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BFCR(06)4 (updated February 2008)

Retention and Storage of Images and Radiological Patient Data

This guidance attempts to draw together recommendations and legal requirements from various sources (as referenced) for the retention and storage of images. The Royal College of Radiologists recognises that the technical constraints of most Picture archiving and communication systems (PACS) preclude the preferential storage of some specific imaging studies over others, and do not permit prospective determination on how long a particular imaging study should be stored. Most institutions are therefore obliged to store studies long enough to cover the requirements for those studies which have to be kept the longest (for example, paediatric images). As technology progresses, it will undoubtedly become possible to set up PACS archive storage rules in an 'intelligent' manner, and at that point the implications of the guidance offered in this document should have a practical realisation.

This document replaces previous advice *Retention of X-Ray Film- Resume of the Issues* [FCR/2/91][1] and *Notes on Access to, Transfer and Storage of Patient Records Created in Radiology Departments* [BFCR(00)3],[2] which are now withdrawn.

1. Introduction

1.1 Radiological request information, images and reports are part of the patient record; their management is governed by a range of statute and advice. The Department of Health issued a guidance document in 2006 *Records Management: NHS Code of Practice* (RMCoP).[3] RMCoP has replaced previous advice *For the Record* [HSC 99/053, WHC 00/71][4] and *Using Electronic Patient Records in Hospitals: Legal Requirements and Good Practice* [HSC 98/153].[5] The advice will incorporate relevant aspects of the Data Protection Act 1998,[6] Freedom of Information Act 2000,[7] Limitation Act 1980[8] and British Standards PD 0008[9] and PD 5000,[10] relating to admissibility of evidence. These guidelines have been prepared for use in the NHS but should also apply to independent and private practice. They should also be considered as best practice for other practitioners using radiology; eg, chiropractors and dentists. In Scotland, current guidance is contained in *Guidance for the Retention and Destruction of Health Records* (MEL (1993) 152.[11] This guidance is due to

be updated and a consultation paper *Retention and Disposal of Health Records* was issued in September 2005, followed by a consultation report in January 2007. Formal guidance has not yet been published. There is an intention to reflect a consistent approach to minimum retention periods across the UK.[12]

2. Records Management: NHS Code of Practice (RMCoP)[3]

2.1 Previous advice in *For the Record*[4] regarded the radiological report as the permanent record, and images and request information of a transitory nature. In *For the Record*, the published retention schedules referred to the report of the radiological examination. The length of time for retention of images was not specified and was based on local determination and policy. The balance lies between the costs of additional storage, versus the needs of the clinical service, whether the original examination has been reported (either within radiology or by clinicians), and the costs of failed litigation due to the inability to produce the image evidence.

2.2 With the development of electronic records and the increasingly integrated nature of the radiological record, the traditional separation between the images and the associated request and report has changed. It is now considered that best practice should move towards retention of image data for the same duration as report and request data. The integrated nature of the radiological record is providing greater cohesion between report and image data. This will have important implications for the configuration of storage systems. This change is reflected in the new advice given in RMCoP.

3. Recommended Retention Schedules

3.1 The minimum retention schedules for radiological records are as follows:

3.1.1 General Patient Records

- 8 years after the conclusion of treatment (England, Wales and Northern Ireland). [RMCoP 7 years but see 3.4 below]
- 6 years after the date of the last entry or 3 years after death (Scotland)

3.1.2 Children and young people

- Until the patients 25th birthday, or if the patient was 17 at conclusion of treatment until their 26th birthday, or until 8 years after the patient's death if sooner.
  If the illness or death could have potential relevance to adult conditions or have genetic implications, the advice of clinicians should be sought as to whether to retain the records for a longer period.
- Scotland - until the patient reaches the age of 25, or three years after death if earlier.

3.1.3 Maternity records

- 25 years after the birth of the child, including stillbirths.

3.1.4 Clinical trials

- 15 years after the completion of treatment.

3.1.5 Litigation

- Records reviewed 10 years after file closed. NB: Once litigation has been notified (or a formal complaint received) images should be stored until ten years after the file has been closed.

3.1.6 Mental health

- 20 years after no further treatment considered necessary; or 8 years after death.
- Scotland - for the lifetime of the patient and three years after death.

3.1.7 Oncology records

- 8 years after conclusion of treatment
- Scotland - for the lifetime of the patient and three years after death

3.2 Screening Mammography[13]

3.2.1 The UK Breast Screening Programmes specify minimum retention periods for both screening mammograms *and* associated reports:

• Normal packet	9 years after date of final attendance [RMCoP 8 years (but see 3.4 below)]
• Screen detected cancers	Indefinitely
• Interval Cancers	Indefinitely
• Interesting Cases	Indefinitely
• Research cases	15 years after date of final attendance
• Age trial cases	9 years after date of final attendance
• Deaths	9 years after date of final attendance

3.2.2 Screening Mammography (Scotland)[14]

Mammograms and reports should be retained as follows

• Normal packet	9 years following last attendance, or 9 years from date of death
• Screen detected cancer	Indefinitely
• Interval cancer	Indefinitely
• Clinical trial	Indefinitely
• Anonymised cases	Indefinitely (educational purposes)

3.3 Product Liability Involved

- 11 years (Consumer Protection Act 1981)[15].

3.4 Minimum retention periods should be calculated from the end of the calendar year following the conclusion of treatment or the last entry in the record.

4. Long-term digital storage

4.1 Long-term digital storage of images raises a number of issues. The image data to be stored should be that which is normally sent to the archive. For some modalities which produce large volumes of raw data (e.g. multi-slice CT) the stored product will be less than the raw data. Where compression is used it is important that the images stored are clinically useful.

4.2 Differential retention requirements will require differential storage periods. Information systems linked to the data storage archives will need to be refined to a degree that all relevant patient history and events (such as cancer diagnosed) will trigger the appropriate message to manage the patients current and prior image data. Until this can be achieved, then data will have to be stored for longer periods and the use of image data compression considered as a means of increasing storage capacity.

4.3 Compression may be used to reduce the storage space required for digital images. Standard compression algorithms can achieve 'lossless' image compression up to a ratio of approximately 3:1. More dramatic space savings may be obtained with lossy compression, where some image data is lost permanently, but to a degree that may not be significant in clinical practice. In circumstances where it is impractical to store lossless images indefinitely, such lossy compression is clearly preferable to the deletion of images. Where lossy compression is applied it is important to ensure the levels chosen are appropriate so that images remain clinically useful. The compression algorithm must be approved and supported by DICOM (Digital Image Communications in Medicine).[16] The RCR expects to produce more detailed advice in due course.

4.4 Any PACS implementation must include robust technical solutions and contractual safeguards that data stored in the long-term archive can be accessed and retrieved over the entire retention period specified above. This may require occasional transfer of such data to new storage media and archive devices before the original storage and retrieval technologies become obsolete. The obligations of the PACS supplier or Service Provider in this respect, should be clearly specified in the original contract and costs identified for the initial support period. Once the original contract lapses, it is the responsibility of the PACS user to put alternative contractual arrangements in place. Storage should be in a secure environment which takes account of the potential risks of theft, flooding and fire. Appropriate backup policies should be developed.

5. Record destruction

5.1 The NHS Organisation has a duty to ensure confidentiality is maintained during the destruction of health records, including when this task is given to a third party contractor.

6. Data Security & Access to Records

6.1 Information Technology security policies are a necessary part of electronic data storage management. They are also necessary to conform with British Standards pertaining to legally admissible evidence. The principles are those of:

- Identification and authentication
- access control
- audit and accountability
- integrity.

6.2 Access control requires a robust password policy. An audit trail should recognise user identity, date and time, patient identification, details of transaction and a sequence number. This should be kept in a backup format, as should unsuccessful transactions. More detail of compliance with standards accepted for legal admissibility of evidence is to be found in:

- BSI PD 0008 Legal Admissibility and Evidential Weight of Information Is Stored Electronically[9]
- BSI PD 5000 Electronic Documents and E-Commerce Transactions As Legally Admissible Evidence[10]

6.3 The Data Protection Act 1998[6] establishes a set of principles with which users of personal information must comply. Two of the principles are as follows:
'Personal data shall not be kept for longer than is necessary for its purpose(s)' and 'Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data'. This sets out clear responsibilities.

6.4 The Data Protection Act 1998[6] gives an individual various rights in relation to the information held about them. Individuals have right of access to obtain a permanent copy or view a record. Such requests must be complied with within 40 days of receipt. The Secretary of State has issued guidance indicating that health care organisations should aim to meet such requests within a 21 day timescale.

6.5 The Freedom of Information Act 2000[7] lays down requirements for public bodies (including the NHS) to make information available on request. These requirements are additional to other access requirements (e.g. the Data Protection Act[6]). From the perspective of records management the organisation should undertake a records audit to determine the location of records and whether or not they should be retained. A system of work for compliance with the Act should be developed.

6.6 Data Protection and Freedom of Information should be managed as part of the Trust's Information Governance structure. Radiology departments should have written protocols for their retention and disposal policies as well as methods for compliance with the Data Protection Act 1998[6] and the Freedom of Information Act 2000.[7] There should be compliance with Duty of Confidentiality according to Caldicott Principles.[17,18]

7. Summary

7.1 The radiological archive is one of text and image data. It is recommended that the retention period for text and image data are equal and comply with the published retention schedules. Compliance with the Data Protection Act,[6] Freedom of Information Act[7] and Principles of Confidentiality are required. If electronic image and text data is to be used as evidence then compliance with the appropriate British Standards is necessary.

8. Acknowledgements

8.1 The Royal College of Radiologists would like to thank the IT Sub-Committee and, in particular, Dr Stephen Davies for producing this publication.

BFCR(06)4
Approved by Board of Faculty on 24 February 2006 [note RMCoP introduced on 05 April 2006]
Updated February 2008

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