The Royal College of Pathologists
Pathology: the science behind the cure

Guidelines on veterinary necropsy practice

Storage and retention of animal tissues and records

January 2026

Authors: Professor Alastair MacMillan, University of Surrey
Professor Roberto La Ragione, University of Surrey
Dr Kate English, University of Surrey

Unique document number	G184
Document name	Guidelines on veterinary necropsy practice: Storage and retention of animal tissues and records
Version number	V2
Produced by	The specialist content of this guideline was produced by: Professor Alastair MacMillan, Visiting Professor, School of Veterinary Medicine, University of Surrey Professor Roberto La Ragione, Professor of Veterinary Microbiology and Pathology, School of Veterinary Medicine and Interim Pro-Vice-Chancellor and Executive Dean, Faculty of Health and Medical Sciences, University of Surrey Dr Kate English, Senior Lecturer in Veterinary Clinical Pathology, University of Surrey.
Date active	July 2025 **(to be implemented within 3 months)**
Date for full review	July 2030
Comments	This document will replace the 1st edition of the *Best practice recommendations: Storage and retention of animal tissues and records*, published in 2020. In accordance with the College's pre-publications policy, this document will be on the Royal College of Pathologists' website for consultation from 5 August to 2 September 2025. Responses and authors' comments are available to view at

	www.rcpath.org/profession/publications/documents-in-development.html. **Dr Brian Rous and Sarah Davies,** **Clinical Leads for Guideline Adjudication**

The Royal College of Pathologists
6 Alie Street, London E1 8QT
Tel: 020 7451 6700
Fax: 020 7451 6701
Web: www.rcpath.org

Registered charity in England and Wales, no. 261035

Contents

Foreword

Guidelines published by the Royal College of Pathologists are guidelines that should assist pathologists in providing a high standard of care for patients. Guidelines for veterinary pathologists also assist pathologists in advising referring veterinarians and the owners or keepers of animals about appropriate treatment. Where veterinary surgeons are undertaking veterinary pathology, they must comply with the Royal College of Veterinary Surgeons (RCVS) Code of Professional Conduct and its supporting guidance. This RCPath guideline provides best practice recommendations that complement, but do not replace, RCVS professional conduct requirements. Furthermore, there are many important legal, ethical, logistical and professional responsibilities for pathologists to consider when carrying out their work. This guideline has been developed to cover most common circumstances. However, we recognise that guidelines cannot anticipate every pathological specimen type and clinical scenario. The guidelines themselves constitute the tools for implementation and dissemination of good practice although occasional variation from the recommended practice may therefore be required if circumstances demand.

The following stakeholders were contacted to consult on this document:

- RCVS
- European College of Veterinary Pathologists
- IDEXX Laboratories Ltd
- Veterinary Pathology Group
- International Zoo Veterinary Group
- American College of Veterinary Pathologists
- European College of Veterinary Clinical Pathology
- European College of Veterinary Microbiology.

No major organisational changes or cost implications have been identified that would hinder the implementation of the guideline.

The information used to develop this guideline was taken from *G184 Best practice recommendations: Storage and retention of animal tissues and records*, originally published in July 2020 at the request of the RCPath Veterinary Pathology Specialty Advisory Committee (SAC) with the following terms of reference: *"*To make

recommendations on minimum retention times for pathology records, tissues and semi-permanent or permanent pathological preparations, including those required for operational use, for education, teaching, training and general scholarship, for research per se, for historical purposes and against the possibility of future litigation, audit or allegations of scientific fraud and to report to Council."

Since the major considerations underlying the development of these guidelines are legal, ethical, logistical and professional, the primary sources of information were current legislation, professional guidance, institutional protocols, standard operating procedures and expert opinion. Published sources were obtained by undertaking a review of legislation.gov.uk, hse.gov.uk and the RCVS Code of Professional Conduct for Veterinary Surgeons. Pertinent information published by the College at rcpath.org was also searched. All relevant legislation, regulations and ethical guidance existing at the time of publication of these guidelines was included.

Published evidence was evaluated using modified SIGN guidance (see Appendix B). Consensus of evidence in the guideline was achieved by expert review. Gaps in the evidence were identified by College members via feedback received during consultation.

A formal revision cycle for all guidelines takes place on a 5-year cycle. The changes will be incorporated into the guideline and the full revised version (incorporating the changes) will replace the existing version on the College website.

The guideline has been reviewed by the Professional Guidelines team, Veterinary Pathology SAC and Lay Advisory Group and was placed on the College website for consultation with the membership from 5 August to 2 September 2025. All comments received from the membership were addressed by the authors to the satisfaction of the Clinical Lead for Guideline Adjudication.

The guideline was developed without external funding to the writing group. The College requires the authors of guidelines to provide a list of potential conflicts of interest; these are monitored by the Professional Guidelines team and are available on request. The authors of this document have declared that there are no conflicts of interest.

1 Introduction

The Human Tissue Act 2004 regulates the removal, storage, handling and testing of human cells, tissues and DNA including organs for transplantation.[1] Consent is the fundamental principle that underpins the legislation but the Act lays down many other responsibilities and constraints on laboratories including licensing by the Human Tissue Authority.[2]

However, there is no equivalent comprehensive legislation covering animal bodies, tissues and other samples, and clear guidelines are currently unavailable. Nevertheless, there are many important legal, ethical, logistical and professional considerations that apply, and this document is intended to provide a framework and guidance for best practice in veterinary pathology laboratories and elsewhere where veterinary pathology is carried out.

In recent times, there have been major changes in attitudes towards the use of data, the use of animals and on issues of consent. Previously, less consideration may have been given to the wider issues and responsibilities that surround and accompany the practice of veterinary pathology. Guidance for medical pathology laboratories was first issued by the College in 1994; subsequent editions have reflected emerging technologies such as genetic testing, the increased use of data storage and the security concerns that accompany it, and society's increasing concern about consent. This need was underlined by the introduction of the Human Tissue Act 2004,[1] which itself was enacted in response to serious public concern following the inappropriate retention of human organs and tissues.

Particularly in the absence of equivalent legislation, it is now clear that similar guidance needs to be established for veterinary pathology laboratories and elsewhere where veterinary pathology is carried out. The scope of veterinary pathology is vast, covering a wide range of species, including companion animals, production animals, zoo animals and wildlife. The purposes for which it is carried out are also diverse, such as for diagnostic or treatment purposes, investigation of disease outbreaks and forensic enquiry. Samples may be collected from the live animal or at post-mortem examination (PME), and they may be processed in veterinary practices, abattoirs or pathology laboratories. These samples may include blood, tissue, faeces, urine, body parts or whole cadavers. PMEs may often be carried out in the field, for example on farms, in hunt kennels or at knacker's yards. Samples are considered animal by-products, and the nature of the sample – and whether

it has been obtained from a live or dead animal – may determine the degree of regulation with which it should be handled in line with guidance for the animal by-product industry.[3] Facilities that regularly conduct PMEs and take samples may be required to be registered as animal by-product handling sites.[4] These samples must be handled and disposed of safely, maintaining good sample tracking and an audit trail, and they must be treated sensitively, particularly when dealing with the remains of companion animals. The introduction of quality accreditation schemes has mandated and formalised these requirements.

Information associated with these materials, such as their origin and identity, the identity of owners, the results of testing and resulting diagnoses, must be treated confidentially. Indeed, the enactment of the Data Protection Act 2018,[5] which is the UK's implementation of the General Data Protection Regulation (GDPR), has imposed an even greater responsibility to protect sensitive data.[6]

In the UK, diagnostic veterinary pathology is covered by the definition of veterinary surgery in the Veterinary Surgeons Act 1966 and can only legally be undertaken by veterinary qualified (MRCVS/FRCVS) pathologists.[7] Veterinary surgeons undertaking veterinary pathology must comply with the requirements of the Royal College of Veterinary Surgeons' (RCVS) Code of Professional Conduct.[8] This includes requirements relating to consent, confidentiality, record-keeping and disposal of animal remains. The RCVS guidance is subject to regular review and update, so where this guideline addresses areas covered by RCVS requirements, we indicate this and refer the reader to current RCVS guidance rather than reproducing it.

This RCPath guideline must be read alongside current RCVS guidance, which takes precedence for matters of professional conduct.[9]

Support can be obtained from the Standards and Advice team on advice@rcvs.org.uk or via 020 7202 0789.

Specific RCVS guidance relevant to veterinary pathology includes:

- client confidentiality[10]
- use and reuse of samples, images, post-mortems and disposal[11]
- informed consent.[11]

Veterinary surgeons have a professional duty of confidentiality to their clients, governed by the RCVS Code of Professional Conduct [*RCVS requirement*]. The duty of confidentiality is

important, but it is not absolute. Information can be disclosed in certain circumstances, including where the client's consent has been given, where disclosure is required by law or can be justified by animal welfare concerns, or when the wider public interest justifies disclosure. The RCVS provides detailed guidance on when and how confidentiality may be breached. Veterinary surgeons must consult the full RCVS guidance on client confidentiality.[10] This guidance is regularly updated and should be read in full to understand the complete context and requirements. Key considerations include:

- circumstances where disclosure without consent may be justified
- non-accidental injury and animal welfare concerns
- deceased animals and risk to other animals in the client's care
- public interest considerations.

The GDPR permits the processing of personal data where it is necessary for compliance with a legal obligation or for the purpose of a legitimate interest (except where the interests or fundamental rights and freedoms of the relevant individual override this). The processing of special category data (e.g. relating to the individual's health or ethnic origin) is more restricted; in this context, it could be disclosed where necessary for reasons of substantial public interest (e.g. to prevent or detect unlawful acts, protect the public against dishonesty, protect public health or prevent fraud). Accordingly, the GDPR is not a barrier to reporting concerns and suspicions to the appropriate authorities.

The RCVS provides specific guidance on obtaining consent for sharing confidential information. Veterinary surgeons should refer to this guidance for detailed requirements on express versus implied consent, verbal versus written consent and circumstances where consent may be implied. In all cases involving personal data, consent must be express, specific and informed *[RCVS requirement]*.

Disclosure may be justified where animal welfare is compromised. When a veterinary pathologist discovers injuries that cannot be attributed to the history provided by the client, they should include non-accidental injury in their differential diagnosis. The RCVS provides guidance for the veterinary team on dealing with situations where non-accidental injury is suspected *[RCVS requirement]*.[8,10] Members of the Veterinary Defence Society can access such guidance on the Veterinary Defence Society's website.[12]

If there is suspicion of animal abuse (which could include neglect) as a result of carrying out pathological investigation, veterinary surgeons should follow RCVS guidance on the

appropriate steps to take, including when and how to discuss concerns with the client and when disclosure to authorities may be justified.

1.1 Target users and health benefits of this guideline

The target primary users of this guideline are veterinary pathologists, veterinary clinicians, veterinary nurses and ancillary staff involved in the PME of animals in clinical veterinary practice and research. This will include veterinary pathology staff in specialist institutes, universities or companies, or veterinarians carrying out occasional PMEs in general practice. It includes staff carrying out gross PMEs or staff handling tissues for histological, cytological or microbiological investigations. The recommendations will also be of value to staff cleaning the facilities and disposing of clinical waste and animal tissues after PMEs have been carried out.

Veterinarians who are members or fellows of the RCVS must adhere to the RCVS Code to Professional Conduct (the Code). Throughout this guideline:

- *[RCVS requirement]* indicates matters governed by the RCVS Code of Professional Conduct, which are mandatory for veterinary surgeons
- *[RCPath recommendation]* indicates best practice guidance from the Royal College of Pathologists

Where RCVS requirements apply, veterinary surgeons should refer to current RCVS guidance as it may be updated more frequently than this guideline.

1.2 Scope of this guidance

This guidance deals with veterinary pathology facilities and does not include veterinary clinical pathology or veterinary microbiology laboratories in its scope. It specifically excludes pathological studies carried out as part of good laboratory practice (GLP) regulatory studies under the UK GLP Compliance Monitoring Programme, which has specific guidance on storage and retention times administered in the UK by the Medicines and Healthcare products Regulatory Agency. The document is intended to provide general guidance on good practice, but additional requirements that may be imposed on research governed by the Animals (Scientific Procedures) Act 1986[13] or clinical trials carried out under the Veterinary Medicines Regulations 2013[14] are not covered.

Unlike medical pathology, where pathological investigation can only be carried out in a hospital setting or pathology laboratories licensed under the Human Tissue Act 2004,

veterinary pathology including PME may be carried out in a wide variety of situations, such as on a farm, in an abattoir, in a knacker's yard, at a hunt kennels, in a veterinary practice and in a veterinary pathology laboratory, although where PMEs are regularly undertaken should be registered as animal by-product handling sites.

In most cases, archived specimens are held primarily to benefit the medical care of the individual animal or group of animals, or for preventative purposes. Such samples will have been collected with the knowledge and written or implied consent of the owner of those animals for the primary reason for collection.

In other cases, samples may be collected for statutory purposes as part of a national disease control scheme or other wider disease control or disease-freedom certification purposes under overarching legislation such as the Animal Health Act 1981[15] or various other primary or secondary legislation that may pertain at the time. In such cases, samples may be collected without the consent of the owner of the animals, but the pathologist will be bound by the requirements under which the samples are collected. Indeed, in some cases, it is not permissible to collect or test samples, such as samples for the diagnosis of tuberculosis (TB) in cattle under Article 10 of the Tuberculosis (England) Order 2014.[16]

Samples may be collected as evidence as part of a criminal investigation, such as to support allegations of animal abuse, wildlife crime or indeed a wide range of other crimes where animals may be involved. The handling, retention and disposal of such evidential samples and accompanying data are dealt with by legislation including the Police and Criminal Evidence Act 1984[17] and code of practice[18] under Part II of the Criminal Procedure and Investigations Act 1996.[19]

Samples are also collected from experimental animals involving studies for scientific or educational purposes, governed by the provisions of the Animals (Scientific Procedures) Act 1986,[13] or as part of clinical trials required to be carried out for marketing authorisations of veterinary medicinal products as a requirement of the Veterinary Medicines Regulations 2013.[14] Retention of records in these circumstances are covered by the specific requirements of the respective legislation.

2 The nature of pathology records

2.1 Clinical and diagnostic records and reports

Depending on the purpose of the pathological investigation, electronic and/or paper records of the results together with the details of the source of the samples and ownership of the animals from which they have been collected will be generated, sometimes along with client financial information. Such records will need to be sent to the requesting veterinarian or agency and be safely stored for an appropriate length of time. Paper records must be securely stored to prevent damage, deterioration or unauthorised access.

Similarly, electronic records should be stored securely and frequent backups made and stored separately. This will need to be done wherever the pathological investigation is carried out; in laboratories or large practices, such administration will be carried out centrally. However, their ease of access and dissemination necessitates even more stringent security arrangements for transmission, such as encryption and password protection. They also carry different risks of corruption or loss from those of hard-copy records; arrangements for regular and accurate back-up are essential. The speed of change in IT provision makes it essential to ensure that such records remain accessible for the full period of their retention and possible use.

There is no single standard requirement for how long records should be stored, but minimal retention periods may be laid down for investigations carried out under statutory schemes, or under laboratory assurance quality systems. In the case of records of pathological investigations carried out as part of criminal or civil court cases, it is wise to keep records indefinitely. In the case of records of routine diagnostic work, it is suggested that records should be kept for a minimum of 5 years. However, with modern IT systems with plentiful storage, archived material may wisely be kept for much longer periods, even where the data has been passed to the requesting clinician. Transmission of electronic records should be in an unalterable format. It is important that these policies are clearly defined and recorded, particularly if the laboratory is accredited under a quality scheme.

Ideally, client financial information and any other personal or sensitive information should be recorded separately from clinical records. This is because only relevant clinical information should be provided to professional or other colleagues in connection with the case.

Depending on the quality system by which the laboratory is accredited or other requirements laid down by legislation or indeed just good practice, other information will need to be stored and retained for a suitable period. For example, under ISO/IEC 17025, individual test calibration records (if applicable), quality assurance records, laboratory staff training and health surveillance, and other relevant laboratory management information should be retained for a period defined in the laboratory's records retention policy.

Field-based or 'penside' PME or testing should also comply, in general, with the foregoing guidelines and be subject to accreditation and quality control procedures to standards equivalent to those that would be expected in a routine laboratory.

[Level of evidence – GPP.]

2.2 Laboratory, post-mortem room and practice working records: reports and documentation for internal use

These include a vast range of daily working documents needed for the day-to-day operation of a laboratory or pathology service such as:

- request forms
- day books
- worksheets
- batch records (of reagent batches linked to series of specimens and specimens analysed as cohorts on automated instruments)
- graphic output from instruments
- refrigerator and freezer temperature records
- photographic records
- catalogues of the pathological archive or museum
- bound copies of reports and records
- point-of-care 'penside' test data
- correspondence
- records of telephoned, faxed and emailed reports and discussions
- equipment maintenance logs

- quality control and quality assurance records
- standard operating procedures
- accreditation documents
- records of inspections.

As these will not ordinarily be shared with the requesting clinician or agency, it is important that these records are safely retained for a period in line with the defined policy. The retention time should be sufficient to reliably cover a period during which the pathological investigation may be in question, but it is prudent to retain such records for as long as possible. Paper records may need to be stored in a different location if storage space is limited in the laboratory; if so, the records should be catalogued for easy access. The criteria for storage described above should apply.

[Level of evidence – GPP.]

3 Recommendations

3.1 The management of records and specimen archives: general comments

Diagnostic record keeping is ultimately the responsibility of the requesting clinician or agency once the laboratory report has been issued. However, the laboratory or practice should retain records for internal uses, such as correlation with results from previous and subsequent specimens, responding to queries or challenge, and audit and quality assurance.

Consent should be obtained for sample collection and use *[RCVS requirement and RCPath recommendation]*. Where storage of material is no longer required for clinical purposes, but is desirable for teaching, quality assurance, audit, research or other purposes of public benefit, the ethical and legal acceptability of continued storage must be reviewed *[RCVS requirement]*. The RCVS provides comprehensive guidance on consent that veterinary surgeons must follow. Veterinary surgeons must refer to current RCVS guidance on informed consent and use and reuse of samples, images, post-mortems and disposal.[11] This RCVS guidance covers who can provide consent, written versus oral consent, contractual relationships, establishing who the client is, mental incapacity, dealing with young persons, consent forms and consent for sample reuse. *[RCPath*

recommendation]. The legitimacy of future storage for such purposes is influenced by the presence or absence of appropriate consent. Clients should consent to sample collection for diagnostic/treatment purposes and, generally, should also reuse of samples for other purposes (e.g. teaching, research, quality assurance). If a referring veterinarian collected the sample, ensure original consent covered potential reuse. Consent forms should be used as an aid to discussion with the client. Retain a copy and provide one to the client.

[Level of evidence – GPP.]

The RCVS has produced detailed guidance on informed consent.[11] This includes guidance on written/oral consent, contractual relationships, establishing who the client is, confirming the client has understood what has been said, mental incapacity, dealing with young persons and children, and consent forms. The client may be the owner of the animal, someone acting with the authority of the owner, or someone with statutory or other appropriate authority. Care should be taken when the owner is not the client; veterinary surgeons must ensure they are satisfied that the person providing consent has the authority to do so. Informed consent, which is an essential part of any contract, can only be given by a client who has had the opportunity to consider the consequences of the proposed action and had the significance and main risks explained to them.

Under current legislation in England and Wales, samples can be taken under the Animal Health Act 1981 as amended for the control of specified diseases, but this legislation arguably provides insufficient powers for general and pre-emptive surveillance testing.[15] Scottish legislation allows the use of samples for more than 1 purpose. There are additional provisions set out in European legislation that relate to the taking of samples.

The legal obstacles to the reuse of samples for general disease surveillance can be overcome with the specific consent of the client. This could be set out in a suitably worded consent form, making the client aware of the reuse of the samples from their animal *[RCVS requirement]*.

If the client's personal data will be collected with, or connected to, the samples from their animal, the consent form should provide clear information about how that data will be used, by whom and for what purpose(s). The form can ask for consent to collect and process the data, or it may be more appropriate to rely on another legal basis, for example if it is necessary to process the data for compliance with a statutory obligation, to perform the contract with the client, to perform a task in the public interest, or possibly for the

veterinary surgeon's legitimate purposes. The form should make clear which basis is being relied on.

The reuse of samples without the consent of the client may be reasonable for animal welfare, education or public interest reasons – for example, disease surveillance by the state, or where obtaining consent of the relevant animal owners is impracticable and the samples are reused anonymously. Nevertheless, consent should be obtained wherever possible, although – where the animal is ill or recently deceased – veterinarians should be mindful that owners may be in an emotional or distressed state at this time *[RCVS requirement]*. Generally, a veterinary surgeon should seek informed consent from the owner to dispose of the cadaver and ensure that any third party involved in the disposal is appropriately licensed, for example if the animal is to be cremated. For detailed requirements, see RCVS guidance on use and reuse of samples, images, post-mortems and disposal *[RCPath recommendation]*.[11]

Generally, a veterinary surgeon should seek client consent before taking and retaining images of animals, especially where it would be possible to recognise the animal and, therefore, possibly the client. Clients should also be informed about the ways in which the images will be used. There are reasons why individual pathologists or heads of departments may wish to retain documents or materials for longer periods than the minimum times recommended here. Reasons for retention of tissue without consent, largely because they are regarded as a necessary part of the process of providing a veterinary diagnostic service, are:

- further diagnosis or ongoing clinical management
- clinical audit (this term should be interpreted selectively to encompass defined, planned and documented audit activities rather than used as a generic reason to retain samples 'just in case')
- quality assurance, including internal quality control and external quality assessment
- teaching and training healthcare staff
- epidemiology
- analysis of data for administrative or other purposes
- direct evidence in litigation

- individual, active research studies for which data or samples are suitably anonymised and current approval is in place for the purpose, given by a recognised research ethics committee of the pathologist's own institution or the Ethics Review Panel of the RCVS[20]
- archives of specimens for which the predictable diagnostic purposes are complete and may in some circumstances be used as tissue banks for anonymous research use.

However, if the material is not needed for clinical purposes, but continued retention is desirable, in some circumstances anonymisation will be necessary. If information is rendered 'not identifiable', this removes it from the remit of the Data Protection Act.[5] Under some circumstances, secure coding of data may have the same effect, but expert advice should be sought, usually from an institution's data protection officer.

Where laboratories or practices are to be closed, or where a contract to provide a pathology service is transferred to another provider, pathologists and laboratory and hospital managers must consider the need to retain and relocate certain records and materials. This maintains continuity of essential data storage, while the records remain accessible at all times for clinical purposes. There should be an explicit agreement as to which organisation assumes responsibility for the retained records and materials; access procedures should be defined clearly and made known to users.

It has been established legally that the mere possibility of pathological material or related documentation constituting material evidence in future litigation is not a sufficient ground for imposing a duty to store indefinitely. As litigation can arise many years after the relevant treatment is complete, maintaining records for extended periods sufficient to satisfy all potential medicolegal interests is unrealistic. It should be noted, however, that once particular legal proceedings have commenced, or there is a reasonable expectation that they are about to commence, any archive destruction policy should be suspended in respect of all documents or specimens relevant to that matter (Criminal Procedure and Investigations Act 1996).[18] It is important that storage conditions under which cells, tissues, derived materials, reagents and records are kept are defined. With regard to reagents, there is clear guidance from the Control of Substances Hazardous to Health (COSHH).[21] These conditions should be clearly recorded as laboratory policies. Regarding records, laboratories or practices should have local policies and procedures to ensure appropriate back-up and secure data storage, with which pathology laboratories should comply. Where specific requirements are needed for particular specimens, for example refrigerated or frozen storage, appropriate arrangements should be in place to ensure

maintenance of the correct storage temperature, including emergency arrangements in case of power supply failure. Appropriate light, temperature and humidity conditions should be provided for temporary storage of ‘transient’ preparations, such as fluorescently labelled cells and tissue sections, and for other ‘wet’ preparations. These requirements are all encompassed by accreditation standards now incorporated under the umbrella of the United Kingdom Accreditation Service (UKAS) used by diagnostic and research laboratories (including contract research organisations).

It should be noted that tissue retention times in commercial settings vary but, generally, tissues are retained by companies for significant periods to support the possible need for subsequent re-evaluation, should the need arise, such as human/ecological safety issues.

[Level of evidence B – Obtaining consent for retention of data and specimens.]

3.2 Documents, electronic and paper records

Laboratories or practices that store data relating to identifiable human individuals must register with the Information Commissioner’s Office. It is important to proceed with caution if there is any doubt. The rules and minimum retention times are not influenced by whether information is in electronic or paper form, although measures to ensure the security and integrity of the information will differ.

The recommendations for retention times listed below are intended to ensure that samples and records remain available for sufficient time for re-examination to be carried out in the event of doubt or dispute and until such time as such uncertainty or challenge becomes unlikely. Many of the times are based on those included in the equivalent document applying to medical pathology laboratories as these have been developed and refined over a number of years.

The suggested times for the retention of samples are based on the type of sample, their lability and whether repeat analysis would be possible or necessary. The suggested times for the retention of records at the pathological facility are based on the type of record, whether it is interim or definitive, whether data may be useful for research or further analysis and whether the record will be retained elsewhere by the submitting client.

3.2.1 Request forms

Request forms should be kept until the authorised report, or any reports on investigations arising from it, have been received by the requester. However, they should not be kept for longer than 1 month after the final report has been dispatched, unless the request form is

used to record working notes, to document client consent for the reuse of tissues for teaching and/or research, or as a worksheet when it should be retained as part of the laboratory record.

3.2.2 Daily work logs (day books and electronic equivalents) and other records of specimens received by a laboratory

It is recommended that these are retained for 8 years to ensure availability for review through at least 2 full cycles of laboratory accreditation.

3.2.3 Protocols or standard operating procedures

Both current and replaced documents should be retained for at least 10 years.

3.2.4 Worksheets or other working records of test results

These should be retained for as long as the associated sample is kept, or until the completed final report is submitted for labile or perishable samples.

3.2.5 Records of telephoned or faxed reports and other correspondence

Note of the fact and date/time that a telephoned or faxed report has been issued should be added to the laboratory electronic record of the relevant report, or to hard copies, and kept for a minimum of 5 years. Clinical information or management advice provided electronically or by fax, or a transcript of such advice given on the telephone, should also be kept as correspondence filed in the case notes.

3.2.6 Final report of investigations

Standard diagnostic reports should be kept for a minimum of 5 years. This retention period must be fully recorded in the laboratory's record retention policy as required by the applicable quality system. However, reports of investigations carried out under statutory or contracted schemes must be kept for the period required by those programmes. Reports associated with criminal or civil court cases should be kept indefinitely.

3.2.7 Point-of-care 'penside' test data

Results should be entered into the case record and the log of tests should be retained for the lifetime of the instrument or 5 years, whichever is longer. As these tests are conducted outside the laboratory premises, appropriate governance arrangements should be defined to ensure adequate retention and confidentiality.

3.2.8 Pathological archive or museum catalogues

These should be kept for as long as the samples or specimens are held or the catalogue updated.

3.2.9 Photographic or other digital records

Images that represent a primary source of information for the diagnostic process (e.g. some macroscopic specimen records, images from PMEs and images of histological slides) should be kept for at least 10 years. In increasingly frequent circumstances, images of pathological specimens are produced as an alternative to storing the specimen itself. At present, this should be done only where it is possible to be confident that the image contains all the diagnostic information in the original specimen, and that its storage will satisfy any possible future requirements. In such circumstances, the images should be stored for at least as long as is recommended for the specimens from which they are derived, with continued accessibility and assured storage conditions to avoid deterioration in quality over time. They must be linked to the case records and appropriately backed up.

Where images represent a means of communication or aide memoire, for example at multidisciplinary meeting or case conference, they may be disposed of when that function is complete.

3.2.10 Batch records, quality control and quality assessment records, accreditation documents, records of inspections and records relevant to production of diagnostic products or equipment

These should be retained for a minimum of 8 years to ensure continuity of data available for laboratory accreditation purposes over 2 inspection cycles and equivalence with performance records for the equipment used.

3.2.11 Temperature records for refrigerators, freezers and cold stores

Plots of continuous records should be summarised regularly to provide summated statistics. Daily records should be retained for at least 2 months; summarised temperature records should be retained for at least 8 years.

3.2.12 Equipment maintenance logs

These should be retained for the lifetime of the instrument plus a minimum of 4 years (to encompass at least 1 full accreditation cycle after the lifetime is complete).

3.2.13 Records relevant to the production of diagnostic products or equipment, and to assay validation and verification

Performance claims must be verified by UKAS before being introduced. Records should be kept of the methods used and results obtained for at least 8 years.

3.3 Samples, specimens and preparations

A wide variety of samples of biological material may be collected and stored as part of a veterinary pathological investigation. Samples include:

- whole carcasses of a variety of species
- stored biological specimens, such as blood, serum, urine, faeces, cells and tissue, including part or whole-body organs
- tissue blocks
- wet preparations, including fixed tissue samples of any size
- stained slides or other permanent or semi-permanent preparations, including electrophoretic strips, immunofixation preparations, nucleic acid and protein blots
- museum specimens
- some rapid-testing cards, dipsticks or strips
- microbiological swabs and cultures, freeze-dried or otherwise preserved
- extracted nucleic acids of patient or cultured microbial origin.

3.3.1 Legal and ethical issues

There are no legal barriers to the reuse of samples for other purposes, including if the samples are collected for disease control purposes under the Animal Health Act 1981.[15] However, reuse requires specific informed consent and the RCVS has provided guidance on this for veterinary surgeons.[11]

3.3.2 Plasma and serum

Diagnostic samples should be kept for at least 48 hours after the final report has been issued by the laboratory unless there is a reasonable expectation that additional testing will be required (e.g. if the final report has requested that a follow-up test is done in parallel with retesting of the original sample). If there is a requirement to store for longer, specimens that have been centrifuged but not separated should be separated to prolong stability.

Other leftover sera or plasma should be stored for as long as is practicable, either frozen or lyophilised, to provide an array of material for future research and disease surveillance purposes. Where possible, laboratories should retain appropriate sera indefinitely to facilitate retrospective studies in identifying emerging infections and vaccination programme monitoring. Special consideration should be taken to determine if the samples contain cells or are cell free. Laboratories must consider the need for consent.

3.3.3 Body fluids, aspirates and swabs (including liquid-based cytology specimens)

These should be kept for 48 hours after the final report has been issued by the laboratory, unless sample deterioration precludes storage.

3.3.4 Whole-blood samples for full blood count

These should be kept for 24 hours after the final report has been issued by the laboratory, unless sample deterioration precludes storage.

3.3.5 Paraffin wax or resin embedded blocks for histology, blocks for confocal/electron microscopy and grids for electron microscopy

Storage for at least 10 years is recommended, if facilities permit. If not, review the need for archiving at 5 years (and at similar intervals thereafter) and select representative blocks for permanent retention.

3.3.6 Release and return of archived diagnostic samples for clinical trial purposes

Translational research using diagnostic samples traditionally seen as ‘surplus’ – is an increasingly frequent component of clinical trials and it can be anticipated that this trend will continue for the foreseeable future. Molecular or immunohistological testing of a pre-existing specimen as a component of selection for trial entry or allocation to a specified trial arm is another increasing requirement. These types of study now predominate over traditional observational studies within clinical trials involving review and return of the original diagnostic material (such as stained histological sections). They are often accompanied by a request to retain material for future, unspecified studies by the academic institution or commercial company coordinating the trial. All organisations involved in the use of animal-derived tissues must seek appropriate consent and ethical approvals. Ethical review can be carried out by an institution’s own ethics review panel or by the Ethics Review Panel of the RCVS.[20]

3.3.7 Wet tissue (representative portion or whole tissue or organ)

These should be kept for 4 weeks after issue of final report.

3.3.8 Museum specimens, where these are generally accessible for undergraduate or postgraduate study (teaching collections not accessible by members of the public)

These may be retained permanently (provided there is no deterioration or until replaced by a better specimen).

3.3.9 Stained slides

Appropriate retention times depend on their nature and purpose, but storage for at least 10 years is appropriate.

3.3.10 DNA and RNA

Appropriate retention times depend on their nature and purpose, but storage for at least 10 years is appropriate.

[Level of evidence – GPP.]

3.3.11 Microbiological culture

Most diagnostic cultures, including viral cultures, can be discarded within 24–48 hours of issuing a final authorised report. Certain organisms of particular clinical importance or unusual pathogens of clinical significance should be retained for at least 7 days or possibly longer for research purposes. Where isolates have been referred to reference laboratories, they should be retained until receipt of the reference laboratory's final report. Whenever cultures are stored, pathology staff have a duty to ensure that specimens are held safely and securely to guard against accidental or non-accidental mishap.

Certain organisms (or tissues or bodily fluids that may contain them) are hazardous and are classified under legislation in the UK. This legislation lists organisms of concern and lays down licensing arrangements and laboratory containment. This is of major importance to the subject matter of this guidance, but space only allows a summary of the issue here – for detailed guidance, readers should consult the Health and Safety Executive guidance.[21] Veterinary pathologists should ensure that they comply with appropriate regulations.

Organisms hazardous to human health are categorised by the COSHH Regulations 2002,[11] which require risk assessments to be carried out and appropriate containment, training and health surveillance to be adopted.

Organisms that could cause serious disease and economic loss to the livestock industry are covered by the Specified Animal Pathogens Order 2008 (SAPO).[22] Those who wish to possess or work with a specified animal pathogen or a carrier (in which a specified animal pathogen may be present) in England, Scotland or Wales need to obtain a SAPO licence.

[Level of evidence B – Retention of potentially hazardous organisms.]

3.4 Disposal

Generally, a veterinary pathologist should seek informed consent from the owner to dispose of the cadaver and should ensure that any third party involved in the disposal is appropriately licensed, for example if the animal is to be cremated *[RCVS requirement]*.

The correct disposal of animal remains, and other waste associated with the provision of a pathology service, is of major importance to the subject matter of this guidance, but space only allows a summary of the issue here. Veterinary pathologists should ensure that they comply with appropriate regulations, including those relating to the handling of animal by-products *[RCPath recommendation]*.

The Hazardous Waste (England and Wales) Regulations 2005 require producers of more than 200 kg of hazardous waste to register with the Environment Agency and comply with a variety of other responsibilities.[23]

[Level of evidence B – Correct disposal of animal biproducts and hazardous waste.]

4 Criteria for audit

As part of our Continuous Quality Improvement programme, the College promotes high-quality clinical audit.[24] Clinical audit is a process that seeks to identify where improvements can be made within healthcare services by measuring them against evidence-based standards.

The recommendations contained within this clinical guideline detail legal, professional and ethical responsibilities and so it should be expected that compliance is high. Deviation from the recommendations may be appropriate for operational reasons, but any variation should be documented along with the rationale adopted.

The following standards are suggested criteria based on these guidelines as being suitable for use in periodic reviews to assure and demonstrate good practice.

- The training records of 100% of established staff must contain evidence that they have received appropriate training on all aspects of this guidance relevant to their work.
- The laboratory or practices storing data relating to identifiable human individuals must be registered with the Information Commissioner's Office.
- 100% of a random sample of clinical submissions must show that the client has consented, including having given consent to further use for research or teaching where appropriate.
- 100% of a random sample of standard diagnostic final reports issued 5 years ago have been retained and are accessible.
- 100% of a random sample of daily work logs (day books and electronic equivalents) and other records of specimens received by the laboratory submitted 8 years ago have been retained and are retrievable.

[Level of evidence – GPP.]

5 References

1. UK Government. *Human Tissue Act 2004.* Accessed January 2025. Available at: www.legislation.gov.uk/ukpga/2004/30/contents
2. Human Tissue Authority. *Guidance for professionals.* Accessed January 2025. Available at: www.hta.gov.uk/guidance-professionals
3. UK Government. *Guidance for the animal by-product industry.* Accessed January 2025. Available at: www.gov.uk/government/collections/guidance-for-the-animal-by-product-industry
4. UK Government. *Handling and storing animal by-products.* Accessed January 2025. Available at: www.gov.uk/guidance/handling-and-storing-animal-by-products
5. UK Government. *Data Protection Act 2018.* Accessed January 2025. Available at: www.legislation.gov.uk/ukpga/2018/12/contents
6. Intersoft Consulting. *General Data Protection Regulation.* Accessed January 2025. Available at: https://gdpr-info.eu/
7. UK Government. *Veterinary Surgeons Act 1966.* Accessed January 2025. Available at: www.legislation.gov.uk/ukpga/1966/36
8. Royal College of Veterinary Surgeons. *Code of Professional Conduct for Veterinary Surgeons.* Accessed January 2025. Available at: www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/
9. The Royal College of Pathologists. *Best practice recommendations for veterinary surgeons seeking pathology expertise.* Accessed January 2025. Available at: www.rcpath.org/profession/guidelines/specialty-specific-publications.html
10. Royal College of Veterinary Surgeons. *Client confidentiality.* Accessed January 2025. Available at: www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/client-confidentiality/
11. Royal College of Veterinary Surgeons. *Use and re-use of samples, images, post mortems and disposal.* Accessed January 2025. Available at: www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/use-and-re-use-of-samples-images-post-mortems-and-disposal/

12. Veterinary Defence Society. *Veterinary Defence Society Webpage.* Accessed January 2025. Available at: www.thevds.co.uk/

13. UK Government. *Animals (Scientific Procedures) Act 1986.* Accessed January 2025. Available at: www.legislation.gov.uk/ukpga/1986/14

14. UK Government. *The Veterinary Medicines Regulations 2013.* Accessed January 2025. Available at: www.legislation.gov.uk/uksi/2013/2033/contents

15. UK Government. *Animal Health Act 1981.* Accessed January 2025. Available at: www.legislation.gov.uk/ukpga/1981/22

16. UK Government. *The Tuberculosis (England) Order 2014.* Accessed January 2025. Available at: www.legislation.gov.uk/uksi/2014/2383

17. UK Government. *Police and Criminal Evidence Act 1984.* Accessed January 2025. Available at: www.legislation.gov.uk/ukpga/1984/60/contents

18. Ministry of Justice. *Criminal Procedure and Investigations Act 1996 Code of Practice.* Accessed January 2025. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/447967/code-of-practice-approved.pdf

19. UK Government. *Criminal Procedure and Investigations Act 1996.* Accessed January 2025. Available at: www.legislation.gov.uk/ukpga/1996/25/contents

20. Royal College of Veterinary Surgeons. *Ethics Review Panel.* Accessed January 2025. Available at: www.rcvs.org.uk/who-we-are/committees/standards-committee/ethics-review-panel/

21. Health and Safety Executive. *Control of Substances Hazardous to Health (COSHH).* Accessed January 2025. Available at: www.hse.gov.uk/coshh/

22. UK Government. *The Specified Animal Pathogens Order 2008.* Accessed January 2025. Available at: www.legislation.gov.uk/uksi/2008/944/contents

23. UK Government. *The Hazardous Waste (England and Wales) Regulations 2005.* Accessed January 2025. Available at: www.legislation.gov.uk/uksi/2005/894/contents/made

24. The Royal College of Pathologists. *Conducting a clinical audit.* Accessed January 2025. Available at: www.rcpath.org/profession/patient-safety-and-quality-improvement/conducting-a-clinical-audit.html

Appendix A Summary of recommended retention times

Note: The retention times quoted below are intended only as a quick reference and the reader is urged to consult the full text in this document and any external guidance or legislation recommended.

Record, document or specimen	Retention time
Request forms	1 month after the final report
Daily work logs	8 years
Protocols or standard operating procedures	10 years
Worksheets	As long as the associated sample is kept
Records of telephoned reports and other correspondence	At least 5 years
Final report of investigations	At least 5 years
Point-of-care ‘penside’ test data	Lifetime of the instrument or 5 years, whichever is longer
Pathological archive	As long as the specimens are held
Photographic or other digital records	At least 10 years
Quality assurance records	At least 8 years
Temperature records	Daily records for at least 2 months and summarised records for at least 8 years
Equipment maintenance logs	Lifetime of the instrument plus a minimum of 4 years
Records of reagent production, equipment or assay validation	At least 8 years
Plasma and serum	At least 48 hours after the final report is issued
Body fluids, aspirates and swabs	At least 48 hours after the final report is issued
Embedded blocks for histology or microscopy	At least 10 years
Wet tissue	4 weeks after issue of the final report
Museum specimens	May be retained permanently
Stained slides	At least 10 years
DNA and RNA	At least 10 years
Microbiological cultures	24–48 hours after issuing the report

Appendix B Summary table – Explanation of grades of evidence

(modified from Palmer K *et al. BMJ* 2008;337:1832)

Grade (level) of evidence	Nature of evidence
Grade A	At least 1 high-quality meta-analysis, systematic review of randomised controlled trials or a randomised controlled trial with a very low risk of bias and directly attributable to the target population or A body of evidence demonstrating consistency of results and comprising mainly well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias, directly applicable to the target population.
Grade B	A body of evidence demonstrating consistency of results and comprising mainly high-quality systematic reviews of case-control or cohort studies and high-quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relation is causal, and which are directly applicable to the target population or Extrapolation evidence from studies described in A.
Grade C	A body of evidence demonstrating consistency of results and including well-conducted case-control or cohort studies and high-quality case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relation is causal, and which are directly applicable to the target population or Extrapolation evidence from studies described in B.
Grade D	Non-analytic studies such as case reports, case series or expert opinion or Extrapolation evidence from studies described in C.
Good practice point (GPP)	Recommended best practice based on the clinical experience of the authors of the writing group.

Appendix C AGREE II guideline monitoring sheet

The guidelines of The Royal College of Pathologists comply with the AGREE II standards for good quality clinical guidelines. The sections of this guideline that indicate compliance with each of the AGREE II standards are indicated in the table.

AGREE standard	Section of guideline
Scope and purpose	
1 The overall objective(s) of the guideline is (are) specifically described	Introduction
2 The health question(s) covered by the guideline is (are) specifically described	Introduction
3 The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described	Foreword
Stakeholder involvement	
4 The guideline development group includes individuals from all the relevant professional groups	Foreword
5 The views and preferences of the target population (patients, public, etc.) have been sought	Foreword
6 The target users of the guideline are clearly defined	Introduction
Rigour of development	
7 Systematic methods were used to search for evidence	Foreword
8 The criteria for selecting the evidence are clearly described	Foreword
9 The strengths and limitations of the body of evidence are clearly described	Foreword
10 The methods for formulating the recommendations are clearly described	Foreword
11 The health benefits, side effects and risks have been considered in formulating the recommendations	Foreword and Introduction
12 There is an explicit link between the recommendations and the supporting evidence	2–3
13 The guideline has been externally reviewed by experts prior to its publication	Foreword
14 A procedure for updating the guideline is provided	Foreword
Clarity of presentation	
15 The recommendations are specific and unambiguous	2–3
16 The different options for management of the condition or health issue are clearly presented	2–3
17 Key recommendations are easily identifiable	2–3

Applicability	
18 The guideline describes facilitators and barriers to its application	Foreword
19 The guideline provides advice and/or tools on how the recommendations can be put into practice	2–3
20 The potential resource implications of applying the recommendations have been considered	Foreword
21 The guideline presents monitoring and/or auditing criteria	4
Editorial independence	
22 The views of the funding body have not influenced the content of the guideline	Foreword
23 Competing interest of guideline development group members have been recorded and addressed	Foreword