



Best practice recommendations

Storage and retention of animal tissues and records

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Foreword

Best practice recommendations (BPRs) published by the Royal College of Pathologists should assist pathologists in providing a high standard of care for patients. BPRs are systematically developed statements intended to assist the decisions and approach of practitioners and patients about appropriate actions for specific clinical circumstances. They are based on the best available evidence at the time the document was prepared. It may be necessary or even desirable to depart from the advice in the interests of specific patients and special circumstances. The clinical risk of departing from the BPR should be assessed and documented.

A formal revision cycle for all BPRs takes place every three years. The College will ask the authors of the BPR to consider whether or not the recommendations need to be revised. A full consultation process will be undertaken if major revisions are required. If minor revisions or changes are required, a short note of the proposed changes will be placed on the College website for two weeks for members' attention. If members do not object to the changes, a short notice of change will be incorporated into the document and the full revised version will replace the previous version on the College website.

This BPR has been reviewed by the Publishing team. It was placed on the College website for consultation with the membership from 19 December 2019 to 16 January 2020. All comments received from the membership were addressed by the authors to the satisfaction of the Clinical Director of Publishing and Engagement.

This BPR was developed without external funding to the writing group. The College requires the authors of BPRs to provide a list of potential conflicts of interest. These are monitored by the College's Publishing 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 legislation covering animal bodies, tissues and other samples, and clear guidelines are not currently available. 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.

1.1 Terms of reference, history and development of this edition

This document was drafted in 2019 at the request of the RCPATH Veterinary Pathology Speciality Advisory Committee to provide guidance to veterinary surgeons regarding the storage and retention of animal tissues in the UK 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.'

1.2 Context

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 and 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 purpose for which it is carried out is 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, 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. Post-mortem examinations may often be carried out in the field, such as on farm, in hunt kennels or knacker's yards. 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 recent enactment of the Data Protection Act 2018, which is the UK's implementation of the General Data Protection Regulation (GDPR),⁴ has imposed an even greater responsibility to protect sensitive data.

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) pathologists.⁵ Overarching all of the foregoing is the responsibility for veterinarians to act professionally and comply with the requirements of the Royal College of Veterinary Surgeons (RCVS) *Code of Professional Conduct*. This, with a number of supporting guidance documents, gives comprehensive guidance on many aspects of the scope of this document, and such advice has been incorporated herein (see also RCPATH guidance note for vets seeking the opinion of a pathologist).

The duty of confidentiality is important, but it is not absolute and information can be disclosed in certain circumstances, for example where the client's consent has been given, disclosure can be justified by animal welfare concerns or the wider public interest, or disclosure is required by law. 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 client's permission to pass on confidential information may be express or implied, except in relation to their personal data where the consent must be express, specific and informed. Express permission may be either verbal or in writing, usually in response to a request, but if given verbally a written note should be kept. Except in relation to personal data, permission may be implied from the circumstances, for example where a client moves to a different practice and clinical information is requested, or where an insurance company seeks clarification or further information about a claim under a pet insurance policy. However, whenever practicable the client's express consent to the disclosure should be sought.

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.⁷

If there is suspicion of animal abuse (which could include neglect) as a result of carrying out pathological investigation, in the first instance and where appropriate the veterinary pathologist must discuss their concerns with the presenting veterinary surgeon who should attempt to discuss their concerns with the client. In cases where this is not appropriate, or where the client's response increases rather than allays concerns, the veterinary surgeon should consider whether the circumstances are sufficiently serious to justify disclosing their client's information without consent. If so, the suspected abuse should be reported to the relevant authorities.

1.3 Scope of the 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.

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 post-mortem examination 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.

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 1981⁸ 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 TB in cattle under Article 13 of The Tuberculosis (England) Order 2014.⁹

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 1984¹⁰ and code of practice¹¹ under Part II of the Criminal Procedure and Investigations Act 1996.¹²

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, and 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, and 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 five years, although 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' post-mortem examinations 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.

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

These include a very wide 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, and, if so, the records should be catalogued for easy access. The criteria for storage described above should apply.

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 use such as correlation with results from previous and subsequent specimens, responding to queries or challenge, audit and quality assurance.

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. The legitimacy of future storage for such purposes is influenced by the presence or absence of appropriate consent. A client should have consented to a sample being taken for initial diagnostic or treatment purposes, whatever the size or species of the animal, whether it is a farm animal or domestic pet and whether the animal is living or dead. However, generally, a client should also consent to any reuse of the sample for other purposes. If the sample has been collected by a referring veterinarian, it is important to ensure that original consent has included the possibility for reuse of the sample for other purposes. Consent forms should be used as an aid to consent, in conjunction with a discussion with the client. A copy of the form should be retained, and another should be given to the client.

The RCVS has produced detailed guidance on informed consent.¹³ 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, and 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.⁸ Scottish legislation allows the use of samples for more than one purpose. There are additional provisions set out in European legislation with regard 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.

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 the collection and processing of 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. 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.

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 periods that are longer 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
- 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.³ 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 and 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 the imposition of a duty to store indefinitely. As litigation can arise very 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).¹² It is important that storage conditions are defined under which cells, tissues, derived materials, reagents and records are kept. With regard to reagents, there is clear guidance from Control of Substances Hazardous to Health (COSHH).¹⁴ These conditions should be clearly recorded as laboratory policies. With regard to 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 in a commercial setting tissue retention times vary, but as a general rule tissues are retained by companies for significant periods of time to support the possible need for subsequent re-evaluation, should the need arise, such as human/ecological safety issues.

3.2 Documents, electronic and paper records

Laboratories or practices storing data relating to identifiable human individuals must register with the Information Commissioner's Office, and 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 has 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.

Request forms

Request forms should be kept until the authorised report, or reports on investigations arising from it, has been received by the requester, but they should not be kept for longer than one month after the final report has been dispatched unless the request form is used to record working notes or as a worksheet when it should be retained as part of the laboratory record.

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 eight years to ensure availability for review through at least two full cycles of laboratory accreditation.

Protocols or standard operating procedures

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

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.

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 five 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.

Final report of investigations

Standard diagnostic reports should be kept for a minimum of five 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 prudently be kept indefinitely.

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 five years, whichever is the longer. As these tests are conducted outside of the laboratory premises, appropriate governance arrangements should be defined to ensure adequate retention and confidentiality.

Pathological archive or museum catalogues

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

Photographic or other digital records

Where images represent a primary source of information for the diagnostic process (e.g. some macroscopic specimen records, images from post-mortem examinations and images of histological slides), they should be kept for at least ten 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.

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 eight years to ensure continuity of data available for laboratory accreditation purposes over two inspection cycles and equivalence with performance records for the equipment used.

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 two months and summarised temperature records should be retained for at least eight years.

Equipment maintenance logs

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

Records relevant to production of diagnostic products or equipment and records of assay validation and verification

Performance claims are required by UKAS to be verified prior to introduction. Records should be kept of the methods used and results obtained for at least eight 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.

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 1981.⁸ However, reuse requires the specific informed consent and the RCVS has provided guidance on this for veterinary surgeons.¹³

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 left-over sera or plasma should be stored for as long as 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 the identification of emerging infections and vaccination programme monitoring. Special consideration should be taken to determine if the samples contain cells or are cell free.

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

Keep for 48 hours after the final report has been issued by the laboratory, unless sample deterioration precludes storage.

Whole blood samples for full blood count

Keep for 24 hours after the final report has been issued by the laboratory, unless sample deterioration precludes storage.

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

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

Release and return of archived diagnostic samples for clinical trial purposes

Translational research using diagnostic samples traditionally regarded 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 greatly 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.

Wet tissue (representative portion or whole tissue or organ)

Keep for four weeks after issue of final report.

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).

Stained slides

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

DNA and RNA

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

Microbiological cultures

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 seven 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 allows only a summary of the issue here so for detailed guidance readers should consult the Health and Safety Executive guidance.¹³ Veterinary pathologists should ensure that they comply with appropriate regulations.

Organisms hazardous to human health are categorized by the Control of Substances Hazardous to Health Regulations 2002 (COSHH),¹⁵ which requires 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).¹⁶ 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.

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.

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 allows only a summary of the issue here. Veterinary pathologists should ensure that they comply with appropriate regulations.

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.¹⁷

4. References

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Appendix 1: Summary of recommended retention times

Note: The retention times quoted above 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	One month after the final report
Daily work logs	Eight years
Protocols or Standard Operating Protocols	Ten years
Worksheets	As long as the associated sample is kept
Records of telephoned reports and other correspondence	At least five years
Final report of investigations	At least five years
Point-of-care 'penside' test data	Lifetime of the instrument or five years, whichever is the longer
Pathological archive	As long as the specimens are held
Photographic or other digital records	At least ten years
Quality assurance records	At least eight years
Temperature records	Daily records for at least two months and summarised records for at least eight years
Equipment maintenance logs	Lifetime of the instrument plus a minimum of four years
Records of reagent production, equipment or assay validation	At least eight 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	Four weeks after issue of the final report
Museum specimens	May be retained permanently
Stained slides	At least ten years
DNA and RNA	At least ten years
Microbiological cultures	24–48 hours after issuing the report