Please copy of Mr Lacey, Mr Potts, Mrs Jenkins + Consultants, Miss Maguire, Miss Mitchell, Miss Walmsley + Mr N Hughes

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Dr. Shepherd

RECORDS STORAGE REPORT

FOR THE

NATIONAL BLOOD TRANSFUSION SERVICE

IN

ENGLAND AND WALES

Prepared on behalf of the National Directorate of the National Blood Transfusion Service

by

Dr.Huw L.Lloyd, Dr.Alan Beal, & Mr. Tony Martina

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RECORDS STORAGE REPORT

1. Overview

1.1 Introduction

Transfusion Centres store a wide range of documents and records and because much of what is carried out relates to individual donations of blood, each donation effectively creates it's own batch record.

There are documents and records relating to finance, to personnel matters and to the management and policy making of each Centre.

Each group of documents or records can be viewed as having to be retained for certain minimum periods to satisfy specific legal requirements, resulting in a plethora of potential storage times.

The need to retain documents and records for use in future potential litigation is increasing as the level of litigation increases and it is imperative that major cases are not lost purely because the relevant documents are not available.

In civil law the burden of proof rests on the plaintiff who has to establish, on the balance of probabilities that the defendant has been negligent. This historic British approach is slowly but surely being eroded by judgements in the Courts and this is likely to be eroded further by an EEC directive, currently in draft form which will result in the burden of proof being reversed so that the accused will be responsible for proving that the 'injury' claimed was not due to the product in question. The product liability legislation contained in the Consumer Protection Act (1987) has already altered the burden of proof in certain cases.

To be of value, any records system needs to be simple, robust and reliable.

1.2 Definitions

For convenience the term 'Records' is used to mean all forms of documents, records and data whatever media they are created in or stored on.

Documents is used to mean information normally on paper, excluding data. It covers letters, minutes of meetings and policy statements, even if transferred to microfilm or held on disc as word processed documents. Data is information stored on any media and consists of output of analytical equipment as well as data on donors and donations.

These definitions are used from this point on in this report.

1.3 Long Term Storage

Leaving aside those records which are of only transient interest and concentrating on those which may be of importance for future litigation the duration of storage is considered with regard to specific Acts of Parliament:

1.3.1 Consumer Protection Act 1987

The product liability legislation contained within the Consumer Protection Act gives specific times within which action may be started; action must begin within three years of being injured and within ten years of the supply of the defective product. The situation for minors is less clear but it is normally considered that time limits will run from the date at which they reach 18 (England and Wales).

1.3.2 Congenital Disabilities (Civil Liability) Act 1976

This Act clarifies the right of a child born disabled to bring civil action for damages. The period for bringing action is 3 years but this runs from the time when it was first realised that a person has suffered significant injury. The lapse between 'injury' and the 'knowledge' of it is without time limit. For a minor the limitation period (3 years) runs from the time he/she attains the age of 18 (England and Wales) and may be extended where material facts are not known.

1.3.3 Limitations Acts 1975 & 1980

The Limitation Act 1975 is concerned with the time limits for actions for personal injuries or arising from death (sic). The Limitation Act 1980 has major significance because it relaxes the rules significantly as it allows for specific discretion so that a claim may proceed even though the 'primary limitation period' has long since expired.

1.3.4 Mental Health Act 1983

A person of 'unsound mind', (that is a person suffering from a mental disorder within the meaning of Section 2 of the Mental Health Act 1983) can bring an action (through his/her 'next friend') without limit of time. Discharge from hospital does not imply that the person is no longer suffering from the disability.

1.3.5 Control of Substances Hazardous to Health Regulations 1988

Paragraph 10 of the regulations (Monitoring exposure at the workplace) states that if it is required under the regulations to carry out any monitoring, then records of the monitoring shall be kept. The records must be maintained for 5 years if the monitoring is general, but if it relates to identifiable employees then the record must be maintained for 30 years.

1.3.6 Buck vs English Electric

Although the deadlines such as they are usually apply, in major cases especially those involving several people or those with a potential significant consequence for others, the time limits will be waived. The case of Buck vs English Electric in which Pneumoniconiosis was the issue is worthy of note. In this case not only was the exposure a long time previously but also the litigants had known of the association of the disease with their work for many years. At that time, before the Limitations Act 1980, the case would have been barred by the 1975 Act, but the courts allowed the case to proceed. Mr Buck first knew that he had Pneumoconiosis in 1959 and the case came to court in 1975. The case was not concluded until after Mr Buck's death.

1.4 Duration of Long Term Storage

It is clear that the time limits on potential litigation have previously been seen as being directly related to time limits in various Acts of Parliament such as the Consumer Protection Act and in certain Health Service regulations. Now with cases such as Buck vs English Electric and the recent HIV litigation these time limits are no longer appropriate. The HIV litigation was looking at policy decisions being made 15 years previously and in the Buck case there was at least an 18 year delay. With slow viruses, disease may only become apparent after even longer periods of time.

It is recommended that all major records are retained for at least 30 years. As most RTC's are not currently retaining records for more than 10 to 12 years, there will be sufficient time to review this policy before any Centre has retained documents for this 30 year period. It may be necessary to increase the storage period further, but the situation can be reviewed again in 10 years time.

There are two other items which would make a 30 year period appropriate. These are requirements under COSHH regulations for certain data to be retained for 30 years and the Public records acts which require that records for permanent retention are transferred from local storage after 30 years.

1.5 Public Records Acts

Records held by Transfusion Services are public records according to the Public Records Acts 1958 and 1967. Some records should be preserved complete but others may be retained on a sample basis Appendix B of HC (89) 20 gives advice on records for preservation and is reproduced as Appendix 4.

Clinical records of individual patients are not normally preserved permanently under the 1958 Act other than by way of samples. Individual donor and donation records probably fall into this category. It would be appropriate to discuss this with the local County Archivist or equivalent before destroying any documents.

The records for permanent preservation under the Acts (see Appendix 4) may not be retained locally for more than 30 years. This may generally be interpreted as 31 years after the year of the last entry in a record (sic).

HC (89) 20 indicates that records not required for permanent preservation and not required for litigation or research purposes should be destroyed.

2. Outline Recommendations

2.1 Storage Categories

2.1.1 Long Term (see para 2.3)

The long term storage period recommendation is 30 years. This covers Donor and Donation records and policy and management records as well as records directly linked to Donor and Donation records such as QA reports.

2.1.2 Intermediate Term (see para 2.4)

The intermediate term storage period recommendation is 10 years. This covers routine personnel records, financial records, (other than annual accounts) and reports, and many of the routine documents on the day to day running of the Service.

2.1.2 Transient Term (see para 2.5)

The transient term storage period recommendation is 2 years.

2.2 Annual Policy Statement Record

During the course of each year various new policies will come into effect. These include for example, the introduction of a new version of the AIDS leaflet, or a change in the supplier of your CMV kits. This record will identify what changes were made and identify precisely when they were introduced. Appended to the record will be details of the new test kit and a copy of the new leaflet etc.

Appendix 7 gives a suggested format for a policy statement record. This record would provide an important support for other documentation and would clarify the situation for occurrences that took place at or near the time of a change in Transfusion Centre policy.

2.3 Long Term Storage

Records for long term storage should be retained for 30 years from the date of creation or date of last entry. In the light of future experience this period may need to be revised upwards. It does however at this stage concur with the 30 year rule on local retention of documents for permanent preservation under the Public Records Acts and the 30 year requirement on personal monitoring records required under the COSHH regulations.

2.4 Intermediate Term Storage

This covers a range of records many of which will require to be held for specific periods of time. Rather than have a series of sections each for specific numbers of years this category provides a pragmatic solution. None of these records will be required for permanent storage under the Pubic Records Act. The means of storage can be adapted to individual Centres requirements. Appendix 5, which is an extract from HC(89)20 shows that there is a profusion of storage times for various documents which are not for permanent storage.

2.5 Transient Term Storage

Those records for transient storage will normally be held locally in their original form. It would be inappropriate to convert them into different storage media. Two years is arbitrary but could be adjusted locally to take account of local needs.

3. Storage Media

3.1 Introduction

The original storage media for records at present is mainly paper, magnetic tape, hard or floppy discs. Some records may already have been transferred onto microfilm. Newer media are the optical discs and write once, ready many (WORM) systems. Computer data can be stored on these systems but high performance digitisers can capture copies of paper documents and convert them into computerised digital images which can then be stored. Microfiche can also be generated from computerised data.

3.2 Paper Records

Any records for permanent retention under the Public Records Acts must be retained as originals. Hence Transfusion Centres will require some long term storage facility for paper records.

It is possible to store paper record quite effectively using high density storage systems specifically designed for the purpose. Particularly where access requirements are relatively low and one or two people can handle all the access requests made, very high densities can be attained.

Moderately high density storage can still be obtained for records requiring higher access rates.

3.3 Microfilm

Microfilm is of two types; Silver Halide and Diazo. The Diazo process should not be used for masters as it has a limited life-span. Silver Halide microfilm if processed properly (see BS 1153) and stored correctly will last for at least 50 years and probably 100 years. See Appendix 1 for further details on managing a microfilming programme.

Microfilm is acceptable as evidence with certain provisos (see Appendix 1 and BS 6498).

3.4 Magnetic Tape

Magnetic tape is sensitive to damage by magnetic fields, dust and damage from the tape reader mechanisms. For further details see BS 4783: Parts 2 & 4. As computer operating systems and hence the method of encoding data on tape change there is a danger that stored Magnetic tape may become unreadable. Tape systems are becoming smaller and equipment to read older media may become unavailable. See para 3.7 on archiving which advises further on this point.

All Centres should be aware that with the increasing pace of change in computer systems, older data storage media or systems will not only become obsolete, but the equipment for reading them will become unavailable.

3.5 Document scanning/digitising

Technology now available allows documents to be scanned and the resultant digitised image transferred to and stored on a variety of computer storage media.

Digitised documents have not yet been shown to be acceptable as evidence in court. The digitised data is open to manipulation before storage and depending on the storage media (see Optical Discs, para 3.6) may be open to manipulation long after original scanning and storage of the document.

Although document scanning has enormous potential it cannot be recommended at the present time for storing documents likely to be used in litigation.

3.6 Optical Discs

Devices are available which have 'write once, read many' (WORM) characteristics. These provide very high density storage. The long term stability of optical discs (30 years plus) has not yet been established.

The combination of document scanning/digitising with optical discs may prove to be a satisfactory way to provide data acceptable for use in litigation. As with microfilm there is an opportunity to manipulate the data before it is stored. This manipulation would be undetectable in the stored digitised image. A third party scanning/digitising and storing the documents on behalf of the data owner (c.f. microfilming bureau) may prove to be acceptable if associated with appropriate documentation and controls.

3.7 Archiving

Archiving of computer data can give rise to retrieval problems as technology changes. If data is transferred to storage media such as magnetic tape a clear policy must be adopted to include all this data in the transfer process when a new computer system is introduced. This requirement must be included in the costings and implementation programme for the introduction of any new computer systems.

3.8 On-line records

With mass on-line memory capacity for computer systems falling in price, there is much less need to archive data onto tape etc. When a new computer system is introduced all the records should be automatically transferred. There will be no separate 'archive' data.

3.9 Storage Safety

All storage media require safe storage. High density paper storage in purpose built accommodation is safe, but there is no option for duplicate copies at another site. Microfilm is sensitive to moisture, including steam, although it is relatively heat resistant. Moisture proof containers of an approved design are required. Computer data must be held at least in duplicate and fireproof safes may be appropriate whether or not data is also held on a separate site. Fire-proof safes must be of an appropriate type for their intended use (some are not suitable for microfilm). Manufacturers data should be checked before purchase.

3.10 Storage Access

All storage records on whatever medium must be stored in a way that prohibits unauthorised access. This is required under the Data Protection Act for computer data but applies to all records which are to be retained. Records held for long-term and intermediate storage will only need to be accessed occasionally. A record of access should be maintained for all secured storage locations.

3.11 Superseded Records

All previous versions of SOP's, procedural documents, computer programmes must be retained. In association with the Annual Policy Statement Record (para 2.2) this will not prove to be a problem. If the annual policy statement record approach is not taken, then an alternative method of ensuring that previous 'versions' are retained will be required.

4 Document Classification

4.1 Introduction

To enable records to be classified for long, intermediate or transient term storage, a scheme is required which will be simple to operate and will not require decisions to be made about each individual record. A document referencing system is proposed in para 4.15 as providing a functional route to semi-automate this process. It is the paper documents that are the most difficult to handle. The bulk basic records associated with Donors and Donations are easily classified. Paragraphs 4.2 to 4.13 provide a guide to classification but it is not intended in any way to be exhaustive. Additional information is available in Appendix D of HC(89)20 (attached as Appendix 5) and covers many documents in the Intermediate category and some in the Transient category.

4.2 Donor and Donation Records

All donor and donation records are classified for long term storage.

4.3 Donation Related Records

All records linked to donations are for long term storage. These include:

Validation reports on new equipment or test/test systems
SOP's on the production and testing procedure
Routine QC results on equipment or tests
Quality Assurance reports
Maintenance records
Equipment upgrade records

4.4 Management Records

All policy statements, minutes of management meetings and meetings involving RTC managers, reports to and responses from the relevant RHA (or equivalent), annual financial statements, annual reports and similar management records are for long term storage.

4.5 Quality Assurance Records

Q.A. reports other than those directly linked to donation records (para 4.3), such as:

Reports on non-conforming product
Major or critical error reports
Internal audit reports and Medicine Inspectorate reports and correspondence with the Medicines Control Agency are all for long term storage.

4.6 Staffing Policies Records

Records relating to staffing policies, recruitment activities, and staffing levels should be retained for long term storage.

4.7 Safety Records

Safety data that can be linked to identifiable individuals should be retained for long terms storage. This includes data relating to the handling of radioactive material and genetically engineered material. (see also Appendix 6)

4.8 Destruction of Documents Records

Records recording the destruction of documents, including the destruction of original documents transferred to microfilm (or scanned/digitised) and the destruction of computer data should be retained as long term storage records in their own right.

4.9 Personnel Records

Personnel records are for intermediate term storage, the storage being dated from the date of the last entry or the date on which the employee leaves, but see para 4.7.

4.10 Financial Records

Annual financial statements and annual reviews are retained long term (para 4.4), but monthly statements, departmental expenditure, records of payments, invoices and similar records should be retained only for an intermediate term.

4.11 Donor Complaints Records

Donor complaints may have to be classified individually. Minor complaints about a cold hall for example would be transient, whilst for a bad bruise complaint it would be worth retaining the documentation for the intermediate term. Records on a major donor incident would be retained for long term storage.

4.12 Patient Incident Records

These may need to be classified into long term or intermediate term storage records. Few would fall into the Transient category.

4.13 Transient Records

The records for transient storage include a wide range of non-critical material from memos about session changes, staff rostering and 'house-keeping' matters to correspondence on building maintenance (excluding that directly related to Component Production etc.) and catering facilities.

4.14 Machine Intermediate Data

The output from analytical equipment which does not form the final result should not be retained. See Appendix 2.

4.15 Document Referencing System

Whilst many records are easy to categorise as stated in para 4.1. It is the bulk of management correspondence that leads to problems. Classification should always be carried out at source. Attempting to classify documents after two or ten years to decide what to retain and what to destroy is time wasting and inefficient. There is an argument that after several years a better view of a documents worth will have been obtained, but this will lead to an idiosyncratic system which is not appropriate and will be hard to defend (or understand) in twenty or thirty years time.

4.15.1 A unified file reference system for all documents in an RTC that do not fall into the bulk donor/donation record arena is outlined.

4.15.2 All secretarial staff and all staff who produce documents on their own word processor would use a unified file reference system. This system will ensure that different people within the organisation, producing documents on the same area of work will use the same basic file references.

4.15.3 All documents (including formal reports, minutes of meetings etc) are to have a full file reference with a date or date code printed on them.

4.15.4 A master index is maintained which cross references all file references to one of the three storage categories, plus an extra indicator for transfer to public records after 30 years.

4.15.5 When a document is prepared, the author will know how long it is to be retained and could chose an alternative file reference if longer storage was felt necessary, although this would again introduce the idiosyncratic element, albeit within a defined structure.

4.15.6 All word processing data files would be destroyed at the same time as their hard copy printouts. (This may not be appropriate for documents for long term storage).

4.15.7 The same index would be used to enable documents to be processed through the system once local storage ceased. For example a document destined for intermediate storage would be held in local files for two years. At two years it would be removed and transferred to the intermediate storage area. This would identify that it could be transcribed onto a different storage medium if required as it would not be a document for permanent storage under the public records acts.

4.15.8 The index could be extended to cover storage records on media other than paper.

4.15.9 The system is sufficiently flexible to cope with various storage media and various RTC's decisions on classification of specific categories of records.

5. Records Storage Policy

5.1 Introduction

The fundamentals of a record storage system have now been outlined. It is necessary for each RTC that adopts a system based on this report or otherwise to have a policy on records storage.

Whatever policy an RTC has, as long as that policy has been reached after due deliberation and is not clearly unreasonable or unlawful, the RTC will have a significant degree of protection should records not be available at a future date due to those records having been destroyed as part of that policy. It is no protection against loss of or damage to documents. The policy is to be a written policy.

If at a later date it is argued that a document should have been retained for longer, a court is unlikely to find against an RTC if it had a written policy.

The policy will take into account many items from available space to available finance. The reason behind the policy should be clearly stated.

In the case of Jinks v West Midlands Health Authority, the Court would not criticise the Health Authority or 'second guess' them on a policy decision based on the most appropriate allocation of resources. The court would not attempt to remake the Health Authority's original policy. This case was not related to Record keeping but the principle is important and comparable.

5.2 The Policy

The elements of a policy will include:-

5.2.1 The policy statement

4.2.2 An SOP for each main group or classification of records

5.2.3 A system for classifying records

5.2.4 SOP's for the methods, processes and recording of the destruction of records. One SOP per record classification and record type (paper, computer data etc).

5.2.5 SOP's for the transfer of Records to other media

5.2.6 Provision of safe and secure storage

5.2.7 Policy for procedures for control of access to records

5.2.8 Policy for the conditions under which records may be removed

5.2.9 A records tracking system

5.2.10 A system for recording policy/procedure changes

5.2.11 SOP's for retrieval systems to obtain hard copy of non-paper records

5.2.12 A system for recording the disposal of records to other authorities (public archivist; other RTC's, RHA etc)

5.3 Document Control

The policy statement and all the procedural documents and SOP's that implement and 'manage' the records storage system should be included in the document control system, along with other SOP's and procedural documents, of the RTC.

6. System Management

6.1 Senior Management

A Senior Manager should be given overall responsibility for the records storage programme. Staff in many parts of the organisation will be involved in various aspects of the correct management and storage of records.

6.2 Documents Manager/Documents Officer

One person will be needed to manage the whole process on a day to day basis. It is suggested that this person is part of the Quality Assurance Department. The importance of documentation to a Quality System is clear and is an integral part of the BSI standard BS 5750.

6.3 Training

There will be a requirement to train staff in the operation of this policy. The training of secretarial staff will be particularly important to ensure that documents are correctly classified at source. Records of the training should be maintained.

6.4 Review/Audit

The operation of the policy should be subject to regular internal audit. It is essential that the Senior Manager responsible knows whether the system is working effectively. It will also add weight to any defence of challenges made to the policy or the operation of that policy.

Because of the potential costs of litigation and because of the cost of operating a comprehensive document control policy, it is essential to know that the system is working properly according to the RTC's stated policy and the detailed procedures.

7. Recommendations

7.1 Basic System

Transfusion Centres should institute a records storage system which enables records of potential significance for litigation to be retained for 30 years. Specific legal obligations must be met such as the COSHH regulations and the Public Records acts. There are requirements for varying storage periods for other data (see Appendix 5) which must be met. The system adopted should enable records to be reliably categorised at source and records must be accessible during storage. Storage in whatever medium must be safe, and secure.

A record of the destruction of records should be maintained, including the destruction of originals after transfer of records to other storage media.

A scheme such as the Annual Policy statement record should be instituted.

A formal written policy should be provided and followed. The system used should be audited and the documents which implement the policy, such as procedural documents and SOP's need to be included in the RTC's document control programme.

The system proposed in this report can be adapted to each RTC's specific requirements and is not dependant on any absolute definitions for record classifications. It is possible to institute the system without a common documents reference system, but will be much more easily implemented if all documents created in the RTC follow a common document reference scheme, linked to a cross-referencing index giving storage categories for each document reference. The proposal will also be applicable in RTC's using different storage media.

7.2 Storage

Records for transient storage are best retained in their original format. There is little benefit in converting them into other formats for periods of at most two years.

Intermediate records for 10 year storage could well be transferred to more appropriate storage media. These records will be bulky and will normally be stored on-site.

Records for long term storage fall into two main groups, the bulk records of donors and donations which are increasingly being held exclusively on computer media, and the written documents such as policy documents, minutes of management meetings and the like. This latter group fall within the purview of the Public Records Acts and should be retained as originals, i.e. paper records.

7.3 Storage Media

Computerised data will be retained on whatever media the particular system uses. It is essential that when a new computer system is installed all previous records whether archived or not are transferred to a medium accessible to the new system.

Records for possible permanent preservation will be retained as originals.

The remainder, which will vary considerably in volume depending on the degree of computerisation of a centre and of course its size, as well as depending on how many functions are not performed in house (finance, estate management, personnel), or conversely are performed in house.

It is this group of records about which a decision has to be taken about the storage medium. Currently this is between original paper record, microfilm and scanned/digitised storage on media such as optical discs.

Microfilms are acceptable as evidence, with the proviso that the originals were destroyed as part of a planned and documented programme of microfilming. The date of destruction should be available and the microfilming should have met certain standards. Storage conditions are also important.

The new digitising/optical disc type storage has not yet been shown to be acceptable as evidence in legal cases. It's potential for manipulation appears to pose a serious problem. It is however the system that will provide maximum storage density and maximum accessibility.

7.4 Storage Space and Storage Quality

The National Directorate in consultation with Transfusion Centre Directors/Chief Executives should consider whether a central storage facility should be provided. This would provide safe, secure storage, preferably in a low cost location. The facility could provide microfilming capability or could maintain quality control (BS 1153) over a single microfilming provider. This would also ensure that all legal aspects were met (BS 6498).

The microfilming of documents is not the most up to date technology and does have problems. The newer technology of scanning/digitising documents will probably provide the way forward. The use of a professional, properly managed facility to transfer documents to optical discs for instance could, with strict access controls ensure that these records were suitable for legal use.

The central facility would provide modern high density paper storage accommodation for records for long term storage.

This facility could also provide an off-site location for RTC's to store back-up computer records and programmes.

All RTC's wishing to use the facility would contribute on a basis pro-rata to their size for the basic facility, and would pay individually for additional facilities. A charge for each document retrieval would be levied. RTC's would receive an annual index of stored records with records for destruction during the next year indicated. The RTC Director/Chief Executive would authorise the destruction of records marked for destruction or alternatively specify extended storage.

This scheme is not unlike the centralised frozen blood bank facility at Birmingham where all RTC's contribute to the basic cost and pay a fee for each 'access'.

8. Summary

A simple, robust scheme for managing and storing records has been proposed. Three categories, Transient (2 years), Intermediate (10 years) and long (30 years) is proposed. To facilitate the long term storage element in particular, consideration should be given to a central facility for Transfusion Services in England and Wales. The possible move to novel storage systems such as Optical discs should be pursued, although at present it is not know whether this type of record will be acceptable as evidence in court. Microfilming remains an acceptable alternative for certain categories of data although paper records will still need to be retained in certain instances and will be the most appropriate for the two year storage of transient records. All RTC's should have a written policy, implemented correctly with written instructions in the form of SOP's or Procedural Documents. A Senior Manager should have responsibility for the records storage programme. A records officer might be accountable to the Quality Assurance Manager. The systems should be included in Internal Audit programmes. The presence of a properly implemented, documented policy with accurate records of the destruction of documents, data or records is at least as important as the final duration of the storage of the records.

APPENDICES

Appendix 1 Microfilming

Microfilm is basically of two types, Silver Halide or Diazo. The Diazo process should not be in use for the production of masters. It is often used to produce copies from masters. Diazos have limited life especially if exposed to light.

Silver Halide if processed and stored correctly will last for at least 50 years and probably 100 years.

Microfilm is acceptable as evidence as long as there is no evidence of tampering and as long as it was prepared at the time expected. This should be in your policy statement. The original should have been properly destroyed once the microfilm copy was verified or at a later date if so specified in your policy document.

If the original is still available the microfilm is not acceptable and a microfilm copy made after litigation started will probably not be acceptable.

BS 6498 : 1984 provides standards for microfilming documents that may be required as evidence. BS 1153:1975 sets out the technical standards and any bureau or in house process should certify that they conform to the relevant standards.

It is advisable to start and end each roll of microfilm with a form identifying the documents, identifying the responsible person who has authorised the microfilming and stating that the procedure has been carried out in accordance with a specified SOP. This form would be signed by the responsible person. It may be advisable to make it clear that the original documents will be destroyed once the microfilm has been checked. Appendix 3 of BS 6498 : 1984, gives more details.

Any records which are to be permanently preserved under the Public Records Acts must not be destroyed. Microfilms of these records are not acceptable to the Public Records Office. There is thus little or no benefit in microfilming these records. See Para 1.5 on the Public Records Acts.

Appendix 2 Machine Intermediate Data

1. Introduction

Most pieces of equipment produce intermediate data, including original optical density readings for instance as well as data held in memory or on a hard disc. Some data is output onto paper and some is available on floppy disc. The data may be intermediate calculations, such as results used to calculate cutoffs or data immediately prior to conversion to 'readable' results such as the ABO group. Just because the equipment provides a printout of some of this data is not sufficient justification to warrant it's retention. Another equivalent machine might have similar data available but not print it out. In that case it could be argued that there is a requirement to extract and store that data.

2. Validation

Any item of equipment or computer programme purchased, or leased or otherwise put into routine use in a Transfusion Centre should be validated before acceptance.

2.1 Hardware

At present there are few checks available on hardware. In some cases independent reports are available and specific 'quality' standards may have been met such as electrical safety (BESB) approval. There is no equivalent of the Medical Devices Manufacturers registration scheme although equipment for use in the USA may have FDA approval.

2.2 Software

Some external validation of computer software is becoming available. If possible the supplier should be persuaded to obtain external validation (e.g. Weinberg Associates) of their software.

2.3 Manufacturers Data

Manufacturers data on the performance of hardware, software or a combination of these should be examined with care to ensure that performance is up to the standard claimed.

2.4 Internal Validation

Before equipment or software enters service in an RTC a formal validation report should be prepared. A validation team will carry out or have carried out on their behalf a range of tests on the system. These tests will be designed to test the system under the conditions in which it will operate. The report will be submitted to the relevant Senior Manager or Transfusion Centre Director/Chief Executive before the system goes 'live'.

2.5 Quality Control

A regular quality control programme will have been agreed before the system is put into operation. Quality control results will be documented and retained within the records storage programme.

2.6 Quality Assurance

A quality assurance programme will have been agreed before the system is put into operation. Quality Assurance reports will be prepared on a regular basis and a programme for action based on the QA reports will have been agreed.

3. Conclusion

With a formal validation of the system and regular, documented and utilised Quality Control and Quality Assurance programmes, and a procedure that follows the manufacturers instructions, then the intermediate data should not be retained, whether it is hard copy paper printout, data on floppy disc or data held internally in memory or on hard disc.

Appendix 3 Extract from HC (80)7 on Retention of Personal Health Records

Time Limits on actions for personal injuries

1. The Limitation Act 1975 amends the law on the time limits within which actions for personal injuries, or arising from death (sic) may be brought. The Congenital Disabilities (Civil Liability) Act 1976, clarifies the right of a child born disabled, as distinct from her/his mother, to bring civil action for damages in respect of that disability. The limitation period for bringing such actions remains 3 years, but this now runs from when it was first realised that a person has suffered a significant injury that may be attributable to the negligence of a third party. The lapse between the 'injury' and 'knowledge' of it is without limit of time. For a minor the limitation period runs from the time he/she attains the age of 18 years and may be extended where 'material facts are not known'.

2. A person of "unsound mind"* can, as long as he/she remains under the disability in question, bring an action without the limit of time through his/her "next friend". After the person's death, the period of limitation will run against his/her personal representative(s). Authorities will appreciate that, in the context of current practices in the care and treatment of mentally disordered persons, discharge from hospital can no longer be regarded as implying that the person has ceased to suffer from the disability.

3. The limitation period of three years applies only to actions which include a claim for damages in respect of personal injuries. In the case of other claims, eg a claim by a mentally disordered patient that he/she has been falsely imprisoned, the appropriate limitation period prescribed by Section 2(1) of the Limitation Act 1939 is six years from the date when the patient ceases to be under a disability or dies.

* The definition of "unsound mind" is not at present prescribed in law but the Department's advice is that a Court would be likely to find that a person suffering from any of the forms of a mental disorder within the meaning of Section 4(1) of the Mental Health Act 1959 (which includes mental handicap and mental illness) would be treated as being under a disability for the purpose of the Limitation Acts.

Appendix 4 Extract from HC (89)20, Appendix B: Records for permanent preservation

CRITERIA FOR SELECTION OF NHS RECORDS FOR PERMANENT PRESERVATION

General

1. The destruction of records worthy of permanent preservation is an irreversible act, while the cost of preserving records worthy of permanent preservation is high and continuing. The criteria which follow are intended to give guidance on the identification, with relative ease, of records of permanent value, avoiding both ill-considered destruction and excessive selection.

2. The officer responsible for public records matters must ensure that records no longer required for local use are reviewed as soon as practicable under the criteria in paragraph 6 below. Those records selected for permanent preservation should be transferred to a place of deposit appointed by the Lord Chancellor for that purpose. The remainder should either be destroyed or be retained by the health authority for its research or litigation purposes.

Guidelines for Selection Under the Public Records Acts

3. The nominated officer should prepare local guidelines supplementing and adapting the criteria in Paragraph 6 below in conjunction with the local record office.

4. In preparing guidelines the nominated officer should bear in mind that selected records are used rarely in isolation but are liable to be used in conjunction with records from other sources and be used for research unconnected with the purpose for which they were created.

5. In deciding whether particular records contain information in sufficient quantity or of such quality that they should be preserved, account should be taken of any informed opinion available, whether from inside or outside the authority. In cases of doubt the advice of the Liaison Officer must be sought.

Records for Preservation

6. Record sets of major reports and publications and of the minutes of the authority and its predecessors, together with those of major committees and sub-committees should be selected for permanent preservation.

7. Records which seem likely to provide material for research should be scrutinised with a view to permanent preservation particularly those relating to:

   i. the history of the authority (including that of its predecessors) its organisations and procedures;

   ii. the history of individual hospitals under the control of the authority, including matters relating to their history before the NHS and under predecessor authorities;

iii. notable events or persons where the records add significantly to what is already known;

iv. major events (whether in national, regional or purely local terms) or trends in political, social and economic events;

v. scientific, technological and medical research and development;

vi. major plans and projects, including projects which have been abandoned or deferred;

vii. industrial relations (not routine staff matters);

viii. records of benefactions in addition to those included in records of non-Exchequer funds (see para 10 of Appendix A).

Financial Records

8. Key financial records are of great importance and may merit permanent preservation. Nevertheless in the course of everyday financial business large masses of documentation are generated which serve no purpose after comparatively short periods of time. They should be retained only for the periods set out in Appendix C. The following must be selected for permanent preservation;

i. one set of the annual accounts and statements submitted to the Secretary of State each year in accordance with the requirements of the National Health Service Acts;

ii. documents relating to the terms of any trusts administered by health authorities whether or not they are included in records of non-Exchequer funds;

iii. key records, in addition to final accounts, relating to building and engineering works such as surveys, site plans, drawings, bills of quantities, contract documents, including those relating to major projects which have been abandoned or deferred.

Property Records

9. Records which are evidence of title must never be destroyed. Examples of documents of title are: title deeds and correspondence relating to the transfer of hospital property to the Secretary of State, to the apportionment and vesting in the Secretary of State of interests in premises used partly for hospital and partly for other purposes; to the purchase, disposal and leasing of property by or to the Secretary of State; and to the transfer and discharge of mortgages. If documents of title have been lost the administrative files relating to the ownership of the land must be retained for as long as the documents of title would have been kept.

Personal Health Records

10. Although personal health records of patients will not normally be preserved permanently, arrangements may be made for samples to be taken (see paragraph 4 of the Appendix A).

Appendix 5 Extract from HC (89)20, Appendix D: Transient records preservation

SUMMARY OF DESTRUCTION PERIODS FOR RECORDS WHICH ARE NOT FOR PERMANENT PRESERVATION

Number and Class of Documents	Period after which documents may be destroyed
Part I - Financial	
1. Salaries and wages records, ie employees' pay cards and personal pay records (except those for part-time doctors and dentists employed by RHA's and HA's which should not be destroyed).	Ten years after the end of the financial year to which they relate.
2. Copies of forms SD55 (ADP) and SD55J (originals are sent to Health Services Superannuation Branch of the Department).	Ten years after the end of the financial year to which they relate.
3. Principal Ledger Records: including such documents as cash books, ledgers, income and expenditure journals, etc.	Six years after the end of the financial year to which they relate.
4. Bills, receipts and cleared cheques.	Six years after the end of the financial year to which they relate.
5. Documents, other than those of permanent relevance in relation to trust funds and the terms of any trusts administered by health authorities.	Six years after the end of the financial year in which the trust moneys became finally spent, or the gift in kind was accepted. (See Note 1)
6. Major Establishment Records: including personal files, letters of appointment, contracts references and related correspondence and records of sick leave (except those for part-time doctors and dentists employed by RHA's and HA's which should not be destroyed).	Six years after the officer leaves the service of the hospital or on the date on which the officer would reach the age of 70, whichever is the later, provided that if an adequate summary of the personal and health record is kept for this period the main records may be destroyed six years after the officer leaves the service of the hospital.

Note 1. Two 'obvious' typographic errors in the original have been corrected.

Number and Class of Documents	Period after which documents may be destroyed
7. Pay Sheets and Records of unpaid salaries and wages.	Six years after the end of the financial year to which they relate.
8. Estimates: including supporting calculations and statistics.	Three years after the end of the financial year to which they relate.
9. Cost accounts prepared in accordance with the directions of the Secretary of State or at the request of the Department.	Three years after the end of the financial year to which they relate.
10. Audit reports	Two years after formal clearance by Statutory Auditor.
11. Minor Accounting Records:	
a. Pass-books, bank statements of accounts, paying-in slips, cheque counterfoils and cancelled and discharged cheques other than cheques bearing printed receipts; accounts of petty cash expenditure; travelling and subsistence accounts; minor vouchers, including duplicate receipt books; income records; laundry lists and receipts; forms AP1, 2, 3 and 4 (used in connection with the supply of surgical appliances), etc.	Eighteen months after the end of the financial year to which they relate.
b. Debtors' record	Eighteen months after the end of the financial year in which the accounts are paid or are written off, but at least six years in respect of any unpaid account which has not been written off.
Part II - Stores, Equipment and Buildings	When the plant to which they relate goes finally out of use.
12. Engineers' inspection reports on boilers, lifts etc.	

Number and Class of Documents	Period after which documents may be destroyed
13. Agreements and simple contracts (and documents subsidiary to these) which are only of temporary or minor importance, ie short-term agreements and minor contracts; papers preliminary or subsidiary to contracts; documents relating to contracts for the supply of goods.	Six years after the end of the financial year in which the agreement or contract expires.
14. Major Stores Records: stores ledgers and equivalents.	Six years after the end of the financial year to which they relate.
15. Minor Stores Records: requisitions, issues note, transfer vouchers, goods received books, etc.	Eighteen months after the end of the financial year to which they relate.
16. Minor Supplies Records: including invitations to tender and unaccepted tenders, routine papers relating to catering and demands for furniture, equipment, stationery and other supplies.	Eighteen months after the end of the financial year to which they relate.
17. Records (other than those of permanent value see Appendix A paras 14 and 15) relating to capital and other building works or improvements; including plans and specifications prepared for temporary purposes and papers relating to them. (See Note 2)	Eighteen months after the end of the financial year in which they ceased to be effective.
18. Inventories not in current use of utensils, instruments, bedding, etc not held on store charge, having a life of less than five years.	Eighteen months after the end of the financial year in which the inventories were in use.

Note 2. The appendix and paragraphs referred to have not been reproduced for this report. The original of HC(89)20 should be referred to if necessary.

Appendix 6 Notes on COSHH regulations

The Control of Substances Hazardous to Health Regulations 1988 came into force on 1st October 1989. Paragraph 10 of the regulations (Monitoring exposure at the workplace) states that if it is required under the regulations to carry out any monitoring, then records of that monitoring shall be kept. The records must be maintained for 5 years if the monitoring is general, but if it relates to identifiable employees then the record must be maintained for 30 years.

A personal risk assessment for each employee should be carried out annually or at any time their job changes or new processes are brought in. It would be advisable to maintain this record for the same 30 year period.

Appendix 7 Annual Policy Statement Record

1.1.91	As per the situation at 31.12.90
11.2.91	AIDS leaflet version 10 introduced for all donors called from today.
22.2.91	AIDS leaflet version 10 and Poster version 10 on all sessions from today.
14.3.91	Revised Malarial areas regulations introduced on all sessions from today.
18.3.91	HIV I/II test changed from Abbott to Wellcome Kit (kit reference W/47AZI) from donations numbered 523186, 601732 and 621109.
19.3.91	All donations collected on 18.3.91 and subsequent, tested for HIV I/II by Wellcome test (kit reference W/47A21).

Relevant documents would be stored with this record.