Scotland and Northern Ireland EQA Scheme in General Histopathology

EQAM02

CONTROL OF TECHNICAL AND QUALITY DOCUMENTS/RECORDS AND OF CLINICAL MATERIAL

ISO 17043:2010 ref	4.3.1
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	5.2	4 Pages (Front, 2, 3, & 5)	Updated location of copies (front pg), added: Table of Contents (pg2), updated NHS Code of Practice to newer version (pg3), changed key holder from QM to Administrator (pg5)

Table of Contents

1 RATIONALE

To define a procedure for the control of all Technical and Quality records, including the Quality Manual.

2 RELEVANT SAFETY DATA, COSHH AND RISK ASSESSMENTS

- "The Retention and Storage of Pathological Records and Specimens" (5th edition, 2015) The Royal College of Pathologists
- Scottish Government Records Management: NHS Code of Practice (Scotland) 2020
- SSA002 "Pathology Department Health and Safety Policy"
- SSA015 Pathology "Health, Safety and Welfare Manual"
- Manual Handling Regulations, 1992
- SRA012 Pathology Department Risk Assessment 'Lifting Heavy Objects'
- Health and Safety at Work Act 1974
- NSAA018 Pathology Health and Safety Manual

The above documents must be read and understood before carrying out this procedure.

3 TECHNICAL DOCUMENTS / RECORDS AND CLINICAL MATERIAL

3.1 Responsibility

The Scheme Secretary has primary responsibility for ensuring that all technical records and clinical material (slides) are stored securely. The Scheme Secretary is the point of contact for members of the Executive Committee to access the documents / slides. Authorisation for viewing of anonymised records by persons other than Management Committee members must be obtained from the Scheme Administrator.

3.2 Technical records retained

The records comprise relevant paperwork from all circulations, (including the pilot circulation), of the Scheme to date as follows for each circulation:

Record Type	Record Format	Storage Area
Instructions to Participants	Emails sent out each circulation & documents attached	Secretary email "sent Circulation Folder" Attached electronic copies saved on H:drive:EQAScheme/circulation Folder
	Current circulation hard copies	Office U6 021 Top drawer filing cabinet
	Completed circulation Hard copies	Secure filing cabinet in area U6 017
Participants Responses	Emailed proformas received each round	Secretary email "Circulation Folder"
	Hard copies	Office U6 021 Top drawer filing cabinet
	Completed circulation Hard copies	Secure filing cabinet in area U6 017
Collated Data for Statistical Analysis	Hard copies of marked responses & Provisional results	Office U6 021 Top drawer filing cabinet
	Checklist document used for provisional results	G:pathdata/EQApathscheme/codes checklist
	Provisional results document for each round	G:pathdata/EQApathscheme Circulation Folder/provisional results table
	Completed circulation Hard copies	Secure filing cabinet in area U6 017
	Electronic data bases	Data Managers' network drive

Information Required for Reports	Email of sent provisional results to participants with attached documents	Secretary email "sent Circulation Folder". Attached electronic copies saved on H:drive:EQAScheme/circulation Folder
	Current circulation hard copies	Office U6 021 Top drawer filing cabinet
	Email ACP minute received from secretary	Secretary email ACP minute folder also H:EQA Scheme / circulation Folder
	Hard copies	Office U6 021 Top drawer filing cabinet
	Completed circulation Hard copies	Secure filing cabinet in area U6 017
Final Reports	Hard copies of final results are posted	
	Email ACP minute sent to all participant along with attached final results letter	Secretary email "sent Circulation Folder". Attached electronic copies saved on H:drive:EQAScheme/circulation
	Hard copies	Folder (second drawer)
Case sources, histories and original case numbers	Emails received from committee members	Secretary email "sent Circulation Folder"
	Hard copies	Office U6 021 Top drawer filing cabinet
	All completed circulations with lab no's.	Secure filing cabinet in area U6 017
Management Meeting Information	New Management Team members letters	H:EQA scheme/EQA/Management Team meeting folder
	Emails of new member letters sent and received	Secretary email Management Team folder, sub folder New Management members
	Assessment Proformas received via email	Secretary email circulation Folder
	Printed hard copy from email	Office U6 021 Top drawer filing cabinet
	Copied over Management Team summary diagnosis	H:EQA Scheme/circulation folder
	Sent emails to Management Team	Secretary email Management Team folder
	Attached previous minute and agenda	H:EQA Scheme/Management Team folder
Minutes	All Management and Exec. Minutes	G:pathdata/EQApathscheme/minutes
	Hard copies	Office U6 021 top drawer filing cabinet
Participant Communications	All emails sent and received	Secretary email "participant folder"
	Hard copies	Office U6 021 filing cabinet
	All memos for expenses-electronic	H:EQA/EQA expenses folder
	Paper copies	Office U6 021 Top drawer filing cabinet
	Telephone log sheets	Office U6 021 filing cabinet
"Poor Performance" Communications	Template letters	Document controlled within Q-Pulse
	Electronic copies	H:EQA Scheme/circulation folder
	Hard copies of letters sent each round	Locked safe in Office U6 021

3.3 Clinical material retained

All slides from all previous circulations are retained for a minimum of ten years. These are stored in two different formats:

- Slides used for test and special educational circulations are stored in order in plastic wallets, in the locked storage cabinet, along with paper records as to slides returned / missing slides.

- Unused slides (including those used in the assessment slide circulation, but not selected for the test or special educational circulations) are retained in plastic wallets, clearly labelled unused slides and placed in boxes in the locked storage cabinet.

3.4 Storage location

Technical records and clinical material (slides) from previous circulations are stored in a lockable cabinet, located adjacent to the EQA office, which is only accessible via a security door.

Slides relating to the current circulation are retained in a locked filing cabinet adjacent to the Scheme Secretary's offices. Documents relating to the current circulation are held in a locked filing cabinet within the Scheme Secretary's office. When not in use, slides and records pertaining to the current circulation must be kept locked in either of these cabinets.

Highly confidential material, such as lists matching participants' names with code numbers, or letters to participants with substandard performance, are retained within a security box in the Scheme Secretary's office.

Two sets of keys exist for both the office and the security box and are retained by the Scheme Secretary and Scheme Administrator.

3.5 Duration of Retention

Clinical material (slides) are to be retained for a minimum of 5 years in accordance with "Retention and Storage of Pathological Records and Specimens" as published by the Royal College of Pathologists, 5th. Edition, 2015, paragraph 168. Our scheme currently retains for ten years. After this period has elapsed, the slides are disposed of in sealed sharps disposable boxes and the Circulation number of those disposed of recorded and kept in "Disposal Record" log sheet within scheme secretary's office.

Records (documents) which are kept by the scheme include: Participants returns, Communications / complaints from participants and quality assurance and safety documentation.

These are to be kept for a minimum of five years in accordance with "Retention and Storage of Pathological Records and Specimens" as published by the Royal College of Pathologists, 5th. Edition, 2015, paragraph 164. Our scheme currently retains for ten years, after which such records are disposed of by way of "confidential waste".

4 QUALITY RECORDS

4.1 Retention of Quality Records

Quality related documents and SOPs are to be held as follows:

- Q - pulse
- Electronic master copy held by the Quality Manager
- Previous versions are stored on Q-Pulse
- EQA Web page (**http://www.pathology.scot.nhs.uk/resources/pathologists-eqa/**) for reference by participants

All other quality related documents are held securely by the Quality Manager.