Trust’s IT department provides all network and hardware support. First-line software support is provided within the department.

Members of staff have their own individual IT accounts which also provide email and internet facilities. All of these accounts are secured by password protection. At induction, all new members of staff undergo mandatory training outlining their responsibilities regarding data protection and security.

All members of staff are encouraged to store their own personal work on the Trust’s shared network storage using a dedicated area mapped to their own personal Trust user account (U:\ drive).

The department uses a commercial laboratory information management system, which is Clinisys Winpath.

Archives of digital macroscopic and electron microscopic images are available across the neuropathology workgroup.

The Data Security SOP NP-MGT-SOP-010 describes the department’s data security processes.

**Consumables, Reagents (Including Calibration Products) and Quality Control Material)**

All consumables, reagents and calibration reference solutions are purchased from approved suppliers. On delivery, all reagents are used in conformity with the Department’s stock control system. The procedures for the purchase of all materials and the stock control of reagents are both described in NP-MGT-SOP-014, NP-MGT-SOP-015, NP-LAB-SOP-015.

The process for making working reagents from chemical stocks contains appropriate health and safety, and quality measures. Details are provided in the appropriate SOPs.

Records of source reagents and personnel creating in-house reagents are made.

Known positive and negative control tissue is obtained from laboratory specimens that have consent for such use, and a record is kept of the specimen number for each of these controls. Refer to NP-QM-SOP-004.

**Information for Users and Patients**

The Neuropathology Department Users’ Manual NP-QM-POL-002 provides full details of the services provided by the department.

The neurosurgical teams provide information for neurosurgical patients.

Some of the muscle and peripheral nerve biopsies received by the department are performed by the department’s own pathologists. Before admission the patients are provided with an information sheet, and meet with the pathologist the evening before surgery to consent to the procedure. These are the only patients who have direct contact with the department.

**Specimen Reception**

Specimens arrive at the Neuropathology Laboratory from a variety of sources and may require immediate attention (e.g. intraoperative brain samples, muscle biopsies, nerve biopsies, and tumour samples for cytogenetics); high levels of vigilance are required to ensure that specimens are delivered within an appropriate time frame (refer to User Manual NP-QM-POL-002) and receive appropriate action upon receipt.

Specimens may arrive from the Brunel Building via the Pneumatic Tube System. For further information refer to NP-LAB-SOP-061.

NP-LAB-SOP-001 describes the processes that ensure that specimens are accompanied by a request form with correct and matching patient identification, date and time information, and clinical data. There is a biopsy request form that conforms to **BS EN ISO 15189**, NP-MGT-FM-011, and the department LIMS is used to record all the required information against the specimen acquisition number.

Specimens from autopsies arrive at the Neuropathology Laboratory from a variety of sources and require prompt attention, see NP-LAB-SOP-001. A copy of the autopsy report should accompany autopsy specimens and should include a copy of the consent for examination and fate of the specimen. However, if this paperwork is missing, it is not appropriate to return the specimen immediately. NP-LAB-SOP-001 describes the procedure to follow to obtain the paperwork. If the paperwork does not arrive within one month, then the specimen must be returned to the originating pathologist, as we have no consent to retain it. Specimens awaiting paperwork are not examined.

Details of the patient and specimen are recorded on the department LIMS against the specimen acquisition number; if no paperwork is received then the information on the specimen label is used and then checked when the paperwork arrives.

**Referral, Loan and Donation of Material**

Cases for referral are only sent to departments that comply with BS EN ISO: 15189 (or the equivalent for overseas departments) – refer to NP-MGT-SOP-008.

WinPath is used to record details of any clinical material sent away for opinion, or lent or donated to other laboratories for further investigation of any kind. Material is only sent away if there is consent for this. There is a documented procedure that ensures loaned samples are recovered in the event they are not returned within a defined time period (NP-MGT-SOP-016).

All material sent away is packaged, labelled and despatched to ensure safety of anyone involved in its transport, as detailed in NP-LAB-SOP-009, and in compliance with current legislation.

**Specimen Preparation**

Neuropathologists perform specimen cut-up and are responsible for the selection of samples, and decide on appropriate testing. Selection of samples from muscle and peripheral nerve biopsies for both light and electron microscopy may be delegated to HCPC-registered Biomedical Scientists.

The equipment, materials, control materials and methods are the responsibility of the biomedical scientists and are documented in the appropriate laboratory SOPs.

There are checks in place to ensure that samples from specimens retain their acquisition number and patient’s surname, as specified in the standard operating procedures set out below.

**Description and Sampling**

Description and sampling of specimens is described in NP-LAB-SOP-003 and photography of specimens, which is usually done at the same time if required, in NP-LAB-SOP-002.

**Paraffin Wax Processing and Embedding**

The samples are processed as described in NP-LAB-SOP-004.

The processor reagents are regularly changed, and this is logged.

The SOP includes measures to ensure samples retain linkage to their laboratory acquisition numbers, and to avoid cross-contamination of specimens.

**Microtomy and Staining of Paraffin Wax Processed Samples**

The SOP NP-LAB-SOP-005 includes measures to ensure that sections produced are suitable for the required demonstration techniques and that there is no cross contamination or incorrect labelling. Quality control sections are stained in parallel where appropriate. Each staining method used within the laboratory has an accompanied SOP.

**Immunocytochemistry**

Immunocytochemistry is performed on paraffin wax processed tissue sections and frozen sections as described in the SOP NP-LAB-SOP-007. In all cases, known positive control material is tested and where appropriate known negative control material is tested. A record is kept of primary antibodies in use and in stock with expiry dates recorded.

It is the Neuropathologists’ responsibility to check the positive and negative staining of the control tissue provided with their sample slides, this includes internal negative staining in a positive control or a composite control which has separate pieces of both negative and positive tissue. This is to ensure that false positive results are excluded. Upon reporting the IHC the Neuropathologist is acknowledging that this process has been done.

**Muscle and Nerve Biopsies**

Muscle and peripheral nerve biopsies are booked with the department in advance, and a list is kept in the laboratory. These biopsies arrive unfixed, in a petri dish or wrapped in cling film. The specimen is sub-divided for enzyme histochemistry and electron microscopy, and also for paraffin histology if there is sufficient tissue available.

There is a service Level Agreement in place with Cardiff and Vale University Hospital to provide a service for the diagnosis of muscle biopsies. These muscle biopsies will arrive frozen.

See the SOP NP-LAB-SOP-013 and NP-LAB-SOP-012.

The residual frozen tissue following the preparation of sections for histochemistry is stored in the -80°C freezer, and is available for molecular genetics studies should these be required. Refer to NP-LAB-SOP-008.

**Urgent Intra-Operative Samples**

Two types of urgent intra-operative samples are received: brain smears; and biopsies for frozen sectioning.

All unfixed specimens are received and prepared in a Class 1 biological safety cabinet.
See NP-LAB-SOP-010 for details.

**Cerebrospinal Fluids**

CSF specimens are prepared for microscopy using a cytocentrifuge.

The labelled reserve from the specimen is stored refrigerated for 7 days after reporting. Refer to the SOP NP-LAB-SOP-011.

**Electron Microscopy**

Specimens for routine examination are fixed using 10% formalin. Electron microscopy is referred to the Electron Microscopy Unit at Cardiff and vale University Hospital in Wales. Images are sent back to the department via a secure web browser and the diagnosis is made by the requesting Neuropathologist.
Refer to the SOP NP-LAB-SOP-032.

**Specimen Reporting**

There are two standard operating procedures in place, NP-MGT-SOP-005 and NP-MGT-SOP-004 that describe the specimen data management activities, including: updating records following specimen reception; entering report text into WinPath; printing and issuing reports; faxing reports (when this is unavoidable); and handling requests for telephone reports. The standard operating procedure also describes the filing of paper copies of reports.

**The Report**

The consultant pathologists are professionally responsible for creating reports that are clear, unambiguous, and sufficiently detailed to allow users to interpret results.

The form of the report is designed to meet the needs of users and the trust medical records system, and complies with BS EN ISO: 15189.

A supplementary report, produced to the same standards, is sometimes issued to provide the results of further investigations performed in this laboratory, or opinions of other pathologist(s) to whom the case has been referred.

Reports are always checked and authorised by a consultant neuropathologist before release from the neuropathology department.

All Neuropathology reports that are authorised, with the exception of autopsy reports, are available immediately after authorisation on ICE.

**Issuing Reports**

The routine procedure for issuing biopsy reports is that, as soon as they have been authorised by a neuropathologist, the Department secretaries email a pdf copy directly to the referring clinician, copied to other appropriate NHS personnel as required. All Neuropathology reports that are authorised, with the exception of autopsy reports, are available immediately after authorisation on ICE. Hard copies can be sent internal mail or Royal Mail.

**Telephoned Reports**

Reports are only issued or discussed on the telephone by a neuropathologist, and the process meets UKAS standards.

**Amended Reports**

Where a neuropathologist wishes to amend the content of a report, this is done by issuing a supplementary report, see {22.1} above. The text of the existing report is never amended.

Should it be necessary to amend the patient information in a case record (for example, if the address to report to changes) then the report is re-issued. In this situation the reporting pathologist checks and signs the new report, and this is clearly documented on the report.

**Clinical Advice and Interpretation**

Clinical advice and interpretation of results is provided in the specimen report by the neuropathologist who signs it. Occasionally users visit the department to discuss a patient with the neuropathologists, or they may telephone.

**Specimen Storage and Disposal**

**Frozen Tissue for Tumour Cytogenetics**

Neurosurgeons select patients who may benefit from cytogenetic studies of their tumours. Unfixed specimens from these patients are received with the formalin fixed biopsy for neuropathology, and these specimens share the same acquisition number.
The standard operating procedure for the storage of these samples NP-LAB-SOP-008 includes instructions for recording the mapping co-ordinates for the storage location in the freezer against the specimen acquisition number. These specimens are stored indefinitely, or until required for testing.

**Frozen Muscle Biopsies**

Muscle biopsies specimens that have been frozen for histochemical testing are kept in the same storage system as the frozen tumour samples (see above) and are also kept indefinitely for possible future testing.

Refer to the SOPs NP-LAB-SOP-013 and NP-LAB-SOP-008.

**Cerebrospinal Fluid Samples**

CSF samples are stored in a laboratory refrigerator for one week after reporting. They are then disposed of into a sharps bin as described in NP-LAB-SOP-011.

**Residual Formalin Fixed Biopsy Tissue**

Many biopsies are processed in their entirety. When there is residual tissue, this is stored in the original biopsy container, filed in numerical order in the cut-up room, for eight weeks. It is then disposed of by maceration and flushing into the drain. Refer to the SOP NP-LAB-SOP-003.

**Biopsy Blocks and Slides**

Sample blocks and slides from paraffin wax processed biopsies are filed in numerical order and kept indefinitely. If blocks or slides are temporarily removed from the files, for further investigations, audit or EQA, a marker slip detailing their whereabouts is inserted in the file. Refer to the SOP NP-LAB-SOP-008.

**Autopsy Specimens**

All specimens are handled respectfully by the Neuropathology Department’s staff from the time of receipt to the point of disposal. Once an autopsy case is complete the fate of residual tissue, specimen blocks and slides is always determined by the consent provided by next-of-kin. The alternatives are as follows:

* Returning the specimen(s) to the originating pathologist
* Returning the specimen(s) to a nominated undertaker for burial or cremation. Where appropriate, this will involve the specimen(s) being reunited with the body remains.
* Retention by the Neuropathology department for research or education.
* Respectful disposal of the specimen(s) by the Neuropathology Department following North Bristol Trust procedures, which comply with legislation.

For details, refer to NP-LAB-SOP-008.

The only exception is where the tissue is evidence in a criminal case, and all material must be retained until the legal proceedings and any sentence are completed, in compliance with legislation and Royal College of Pathologists’ guidelines.

**Electron Microscopy Specimens**

All tissue for electron microscopy is sent to the referral laboratory for processing.

Processed blocks of tissue are returned to the department by the referral laboratory once diagnosis is complete (approximately every three months). The department will then transfer these for storage at CellNass.
Refer to the SOP NP-LAB-SOP-032.

**Evaluation and Quality Assurance**

**Assessment of User Satisfaction and Complaints**

Assessment and evaluation is performed by the meetings and questionnaire described in section 6.8 above. See NP-MGT-SOP-001 and NP-MGT-SOP-002.

**Internal Audit of Quality System & Laboratory Processes**

The Quality Manager is responsible for auditing the quality system, and the results are recorded and discussed at the bimonthly departmental meetings.
See NP-QM-SOP-006 and NP-QM-FM-014.

**External Quality Assessment**

The laboratory takes part in three UK NEQAS schemes: for neuropathology technique, for muscle biopsies, and for Immunocytochemistry (neuropathology). The results from these schemes are kept for ten years. The results are discussed at laboratory and department meetings and a plan is made for improving quality where possible. The Quality Manager records the action plan and results, see NP-QM-SOP-005. The laboratory standard operating procedures are then amended if appropriate.

The laboratory also participates in an interlaboratory comparison scheme for cerebrospinal fluid analysis with Cardiff and vale University Hospital and a large block scheme with John Radcliffe Hospital.

The neuropathologists participate in the British Neuropathological Society NEQAS scheme.

See NP-QM-SOP-002.

**Quality Improvement Programme**

The quality improvement programme is designed to use the information gathered by the quality system to maintain and improve laboratory services. This is implemented by the following means: -

* Regular staff meetings where everyone can put forward and discuss ideas
* Monitored action plans with review dates after each round of EQA
* Monitored action plans with review dates after each internal audit
* Monitored action plans with review dates following on from internal quality control and untoward incident reports
* Monitoring, recording and responding promptly to the views and needs expressed by users.
* Annual quality system reviews, which are key to the evaluation of continuous quality improvement, and setting quality objectives.

Quality improvements are documented on the quality improvement spreadsheet where corrective and preventive action is recorded NP-QM-SOP-005 and NP-QM-SOP-012.

**Business Continuity Plan**

This plan supplements the information provided in the Department’s Business Continuity Plan (NP/QM/POL/005), which is a document that forms part of NBT’s collection covering the business activities of the whole Trust.

The purpose of this plan is solely to elaborate on how the various aspects of the Department’s activities should be prioritised in the event of unforeseen circumstances.

The main factors impacting on the performance of the department are staff shortages, equipment breakdown, loss of power, loss of water supply, lack of liquid nitrogen and fire.

**Staff Shortage**

In the short-term this is likely to be due to sickness, possibly in addition to member(s) of staff being on planned annual leave. In the laboratory, this situation would be tackled by a combination of:

* Concentrating only on the highest priority aspects of the service as dictated by staff resources (see below for details).
* Asking staff on leave to cancel if they have no pre-booked arrangements, and to return to work to cover an extreme emergency.

Secretarial staff shortages can be overcome in the very short term (e.g. no cover available for a single day) by transferring telephone enquiries to the laboratory, and organising a member of the technical staff to transcribe and print urgent specimen reports. This arrangement only provides for very rudimentary secretarial cover, and it is at the expense of the Department scientific service. Longer term shortages would need to be covered by contracting locum secretarial staff via the NBT Xtra bank team.

In the future, this problem could arise due to the department having one or more unfilled vacancies. Any future constraints affecting post(s) being advertised and filled, or an inability to recruit staff of a suitable calibre would be likely to compound this potential problem.

**Equipment Breakdown**

All major pieces of equipment used for the preparation of specimens in the Department are covered by service contracts, many of which include emergency breakdown cover. In the event of an early repair not being possible, many of the processes that are automated can be performed manually, but with the obvious increased demands on staffing resources. An exception is the processing of routine neurosurgical cases where there are two tissue processors. Contingency plans are in place with the Cellular pathology Department at North Bristol NHS Trust for certain items of equipment.

**Loss of Power**

This situation would only be a problem if the Trust’s emergency generator system failed to operate. All of the equipment in the Pathology Sciences Building is on an uninterrupted power supply, so this is very low risk. We would however as a consequence, be without:

* IT facilities, and therefore the ability to book in specimens electronically, and check for patient history. We have a contingency system in place for a stop-gap ‘written’ booking-in of specimens.
* Electric lighting, which would significantly increase the element of risk associated with many laboratory activities, especially at times of low, or no, natural light.
* Tissue processors. Specimens are processed over-night but would be left in a fail-safe condition if the instrument stopped, so the risk of destruction of critical specimens is very low. Should the disruption to power be likely to occur over an extended period of time, specimens can be retrieved from a tissue processor and the remaining stages of the process performed by hand.
* The Immuno-staining machine. This instrument is not left to run untended, so a power failure would only necessitate manual intervention to retrieve the slides and to continue the immuno-labelling process by hand. Any additional immuno-labelling work would also have to be performed manually. This is a time consuming activity that would impose an additional burden on the department at times of staff shortage.
* The CSF cytology service due to the cyto-centrifuge being inoperable. This would not be a problem in the short-term, but over a period of more than 72 hours, samples awaiting preparation will start to deteriorate.
* All light microscopes, which are electrically powered. The neuropathologists would therefore be unable to examine slides to provide diagnostic opinion.
* -80ºC freezer. To maintain the low temperature of the stored specimens, this instrument would not be opened in the event of a loss of power. Contingency plans have been made with the South West Dementia Brain Bank if loss of power remains.
* Fume extraction facilities, required for many laboratory processes involving the use of potentially hazardous specimens or reagents.

**Loss of Water Supply**

This would have a severe affect on our slide staining procedures. A supply of running tap water is essential for washing slides at various stages during most of our routine staining methods.

We would also be unable to flush away many of the reagents used in performing our wide range of laboratory procedures.

Should we be without water, all of our staining would have to be temporarily relocated elsewhere.

**Lack of Liquid Nitrogen**

We rely on using liquid nitrogen for the rapid freezing of samples of all our muscle biopsy specimens, the tissue being sectioned in a frozen state to provide material for a range of enzyme histochemical techniques used in the diagnosis of muscle disease. Shortage of this material would result in our last-minute cancellation of any pre-booked muscle biopsy procedures.

BOC deliver liquid nitrogen on a weekly basis and Neuropathology share the stock with Pathology. The cylinder is kept so that it should not be emptied, ready for filling so this is low risk.

**Fire**

Although appropriate safety measures are routinely applied to minimise the risk, should the Department be affected by fire there would inevitably be a severe impact on at least some aspects of the service. Of immediate concern would be the need to evaluate the extent of the damage caused, and if possible to retrieve unfinished and unreported work for completion elsewhere.

There would then be the need to make alternative arrangements for the temporary relocation of all, or some aspects of, the neuropathology service, depending on the extent of the damage, until a full appraisal of the situation has been carried out and the necessary laboratory and office facilities restored.

During this period, the work priority is as indicated in section 25.7 below.

**Priorities for Maintaining the Neuropathology Service:**

The services listed below have been given a star rating to indicate priority.
( = high priority; = medium priority; = low priority)

* **Neurosurgical Biopsies ()**

Our key priority in providing high quality patient care is to maintain a reliable and efficient neurosurgical biopsy service, an aspect of our work where specimen turn-around is crucial in the provision of a timely diagnostic report.

In the event of staff shortage or other disruption to our facilities, this aspect of our service would have highest priority, in terms of both intra-operative reporting when required, and providing the main diagnostic report(s). Any constraints would be due to the unavailability of any necessary technology for reasons indicated above.

Although very infrequently, there are times when there is not a neuropathologist available to examine intra-operative specimens, but should this situation arise, arrangements will normally have been made with the surgeon.

* **CSF Cytology ()**

The initial stage of preparing a cerebral spinal fluid (CSF) specimen for microscopy is performed using a cyto-centrifuge to sediment onto microscope slides the cells in an unfixed sample. CSF samples must therefore be processed within a few of hours of receipt to avoid deterioration of the sample. CSF specimens may be left in a ward fridge for up to 72 hours if they are collected outside of the Neuropathology Department’s opening times. Storage in a fridge for longer periods or at room temperature for more than a few hours will render the specimen diagnostically useless.

* **Muscle Biopsies ( to )**

Muscle biopsy specimens are received by the Department unfixed. Consequently the initial stages of processing these specimens must be performed urgently.

In the event of staff shortage, the specimen will be dissected and a sample rapidly frozen using liquid nitrogen and then put into storage in the -80ºC freezer () until staff resources are available to continue work on the case (). The remaining tissue will be stored in appropriate fixative solutions for future paraffin histology and electron microscopy when staff resources permit ().

* **Nerve Biopsies ( / )**

Most nerve biopsies performed by clinicians at NBT are received unfixed. On receipt it is a high priority () to dissect the specimen and place a sample in glutaraldehyde fixative for electron microscopy and put the remaining tissue into formalin for paraffin histology. Once placed in these fixative solutions the samples become a lower priority (), and can be stored until staffing resources allow further work to be performed. Specimens from elsewhere are usually sent to the Department in fixative, and can be treated as low priority ().

* **Autopsy Specimens ()**

These are generally of low priority and their progress through the laboratory would only be compromised by an extended period of staff shortage.