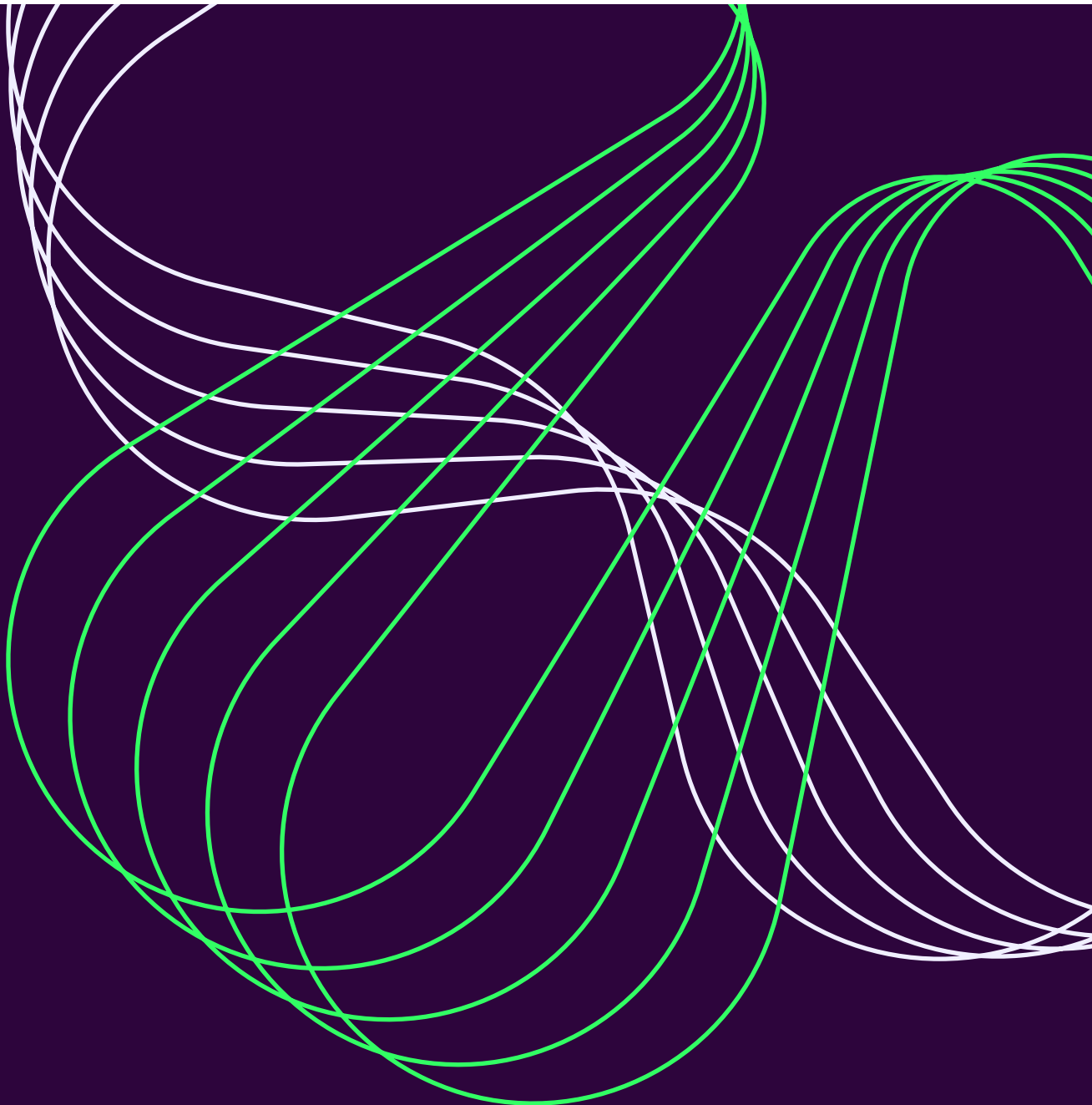


Application of the Records management code of practice to radiology record retention protocols



The Royal College of Radiologists



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Background

In 2021 NHSX published a revision to the Records management code of practice for health and social care ('the Code'), which sets out what people working with or in NHS organisations in England need to do to manage records correctly.¹ At its core are a set of criteria that define the minimum retention period for different record types. The Code is based on legal requirements and professional best practice, including the Data Protection Principles as set out in the UK General Data Protection Regulation (GDPR) and Data Protection Act 2018.² While a number of the considerations below may be of value to NHS organisations elsewhere in the UK and others around the world, the specific legal framework of each individual country will always have primacy.

Radiology (and associated disciplines, such as radiotherapy) images and reports are classed as a 'general health record' in the Code, and their retention refers to both clinical and non-clinical purposes, as detailed below. The Code applies to all patients (NHS and private) treated on NHS premises, as well as NHS patients treated by a contracted provider, including GP services and the private sector. The purpose of this document is to interpret the Code from a radiology digital record perspective, providing guidance to radiology staff, information technology (IT) departments and system vendors on the implications of the Code for radiology record retention and how these might be addressed using digital solutions.

In the radiology world, various systems may be responsible for life cycle management, such as a vendor neutral archive (VNA), radiology information system (RIS), picture archiving and communication system (PACS), electronic patient record (EPR) or an independent IT system. In line with the Code, this document references the records management system (RMS), but the principles are applicable across any of the above systems. To enable life cycle management, the RMS must be able to automatically aggregate metadata from source systems or process manually entered flags in order to identify records that have exceeded their retention period. It must conform to vendor neutral standards on image object change management (IOCM) if communicating with PACS and other systems that hold images.

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Should records be kept forever?

Primarily due to space and cost reasons, physical records (eg, X-rays, paper notes) have in the past been relocated off-site or disposed of entirely after an arbitrary, locally defined time period. Similar pressures also apply to digital records, including the costs and physical space required for storage media, as well as the energy costs of long-term storage. Combining the strategies described below with the use of lower-energy archive solutions can have a substantial impact on lowering the carbon footprint of radiology. Additionally, record migration to new RIS, PACS or VNA solutions as suppliers are changed or hardware is upgraded is having increasing time and financial implications.

The UK GDPR states that information cannot be kept for 'longer than is necessary for the purposes for which the personal data are processed', but it does not set a specific time limit. In relation to the purpose of healthcare, it could be argued that an imaging record is potentially useful many years after it was created and that the absence of a record following deletion is more harmful to the patient than keeping the record for their entire lifetime 'just in case'. However, this argument has not been tested in an English court before now.

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Methods of reducing storage records

Storage location

In the same way that patient notes or film packets previously were often moved to off-site storage, it may be appropriate for digital radiology records to be moved to a long-term storage archive for part of their minimum retention period. This may be off-site, either within cloud storage or even an off-line repository. However, the Code is clear that such records should remain accessible for future clinical care. In practice this means ensuring their existence is fully visible to end users and that the record can be retrieved in a clinically useful time frame.

Compression

As utilised by the Scottish National PACS programme for many years, image compression can be extremely useful in terms of reducing the storage requirements for imaging. Image compression techniques may be lossless, such that the original data can be reconstituted, or lossy. Lossless compression often results in only modest reductions in data size (around 2:1), but it can still be useful in relation to studies for which lossy compression is deemed clinically or technically inappropriate.

In comparison, lossy techniques can achieve compression ratios of 20:1 or higher, depending upon the modality and body part in question. Although several international guidelines have been published previously (including by the RCR), many of these have either not been updated since or have been withdrawn. There is also inconsistency in the recommendations for levels of 'acceptable compression'. On the assumption that records are less likely to be viewed with each passing year, it may be appropriate to consider applying further, more aggressive compression after a certain period has elapsed. However, the potential impact on image quality from multiple cycles of compression causing cumulative degradation must be considered.

Whichever method is chosen, the Code mandates that digital information must always be stored in such a way that it can be recovered in an accessible format by future systems.

Series rationalisation

For computed tomography (CT) at least, a particular body region may be represented by multiple complementary datasets or series, with variations in plane, slice thickness, sharpness and window levels. Modern PACS should be more than capable of reconstructing such series 'on the fly' from a standard thin-slice axial dataset, thereby making it viable to select only this one series for long-term storage.

If local factors require that all the other reconstructions are also sent to the live PACS for initial reporting then an equivalent approach would be to discard these 'duplicate' series from the local or archive storage after a set period of time, leaving only the thin-slice

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data. However, care must be taken to ensure that any saved key images or structured displays remain functional, particularly where findings of note have been highlighted. Additionally, applying this approach to a cohort of similar exams without the need to manually check every case entirely depends upon the content management system (CMS) being able to accurately identify suitable series based on digital imaging and communications in medicine (DICOM) tags, other metadata or image features.

The Code is clear that records must be authentic, reliable, integral and usable throughout their life cycle. It does not however specifically address whether the record must remain unadulterated during the minimum retention period (ie, without partial data loss due to lossy compression or series rationalisation). If either of these approaches are being considered, it is important that expert advice is sought.

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Radiology record retention requirements in the code

The Code defines minimum retention periods for many record categories, as well as defining circumstances in which these periods can be extended.

- a. Default minimum retention periods are:
 - **Adults:** 8 years from when the patient was last seen
 - **Children:** until the child's 25th birthday (or 26th birthday if 17 when last seen)
- b. Direct clinical care exceptions are:
 - Cancer diagnosis: 30 years from diagnosis or 8 years after the death of the patient, whichever is later³
 - Creutzfeldt-Jakob disease (CJD) diagnosis: 30 years from when the patient was last seen or 10 years after the death of the patient, whichever is later
 - Transplantation: 30 years from the date of transplant
 - Continuity of care purposes (chronic diseases or illness that may reoccur): 20 years from when the patient was last seen or 10 years after the death of the patient, whichever is later
 - Screening (including mammography): 10 years from the study acquisition date
 - Obstetric ultrasound (mother's record): 25 years from when the patient was last seen.

Other exceptions are:

- Public inquiry (eg, COVID, historic child sex abuse, infected blood)
- Subject access request (SAR), Freedom of Information Act (FOIA) request
- Legal proceedings
- Coroner's inquest
- Selected for permanent preservation under the Public Records Act.

Note: 'Last seen' relates to any visit (not just to radiology) to the organisation that stores the record and is responsible for its retention. With the recent expansion in the use of virtual clinics and home monitoring, it would seem appropriate to also include these methods of contact within this definition.

Role of the RMS

In order for the RMS to calculate the relevant period, it must have visibility of several data fields, including those relating to patient demographics (dates of birth, death, discharge, imaging study), which should already be available via existing HL7 interfaces. More challenging is disease classification data (ICD10 code), which most likely already exists in a clinical coding system but, within the NHS at least, is unlikely to be shared with an existing RMS. Even if not directly linked, it may still be possible for the source system to

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be manually searched for relevant cases on a regular schedule, an approach that would also apply to the 'other exceptions' category. In this case a flag should then be manually set in the RMS to support automatic processing when the retention period has expired

Record appraisal

Once the minimum retention period has been reached (as indicated by the RMS), the Code mandates that an appraisal is carried out. In the absence of any indication for continued retention, a decision can be made to delete the record, but this process must be fully auditable, with a metadata stub showing what has been destroyed being retained within the RMS. For well-managed digital records, the decision-making process and resultant outcome can be applied to an entire class of records at once, rather than each record in turn.

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Recommendations: a real world approach

Irrespective of whether an organisation implements record destruction as part of a life cycle management policy, the Code must still be followed with regard to how imaging records are stored and maintained. Organisations are therefore encouraged to review existing procedures to ensure compliance.

As discussed above, the majority of care providers impacted by the Code do not have digital systems that will allow the RMS to automatically and accurately identify records that are subject to continued retention beyond the 'default patient' period. It is also unlikely that few institutions will have the necessary staff resources available to complete this process manually.

In recognition of these limitations and on the assumption that long-term record storage is in the best interests of the patient, a simple retention period algorithm that could be adopted would be the latest of:

- a. 30 years from when the patient was last seen
- b. 10 years after the death of the patient.

Additionally, it is recommended that NHS organisations review current image storage practice, with the aim of limiting the volume of data being stored long term and thereby reducing the financial and environmental burden.

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References

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The Radiology Informatics Committee

The Royal College of Radiologists
63 Lincoln's Inn Fields
London, WC2A 3JW, UK



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is a Charity registered with the
Charity Commission No 211540.

+44 020 7405 1282
enquiries@rcr.ac.uk
rcr.ac.uk

Instagram X @RCRadiologists



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