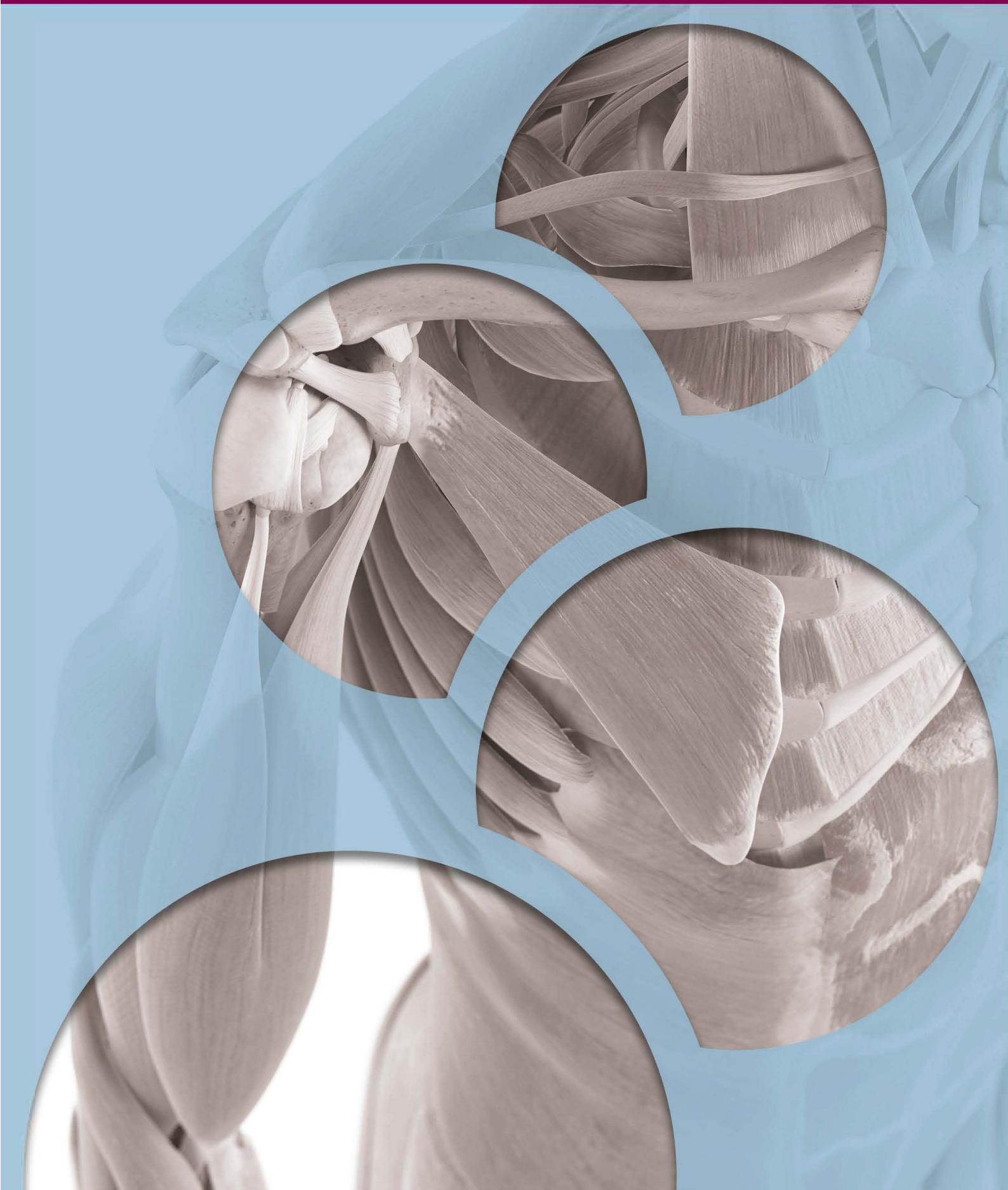
C Anatomical Examination

HTA Human Tissue Authority

Standards and guidance



Anatomy Licensing Standards and Guidance

Revision history

Version	Date	Changes
1.0	23/01/2016	First version published
2.0	24/01/2023	Guidance updated

About the guidance documents

1. The purpose of these guidance documents is to assist licensed establishments to meet the HTA's licensing standards. The documents contain additional information and examples of how to meet certain Standards.
2. These documents will be reviewed regularly to include additional guidance. In reviewing these documents, we will take into consideration enquiries, inspection findings and additional examples of good practice.
3. For further guidance on meeting the HTA's standards, please contact the HTA either by:
    a) Email: enquiries@hta.gov.uk
    b) Telephone: 020 7269 1900

About the Standards

1. In order to obtain an HTA licence, the applicant must demonstrate that:
    a) the premises where the activity will take place are suitable; and
    b) the proposed Designated Individual is a suitable person to supervise the activity.
2. As part of the application process, the HTA will assess whether the establishment can meet a number of licensing Standards. These were developed in consultation with representatives from the Anatomy sector. These relate to the consent provisions of the Human Tissue Act 2004 (HT Act), governance and quality systems, traceability and premises.
3. The Standards reinforce the HT Act's intention that:
    a) consent is paramount in relation to activities involving the removal, storage and use of human tissue;
    b) bodies of the deceased and organs and tissue removed from bodies are treated with respect;
    c) the dignity of the person, whether living or deceased, is maintained.
4. The HTA works with establishments through its inspection process to help them comply with these Standards.
5. The Standards are grouped under four headings: Consent (C); Governance and quality systems (GQ); Traceability (T); and Premises, facilities and equipment (PFE). Under each of these headings, there are overarching statements, from which the standards flow.

Guidance on the Standards

Consent Standards

Establishments meeting the consent Standards will be able to demonstrate that their processes for seeking and gaining consent comply with the HT Act and the HTA's Codes of Practice. The Standards also cover the documentation and information used to support the establishment's consent procedures, and ensure that staff involved in seeking consent are suitably trained and equipped for the task.

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice

a) **Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.**

b) **Consent forms are available to those using or releasing relevant material for a scheduled purpose.**

c) **Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.**

Guidance

Where establishments receive specimens from other organisations, they are expected to have agreements in place to ensure that consent is obtained in accordance with the regulatory requirements. These agreements should be reviewed periodically to ensure that material is used, handled, stored, transported, and disposed of in accordance with the donors' wishes and the consent given.

d) **Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.**

Guidance

It is important that information used to support the seeking of consent covers what is needed for potential donors to make informed decisions. This means all anticipated uses for donated material are covered, such as surgical training and the making of images.

Although taking photographs of human material is not covered by the HT Act, if an establishment intends to allow photographs to be taken of specimens to facilitate training, it is good practice for this to be included in the consent information. A number of establishments include this in their bequeathal, process

and strictly control any photography in accordance with the consent obtained.

e) **Language translations are available when appropriate.**

f) **Information is available in formats appropriate to the situation.**

Guidance

Establishments should ensure that the consent process provides full information to donors in a variety of suitable formats. For example, the fonts used in bequeathal booklets and consent forms should be clear and of an appropriate size to be easily read.

General guidance for Standard C1

We have published model consent forms for body donation for anatomical examination, which can be found on our website. A number of establishments use these model consent forms as the basis for their own consent forms.

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent

a) **There is suitable training and support of staff involved in seeking consent.**

b) **Records demonstrate up-to-date staff training.**

c) **Competency is assessed and maintained.**

General guidance for Standard C2

The HTA does not specify or endorse any particular training course or package relating to the regulatory and/or legal frameworks. Training can be developed and delivered locally or externally-developed training can be sourced. Official HTA guidance is published on our website and should be considered as the definitive source of information for matters within our remit. It is important that consent training is not considered a one-off event and that proficiency in seeking consent is upheld.

There is no set requirement for the frequency of consent training. Consent-seekers are expected to maintain awareness of current standards through reference to published guidance and relevant policies. Training may need to be updated when new policies or practices have been implemented.

Governance and quality system Standards

Establishments meeting these Standards will be able to demonstrate that they have a suitable governance framework, underpinned by clear and controlled documentation, effective audit, staff training and organised record-keeping. In addition, they will have an effective system of risk management and suitable systems to deal with adverse events.

GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process

a) **Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.**

Guidance

At a minimum, it is expected that most establishments will have standard operating procedures (SOPs) covering the following activities:

- consent;
- receipt;
- labelling;
- specimen preparation / preservation;
- storage;
- incident management;
- relevant transport arrangements;
- cleaning and decontamination;
- disposal.

An SOP should be a clear and accurate representation of an existing procedure or process, preferably set out in the format of a stepwise guide. SOPs should be understandable to enable new staff to follow a procedure from beginning to end.

They should be detailed enough to ensure uniformity between staff in the performance of a specific function and should be followed to the letter by all staff who have been appropriately trained.

People undertaking the processes should be involved in developing the SOPs to ensure that the written procedures reflect actual practices; however, the author of an SOP should not also be the only person who reviews it. Regular review of SOPs will help to prevent incremental departure from written processes with passing time and allow establishments to identify improvements. Establishments should introduce a system to record that staff have read and understood SOPs.

Access to the facility should be strictly controlled with clear policies and procedures which protect bodies, body parts and other specimens from harm and breaches of confidentiality.

b) **There is a document control system.**

Guidance

Governance documents should include:

- revision history and version number;
- effective from' date;
- review date (at least every three years);
- pagination;
- author and reviewer names (which should be different).

c) **There are change control mechanisms for the implementation of new operational procedures.**

Guidance

Change control mechanisms should be proportionate, taking into account the risks of any planned changes, any validation required, any training required and how implemented changes will be reviewed.

d) **Matters relating to HTA-licensable activities are discussed at regular governance meetings, involving establishment staff.**

Guidance

All staff working under the HTA licence should be aware of the governance arrangements in place, and they should be represented at governance meetings.

Overall governance processes should be supported by regular meetings with staff at the establishment who are engaged in licensed activities. Formal meetings should be minuted and the actions should be noted and followed up.

Documented minutes of meetings should be distributed to all relevant staff to help to ensure that they are aware of all important information relating to licensed activities at the establishment. National and local information relevant to activities should also be disseminated.

e) **There is a system for managing complaints.**

Guidance

It is expected that an establishment will have a complaints process to deal with both internal and, if necessary, external complaints.

General guidance for Standard GQ1

A formal quality management framework helps to establish minimum expectations for governance and quality systems, and facilitates continuous improvement.

The work of the staff at the establishment must be subject to a system of governance. This means that there should be clear reporting lines and accountability (particularly with regard to individual staff and the DI), documented roles and responsibilities.

Establishments are encouraged to have an over-arching quality document

which provides an overview of the establishment's main purpose, organisation and structure, and approach to governance and quality. This document should be accessible to all staff involved in licensed activities.

GQ2 There is a documented system of audit

a) **There is a documented schedule of audits covering licensable activities.**

b) **Audit findings include who is responsible for follow-up actions and the timeframes for completing these.**

General guidance for Standard GQ2

Audits will demonstrate compliance with HTA standards and demonstrate whether establishments are meeting the requirements of their own systems. A documented schedule of audits should be in place at each establishment.

Vertical audits of records and specimens will allow the establishment to assure itself that specimens and records are fully traceable from consent to disposal. Records, including records of consent, should be audited regularly to ensure completeness, accuracy and legibility. Auditing should take into consideration the type of collection and the intended use of the material. For example, collections that remain unchanged over time may not require regular audits of the consent records.

Audits should ideally include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect actual practices and to identify areas for improvement.

Audits should include security measures and facility access records.

Audit processes can benefit from being undertaken by a person who is not normally involved in the activity at the establishment: a 'fresh eyes' view. Internal auditors should not be involved in auditing their own work.

Some establishments may be able to make use of existing in-house expertise or services.

All audit findings and related corrective and preventative actions should be recorded to allow the establishment to demonstrate compliance with HTA Standards and follow-up outstanding actions.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

a) **Qualifications of staff and all training are recorded, records showing attendance at training.**

b) **There are documented induction training programmes for new staff.**

c) **Training provisions include those for visiting staff.**

d) **Staff have appraisals and personal development plans.**

General guidance for Standard GQ3

Training and induction packages help to ensure that staff are fully trained on all policies and procedures relevant to their work. Establishments should ensure that training and development plans are in place to maintain competence and that these are reviewed periodically. In assessing individual needs for training, DIs are expected to consider the full range of people who may access relevant material.

The HTA does not specify or endorse any particular training course or package relating to the regulatory and/or legal frameworks. Training can be developed and delivered locally or externally-developed training can be sourced. Official HTA guidance is published on our website and should be considered as the definitive source of information for matters within our remit.

Staff should be encouraged to attend professional meetings and training events to ensure that they keep abreast of good practices in their areas of expertise.

GQ4 There is a systematic and planned approach to the management of records

a) **There are suitable systems for the creation, review, amendment, retention and destruction of records.**

Guidance

Documented records are used by establishments to evidence traceability and ensure a robust audit trail. In this context, traceability refers to the completeness of auditable information about every step in the pathway for the use of relevant material, from consent through to disposal.

Documented procedures and/or policies for the creation, review, amendment, retention and destruction of records are required to help to ensure that records are maintained appropriately. These should detail the frequency of document review required to ensure that documents are regularly reviewed and updated as necessary.

b) **There are provisions for back-up / recovery in the event of loss of records.**

Guidance

Records may be in various formats, including paper based, electronic, or stored

on recordable media.

A centralised system for the storage of records can help to ensure that records are regularly backed up.

c) **Systems ensure data protection, confidentiality and public disclosure (whistle- blowing).**

Guidance

Establishments are expected to have due regard to other relevant legislation, including compliance with data protection legislation where tissue has been obtained from the living, and compliance with professional guidelines where applicable.

GQ5 There are systems to ensure that all adverse events are investigated promptly

a) **Staff are instructed in how to use incident reporting systems.**

b) **Effective corrective and preventive actions are taken where necessary and improvements in practice are made.**

General guidance for Standard GQ5

All establishments licensed by the HTA are required to have an internal system for reporting adverse events and, where necessary, instigating an investigation or root cause analysis.

Clearly assigning responsibilities for incident management is important. As the DI is responsible for licensed activities at the establishment, there should be a process in place to allow them to be made aware of adverse events so that proper investigation and reporting can take place. There should be an adverse incident SOP detailing how adverse incidents are logged, reported, addressed and monitored.

Although there is currently no requirement for establishments in the anatomy sector to report adverse incidents to the HTA, if a DI has concerns about an adverse event, they are encouraged to contact us for further advice.

Examples of adverse events include:

- security breaches;
- loss of dignity of the deceased (interference with a body, damage to a body through lapse in care, misuse of a body or specimen);
- unconsented photography of a body;
- storage and/or use of a body or body part that is not in accordance with the given consent;
- incorrect disposal;
- body parts / cadaver / prosection loss;

- incomplete records;
- loss of traceability;
- fridge/freezer warming or breakdown.

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

a) **There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.**

Guidance

All establishments should identify the risks inherent in the key activities, and procedures should be developed in consideration of and to mitigate these potential risks where appropriate. Establishments may tend to focus risk assessments on health and safety issues which, in themselves, are not sufficient to meet our Standards. DIs should also assess the risks associated with licensed activities. Documented risk assessments should include an evaluation of the level of the risk and, where appropriate, the mitigating actions identified and the level of residual risk remaining.

Risk assessments should include the risks relating to the premises, practices and procedures connected with licensed activities, including:

- loss of or damage to specimens;
- loss of traceability;
- receiving specimens without appropriate consent documentation;
- storing and using specimens retained for further use without appropriate and valid consent;
- storage of anatomical specimens and contingency arrangements;
- transport of specimens to and from the establishment;
- security arrangements.

b) **Risk assessments are reviewed regularly.**

Guidance

Risk assessments should be reviewed periodically (typically, every 1-3 years) and the actions to mitigate risks updated as necessary.

Risk assessments should also be reviewed following an incident.

c) **Staff can access risk assessments and are made aware of risks during training.**

Guidance

By documenting risk assessments, staff are made aware of identified risks, which helps to prevent risks materialising and informs the development of procedures and relevant documentation.

Traceability

Establishments meeting these Standards will be able to demonstrate full traceability for the human material for which they are responsible, from receipt to final disposal/disposition. HTA inspectors will test this through traceability audits carried out on site and we expect establishments to take a pro-active approach to assuring themselves of effective traceability throughout the lifetime of their licence. In addition, as the final traceability step, they will have established disposal arrangements which are in accordance with the HTA's Codes of Practice.

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail

a) **There is an identification system which assigns a unique code to each donation and to each of the products associated with it.**

b) **A register of donated material, and the associated products where relevant, is maintained.**

c) **An audit trail is maintained, which includes details of when and where the bodies or tissue were acquired, the consent obtained, the uses to which any material was put, when and where the material was transferred, and to whom.**

d) **A system is in place to ensure that traceability of relevant material is maintained during transport.**

e) **Records of transportation and delivery are kept.**

f) **Records of any agreements with courier or transport companies are kept.**

g) **Records of any agreements with recipients of relevant material are kept.**

General guidance for Standard T1

The DI is responsible for the body and body parts of the deceased from the time of donation until the burial, cremation, disposal or return to the family. Full traceability should be ensured during transportation; records of transportation and delivery should be kept. Records should also be kept of any transfer agreements with recipients of relevant material and of any written agreements with couriers or transport providers. There is further guidance on labelling and loan arrangements in the Code of Practice relating to anatomical examination.

A register of donors and specimens should be maintained which should allow all specimens to be identified and traced through to the consent documentation.

Records of loan arrangements should be kept and include important details, including: the location where specimens will be stored whilst on loan, dates that specimens have left and arrived at each site, and the

condition of specimens. We have produced model loan arrangement templates which are available on our website. A SOP documenting the process of arrangements for the transport and loan of specimens will help to ensure that the traceability of specimens is maintained.

T2 Bodies and human tissue are disposed of in an appropriate manner

a) **Disposal is carried out in accordance with the HTA's Codes of Practice.**

b) **The date, reason for disposal and the method used are documented.**

General guidance for Standard T2

Establishments should carefully document disposal. Supporting procedures should detail the requirements for recording the details of disposal, including the date, reason and method. Records of disposal should be kept in order to provide a complete audit trail from donation through to final disposition.

Premises, facilities and equipment Standards

Establishments meeting these Standards will be able to demonstrate that their premises and facilities are appropriate for their licensed activities and are safe, secure and clean. In addition, establishments will have systems for on-going monitoring to ensure all key quality specifications are maintained. These Standards also cover equipment, ensuring that it is appropriate, and suitably maintained, and that it does not present an impediment to the staff using it.

PFE1 The premises are secure and fit for purpose

a) **An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.**

Guidance

Premises are expected to be clean, well maintained, secure and subject to a programme of planned preventative maintenance. Suitable environmental controls should be in place to avoid potential contamination. For example, floors, walls and work surfaces should be of non-porous construction and free of cracks and chips.

Premises should be reviewed periodically to ensure they continue to be suitable. This should include the review of relevant risk assessments and auditing activities that help to identify areas requiring rolling maintenance, refurbishment or upgrade. This will help to ensure that remedial actions are implemented in a timely manner so that the premises and facilities remain fit for purpose.

b) **Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.**

Guidance

The DI, or persons acting under their authority, should use a controlled-access system to monitor entry into the facility during the day and outside working hours. There should be documented arrangements for access as well as a system for recording who has been in the facility, the nature of their business and when they arrived and left.

Anyone entering the facility should have a legitimate right of access and audits should scrutinise the purpose, frequency and duration of access and be particularly alert to unusual patterns, times of entry or other unexplained or suspicious activity, which must be investigated immediately.

Staff and authorised visitors and contractors should be aware of the establishment's security arrangements. Authorised visitors and contractors should also be supervised while in the facility.

Establishments are expected to have policies in place to review and maintain the

safety (and monitoring) of staff (including maintenance, security and cleaning staff), visitors and other relevant people, such as students or donors.

Since anatomy establishments frequently host teaching sessions, registers of visitors, including all students, should be completed. Establishments may also restrict the number of students taking part in teaching sessions in the facility to ensure that anatomical examination can be well supervised and conducted safely and efficiently.

Examples of other measures that have been implemented by anatomy establishments to support security, dignity and safety include comprehensive induction packages for students, detailing the requirements of the HT Act and the HTA's Codes of Practice. Some establishments have also introduced a local code of conduct, which students are required to acknowledge before entering the facility.

Lone working arrangements should also be overseen and authorised by the DI.

c) **There are documented cleaning and decontamination procedures.**

Guidance

Documented cleaning and decontamination procedures should be supported and evidenced by completed schedules.

PFE2 There are appropriate facilities for the storage of bodies and human tissue

a) **There is sufficient storage capacity.**

b) **Storage arrangements ensure the dignity of the deceased.**

Guidance

Practices such as bodies being stacked on each other, leaving bodies and other specimens inappropriately uncovered, or storing bodies in unsecured areas should not take place.

Staff should be encouraged to raise concerns regarding any behaviours within the facility which could compromise the dignity of the deceased.

c) **Storage conditions are monitored, recorded and acted on when required.**

Guidance

Documented temperature monitoring allows establishments to easily visualize and identify when temperatures are out-of-range. It can also demonstrate temperature trends, to identify when storage conditions may be deteriorating and to alert staff to developing equipment failure. Temperature alarms should be regularly tested and manually challenged periodically to ensure that they are operating as expected.

Signs should be added to freezers to define alarm set points for the temperature ranges so that staff are visually reminded of minimum and maximum

temperatures.

Where storage is critical, an appropriate remote temperature monitoring alarm and callout system may be required.

Where material can be stored at ambient/room temperature, this does not mean that storage conditions do not need to be monitored.

d) **There are documented contingency plans in place in case of failure in storage area.**

Guidance

Establishments are expected have contingency arrangements in place should there be an emergency situation that renders the premises unsuitable for the storage of bodies or human tissue; this may involve same-site transfers or may need to be through a formalised arrangement with another HTA-licensed establishment for transfer of material.

General guidance for Standard PFE2

Areas used for the storage and use of human tissue must provide an environment that is safe for those working under the licence, preserving the dignity of the deceased and the integrity of the tissue.

Refrigerators, freezers and other vessels which contain human tissue should be appropriately labelled so that staff are aware of the necessity to maintain the quality, safety and security of such material and prevent mix-ups with other tissues.

Human tissue must be stored in such a way that it minimises the risk of contamination to those working under the licence. If necessary, the DI should work with health and safety personnel to implement environmental controls and appropriate equipment to reduce the risk of contamination.

Where there is also storage and use of non-human material, establishments are expected to have due regard for any known consent limitations based on cultural, religious or philosophical principles.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

a) **Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.**

Guidance

Establishments are expected to ensure that equipment is regularly maintained and suitable for use.

Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining.

b) **Users have access to instructions for equipment and are aware of how to report an equipment problem.**

Guidance

There should be a system for renewing items that are no longer suitable or fit for purpose.

c) **Staff are provided with suitable personal protective equipment.**

Guidance

Establishments are expected to give staff access to the protective clothing, materials and equipment they need.

Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

Critical shortfalls

A critical shortfall is:

- a shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions; or
- a combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

- a notice of proposal being issued to revoke the licence
- some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
- a notice of suspension of licensable activities
- additional conditions being proposed
- directions being issued requiring specific action to be taken straightaway

Major shortfalls

A major shortfall is non-critical shortfall that:

- poses a risk to human safety and/or dignity;
- indicates a failure to carry out satisfactory procedures;
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines;
- has the potential to become a critical shortfall unless addressed; or

- is combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

Minor shortfalls

A minor shortfall is one which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.