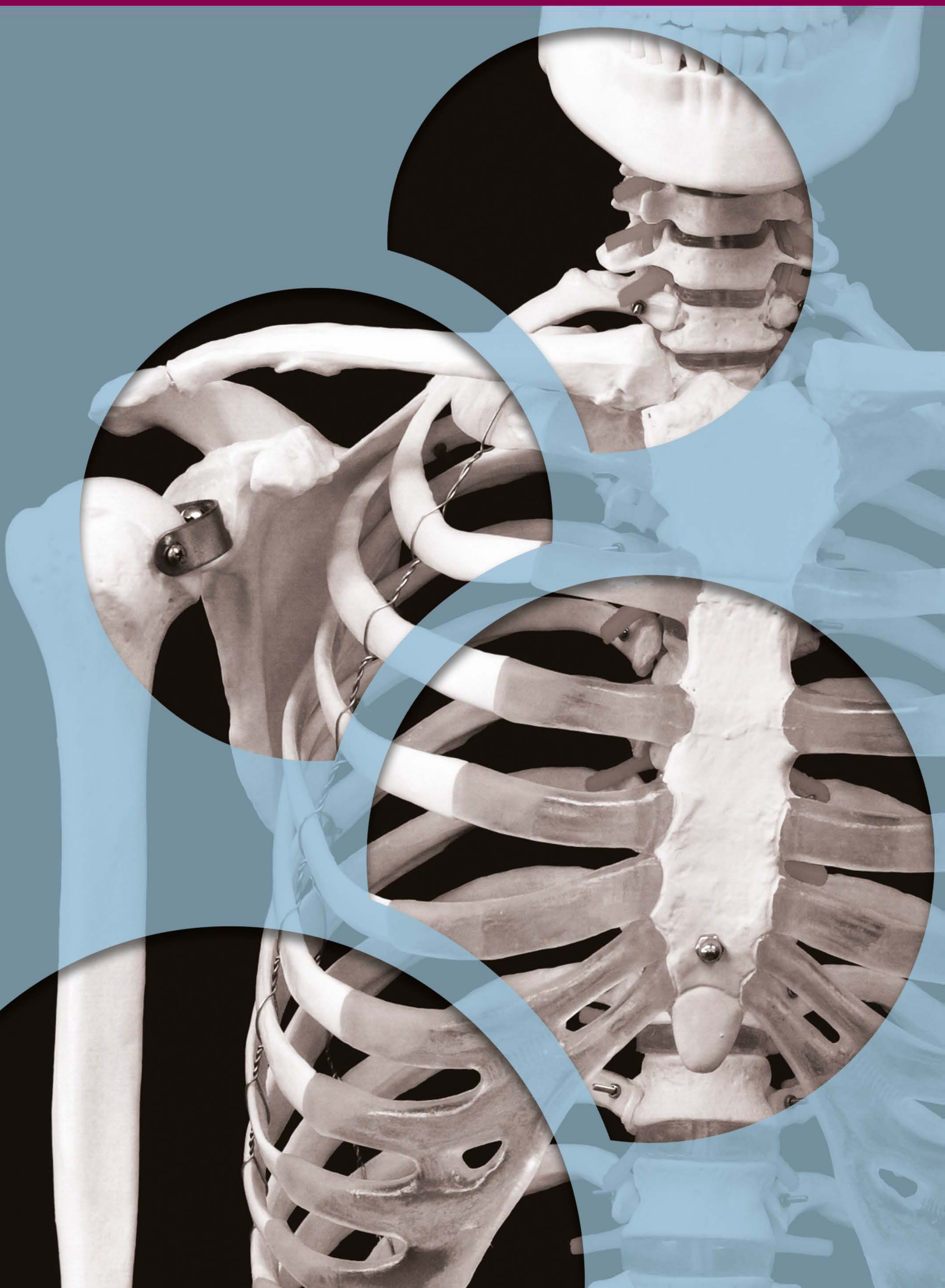
D Public Display

HTA
Human Tissue Authority

Standards and guidance



Public Display Licensing Standards and Guidance

Revision history

Version	Date	Changes
1.0	23/01/2016	First version published

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

4. 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.
5. 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 Public Display sector. These relate to the consent provisions of the Human Tissue Act 2004 (HT Act), governance and quality systems, traceability and premises.
6. 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.
7. The HTA works with establishments through its inspection process to help them comply with these Standards.
8. 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.

Consent (C)

9. Establishment's 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.

Governance and quality systems (GQ)

10. 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.

Traceability (T)

11. 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 the HTA expects 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.

Premises, facilities and equipment (PFE)

12. Establishments meeting these Standards will be able to demonstrate that their premises and facilities are appropriate for the licensed activities taking place and that they 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.

13. The HTA licensing Standards which are applicable to the Public Display sector are included at Annex D and on the HTA website. The Standards are supported by comprehensive guidance notes.

Guidance on the Standards

Consent

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in its codes of practice

a) If the establishment is required to seek consent, a process is in place which is in accordance with the requirements of the HT Act and the HTA's Codes of Practice, and records of consent are maintained.

b) If relevant, there is training for staff on how to seek consent for the public display of human material, which addresses the requirements of the HT Act and the HTA's Codes of Practice and records demonstrate attendance.

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

Guidance

Establishments should seek to receive written assurance that, for imported specimens, the donor's consent was sought in line with that country's requirements

C2 Information about the consent process and the activity for which consent is sought is provided

a) There is written information about the consent process for those giving consent, which reflects the requirements of the HT Act and its codes of practice

b) Standard operating procedures (SOPs) specify how information on consent is provided.

Governance and quality systems

GQ1 All aspects of the establishment's work are governed by documented policies and procedures

a) There are collections management policies and procedures, or equivalent, governing the storage and public display of bodies and human tissue which give due regard to the dignity of the deceased. These should include, as relevant to the establishment's activities:

   i. an overarching policy on the care and treatment of exhibits containing human tissue;

   ii. seeking consent for donation of bodies and human tissue for public display;

   iii. specimen acquisition e.g. by bequest, exchange, loan or purchase from another individual or organisation nationally or internationally;

   iv. specimen preservation, monitoring and conservation;

   v. control of environmental conditions;

   vi. the management of sensitive material, such as fetal remains;

   vii. transportation of specimens e.g. on loan to or return to other collections;

   viii. the disposal/deaccession of specimens;

   ix. storage contingency arrangements;

   x. the creation, amendment, retention and destruction of records;

   xi. the management of incidents and complaints.

   Guidance

   Individual SOPs for each activity are not required; some SOPs will cover more than one activity. Where appropriate, procedures should be developed in consideration of potential risks. For example, where staff undertake cleaning of material on public display, the procedure should be based on the assessment of risk to staff from contamination and the cleaning materials they will be exposed to, as well as the potential risk of damage to the item being cleaned.

b) There are procedures that govern the work of temporary staff and contractors, which ensure that they are sensitive to the special status of human remains and exhibits consisting of human material.

c) Regular governance meetings are held; for example, health and safety and risk management committees, that have agendas and minutes.

Guidance

Team meetings provide an ideal opportunity to pass on relevant information to staff working under the licence, as well as allowing them to raise any issues or concerns.

d) Policies and procedures are reviewed regularly and are version controlled.

Guidance

Governance documentation should be up to date, subject to regular review and reflective of good practice, including guidance from organisations such as Arts Council England and the Department for Culture, Media and Sport (DCMS).

GQ2 There is a documented system of audit

a) There is a documented system of audit, which includes records of traceability and specimens.

Guidance

Audits should include compliance with documented procedures; the completion of records; and traceability

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

a) There are clear reporting lines and accountability, and documented roles and responsibilities.

b) There is documented induction and training for staff, which includes the handling of human remains; attendance at training is recorded.

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.

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

GQ5 There are systems to ensure that untoward incidents are investigated promptly

a) There is a system for reporting and investigating serious untoward incidents.

Guidance

This should include incidents relating to the safety and integrity of human material and those that may impact on the establishment's ability to meet the requirements of the HTA codes of practice and licensing Standards. Staff should understand what is meant by an incident and be familiar with the procedure to follow when such an incident occurs.

Serious incidents should be reported to the HTA.

b) Corrective and preventive actions are taken where necessary and improvements in practice are made.

GQ6 Risks associated with the establishment's practices and processes in relation to the storage and display of human material are assessed and monitored

a) Risk assessments are documented.

Guidance

Risk assessments should consider risks to, for example: tissue traceability; storage of specimens; and dignity of the deceased. Where actions are identified to mitigate risks, these should have deadlines for completion and a person responsible for completing them.

For risk assessments to be meaningful, they should be undertaken by a suitably trained person, who has an objective view or who is following an established risk-assessment process. It may not be appropriate for staff working under the authority of the licence to undertake their own risk assessments. In any event, the results of risk assessments should be shared with staff so that they have an understanding of the issues identified.

b) Risk assessments set out steps taken to mitigate risks

c) Risk assessments are reviewed regularly

Guidance

Risk assessments should be reviewed every 1-3 years

d) Staff can access risk assessments and are made aware of them in training

Traceability

T1 A coding and records system facilitates traceability of bodies and human tissue

a) Bodies and human tissue are traceable through a unique identification number or code.

Guidance

Procedures relating to indexing and record-keeping should reference the establishment's system of labelling bodies and body parts.

b) The system of record-keeping should include the location of material at the establishment and may include a description or photographic record and details of any specialist storage conditions, shelf-life or contamination risk.

T2 Records of traceability are maintained

a) Records of receipt, storage, transportation and delivery of bodies and human tissue are maintained.

b) Disposal or de-accession records include the date, reason and method of disposal/de-accession.

Guidance

If relevant material is loaned to or borrowed from another licensed establishment, consideration should be given to minimising the likelihood of theft or damage during transport. Loan agreements should define how the material is preserved and any potential contamination risks associated with it. There should be clear instructions on how to deal with an untoward incident and contact details for the person responsible at the establishment loaning relevant material.

c) Where applicable, disposal arrangements reflect specified wishes of the donor.

Premises, facilities and equipment

PFE1 The premises and facilities are secure and safeguard the dignity of the deceased and the integrity of human tissue

a) Areas used for storage or public display provide an environment that is safe for staff and visitors and preserves the integrity of the material and the dignity of the deceased.

Guidance

As advised in the DCMS Guidance for the care of human remains in museums*, visitors should not come across human remains unaware. The establishment should give consideration to suitable signage, explaining the presence of bodies, body parts or other relevant material and the requirement to treat them with dignity and respect.*

b) The establishment is clean, well maintained and subject to a programme of planned preventative maintenance.

c) Staff have access to the protective clothing, materials and equipment they need.

d) A documented risk assessment has been carried out of the premises to ensure that they are appropriate for the licensed activities.

Guidance

An assessment can cover such risks as fire, theft and vandalism.

e) There are policies in place to review and maintain the safety of staff and visitors.

f) The premises are secure with controlled access to bodies, human tissue and records.

g) Security measures include the use of lockable display areas and alarm systems.

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

a) Where chemicals are used for preservation, the area is adequately ventilated to control exposure.

Guidance

Control of Substances Hazardous to Health (COSHH) regulations require the exposure of formaldehyde to be controlled as low as possible and below the maximum exposure limit (2 ppm). This may include regular monitoring of formaldehyde levels and continuous operation of extract ventilation.

b) Critical storage conditions are monitored and recorded

Guidance

This could include, for example, temperature; humidity, dust or light levels, in storage and display areas.

c) There are systems to deal with emergencies.

Guidance

This could include, for example, fire, flood, power failure or public disturbance.

d) There is a documented contingency plan for storage of bodies and human tissue.

Guidance

For example, the establishment could have arrangements for material to be transferred to alternative licensed premises.

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 a non-critical shortfall that:

- poses a risk to human safety and/or dignit;
- 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 a 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 shortfall 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.