Scotland and Northern Ireland EQA Scheme in General Histopathology

EQAM01

DOCUMENT PREPARATION AND CONTROL

ISO 17043:2010 ref	5.3
LOCATION OF COPIES	Q-Pulse (Electronic Master) Master Copy held by Quality Manager Standard Operating Procedures – Scottish Pathology Network
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Review and Amendment History			
Date Reviewed / Amended	**Version Replaces**	**Pages Changed**	**Details of review/Amendment**
Feb 2021	4.1	4 Pages (Front, 3, 4, & 2)	Updated: location of copies (front pg), version number for the DSE Policy (pg3), the head & footer section 3.3.1 (pg3), identification codes 3.3.2 (pg4). Added: Table of Contents (pg2),

Table of Contents

1 PURPOSE

To define the procedure for preparation and control of all documents, including the Quality Manual, procedures and forms.

2 SAFETY DATA, COSHH AND RISK ASSESSMENTS

NHST "Display Screen Equipment Policy" v2.2 August 2017 to May 2020
Health and Safety (Display Screen Equipment) Regulations, 1992 (minor updates 2002)
MAA 001 "Document Control within Q-Pulse"

The above cross references should be read and understood before carrying out this procedure

3 DOCUMENTATION PREPARATION

3.1 Responsibility

The permanent members of the Management Committee (the Executive Team) are responsible for requesting, and writing, all documentation.

All data entries, changes and checks of document hard copies shall be initialed and dated at the time they are made, by the staff member concerned.

3.2 Editing and Verification

All scheme procedures, template letters, template forms and necessary external documents will be administered within Q-Pulse, a Quality Management administration programme available within NHS Tayside. Preparation of draft documents and authorisation will all be carried out within Q-Pulse.

After preparation and before issue the documents will be verified for practical use by the scheme quality manager, who will also edit for clarity, accuracy, suitability and proper structure before authorisation by relevant members of the Executive Team.

3.3 Identification and Format

3.3.1 Headers and Footers

All documents will carry a header and footer that will carry information as shown in this document, with the exception of official external documents.

Header will include: document reference number, version number, date of current issue, author, authoriser and pagination.

Footer will include: Document title and the schemes name.

The headers and footers shall be filled within the template. The document must be given a file name consisting of its index code.

3.3.2 Identification Code

The ***document reference number*** for scheme procedures will consist of a four letter-two number index code e.g. ABCD01. The first 3 letters shall be "EQA" with the fourth letter used to denote the type of document:

- M for Management
- O for Operational
- Q for Quality
- I for Information Technology

The file will then be stored in the appropriate location within Q-Pulse.

3.4 Contents

The front page of scheme procedures will include the Scheme title, document title, ISO standard reference, location of copies and authorising signatories.

A table of contents is available on scheme procedure documents that would benefit from this.

3.5 Template Letters and Forms

All template letters and forms used within scheme documentation currently have templates stored in the EQA scheme folder on the departmental G: Drive. These are also controlled within Q-Pulse and their headers will include the version number and date of issue with the footers containing file name and path along with the date last printed. The latest version of Q-Pulse makes embedding of all documents compulsory, thus over time, all letters and forms will be physically moved from the folders on the departmental G: Drive to within the Q-Pulse system.

4 DATA HANDLING

No data will ever be deleted from Q-Pulse. When a document is withdrawn from use it is archived within the obsolete section within Q-Pulse.

5 DOCUMENT CONTROL

5.1 Responsibility

Relevant members of the Executive Team shall be responsible for authorising the quality manual and all other documents pertaining to the scheme.

5.2 Authorisation

When the authorisation of the document has been signed off it is then a controlled document. The master copy of the documents will be held by the Quality Manager with a back-up copy help by the Scheme Secretary.

External documents will also be controlled within Q-Pulse, i.e. documents issued by the Royal College of Pathologists, NSD etc., but these will not require a signed authorised copy as they originate out with the scheme.

5.3 Issue

All participants have access to all of the scheme procedures via the scheme web page: **http://www.pathology.scot.nhs.uk/resources/pathologists-eqa/**

Any potential change ratified by the Royal College of Pathologists Steering Committee will be notified to participants.

5.4 Removal of Redundant Documents

When a new revision of a document has been authorised it will be the responsibility of the Quality Manager to ensure that the redundant Master Copy is updated and Q-Pulse kept up to date. The Master Copy will be kept electronically as a record of change.

5.5 Initiation of Amendments

Any member of the scheme can suggest changes to controlled documents. Suggestions will be reviewed by the Executive Team.

5.6 Amendment and Revision

If the amendment is considered to be a required procedural change then the document must be amended by the author, quality manager or scheme administrator. If the change is a major one, then ratification must be sought from the Royal College of Pathologists Steering Committee.

5.7 Computer Disk Storage

All data and documents are kept on NHS servers administered by E Health, who are responsible for backing up the servers. A separate backup of the Q-Pulse database is performed automatically every night by standard SQL Server backup procedures.

6 DOCUMENTATION AUDIT

6.1 Audit

At regular intervals the Quality Manager will instigate document audit to ensure they do not contain non-conformances. Special attention will be paid to the following:

- All documents must be authorised
- All documents must be valid and contain no major hand-written changes.

The result of such audits will be recorded and discussed at meetings of the permanent members of the Management Committee

6.2 Non-Conformance

Any document that either fails audit or has been proved to be inaccurate will be amended and reissued by the scheme administrator or the quality manager. All non-conforming copies except the Master copy will be removed.