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## Scope- About the Visual Electrodiagnostics Testing Service

The Visual Electrodagnostic Testing Service is run within the Electrodagnostic Testing Unit located in the School of Optometry & Vision Science, provides a clinical testing service for ophthalmologists in the region and as such is linked to the regional NHS Trusts and private hospitals.

The service offers a range of key diagnostic tests that form part of the clinical ophthalmological assessment of patients who may be suffering from a variety of hereditary or acquired eye disorders.

Testing, which conforms to current International Society for Clinical Electrophysiology of Vision (ISCEV) standards, includes:

- Visual evoked potential (VEP) recording
- Pattern and flash electro-retinography (ERG)
- Electro-oculography (EOG)

At present, there is little or no provision for this kind of diagnostic testing in the xxxxxx region and patients are being sent to centres in Manchester, Sheffield and Newcastle in order for these tests to be performed. This is unsuitable from both the point of view of patients, as well as for clinicians who are exploring ways to improve waiting times.

We provide a quality visual electrodagnostic service to the local region, embedded into the existing academic research and clinical infrastructure of School of Optometry & Vision Science.

The Visual Electrodagnostic Testing Service is fully committed to providing a customized service tailored to the needs of individual patients. In order to achieve and maintain the high standards to which the Electrodiagnostics Unit aspires, an effective Quality System has been established to provide

- Quality in communications: defined management processes and responsibilities, clear patient interaction processes.
- Quality staff: by role and responsibility definition, appropriate training and CPD,
- Quality services: clear accountability, controlled working processes and the maintenance of records that allow complete traceability.

The overall Quality System that is intended to meet the requirements of the Care Quality Commission is described in this Quality Manual.

All Visual Electrodagnostic Testing Service staff and members of management team are required to familiarise themselves with the contents of this Quality Manual and to uphold the systems and procedures detailed within it.

By adopting this quality system, the Visual Electrodagnostic Testing Service aims to provide services of notable standard and achieve customer satisfaction, whilst seeking to continuously improve all aspects of its operations. To attain this goal, all staff members must be aware and committed to their own quality responsibilities and look to the full support of The Visual Electrodagnostic Testing Service management with regard to individual training and personal development.

## References

Care Quality Commission: Guidance about compliance. Essential standards of quality and safety, March 2010.

In addition the Electrodiagnostics Unit also makes reference to ISO9001:2000 and other relevant British or International Standards or customer specifications, as appropriate.

## Terms and definitions

The following terms apply:

The organization: The Visual Electrodiagnostic Testing Service, also know by the acronym VETS

The location: The Electrodiagnostics Unit, also know by the acronym EDU

QS: the VETS's quality system

Service user: any patient attending the Electrodiagnostics unit and any patient relative, carer or guardian accompanying the patient.

## Quality System

### Introduction

The VETS Quality System is based on the requirements and guidance of the Care Quality Commission. The Quality System integrates organisational structure, procedures, processes and resources in order to ensure that that all services deliver the necessary results and meet service user requirements.

In order that the VETS can continually improve performance, the roles and responsibilities of all personnel are clearly defined and procedures that describe the processes necessary to ensure the establishment, implementation and maintenance of the quality system have been prepared.

### Documentation

In order to maintain this assurance a documented quality system has been developed to demonstrate that all work undertaken, by the VETS, conforms to specification requirements. The documented system is comprised of:-

## **The Quality Manual**

This document outlines the quality policy of the VETS which is implemented using operating procedures and shows how the requirements of the Care Quality Commission are met.

## **Quality Processes and Procedures**

These documents detail the processes and procedures necessary to achieve Product Realisation and are the basis of Operational Control. They appear in various formats including standard operating procedures (SOPs), forms and diagrams.

The QS process map (ED/QP1) shows how the output from one process forms the input to the next. It also highlights how quality is achieved by controlling each stage of the process.

The following list outlines the key processes the VETS employs. Schematics of these processes are included at the end of this manual.

ED/QP1-QS Process map

ED/QP2-Document Control

ED/QP3-Quality Records

ED/QP4-Staff Training and Human Resources

ED/QP5-Internal Audit

## **Standard Forms**

The VETS uses standard forms for many processes. A full list of all standard forms is maintained and updated as required (see Document Control below).

## **Document Control**

The VETS director is responsible for the planning of document control procedures but may delegate the implementation of such procedures to other suitably trained staff. The Quality Manual, Standard Operating Procedures and other controlled documents have unique reference numbers. A master list identifying the current revision status and circulation is maintained.

All master copies of Quality documents are authorised, on the front page, by the VETS director.

All Manuals and Procedures issued within the organisation have controlled status.

Formal documents produced by the company are reviewed, modified and authorized, as part of the appropriate procedures.

Standard forms used in conjunction with the Quality System are also controlled.

## **Associated Documentation**

ED/QP1-Quality Management System Process map

ED/QP2-Document Control Process

## Quality System Records

The policy of the VETS is to retain quality records in order to demonstrate conformance to the requirements and to show that the Quality System is effective.

Procedures written by the VETS will define how long quality records are retained. Records may however be retained for longer periods of time, depending upon service user and service commissioner requirements.

Any hard copy records relating to service users will be stored in a secure manner. Longer term archiving will utilize a secure archive (e.g. the archive facility in the Institute of cancer Therapeutics).

## Computer Records

All PCs are connected via a local area network and business critical data is automatically stored on a central fileserver with secure access. All data stored on the fileserver is backed up daily by the University's central computing department.

Access permissions are determined by the Electrodiagnostics Unit manager with the overall aim of ensuring that data is stored securely and confidentially.

## References

ED/QP1-QS Process map  
ED/QP3-Quality Records Process

## CQC Compliance

The VETS will operate in compliance with the Guidance of the Care Quality Commission. The key outcomes for clinical governance are all described briefly below and are covered in more detail through individual policy documents, procedures, forms and information leaflets. Additional outcomes may also be covered below whilst a number of outcomes were not considered relevant to the operations of the EDU.

## Patient Involvement and Information

### **Outcome 1: Respecting and involving people who use the service**

The VETS will operate in accordance with the University's policies and national legislation covering Equality and Diversity, Equal Opportunities, Dignity and Respect, Religion and Belief and Race Equality. The overall aim is to ensure that all service users are treated with dignity and respect, understand the services being provided and have an opportunity to comment on those services. In order to do this staff working within the EDU will have appropriate training and experience; patients will be provided with comprehensive information in the form of Patient Information Sheets

### **Outcome 2: Consent to care and treatment**

All services users will have been referred to the VETS and should have some prior knowledge of the diagnostic procedures that will be used. Prior to arrival at the EDU all service users will be provided with user information regarding the diagnostic processes carried out both in written form and through discussion with the provider. At all times the service user will be made aware of what procedures are used and be encouraged to give feedback and agreement.

### **Outcome 3: Fees**

Service users will normally be referred to the VETS through the NHS. Any fees for these service users will be covered through contracts between the VETS and the referring parties. Where service users are referred privately any costs will be made known to the service user in advance of attendance at the EDU.

## **Personalised care, treatment and support**

### **Outcome 4: Care and welfare of people who use services**

The VETS will ensure that service users will have an effective and safe experience by assessing the needs of service users and planning their service delivery. Where appropriate, adjustments will be made to reflect people's needs, values and diversity. The VETS will ensure that arrangements are in place for dealing with foreseeable emergencies.

### **Outcome 6: Cooperating with other providers**

As noted above, service users will only attend the EDU through referral. The VETS will cooperate with referring bodies to ensure that individual service user needs are understood, information is shared in a confidential manner and services are delivered in a coordinated and timely manner.

## **Safeguarding and Safety**

### **Outcome 7: Safeguarding people who use services from abuse**

As part of the University, the VETS will follow the relevant policies of the University to ensure that service users are protected from abuse and that their rights and dignity are respected. Appropriate procedures are therefore in place to identify and prevent abuse or to respond to any risk of abuse occurring. All EDU staff will have undergone appropriate training as provided by the University.

### **Outcome 8: Cleanliness and infection control**

As part of the University's Estates policy, the EDU will be maintained to an appropriate standard of cleanliness and hygiene so that service users, providers and others are not exposed to infectious risks. All cleaning staff undergoing appropriate training and the Health and Safety policies are part of the training of all staff. In addition the cleaning requirements of equipment used in service provision are detailed in specific procedures.

### **Outcome 9: Management of Medicines**

Whilst the VETS will not dispense or administer any medicines, staff will undertake to ensure that all users have access to any medications they bring with them at need. As part of the diagnostics service, where the service user is taking medication linked to the diagnostics process any adverse findings or changes in diagnostic outcomes will be recorded and reported to the referring body.

### **Outcome 10: Safety and suitability of premises**

The VETS will work with the School of Life Sciences Health and Safety Officer to ensure that the premises conform to appropriate safety standards. All staff have training in Health and Safety procedures and a copy of the University's policy will be available within the EDU. The safety and wellbeing of service users whilst on the University campus is also enhanced through various policies covering Estates and Security Services. The VETS is also very aware of the needs of service users, particularly minors, and all reasonable efforts are made to ensure the premises are suitable for the designated purpose.

### **Outcome 11: Safety, availability and suitability of equipment**

The VETS maintains an equipment policy that ensures all equipment is appropriately safety checked (e.g. portable appliance testing) and risk assessed before use. The policy also covers care and maintenance of equipment. Where appropriate, individual service user needs will be taken into consideration to ensure that all users are comfortable when undergoing diagnostic procedures.

## **Suitability of Staffing**

### **Outcome 12: Requirements relating to workers**

The VETS operates within the HR policies and procedures of the University. Recruitment is through a well defined and rigorous process and, where appropriate, CRB checks will be carried out before staff are permitted to work in the EDU. The University encourages staff to become members of professional organizations and to take part in ongoing CPD.

### **Outcome 13: Staffing**

Due to the specialized nature of the VETS activities, diagnostic appointments will only be made at limited times when the availability of suitable staff is confirmed. Any cancellations of diagnostic appointments due to illness, injury or unforeseen circumstances will be made as rapidly as possible and users offered an alternative appointment as near to the original date as possible.

### **Outcome 14: Supporting workers**

In accordance with the University's HR policies, the VETS director will ensure that all staff are properly trained, supervised and appraised (including the manager). All staff will be encouraged to acquire further skills and qualifications relevant to the work undertaken.

## Quality and Management

### **Outcome 15: Statement of purpose**

The introduction to this manual gives a brief overview of the services provided by the EDU. A full statement of purpose, in accordance with Schedule 3 of the Care Quality Commission (Registration) Regulations 2009 is available as a separate controlled document.

### **Outcome 16: Assessing and monitoring the quality of service provision**

Assessing and monitoring of service provision underpins the VETS's commitment to provide a quality service and in seeking to continuously improve service delivery. Assessment and monitoring are carried out through a range of methods including formal and informal service user feedback, complaints, external feedback from partner organizations and internal audits. All feedback will be documented and reviewed at regular management meetings. Complaints will normally be dealt with by the VETS director in the first instance and will be reviewed at management meetings along with any preventive and corrective actions. Complaints may also be made to the Dean of the School of Life Sciences or the Head of the School of Optometry and Vision Sciences if they relate to the VETS director. Internal audits will be conducted by the School of Life Sciences Health and Safety Officer and any additional quality systems adviser as required.

### **Outcome 17: Complaints**

As noted above, monitoring of complaints forms a key part of the assessment and monitoring process. The VETS maintains a system for informing all service users of the complaints procedure and undertakes to consider fully, respond appropriately and seek to resolve any complaints made. Where complaints touch on the procedures and processes of the unit they will form part of the continuous improvement process.

### **Outcome 21: Records**

Records retained in the EDU will cover all aspects of the VETS operations, staffing and training, facilities and equipment and service user information. All personal records relating either to staff or service users, will be stored in a secure manner and remain confidential. The duration of service user records retention will be determined in consultation with referring organizations (see Outcome 6).

## Suitability of Management

### **Outcome 23 Requirement where the service provider is a body other than a partnership**

The VETS director will act as the nominated individual as defined in Section 5 of the Social Care Act 2008 (Regulated Activities) Regulations 2010. In accordance with the University HR policies the nominated individual will be of good character and physically and mentally able to do the job. The nominated individual's personal records will evidence that they are appropriately skilled and have been subject to the necessary checks as described in Section 3 of the Social Care Act (Regulated Activities) Regulations 2010.

### **Outcome 25: registered person: Training**

In accordance with the University HR policies the management of the School of Life Sciences will ensure that the nominated individual/manager undertakes, from time to time, appropriate training. All such training will be documented in personal training records.

### **Outcome 26: Financial Position**

The VETS will operate as part of the School of Life Sciences at the University and its finances will be monitored on a monthly basis the School's management accountant. The VETS will be covered by the insurance and indemnity arrangement of the University.

### **Outcome 27: Notifications – Notice of Absence**

The VETS will notify the CQC of any planned absence from work of the registered manager if this absence will be of 28 days or more. Such absences will be notified a minimum of 28 days in advance. Where prolonged absence is unplanned, i.e. in an emergency, the CQC will be notified at the earliest opportunity by a delegated EDU management team. Where alternative means of running the service during periods of notified absence are available, the CQC will be informed of how service delivery will be maintained. The CQC will also be informed, within seven day, of the return to work of the registered manager.

### **Outcome 28: Notice of Changes**

The CQC will be informed of any significant changes to the service in a timely manner. Significant changes include replacement of the registered manager, alterations to the services provided or in the organizational structure and finally, should the service close.

## **Responsibility and Authority**

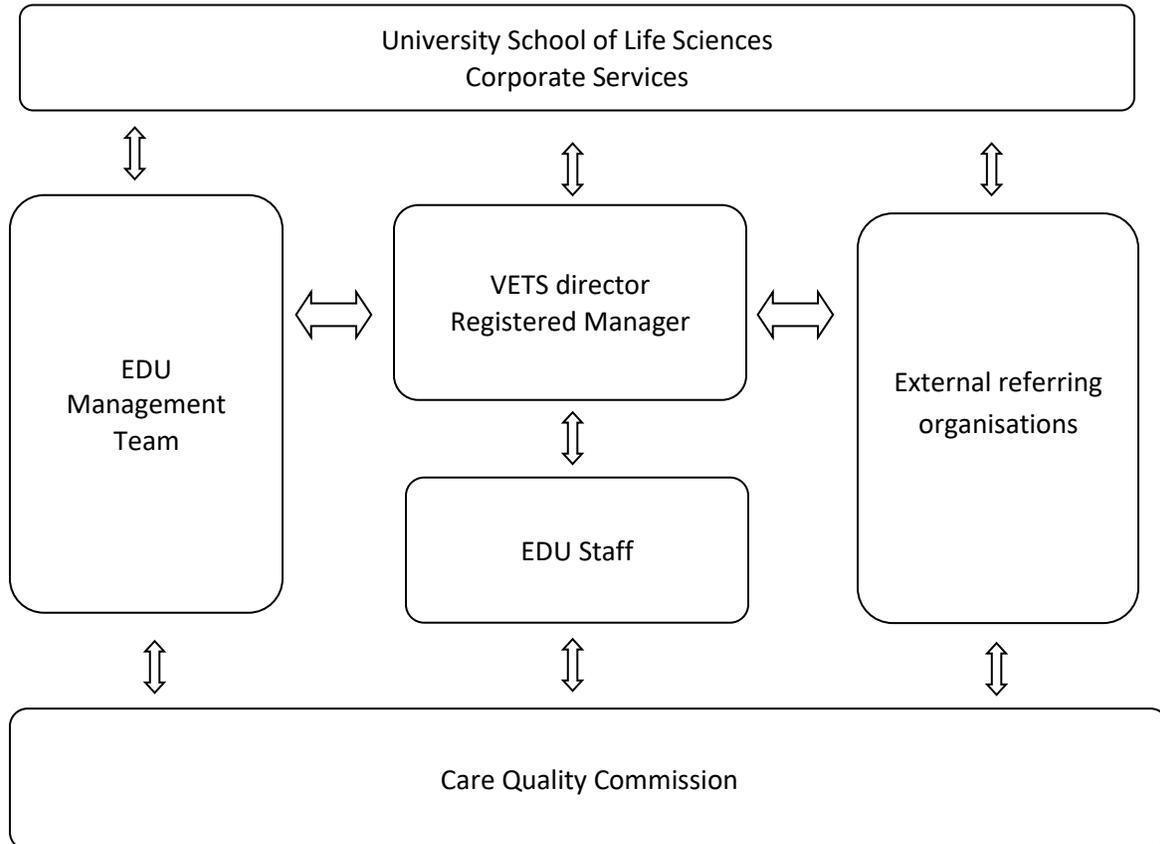
Specific responsibilities within the Visual Electrodiagnostics Testing Service and with particular reference to the quality management system are defined below:

**The VETS director** has the ultimate responsibility for controlling, directing and coordinating all management activities, including QS, throughout the unit. The VETS Director will be the CQC registered manager and will report to the EDU Management Team.

**The EDU Management Team** will consist of the VETS director, School of Life Sciences Health and Safety Officer, the Head of the School of Optometry and Vision Science (BSOVS) and the Business Manager for BSOVS. Other relevant personnel may be asked to join this management team. The EDU Management Team has the responsibility to ensure that the management of the VETS is conducted as detailed in this manual.

**All EDU Staff Members** are responsible for Quality Systems implementation and maintenance. Staff are also responsible for ensuring that their training records are maintained and kept up to date.

## Organization chart



## Quality System Review

The QS, including this manual, is systematically reviewed at least once per year to ensure its continued performance and effectiveness. Management Review meetings are attended by all members of the management team, where possible, and records of agreed and outstanding actions are retained.

As a minimum, the following items are discussed:

- i) Results of internal and external audits
- ii) Customer feedback (compliments and complaints)
- iii) Corrective and preventive actions
- iv) Follow-up actions from previous meetings
- v) Changes that could affect the QS
- vi) Recommendations for improvement

## Quality System Improvement

The VETS is committed to a policy of continuing improvements in its methods and the services supplied to users. An important element of this is the analysis any problems that may occur with a view to long term prevention.

### Corrective Action

The VETS operates procedures for handling internal problems and service user complaints. Any action required is recorded and discussed by the management team to consider any long term implications.

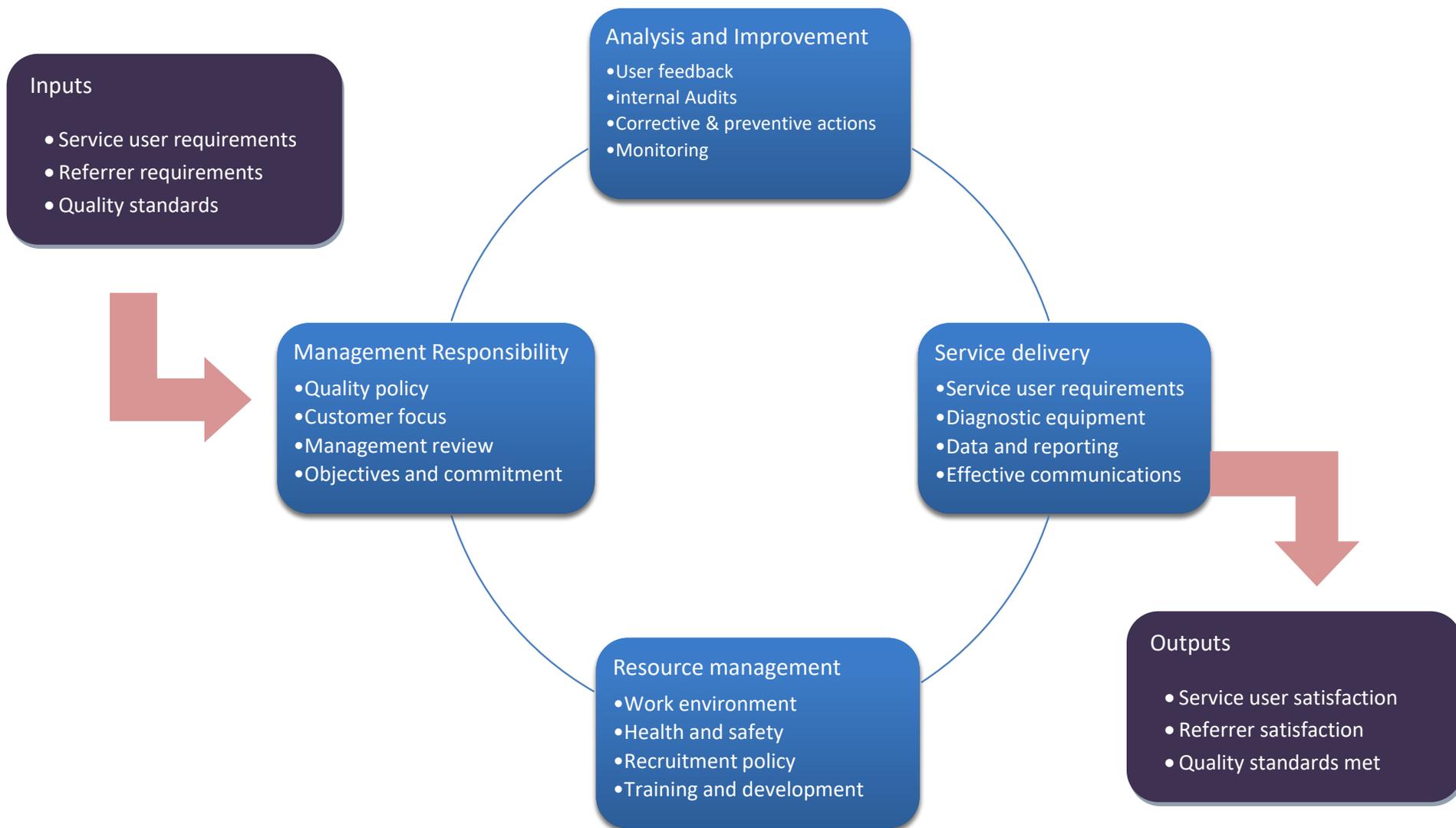
### Preventive Action

Preventive action is addressed in a number of ways, for example:

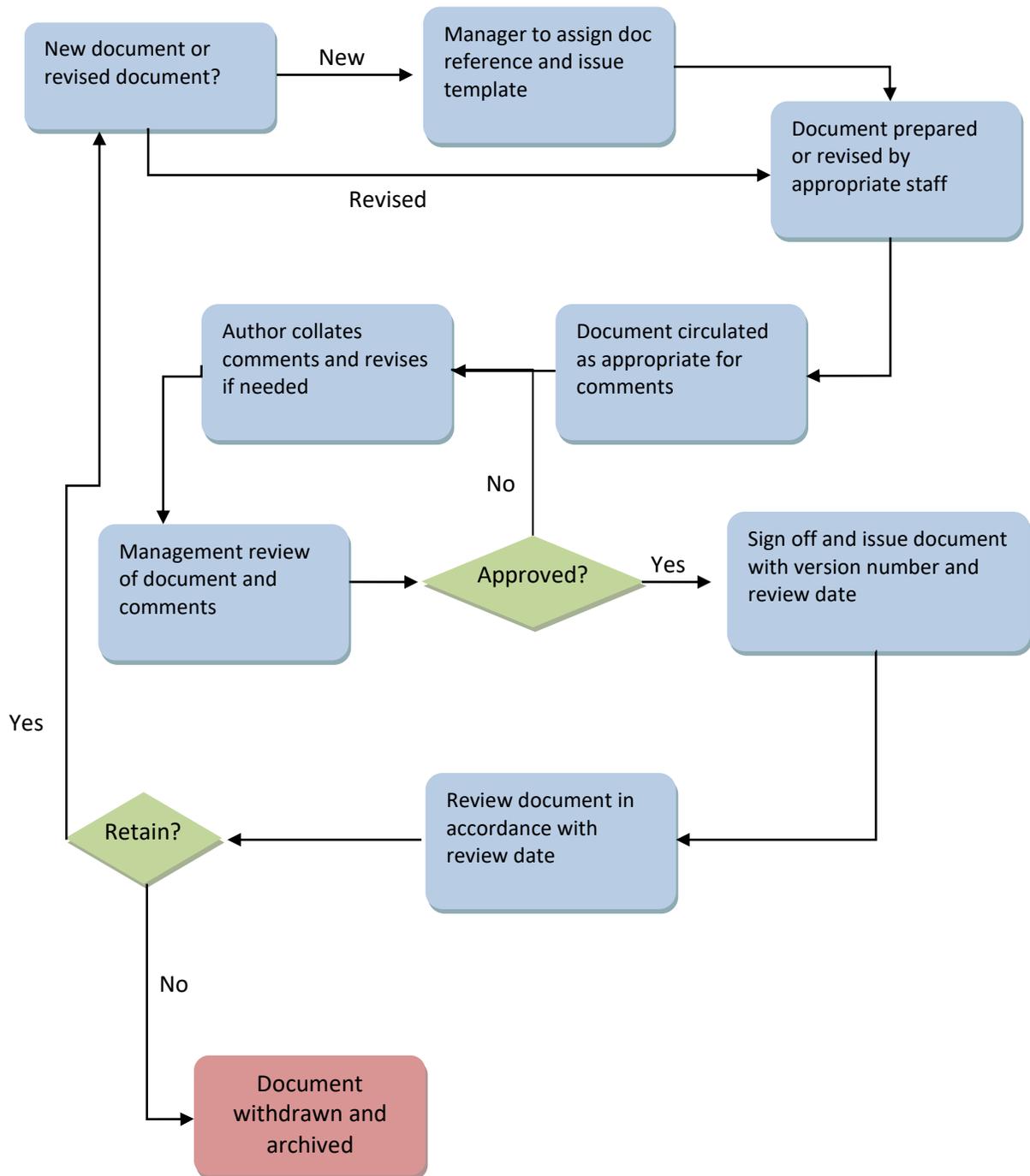
- i) the QS procedures incorporate various checks to ensure that potential problems are identified, recorded and resolved,
- ii) an important aspect of the internal audit process is the recording of observations to highlight potential problems and possible improvements,
- iii) empowering all staff to come forward with proposals for improvement

The effectiveness of any actions taken are monitored through the analysis of subsequent performance. This is reviewed periodically and discussed at Management Meetings.

## ED/QP1-QS Process map



## ED/QP2-Document Control

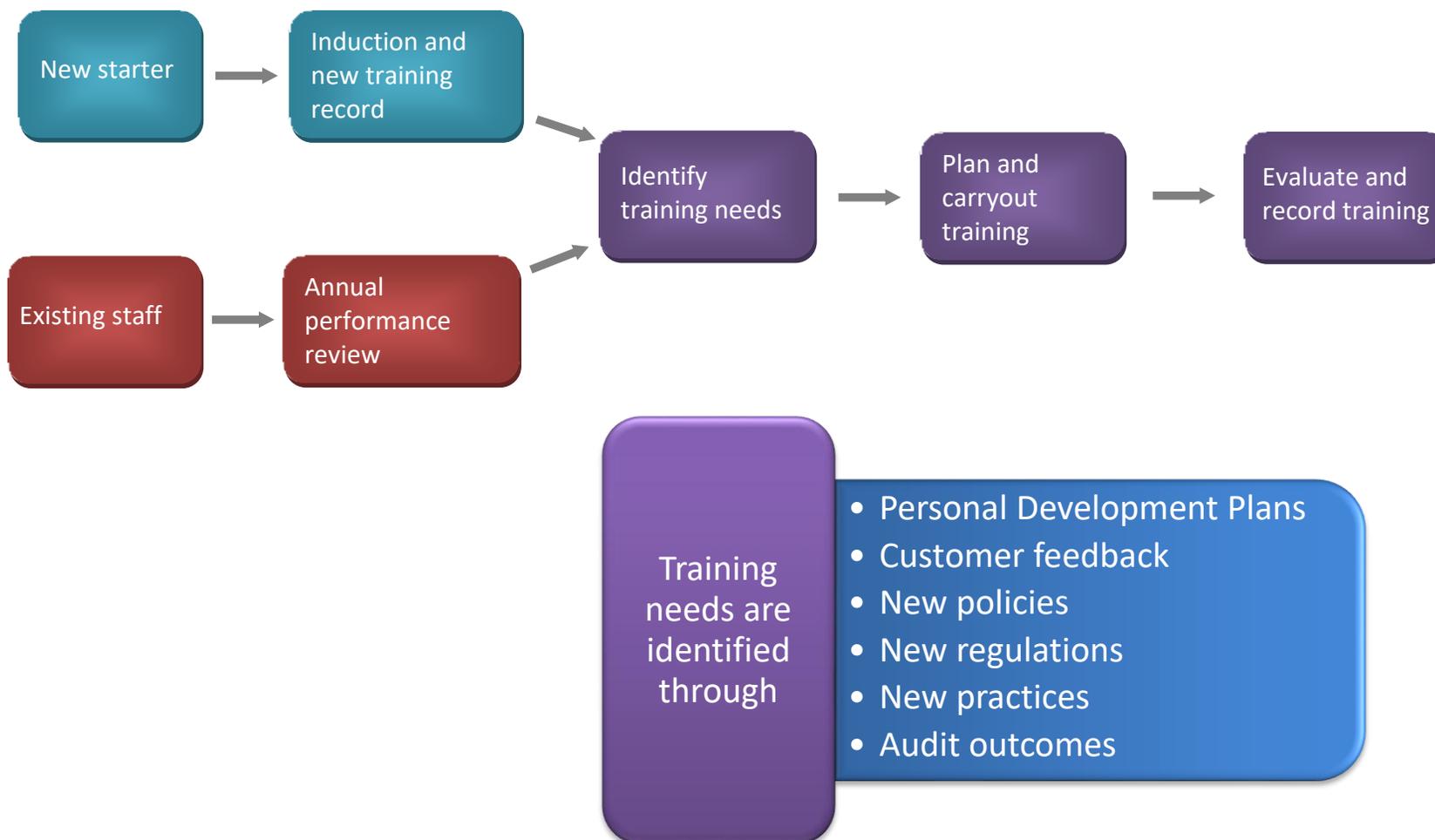


## ED/QP3-Quality Records

Quality Control	<ul style="list-style-type: none"><li>• Internal/external audits</li><li>• Service user feedback and complaints</li><li>• Corrective and preventive actions</li><li>• Management review</li></ul>
Facilities	<ul style="list-style-type: none"><li>• UoB policies</li><li>• Equipment logs</li><li>• Cleaning and maintenance records</li><li>• Service user records</li></ul>
Staff	<ul style="list-style-type: none"><li>• UoB policies</li><li>• Equipment logs</li><li>• Cleaning and maintenance records</li><li>• Service user records</li></ul>
Service delivery	<ul style="list-style-type: none"><li>• Quality Manual</li><li>• Operating procedures</li><li>• Other controlled documents</li><li>• Staff records</li></ul>
Service user records	<ul style="list-style-type: none"><li>• Appointments and letters of invitation</li><li>• Diagnostic reports and data</li><li>• Consenting and information</li><li>• Feedback</li></ul>
External referring organisations	<ul style="list-style-type: none"><li>• Contracts</li><li>• Service level agreements</li><li>• Appointment system</li><li>• Referral records</li></ul>

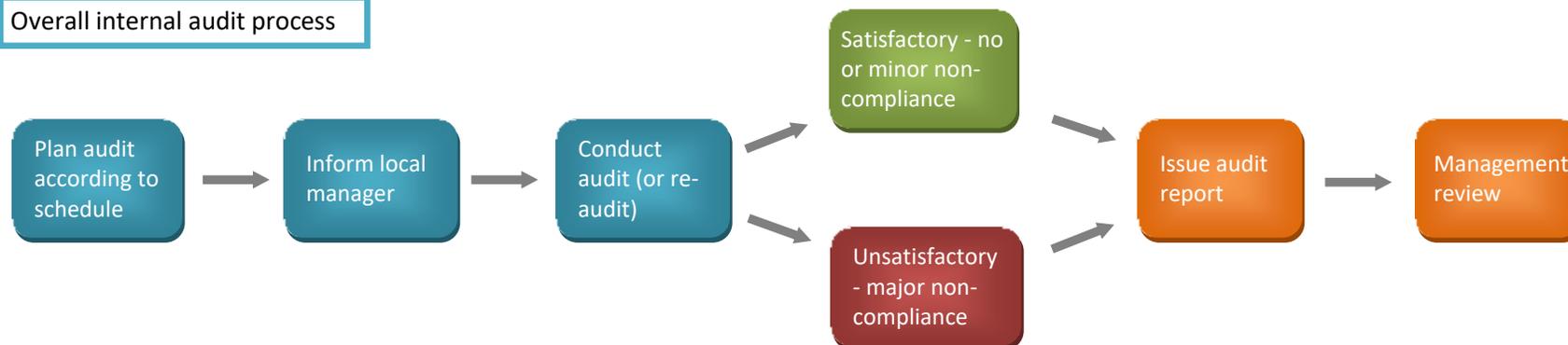
## ED/QP4-Staff Training and Human Resources

### Overall staff training process



## ED/QP5-Internal Audit

### Overall internal audit process



### Satisfactory audit



### Unsatisfactory audit

