Blackpool Teaching Hospitals NHS
NHS Foundation Trust

Biochemistry Department

Standard Operating Procedure: SOP GCHEM-302

Title:	**The Retention and Storage of Biochemistry Samples and Records.**

1. APPLIES TO:

All MLA's, BMS's and Clinical Scientists

2. INTRODUCTION

2.1 The policy adopted within the Biochemistry department attempts to meet the spirit of The Royal College of Pathologists guidelines published in April 2015.

http://www.rcpath.org/Resources/RCPath/Migrated%20Resources/Documents/G/G031_RetentionAndStorage_Apr15.pdf

The original Working Party for this guidance was appointed in 1994 by the Council of The Royal College of Pathologists, with the following terms of reference: "To make recommendations on minimum retention times for pathology records, tissues and semi-permanent or permanent pathological preparations, including those required for operational use, for education, teaching, training and general scholarship, for research per se, for historical purposes and against the possibility of future litigation, audit or allegations of scientific fraud and to report to Council".

Storage of electronic records also poses evolving challenges, particularly for data security and continued availability in accessible formats at reasonable cost as hospitals' information platforms are updated. Increased diversity of point-of-care testing has warranted further advice. Guidance for bodies providing external quality assessment programmes has been extended to reflect feedback since the introduction of this topic in the 2009 edition. Transition to laboratory accreditation by UKAS against ISO standards 15189, 18025 and 17043 has implications for the inspection cycle time over which some records should be held. A general principle in all versions of this document has been to advise retention of relevant records for three inspection cycles; this would lead to an extension from ten to 12 years, anticipating an overall cycle time of four years to complete all elements of the cumulated annual inspections against ISO standards. This is becoming an unreasonable and unnecessary burden and we therefore propose to recommend retaining relevant records for two accreditation cycles (eight years). With increasing experience of accreditation against these ISO standards, it may be possible, in the next iteration of this guidance, to recommend reducing storage times for relevant documents to the length of a single cycle plus a safety margin (say, five years).
To date, medical records legislation has not been amended to extend retention requirements in line with increased longevity in the general population. Should this change before publication of a future revised edition of this guidance, references to 30-year retention of records and specimens, where these constitute primary medical records, will need extending to match any new, legally defined minimum period. A

new EU data protection regulation is also currently under consideration (January 2015), which may impose new consent requirements for patient data and sample sharing; general principles arising from Article 8 of the Human Rights Act (1998) also require consideration.

2. SCOPE OF THE GUIDANCE

In most cases, records and archived specimens are held primarily to benefit the medical care of the patient concerned, as part of that patient's medical record. In relation to data protection law, it is reasonable to infer that the information held in pathological records was generated legitimately in the first instance and that patients are aware of its continued existence within the confidential archives of the hospital. Indeed, patients would have legitimate grounds for complaint if their future healthcare was compromised because technical details of their previous investigations had been erased without their knowledge. We can therefore assume that pathologists have legitimate authority to retain records and archives for the benefit of individual patients, relying only on the consent that was a clinical requirement for their original generation.

It must be emphasized that this document is concerned with the retention and storage of pathological records and archived specimens, not their use. Detailed guidance regarding the physical conditions (including security) of storage are also not within the remit of this guidance, other than the general proviso that stored records and specimens should remain intact and accessible for the full term of their retention

3. THE NATURE OF PATHOLOGY RECORDS

3.1 Clinical and diagnostic records and reports.

These are hard copy or electronic records of the results of pathological investigation(s) sent or made available to the requesting clinicians, with the expectation that they will be stored within the patient's individual clinical record. With respect to computer - generated, electronic records, the same criteria that cover conventional records apply, unless they have been converted to hard copy records and preserved as such.

Arrangements should be in place for frequent and secure back - up of electronic data. These are usually administered centrally within hospitals for all laboratory sections encompassed by their pathology IT systems.

3.2 Laboratory working records: reports and documentation for internal use

These include:

- Request forms
- Day books
- Worksheets
- Batch records (of reagent batches linked to series of specimens; also specimens analysed as cohorts on automated instruments)
- Graphic output from instruments
- Refrigerator and freezer temperature records
- Photographic records
- Catalogues of the pathological archive or museum
- Bound copies of reports and records
- Point – of - care test data
- Correspondence
- Records of telephoned, faxed and emailed reports
- Equipment maintenance logs
- Quality control and quality assurance records
- Standard operating procedures
- Accreditation documents
- Records of inspections.

(This list is not exhaustive.)

4. SPECIMENS

These include:

- Stored human biological specimens such as blood, serum, urine, faeces, cells and tissue (including part or whole body organs)
- Stained slides or other permanent or semi-permanent preparations including electrophoretic strips, immunofixation preparations, nucleic acid and protein blots
- Museum specimens
- Test cards (e.g. neonatal screening [Guthrie test card] and faecal occult blood test cards)
- Some POCT strips.

The management of records and specimen archives: general comments

Diagnostic records are properly retained in individual patient notes or in electronic form. The safekeeping of these records is primarily the responsibility of hospital records departments or recipient general practitioners or private practitioners, once the pathologist has issued the reports. The primary purpose of diagnostic records retention by laboratories is for internal use: correlation with results from previous and subsequent specimens, responding to queries from other healthcare professionals, audit and quality assurance. When information relevant to clinical care has been recorded in the laboratory, either formally or informally, the occurrence and its content should be copied to the patient's primary medical record or signposted in that record for cross-reference if transcription is not feasible.

Where storage of material is no longer required for clinical purposes, but is desirable for teaching, quality assurance, audit, research or other purposes of public benefit, the ethical and legal acceptability of continued storage must be reviewed. The legitimacy of future storage for such purposes is influenced by the presence or absence of appropriate consent. This will depend on the intended future use; storage of relevant material for a scheduled purpose under the terms of the Human tissue Act 2004 requires an appropriate licence, even for de-identified specimens.

There are reasons why individual pathologists or heads of departments may wish to retain documents or materials for periods that are longer than the minimum times recommended here. The following reasons for retention of tissue obtained from living individuals are legally permissible without patient consent, largely because they are regarded as a necessary part of the process of providing healthcare:

- Further diagnosis or ongoing clinical management
- Clinical audit (this term should be interpreted selectively to encompass defined, planned and documented audit activities rather than being used as a generic reason to retain samples 'just in case')
- Quality Assurance, including internal quality control and external quality assessment
- Teaching and training healthcare staff
- Epidemiology
- Analysis of data (such as case mix) for administrative or other purposes
- Direct evidence in litigation
- Individual, active research studies for which data or samples are suitably anonymised and current approval is in place for the purpose, given by a recognised Research Ethics Committee (REC). Specimens used for such research may continue to be held for audit of the completed research but such storage must be under an HTA licence unless there is continuing REC approval for the particular study or REC approval for further use is pending. Consent is needed for the continued storage of

specimens for any of the scheduled purposes set out in Schedule 1, Part 1 of the Human Tissue Act 2004 (see Appendix 2 and Bibliography)

The recommendations that follow refer to the minimum times of retention that are consonant with acceptable practice. Many laboratory professionals will have good and cogent reasons for retaining records and materials for much longer periods. Increasing longevity, although not yet reflected in a change of medical records legislation, provides justification for considering the retention of primary records and permanent specimens beyond the current statutory 30 years.

5. RETENTION AND STORAGE TIMES, AND LOCATION OF SAMPLES AND RECORDS.

A summary of the retention and storage of pathology samples and records on the Blackpool Teaching Hospitals Victoria Hospital site is given in Table 1.

Table 1

Sample / Record	Retention Policy / Time	Storage area	Disposal method
Blood samples Paediatric sample tubes Urine/fluid/faeces samples	17,200 blood samples in Beckman Coulter Automate archive racks. Equivalent to approximately 7 days dependant on workload 7 days 7 days	Deleted for security reasons	Yellow bag clinical waste Yellow bag clinical waste Yellow bag clinical waste
Method evaluations & Change Control documentation	At least 8 years.	Deleted for security reasons	Household waste pathway
Reagent audit trails/Batch records	8 years	Deleted for security reasons	Household waste pathway
Electrophoretic strips	5 years	Deleted for security reasons	Bench bag → yellow bag clinical waste
EQA data	8 years	Deleted for security reasons	
EQA investigation reports	5 years	Deleted for security reasons	Confidential waste pathway
IQC data	8 years	Deleted for security reasons	Household waste pathway
Records of service inspections and instrument maintenance	Lifetime of instrument + 4 years	Deleted for security reasons	Household waste pathway
Computer Status listings	Until the final report has been authorised	Deleted for security reasons	Confidential waste pathway
Worksheets	Until the final report has been authorised	Deleted for security reasons	Confidential waste pathway
Reagent Lot Numbers and Evaluations	7 years	Deleted for security reasons	Confidential Waste pathway

Staff Attendance sheets		7 years	Deleted for security reasons	Confidential Waste pathway.
CPD		7 years minimum	Deleted for security reasons	
Day book for results		8 years from specimen receipt	Deleted for security reasons	Confidential waste pathway
Original request form and add-on requests		2 days hard copy, and 3 months on Therefore software, unless complicated or sendaway test, then for 1 month after completion in Biochemists Office.	Deleted for security reasons	Confidential waste pathway
Referred tests	Request form		Deleted for security reasons	Confidential waste pathway
	Returned reports		Deleted for security reasons	
Returned reports of ref			Deleted for security reasons	
Surplus samples		7 days	Deleted for security reasons	Yellow bag clinical waste
Medical Jurisprudence		At least 6 months	Deleted for security reasons	Bench bag→ yellow bag clinical waste
Telephoned reports		5 years minimum	Deleted for security reasons	
Clinical Scientist's repeat requests		1 month	Deleted for security reasons	Confidential waste pathway
Clinical advice		30 years	Deleted for security reasons	
Untoward Incident forms		Permanently	Deleted for security reasons	
Analyser hardcopy and listings.		2 weeks	Deleted for security reasons	Household waste pathway
Accreditation documents		8 years or until superceded	Deleted for security reasons	Confidential waste pathway
Audit documentation		10 years	Deleted for security reasons	
Staff training records and Staff Qualification Records.		For lifetime of employment in this Trust	Deleted for security reasons	
Records of specimens not analysed		4 years minimum. Primary request information to be retained and reason for discard	Deleted for security reasons	Confidential waste

Protocols/SOPS	Current and updated protocols for 30 years minimum	Deleted for security reasons	
Photographic records	30 years	Deleted for security reasons	Confidential waste
Fridge monitoring records	8 years	Deleted for security reasons	Household waste
Equipment maintenance logs	Lifetime of analyser plus 4 years	Deleted for security reasons	Household waste
Documents relevant to procurement/use/modification and supply of instrumentation	At least 8 years	Deleted for security reasons	Confidential waste
Records relevant to diagnostic products or equipment	8 years	Deleted for security reasons	Household waste
Manufacturer bulletins/Field safety notices etc	8 years	Deleted for security reasons	Household waste
		Deleted for security reasons	

Sample/Record	**Retention Policy/Time**	**Storage Area**	**Disposal Method**	**Notes**
STS SOPs	8 years electronic.	Deleted for security reasons		
IQC Lot Run Up/QC Manufacturers Inserts	8 years paper and electronic.	Deleted for security reasons	Paper copies by confidential waste	
IQC mean and SD Changes	Paper copies 8 years.	Deleted for security reasons	Paper copies by confidential waste	
Weekly IQC Checks	Paper copies 1 year. Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	
Monthly IQC Checks + Monthly IQC Report	Paper copies 1 year. Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	
D-100	8 years electronic.	Deleted for security reasons		
Med.Lab.	8 years electronic.	Deleted for security reasons		
Minicap	8 years electronic.	Deleted for security reasons		

Uvikon	8 years electronic.	Deleted for security reasons		
COSHH Risk Assessments	Life time required.	Deleted for security reasons	Paper copies by confidential waste	
MSDS	Life time required.	Deleted for security reasons		
Operator manuals	Life time required.	Deleted for security reasons		
Manufacturers bulletins	Life time required.	Deleted for security reasons		
Reagent/Cal logs	8 years electronic.	Deleted for security reasons		
Stock Sheets	Paper copies 1 year.	Deleted for security reasons		
Delivery Notes	Paper copies 8 years.	Deleted for security reasons		
Acceptance testing rgts/cal/QC	Paper copies 1 year. Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	
Maintenance Log Tick Sheets	Paper copies 1 year. Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	
Cryoglobulins results	Paper copies 1 year. Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	
Change control/New Assay evaluations	Paper copies 3 year. Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	
Training Logs	Updated yearly	Deleted for security reasons	Paper copies by confidential waste	
STS Competencies	Updated yearly.	Deleted for security reasons	Paper copies by confidential waste	
pH meter QC records	Paper copies 1 year. Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	
Pipette check	Paper copies 1 year. Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	
Quantification of cryoglobulins	Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	

EQA Request Cards	3 months	Deleted for security reasons		
Staff Daily tick sheets	Paper copies 1 year. Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	
Staff weekly tick sheets	Paper copies 1 year. Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	
Staff monthly tick sheets	Paper copies 1 year. Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	
Temperature charts	Paper copies 1 year. Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	
Xanthochromia Results	Paper copies 8 year. Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	
EPH worksheets	Paper copies 8 year.	Deleted for security reasons	Paper copies by confidential waste	
Sweat test results	Paper copies 1 year. Electronic 8 years.	Deleted for security reasons	Paper copies by confidential waste	
Electrophoresis Fixes	Fixes stored for 8 years.	Deleted for security reasons		
BJP Fixes	BJP stored for 8 years	Deleted for security reasons		
Overdue post	Paper copy 3 years	Deleted for security reasons	Paper copies by confidential waste	
DSS faxes	1 month	Deleted for security reasons	Paper copies by confidential waste	
UTOX cards	1 month	Deleted for security reasons	Paper copies by confidential waste	
DSS forms	1 month	Deleted for security reasons	Paper copies by confidential waste	
Referral labs.info	Updated every 2 years	Deleted for security reasons		

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