



Quality Manual & Local Operational Guidelines

Reference Number: 00

Approved By:	
Date Implemented:	
Version:	
Supersedes:	
Author:	SVT Professional Standards Committee &
Person Responsible for Document & Position:	
Reviewed by:	
Next Review Date:	

Abbreviations and acronyms

Abbreviations & Acronyms	
QMS	Quality Management System
QA	Quality Assessment
SOP	Standard Operating Procedures
IQIPS	Improving Quality in Physiological Services
UKAS	United Kingdom Accreditation Service
SVT	Society for Vascular Technology GB&I
AVS	Accredited Vascular Scientist
HCPC	Health and Care Professions Council
RTT	Referral To Treatment
KPIs	Key Performance Indicators

This template is a starting point for a services QM. The authorship front sheet should retain the SVT as well as service specific names. The red text is a guide to suggest edits required and should be deleted as necessary.

Changes & Updates

Description of changes & updates	By	Date

Table of contents

Table of Contents	Page
i. Abbreviations	1
ii. Changes & Updates	2
iii. Table of Contents	3
1. Quality Manual Introduction, Aim & Objectives, & Scope	
1.1. Introduction	
1.2. General Information	
1.3. Purpose & Mission Statement & Values	
1.4. Scope	
2. Quality Policy* You may wish to have a separate Quality Policy Doc	
2.1. Quality Statements	
2.2. Local KPI's & Targets	
3. Organisation Management, Structure and Responsibilities	
3.1. Organisational Chart	
3.2. Conflict of interest	
3.3. Internal communication	
3.4.	
4. Service Staff Roles, Responsibilities, & Competencies	
4.1. Staff Roles & Responsibilities	
4.2. Specific Roles & Responsibilities	
4.3. Visiting Staff/Students, Clinical Observers & Work Experience	
4.4. Training & Competencies	
5. Staff & Service Management	
5.1. Appraisals	
5.2. Sickness & Absence Management	
5.3. Recruitment & Retention Management	
5.4. Service Planning & Delivery	
6. Facilities, Environment & Security	
6.1. Facilities	
6.2. Environment	
6.3. Security	
7. Equipment Management	
7.1. Selection & Procurement	
7.2. Equipment Basic Specifications	
7.3. Equipment Use	
7.4. Equipment Quality Analysis, Servicing & Safety Testing	
7.5. Decommissioning	
8. Uncertainty of Measurement	
8.1. UoM Definition	
8.2. UoM Considerations	
8.3. Ultrasound Probe Resolutions and UoM	
8.4. Imaging Tests	
8.5. Non-imaging tests	
8.6.	
9. VSU Audit & Management of Non-Conformity	
9.1. Audit Processes	
9.2. Clinical Diagnostic Audits	
9.3. Service Audits	
9.4. Quality Indicators	
9.5. Annual Management Review & Performance Reports	

9.6. Management of Non-Conformities	
10. Infection Prevention & Control	
10.1. Staff	
10.2. PPE	
10.3. Environment & Equipment	
10.4. Hand Hygiene	
10.5. Barrier nursed patients	
10.6. Immunocompromised Patients	
10.7. Sterile procedures	
11. Emergency Procedures	
11.1. Cardiac/Respiratory Arrest Incidents & management procedures	
11.2. Fire incidents & management procedures	
11.3. Major Incidents & management procedures	
11.4. Emergency Call Button Testing & management procedures	
12. Health & Safety, & Risk Management	
12.1. Medical Device Safety	
12.2. Ultrasound Safety	
12.3. Equipment Safety	
12.4. Environmental Safety	
12.5. Manual Handling	
12.6. Risk Management	
12.7. COSHH	
12.8. Reporting of Clinical Issues and Concerns	
13. Customer (Patient and other service users) Experience	
13.1. Patient Feedback Systems	
13.2. Concerns & Complaints	
13.3. Patient Information	
14. Documents, Records & Information Management	
14.1. Document Control	
14.2. Data Protection & Access	
14.3. Records & Information Management	
14.4. Information management systems	
15. Legal Liability	
15.1. Organisational structure	
15.2.	
16. Business Continuity Plans	
16.1. Cross Site Working	
16.2. IT Failure & Major Equipment Failure	
16.3. Staff Absence	
17. Document Control	
17.1. Document/Policy List	
17.2. Approval Process	
17.3. Equality Impact Assessment	
17.4. Dissemination & Implementation	
17.5. Review & Monitoring, Version Control & Document Archiving	
17.6. Key Words	
18. Other Resources	
18.1.	
18.2.	

1. Quality Manual Introduction, & Scope

1.1. Introduction

Describes the Quality Management System (QMS)

1.2. General Information

A Description of the service, location, size, staff, operating hours, main address etc

1.3. Purpose, Mission Statement & Values

States the purpose, mission statement and values of the service.

1.4. Scope

Explains who the QMS applies to (staff/patients/carers/referrers/etc).
May include requirements in relation to relevant parent organisation QMS

2. Quality Policy

(May be a separate document)

Short document that establishes what quality means to the organisation/service.

Includes:

measurable quality objectives/KPIs/targets that are regularly reviewed
processes for continuous improvement

processes for internal/external benchmarking

Assures consistency in performance across activities

2.1. Quality Statement

Describes quality in relation to the service

2.2. Organisation & Local KPI's & Targets

States KPIs/Targets

3. Organisation & Management Structure and Responsibilities

Overarching description

3.1. Organisation Chart

Detailed structure includes lines of responsibility within and outside the service (clinical management groups/corporate/directorates/etc)

3.2. Conflict of interest

Describes processes for declaring any conflict of interests

3.3. Internal communication

Describes processes

4. Staff Roles, Responsibilities and Competencies

Describes defined responsibilities and accountabilities, including professional leadership, advice, budget control and risk management.

4.1. Staff Roles & Responsibilities

Describes specific roles and may include the following responsibilities:

- referral acceptance/vetting
- Access to information systems
- appropriate delegation
- service provision
- reporting lines
- performance of tasks
- planning/scheduling
- checking/supervision/teaching
- co-ordination/liaising

4.2. Specific Roles & Responsibilities

Additional Role	Staff Name
Examples may include:	
Fire officers	
Health & Safety Lead (Including Risk Assessments, COSHH & management of Non-Conformities)	
Infection & Prevention Lead	
Audit Lead	
Education & Training Lead	
Imaging (CRIS/PACS) Lead	
Clinical & Service Development Lead	
Research Lead	
Ultrasound QA	

4.3. Management of Visiting Staff/Students, Clinical Observers & Work Experience

Describes required processes

4.4. Training & Competencies

Describes the training, supervision and management/assurance of competencies required for the staff in the service

5. Staff & Service Management

5.1. Appraisals

Describes the processes for management of appraisals including assurance that required processes are followed

5.2. Sickness & Absence Management

Describes the processes for management of sickness and other absences including assurance that required processes are followed.

5.3. Recruitment & Retention Management

Describes the processes for recruitment and retention of staff including assurance that required processes are followed.

5.4. Service Planning

Describe the processes for service planning at a local and wider service level including management review and monitoring/assurance that processes are followed. ...

6. Facilities, Environment and Security

6.1. Facilities

Describe the service global environment and facilities
Describe local level design layout etc and standards
Describe facilities management and monitoring

6.2. Environment

Environment local standards and expectations, policies and processes, monitoring etc...

6.3. Security

local standards and expectations, policies and processes, monitoring etc...

7. Equipment Management

7.1. Selection & Procurement

Describes processes for e.g. securing funding, machine trials and selection and procurement including required processes of the parent organisation. Maintenance of an asset register including planned replacements.

7.2. Equipment Basic Specification

Describes technical details of equipment to perform required tasks

7.3. Equipment Use

Personnel and processes for equipment use

7.4. Equipment Quality Analysis, Servicing & Safety Testing

Describes processes for assuring quality and safety of all equipment, including requirements of parent organization and professional body advice. May include servicing, calibration, safety testing and daily/weekly/monthly checks. Documentation of training and competency and processes for management of any equipment failure. Processes for communication of any health and safety alerts relating to equipment.

Clinical equipment may include:

- Ultrasound Machines
- Handheld Doppler
- Manual BP Cuff / Sphygmomanometer
- Treadmill
- PPG/Laser Doppler /TcPO2
- Examination Couch
- Patient aids/support devices

7.5. Decommissioning

Describes processes

8. Uncertainty of Measurement (UoM)

8.1. UoM Definition

UoM is the quantification of variability that exists in any measurement, and to understand what an acceptable range is.

8.2. UoM Considerations

Describes how UoM relates to Vascular diagnoses carried out in the service taking account of professional body guidance. Includes consideration of the effect of the following on UoM:

- Staff
- Patient
- Equipment
- Methodology
- Environment

8.3. Ultrasound Probe Resolutions and UoM

Describes how resolution measurements for every probe are quantified and applied to the values/units used for reporting to appropriate levels of precision/accuracy. May include use of phantoms/services of subcontractors

8.4. Imaging Tests

Describes how UoM affects these processes

8.5. Non-imaging tests

Describes how UoM affects these processes

9. Audit & Management of Non-Conformity

9.1. Audit Processes

All diagnostic services need to carry out an internal audit of their processes and performance of tests to ensure delivery of a competent service.

Describe purpose and overview of processes including who is responsible
Include horizontal and vertical audit procedures

9.2. Clinical Diagnostic Audits

Description of all audits to assure the quality of clinical diagnoses

9.3. Quality Indicators

Statement of quality indicators and description of processes to assure these are achieved. Includes processes for reporting. Consider

- DNA rates
- Waiting list times
- Reporting completion and turnaround times
- Diagnostic test figures & breakdowns
- Staff efficiency
- Referral pathways
- Patient satisfaction

9.4. Annual Management Review

Describes timescales and processes

9.5. Management of Non-Conformities

Describe definitions, responsibilities and processes for management of any non-conformities related to all parts of the service.

Consider recording of non-conformities, trend identification, root cause analysis and appropriate corrective and preventative actions.

Consider:

Criteria/definition of non-conformity

Responsibilities for prevention and management of non-conformity

Training

Documentation

Communication

Immediate actions to mitigate the effect and remove the root cause

Consideration of need for recall of results/patients, repetition of tests, clinical escalation

Documented review meetings to analyse, predict and manage potential future non-conformities

10. Infection Prevention & Control

Describes processes to assure prevention and control of infection.
Consider how this relates to:

10.1. **Staff**

10.2. **PPE**

10.3. **Environment & Equipment**

10.4. **Hand Hygiene**

10.5. **Barrier nursed patients**

10.6. **Immunocompromised Patients (Reverse Barrier Nursed)**

10.7. **Sterile procedures (and scanning surgical wounds)**

11. Emergency Procedures

Describes processes to assure appropriate management of:

11.1. Cardiac/Respiratory Arrest Incidents

11.2. Fire incidents

11.3. Major Incidents

11.4. Emergency Call Button Testing

12. Health & Safety and Risk Management

Describes processes to assure Health and safety and Risks are appropriately managed. Consider:

- 12.1. Medical Device Safety**
- 12.2. Ultrasound Safety**
- 12.3. Equipment Safety**
- 12.4. Environmental Safety**
- 12.5. Manual Handling**
- 12.6. Risk Management**
- 12.7. COSHH**
- 12.8. Reporting of Clinical Issues and Concerns**

13. Patient and service user Experience

Describes processes to collect, manage, report and act on patient, referrer and other service user feedback. Consider

13.1. **Feedback Systems**

13.2. **Concerns & Complaints**

13.3. **Patient, referrer and service users Information**

14. Documents, Records and Information Management

Describes processes to assure integrity, format, approval, dissemination, availability, security and review of documents, records and information pertaining to the service. Consider:

- 14.1. Document Control**
- 14.2. Data Protection & Access**
- 14.3. Records & Information Management**
- 14.4. Information management systems**

15. Legal Liability

Describes who is legally responsible for the service which may be autonomous or part of a larger parent organisation. Consider:

15.1. Organisational structure

16. Business Continuity Plan

Describes processes for assurance of business/service continuity. Consider:

16.1. **Cross Site Working**

16.2. **IT Failure**

16.3. **Staff Absence**

17. Document Control

Describes processes for control of all documents. Consider:

- 17.1. Document /Policy List
- 17.2. Agreed format, approval Processes, prior to release of documents
- 17.3. Equality Impact Assessment
- 17.4. Security, dissemination & availability
- 17.5. Review & Monitoring, Version Control & Document Archiving
- 17.6. Key Words

18. Other Resources

Links to Professional Body and other relevant articles/websites