



Memorandum of Understanding between the United Kingdom Accreditation Service and the Human Tissue Authority

Background

The purpose of this Memorandum of Understanding (MoU) is to set out a framework to support the working relationship between the United Kingdom Accreditation Service (UKAS) and the Human Tissue Authority (HTA).

This MoU relates only to HTA regulatory activity in the post mortem sector in England, Wales and Northern Ireland.

The collaboration between the UKAS and the HTA aims to reduce the burden of regulation on organisations that are subject to site-visit inspection by the HTA and assessment by UKAS, whilst maintaining public confidence in post mortem services.

Where an organisation is given the opportunity and chooses to participate in the scheme, UKAS will assess compliance with selected HTA standards that have been mapped to specific requirements of ISO 15189 as part of the accreditation assessment of medical laboratories whose activities include mortuary services licensed by the HTA.

The United Kingdom Accreditation Service (UKAS)

UKAS is the only national accreditation body in the UK recognised by government to assess, against internationally agreed standards, organisations that provide certification, testing and inspection and calibration services. UKAS assesses and accredits laboratories in accordance with the requirements of ISO/IEC 17025 and medical laboratories in accordance with the requirements of ISO 15189. Some of these laboratories include mortuary services within the scope of their accreditation.

Accreditation by UKAS demonstrates the competence, impartiality and performance capability of these laboratories and services. Accreditation of a medical laboratory to ISO 15189, demonstrates that the laboratory operates a quality system; is technically competent; has competent practitioners and is able to generate technically valid results. More information about UKAS can be found [here](#).



The Human Tissue Authority

The HTA is an Executive Non-Departmental Public Body sponsored by the Department of Health. HTA was established under the Human Tissue Act (HT Act) 2004 – which covers England, Wales and Northern Ireland. HTA licenses and inspects organisations that remove, store and use tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions. HTA sets standards that licensed establishments must meet on: consent; governance and quality systems; premises, facilities and equipment; and disposal. Compliance with these standards demonstrates that statutory and regulatory requirements are met.

The HTA issues Codes of Practice setting out general principles which should be followed in carrying out activities governed by the HT Act.

The HTA and UKAS intend that their working relationship will be characterised by the following principles:

- a) a shared understanding of the importance of maintaining public confidence in the delivery of post mortem services and the retention and use of human tissue;
- b) a commitment to reducing the burden of inspection;
- c) the need to make decisions which adhere to the principles of better regulation i.e. are risk-based, transparent, accountable, proportionate, consistent, and targeted;
- d) a focus on working together by sharing information about relevant regulated/accredited services;
- e) respect for each organisation's independent status and right to make different decisions about compliance given that different regulations apply;
- f) the need to maintain public and professional confidence in the two organisations; and
- g) the need to use resources effectively and efficiently through appropriate coordination and information sharing.

Agreement made in May 2015

between

The Human Tissue Authority

and

The United Kingdom Accreditation Service

1. Background

1.1. This Agreement applies to the work of the United Kingdom Accreditation Service (UKAS) and the Human Tissue Authority (HTA) within the post mortem sector. It will have an impact on any organisation licensed by the HTA and accredited by UKAS that is offered and opts for a joint inspection to assess compliance with ISO 15189 and selected HTA post mortem sector standards.

2. Definitions

2.1. In this Agreement:

2.2. 'HTA Standards' are the standards that HTA-licensed establishments are expected to meet to demonstrate compliance with the statutory requirements of the Human Tissue Act 2004 and HTA's regulatory requirements. The standards change from time to time and the HTA will inform UKAS when this is the case and work with UKAS to update relevant inspection documentation.

2.3. 'ISO 15189 *Medical laboratories – requirements for quality and competence*' is the globally recognised ISO standard intended to improve the quality and reliability of medical laboratories and used as the basis for awarding accreditation.

2.4. 'laboratory' means a laboratory service that includes mortuary services in the scope of its UKAS accreditation.

3. UKAS obligations

3.1. UKAS agrees to assess compliance with ISO 15189 and HTA standards, as selected by HTA where they overlap with ISO 15189, during joint inspections of laboratories conducted with the HTA.

- 3.2. UKAS will not charge the HTA for this work, but may recoup costs directly from the organisation being assessed. UKAS will notify the HTA if its Terms of Business change, and will liaise on a regular basis with regards to arrangements under this MoU.
- 3.3. UKAS will share with HTA on a quarterly basis its master spreadsheet of assessment visits in order that HTA can identify potential candidates for a joint inspection.
- 3.4. Where a laboratory has agreed to a joint inspection, UKAS will provide HTA with any information pertinent to the conduct of HTA-licensed activities that it receives from the laboratory at least four weeks prior to the date of the joint inspection, as set out in the jointly-drafted SOP on joint inspections. This shall include at least:
 - (a) general observations or any concerns regarding the performance of the laboratory where the laboratory might not satisfy the requirements of ISO 15189 where these overlap with HTA Standards;
 - (b) copies of any relevant quality management documentation
 - (c) a copy of the UKAS assessment visit plan
- 3.5. At a joint inspection, UKAS assessors will assess compliance with HTA licensing standards that have been mapped to ISO 15189. At the conclusion of the inspection, details of any identified nonconformities against ISO 15189 and the HTA requirements are to be documented and presented to HTA in an agreed format. UKAS assessors will be regarded by the HTA as duly authorised persons for that purpose.
- 3.6. Following a joint inspection, UKAS assessors will submit a final copy of the nonconformities identified against individual HTA and UKAS assessment criteria, and a summary of their findings against relevant HTA Standards, including a list of documents they reviewed, within 10 working days of the joint inspection. This shall be in the format set out in Appendix 1.
- 3.7. In addition, on an ongoing basis, UKAS will, in every instance, provide the HTA with
 - (a) any relevant information received from or about the laboratory which would be of perceived benefit to HTA with regards to ensuring ongoing conformity with HTA standards;
 - (b) details of any decision on suspension, or withdrawal of accreditation, whether voluntary or imposed
- 3.8. UKAS shall provide HTA in writing with full information about each of the matters referred to in sub paragraphs (a) and (b) of clause 3.7 within seven days of the details becoming known to UKAS.

General



- 3.9. UKAS shall provide the HTA with details of the criteria (Technical Competence Criteria - TCCs) used for selecting assessors for the range of HTA activities covered by accreditation. In addition the specification for individuals to perform the role of:
- (a) assessors;
 - (b) lead assessors;
- will be provided. Any proposed changes or additions to these criteria will be communicated to the HTA prior to them being agreed.
- 3.10. UKAS shall when requested collaborate with the HTA in the production of guidance on the Standards for assessors and laboratories.
- 3.11. UKAS shall treat any information received from the HTA as confidential and shall not release any information so obtained to a third party without the prior permission of the HTA unless required to do so by law, in which case UKAS shall notify the HTA of any disclosures they are required to make, unless prohibited by law from doing so.

4. HTA obligations

- 4.1. HTA shall treat all information received from UKAS as confidential and shall not release any information so obtained to a third party without the prior permission of UKAS, unless required to do so by law which, for the avoidance of doubt, shall include the Freedom of Information Act and Data Protection Act. Where HTA receives a request for information under FoI, it will notify UKAS of the request and the information it is intending to provide.
- 4.2. From information provided by UKAS, the HTA will identify laboratories in the post mortem sector suitable for a joint inspection, taking into consideration the laboratory's previous licensing history and risk rating.
- 4.3. HTA shall be responsible for contacting laboratories to seek their agreement to a joint inspection and informing UKAS if they opt for a joint inspection.
- 4.4. At least four weeks prior to a joint inspection, HTA will provide UKAS with information pertinent to the laboratory, for example, previous HTA inspection reports and compliance information.
- 4.5. The HTA shall not delegate its licensing function, but will consider information provided by the UKAS assessment team in its regulatory decision making following the inspection. HTA will inform UKAS of any regulatory action taken following the inspection.

- 4.6. HTA shall provide UKAS with any feedback received about the conduct and performance of UKAS assessors.
- 4.7. HTA will inform and consult with UKAS on impending changes to the HTA Standards and any other relevant documents and will liaise on a regular basis with regards to arrangements under this MoU.
- 4.8. Where UKAS requests clarification of any HTA documents, HTA will provide UKAS with clarification within 14 days of the request.
- 4.9. HTA shall be entitled to use any of the information supplied by UKAS in accordance with this agreement in the execution of its regulatory functions.
- 4.10. HTA shall retain the right to carry out inspections and investigations, or any other regulatory activity, outside of this agreement irrespective of whether the activity or laboratory of interest is accredited for example where:
 - (a) There appears to be a risk of breach of a regulatory requirement
 - (b) There appears to be a potential risk to public safety or public confidence
 - (c) HTA considers it necessary in pursuit of their statutory objectives.
- 4.11. HTA shall, as necessary, collaborate with and provide technical and drafting assistance to UKAS for the guidance for assessors and laboratories.
- 4.12. HTA shall retain the right to decline scheduling of a joint inspection. When declining a joint inspection HTA will give the reasons for doing so to UKAS and the laboratory.

5. Liabilities

- 5.1. HTA shall not be liable to UKAS for any loss or damage including injury to reputation suffered by UKAS as a result of any of the HTA activities or reports.
- 5.2. UKAS shall not be liable to HTA for any loss or damage including injury to reputation suffered by HTA as a result of any UKAS activities or reports.

6. Costs and expenses

- 6.1. All parties shall be responsible for their own costs and expenses incurred as a result of this agreement.

7. Miscellaneous

- 7.1. The proposed process for review of the Memorandum of Understanding is for UKAS and HTA to meet twice a year in April and October to review the activities taking place



under the MoU.

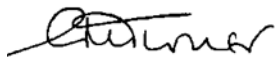
7.2. HTA and UKAS shall inform each other in writing of any changes in legislation or their procedures that may affect this Agreement, within seven days of the change being known.

7.3. The terms of this Agreement may be varied by the agreement of both parties in writing.

8. Termination

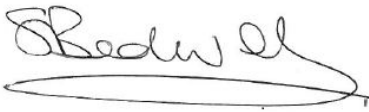
8.1. Either party may terminate this Agreement by giving the other three months written notice, or with seven days notice if either party fails to meet its obligations under this MoU. In the event that the agreement is terminated, inspections already scheduled may continue as planned.

8.2. Both organisations have a complaints and appeal process which will be used if the event that either has a grievance about the other in relation to the conduct of their activities under this MoU.



Director
The United Kingdom Accreditation Service

Date: 1 May 2015



Director of Regulation
Human Tissue Authority

Date: 1 May 2015

