NHS
National
Services
Scotland

Document Storage, Retention and Disposal Policy

Version 5.0

Version:	5.0
Document Type:	Policy
Owner/Author:	Head of Corporate Affairs/Corporate Records Management
Review Date:	January 2011

SNBTS DOCUMENT REQUEST No:

2012/00147

DOCUMENT CONTROL SHEET:

The Policy will be reviewed bi-annually and also updated when required taking into account any new legislation and the operational requirements of the NSS.

Key Information:

Title:	Document Storage, Retention and Disposal Policy
Date Published/Issued:	January 2003
Date Effective From:	January 2003
Version/Issue Number:	5.0
Document Type:	Policy
Document status:	Final
Author:	John Francis, Acting Director of Performance Management and Trish Ruddy, CSA Data Protection Officer
Owner:	Jan Lyell, Head of Corporate Affairs/Corporate Records Management
Approved by and Date:	Stuart Bain, Chief Executive and CSA Board January 2003
Amendments approved by:	NSS Partnership Forum 26 January 2009
Contact:	Tracey Gill, Corporate Records Manager
File Location:	G:\Execoff\03 Corporate Governance\Information Governance\Records Management\Policies & Procedures - Guidelines\Document Storage & Retention Policy\Policy Finals

Revision History:

Version:	Date:	Summary of Changes:	Name:	Changes Marked:
1.0	27 Jan 2003	Initial Release	JF/TR	
2.0	14 Jun 2005	HPS	SH	
3.0	16 May 2006	HDL (2006) 28	SH/TG	
3.1	1 Aug 2006	Divisional Changes	TG	
3.2	11 Aug 2006	Changes to text	KK/SH/ TG	
3.3	26 Jun 2007	HFS schedule added Update CLO and NSD schedules	TG	
3.4	27 Jul 2007	Amendments to ISD Schedule	TG/PM/ JC	
3.5	26 Sept 2007	Amendments to HR Schedule	CH/TG	
3.6	3 Oct 2007	Amendments to SNBTS Schedule to reflect European Directive 2005/61/EC	SH/TG	
3.7	19 Oct 2007	Amendments to HR Schedule to reflect Equal Pay	CH/TG	
4.0	20th Nov 2007	Final		
4.1	15th Jan 2008	Amendments to layout to include authorised to dispose column. Amendments to SHSC schedule. Text corrections	MW/TG FF	Y Y
4.2	12th Feb 2008	Amendments to ISD Schedule	PM/TG	Y
4.3	14th Jul 2008	Update and review in line with release of Records Management: NHS Code of Practice (Scotland)	TG	Y

4.4	8th Oct 2008	Amendments following Divisional Consultation before submission to NSS Policy Review Group	TG	Y
5.0	16th Oct 2008	Final	TG	

Approvals: This document requires the following signed approvals.

Name:	Signature: *(page 67)*	Title:	Date: *(page 67)*	Version:
Ian Crichton		Chief Executive, Joint Chair of Partnership Forum		5.0
Aileen Stewart		Staff Side Chair, Joint Chair of Partnership Forum		5.0

Distribution: This document has been distributed to

Name:	Title/Division:	Date of Issue:	Version:
Executive Management Team		24th Oct 07	3.7
Senior Divisional Records Management Leads		29th Nov 07	4.0
Local Records Management Champions			4.0
Corporate Records Management page - geNSS		29th Nov 07	4.0

Linked Documentation:

Document Title:	Document File Path:
Records Management: NHS Code of Practice (Scotland)	http://www.scotland.gov.uk/Resource/Doc/230203/0062364.pdf
Statutory Instrument 2006 No 2013 The Blood Safety and Quality (Amendment) Regulations 2006	http://www.sehd.scot.nhs.uk/mels/HDL2006_28.pdf

Schedule 12: Scottish National Blood Transfusion Service

The guidance below is based on that published in the Retention of Pathological Records and Archives, a Report of the Working Party of the Royal College of Pathologists and the Institute of Biomedical Science (Second Edition, 1999). Statutory Instrument 2005 No. 50 relating to the Blood Safety and Quality Regulations and Human Tissues (Scotland) Act 2006.

For completeness the retention periods of physical samples are also included.

A: Documents and Paper Records

Record Type	Retention Period	Authorised to Dispose
Day Books and other record of specimens received by a laboratory	30 calendar years	Head of Service
Protocols or Standard Operating Procedures	Both current and outdated protocols and SOPs should be dated and kept permanently on file	Head of Service
Worksheets	Keep for the same length of time as related permanent or semi-permanent specimens or preparations	Head of Service
Laboratory Files cards or other working record of test results for named patients	30 calendar years	Head of Service
Records of telephoned reports	Log on patient's file card or other working records	Head of Service
Reports, copies	Permanently for historical or research	
Surgical (histological) reports	Hard copy lodged in patient's notes. Bound copies of reports, if made, kept permanently by the laboratory	Head of Service
Post mortem reports	Report should be lodged in patient's record. Bound copies of reports, if made, kept permanently. *(See also Section D)*	Head of Service
Correspondence on patients .	Should be lodged in patient's record. Otherwise, kept permanently	Head of Service
Near-patient test data	Results should be entered on patient's record; log should be retained for lifetime of instrument	Head of Service
Bound copies of reports/records, if made	Permanent	

Pathological archive/museum catalogues	Permanent	
Photographic records	Permanent	
Batch records results	Permanent	
Internal Quality Control and Quality Assurance (QMS) Records	Permanent	
External Quality Assurance Records	Subscribing laboratories, 30 calendar years.	Head of Service
Accreditation documents; records of inspections	Permanent	
Lab Equipment maintenance Logs	30 years if appropriate to traceability from donor to patient. Other non-critical equipment lifetime of instrument.	Head of Service
Records of service inspections, maintenance of lab Instruments	Lifetime of instrument but minimum ten years	Head of Service
On-line diagnostic electronic records	30 years	Head of Service
Neonatal Screening Test Cards	20 years or longer if no deterioration has occurred. Such cards may be useful as sources of DNA or retrospective analysis and research	Head of Service
Records relevant to production of products (diagnostics) or equipment	Comprehensive records relevant to procurement, use, modification and supply: 11 years	Head of Service
Records relating to organ transplantation	Records not otherwise kept or issued to patient record that relate to investigations or storage of specimens relevant to organ transplantation or retention of semen or ova should be kept permanently	Head of Service
Computer databases used for blood and tissues	Permanent	
Donor Records (blood and tissue)	30 years	Head of Service
Donor Session Records and session reconciliation paperwork	30 years	Head of Service
Processing Batch Manufacturing Records, miscellaneous documentation including: reconciliation, processing steps, cold chain, issues, transport	30 years	Head of Service
Donor Testing Records	30 years	Head of Service
Quality Management System Records including: Incident reporting, Recall, Change Control, Validation, Quality Control data, consumable QC data, Environmental Monitoring	30 years	Head of Service
Traceability records (blood and tissues)	30 years	Head of Service
Haemovigilance records (SABRE/SHOT/HTA reports)	15 years	Head of Service
External Inspection reports (MHRA, HTA, CPA, etc(and follow up	Permanent	

B: Specimens and Preparation's

Record Type	Retention Period	Authorised to Dispose
Plasma/Serum (patient samples)	48 hours after final report has been issued by the laboratory. Special considerations apply to samples, especially those pertaining to possible risk exposure, for virological examination. In cases of transplantation, donor/recipient sera, with the records pertaining, must be kept for 30 years post transplantation	Head of Service
Plasma/Serum (donor samples)	Permanent	
Body Fluids/Aspirates/Swabs	48 hours after final report has been issued by the laboratory except for those, such as urine, that are easily and noninvasively repeated, which may be destroyed as soon as the examination is concluded	Head of Service
Wet Tissue (representative aliquot or whole tissue or organ)	4 weeks after final report	Head of Service
Whole blood samples, for full blood count	24 hours	Head of Service
Frozen sections: (unless further processed)	The minimum retention time for reporting practice is 4 weeks after the final report but they should be retained for 10 years or indefinitely for research purposes	Head of Service
Paraffin blocks	Select representative blocks, showing main pathology, or permanent retention and review need for archiving at 10 year intervals, as storage can be a problem. Special considerations apply in forensic practice. Post mortem blocks that do not relate to the cause(s) of death or putative contributory factors (normal tissue) need to be kept longer than the issue of the full post mortem report other than exceptionally, unless to be retained as control material for research or study purposes	Head of Service
Blocks for electron microscopy, DNA analysis	Permanently; minimum lifetime of patient. It is important that specimens for DNA analysis be stored for later analysis of mutations in patients with familial cancers. Such samples should be held for 5 years after the death of the patient	Head of Service
Museum specimens, where these are generally accessible for	Permanently (provided there is no deterioration, or until	Head of Service

undergraduate or postgraduate study (teaching collections)	replaced by a better specimen)	
Stained slides	a) microbiological: 7 days after final report b) blood films, routine: 7 days after final report c) cytogenetic: 2 years after final preparations: report if photographic record kept; 5 years otherwise d) bone marrow smears: 20 years minimum; ideally over lifetime of patient e) cytology, including 10 years minimum, longer population screening: if possible, to cover at least one recall visit f) histology: 10 years; permanently if practicable. Unstained (spare) sections and electron microscopy sections kept similarly	Head of Service
Serum	That from the first pregnancy booking visit should be kept for 1 calendar year by Microbiology/Virology laboratories to provide a baseline for futher serological or other tests for infections or other disease during pregnancy and after delivery. Because of its rarity and value to future research, wherever possible, fetal serum (cordocentesis) should be kept permanently. Serum taken after needlestick injury or other hazardous exposure should be kept for a minimum of 2 years. Other left-over sera or plasma should be stored for as long as practicable to provide an array of material for future research. *(see also Section C)*	Head of Service
Human DNA	4 weeks after final report for diagnostic specimens; permanently if to be used for research or if specifically needed for family studies in those with genetic disorders. The need for retention of diagnostic specimens should be assessed at the time of issuing the final report. Specimens that were used in a linkage study should be kept for 10 years, and research specimens permanently.	Head of Service
Microbiological cultures	Most positive cultures can be discarded within 24-48 hours of issuing final authorised report. Specified cultures of clinical importance (blood culture isolates, CSF isolates,	Head of Service

	enteric pathogens, multiply or methicillin resistant Staph. Aureus, 'outbreak' strains, M. tuberculosis, Group A streptococci, and unusual pathogens of clinical significance) should be retained for at least 7 days. Where isolates have been referred to Reference Laboratories they should be retained for at least 7 days after the issue of their final report	
Freeze dried or other permanently preserved cultures	Permanently where archived in collections accessible for study, such as those nationally or locally recognised	Head of Service

C: Documents, Paper Records, Specimens and Preparations: Specific advice for transfusion laboratories

Minimum requirements for retention times may differ from these detailed in Sections A and B; *in all instances the longer period is recommended.*

Record Type	Retention Period	Authorised to Dispose
Request forms for grouping, antibody screening and cross matching	30 years	Head of Service
Worksheets	30 years	Head of Service
Results of grouping and antibody screening	30 years	Head of Service
Blood Bank Register	30 years	Head of Service
Refrigeration Charts	30 years	Head of Service
Freezer Charts	30 years	Head of Service
Clotted blood for grouping, antibody screening and saving and/or cross matching	1 week at 4°C	Head of Service
Serum from requests for grouping, antibody screening and saving	1 week, optimally at -30°C or colder	Head of Service
Serum for cross matching	No minimum time is recommended. Storage should optimally be at -30°C or colder. May be stored for up to 1 month, and occasionally longer, prior to a planned procedure, provided no blood components are given	Head of Service

	during this time and that the patient has not been transfused or pregnant in the preceding 4 months.	
Serum following a cross-match or transfusion	1 week. Storage should optimally be at -30°C or colder. This serum may only be used for the investigation of transfusion reactions and not for further cross-matching	Head of Service

D: Research Data and Records

Record Type	Retention Period	Authorised to Dispose
Confidential named patient data (documentation) collected in the course of investigation and held separately from patient's records	Destroy or anonymise 6 months after the research has been completed, the data analysed, and final publication of findings has been made. If further recourse to named data is anticipated, it should be kept indefinitely. Working records and other research data should be retained permanently to rebut allegations of scientific fraud if such are made	Head of Service
Records and clinical trial data on medicines	15 years (Good Clinical Practice) from completion of trial. The provisions of the Data Protection Act (1988) must be observed for these as for other pathological records	Head of Service

Protein Fractionation Centre (SNBTS)

A: Product Documentation SOP 143 0002

Record Type	Retention Period	Authorised to Dispose
Batch History Issue Sheets	Permanent	
Purchasing Specifications	5 years	Head of Service
Commissioning	5 years	Head of Service
Validation Reports	5 years	Head of Service
Technical Reports	5 years	Head of Service

B: Product Batch Records SOP 143 0002/143 0005

Record Type	Retention Period	Authorised to Dispose
Finished Product Batch Records	Permanent	
Broth Fill Records	Permanent	

C: Intermediate Batch Records SOP 143 0002/143 005

Record Type	Retention Period	Authorised to Dispose
Plasma Pool Normal / Specific	Permanent	
All Intermediate Batch Records	Permanent	

D: Reagents / Buffers Batch Records SOP 143 0002/143 005

Record Type	Retention Period	Authorised to Dispose
Reagents / Buffers / LISS	5 years	Head of Service

E: Raw Materials Documentation SOP 143 0002/143 0005/143 0001/1410029

Record Type	Retention Period	Authorised to Dispose
Purchasing Specification	5 years	Head of Service
Batch Records for Raw Materials	5 years	Head of Service

F: Library Samples SOP 143 0001 / move Samples section to separate document

Record Type	Retention Period	Authorised to Dispose
All existing product samples	Permanent	
Crystalloids	Expiry + 1 year	Head of Service
Chemicals	Expiry + 1 year	Head of Service
Intermediate FRII Powders	Permanent	
WFI	Expiry + 1 year	Head of Service
Manufacturing Materials (eg: bottles, closures)	Expiry + 1 year	Head of Service
Manufacturing Materials All Primary Packaging (Leaflets, boxes, labels)	Permanent	

G: GLP Studies and Test Materials SOP 168 0002

Record Type	Retention Period	Authorised to Dispose
GLP Study Records	Permanent	

H: Primary Records SOP 143 0005

Record Type	Retention Period	Authorised to Dispose
Aseptic Dispensing Records	5 years	Head of Service
Autoclave Run Sheets	5 years	Head of Service
BPL Supernatant Deliveries	Discard	Head of Service
Commissioning Documentation	Permanent	
Defect Reports	Permanent	
Donor Guidelines	Permanent (discard if duplicated elsewhere)	
Electronic Records	*Need to define*	Head of Service
Environmental Monitoring Printouts and Records	5 years	Head of Service
Epidemiology Data	Permanent	
Finance and Purchasing Forms etc	See Schedule 4	Head of Service
Formaldehyde Fumigations	Discard	Head of Service
GLP Audit 1998 – 2005	Permanent	
In House Audits	30 years	Head of Service
Incident Reports	Permanent	
Iron Mountain Records	Permanent	
Laboratory Records	30 years	Head of Service
Master SOPs	30 years	Head of Service
MHRA Audits, Reports, Correspondence	Permanent	
Microfiched Reports	Permanent	
Change Control	30 years	Head of Service
National SOPs PFC QA Copies	Discard	Head of Service
NEQAS	Discard	Head of Service

NIBSaC	Retain correspondence, info plasma pools to PLASMA section, otherwise discard	Head of Service
Permit to Work	10 years	Head of Service
PFC self inspections / in-house audits	30 years	Head of Service
PFC Signature List	Permanent (unless finance then 3 years after last audit)	Head of Service
Pharmacovigilance records	Permanent	
Plasma Records / Transport / Plasma Recalls	Permanent	
Product Indent Forms	Discard	Head of Service
Purchasing Specifications	5 years	Head of Service
Recalled SOPs (inc withdrawn)	30 years	Head of Service
Reduced Testing	Discard	Head of Service
Regulatory Affairs (i.e. Licences)	Permanent	
Risk Assessments	Review after 5 years	Head of Service
Sactti Working Group (vCJD)	Permanent	
Superseded SOPs	30 years	Head of Service
Suppliers data (documentation and general correspondence)	5 years	Head of Service
Suppliers Validation Guidelines	5 years	Head of Service
Technical Agreements for Service Providers	5 years	Head of Service
Technical Reports	5 years	Head of Service
Test Kit Files	Permanent (move to SNBTS central archive in HQ)	
Validation Reports / Re Validations	5 years	Head of Service
Viral Kill Records	Permanent	
Water Dossier	5 years	Head of Service
		Head of Service