



Memorandum of Understanding (MoU) between the Care Quality Commission and the Human Tissue Authority

1. The purpose of this Memorandum of Understanding (MoU) is to set out a framework to support the working relationship between the Care Quality Commission (CQC) and the Human Tissue Authority (HTA).
2. The CQC is the regulator of health and adult social care in England. The HTA is the regulator for the safe removal, use and disposal of human tissue and organs in the UK. The responsibilities and functions of the CQC and HTA are set out at Annex A.
3. This MoU relates only to regulatory activity in England. It does not override the statutory responsibilities and functions of the CQC and HTA and is not enforceable in law. However, the CQC and HTA agree to adhere to the contents of this MoU.
4. More detail about the working relationship between the CQC and the HTA is set out in a Joint Working Protocol, included as Annex B of this MoU.

Principles of cooperation

5. The CQC registers those who provide and manage regulated activities in relation to health and adult social care in England, and monitor their compliance with the regulatory requirements they have to meet, including the national standards of quality and safety. The HTA licenses and inspects organisations that remove, store and use tissue for medical treatment, post-mortem examination and teaching; it has responsibilities across the UK. There are some services which are registered with the CQC and hold one or more HTA licence; it is mainly in relation to these services where the CQC and the HTA will work together in cooperation as appropriate.
6. The CQC and the HTA intend that their working relationship will be characterised by the following principles:
 - a. the need to make decisions which protect and promote patient health, safety and welfare and promote high quality health care
 - b. a focus on working together by sharing information about relevant regulated services;
 - c. respect for each organisation's independent status and right to make different decisions about compliance given that different regulations apply;
 - d. the need to maintain public confidence in the two organisations
 - e. openness and transparency between the two organisations as to when cooperation is and is not considered necessary or appropriate;
 - f. the need to use resources effectively and efficiently through appropriate coordination and information sharing; and
 - g. the aim of learning from each other about good practice in regulation and working together to collectively influence policy where relevant.

7. The CQC and the HTA are also committed to transparent, accountable, proportionate, consistent, and targeted regulation (the principles of better regulation).

Exchange of information

8. Cooperation between the CQC and the HTA will often require the exchange of information. Exchange of information will be expected where either the CQC or the HTA identifies concerns about an organisation and those concerns are considered to be relevant to the other party's regulatory functions. The Joint Working Protocol (JWP) in Annex B sets out the detailed arrangements for sharing information between the parties.
9. All arrangements for co-operation and exchange of information set out in this MoU and the JWP will take account of and comply with the Data Protection Act 1998, section 76 Health and Social Care Act 2008, Human Tissue Act 2004 and human tissue secondary legislation, and all relevant CQC and HTA legislation relating to these matters and respective Codes of Practice, frameworks or other policies relating to confidential personal information and information issues.

Resolution of disagreement

10. Any disagreement between the CQC and the HTA will normally be resolved at working level. If this is not possible, it must be brought to the attention of the MoU managers identified at Annex C. The parties should aim to resolve disagreements in a reasonable time.

Duration and review of this MoU

11. This MoU is not time-limited and will continue to have effect unless the principles described need to be altered or cease to be relevant. The Annexes of the MoU will be reviewed after a period of 12 months commencing on the date on which it was signed by the Chief Executives of the two organisations. Any changes made to the Annexes, should be confirmed by relevant governance structures in each organisation; they do not require sign-off by the Chief Executives unless it is specifically deemed necessary. The MoU may be reviewed at any time at the request of either party.
12. The review of the annexes will include:
 - a. checking that relevant organisational, staff and contact details are current; and
 - b. reviewing whether the objectives of the joint working protocol have been met and whether the processes for sharing information need to be amended to improve effectiveness or efficiency.

13. Both organisations have identified an MoU manager at Annex C and these will liaise as required to ensure this MoU is kept up to date and to identify any emerging issues in the working relationship between the two organisations.
12. Both the CQC and the HTA are committed to exploring ways to develop increasingly more effective and efficient partnership working to promote quality and safety within their respective regulatory remits.
13. A Joint Working Group and Sub-group will oversee the development of operational working arrangements that support the delivery of the principles outlined in this MOU.

Signed



David Behan
Chief Executive
Care Quality Commission

Date: 4 January 2013



Alan Clamp
Chief Executive
Human Tissue Authority

Date: 4 January 2013

Annex A: Responsibilities and functions

1. The Care Quality Commission (CQC) and the Human Tissue Authority (HTA) acknowledge the responsibilities and functions of each other and will take account of these when working together.

Responsibilities and functions of the CQC

2. The responsibilities of the Care Quality Commission (CQC) are set out primarily in the Health and Social Care Act 2008 as amended (the 2008 Act) and the accompanying Regulations (as amended).

CQC's role is to protect and promote the health, safety and welfare of people who use health and social care services. It does this to encourage:

- The improvement of health and social care services
 - The provision of services that focus on the needs and experiences of people who use those services
 - The efficient and effective use of resources
3. CQC's purpose is to drive improvements in the quality of care through the unique function of measuring whether services meet national standards of quality and safety.

To do these things CQC

- Registers providers against national standards of quality and safety. These are the standards providers have a legal responsibility to meet and that people have a right to expect whenever or wherever they receive care.
- Monitors and inspects providers against those standards, carrying out inspections regularly, at any time in response to concerns. We also carry out themed inspections, themed reviews and specialist investigations based on particular aspects of care.
- Takes action if we find that a service isn't meeting the standards, using a range of powers. These include issuing a warning notice, restricting admissions, fining a provider or manager, and if necessary, cancelling a provider's or manager's registration or prosecuting them.
- Involve people in our work, working with local groups, national organisations and the public to make sure that the views and experiences of people are at the centre of what we do.

- Publish information about whether or not services are meeting the standards and national reports on key themes, and reports on the state of care.

Responsibilities and functions of the HTA

4. The responsibilities and functions of the HTA are set out primarily in the Human Tissue Act 2004 (HT Act), the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (Q&S (Organs) Regulations). In summary they are to:
 - issue licences under the HT Act, Q&S Regulations and Q&S (Organs) Regulations
 - inspect establishments licensed under the HT Act, Q&S Regulations and Q&S (Organs) Regulations
 - issue Codes of Practice setting out general principles which it considers should be followed in carrying out activities governed by the HT Act.
 - promote compliance with the HT Act, Q&S Regulations, Q&S (Organs) Regulations and Codes of Practice
 - provide advice and information for persons to whom licences apply or persons who may wish to undertake activities which are governed by the HT Act, Q&S Regulations and Q&S (Organs) Regulations.

Annex B: Joint working protocol

Introduction

The Care Quality Commission (CQC), Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) carried out some joint work in 2011/12 to look in detail at the three regulatory regimes. This was to identify possible ways in which we could reduce or improve regulatory overlaps for the benefit of registered or licensed organisations, and to develop mechanisms for sharing information about organisations where they are registered or licensed by more than one of the regulators. The work was carried out by a Sub-working group (SWG) which included representatives from each regulator, reporting to a Joint Working Group (JWG) of directors and senior managers from all three.

One output of this tripartite working group is the bilateral Joint Working Protocol between the CQC and the HTA included in this annex. The JWP sets out the detail of the working arrangements between the CQC and the HTA in two parts – **Operational protocols** which will be carried out by each regulator’s registration and inspection staff, and **Joint management arrangements** which will be carried out by members of the SWG or JWG.

The CQC and the HTA necessarily use different terminology to describe some aspects of their work, according to its governing legislation. Where this document refers to organisations, it also means registered or licensed providers.

Operational protocols

1. Master list

1.1 What information is in the master list?

A ‘master list’ has been developed which identifies all the organisations that are registered or licensed by both the CQC and the HTA. This list will enable each regulator’s staff to check whether an organisation is also regulated by the other. The main purpose of this is to facilitate information sharing between the regulators’ staff about organisations they ‘share’.

CQC registers a significantly higher number of providers than the HTA, therefore, CQC registered providers are only included on the master list if they are also licensed by the HTA. All HTA licences are included on the list; for completeness the master list includes HTA-licensed organisations outside of England in other parts of the UK.

The name and email contact details of the CQC compliance inspector allocated to each CQC-registered provider on the list will be included to facilitate sharing of information relating to an organisation’s compliance (see 2.2 below). There will be a single point of contact in the HTA for sharing this type of information.

1.2 Maintaining the list

It has been agreed that the Data Management team at CQC will maintain the list and keep it up-to-date. This will be done by the HTA providing CQC with information whenever a new organisation is licensed, or an existing licence is revoked, suspended or changed. That information will be provided by the central contact person in the HTA.

The information supplied will include:

- For new providers: the name of the service, contact details and licence details.
- For revocations or suspensions of existing licences: details of the cancellation or suspension.
- For changes to licences: details of amendments to the services' licence including contact details, provider details or changes to the licence itself.

When new information is received, CQC's Data Management team will refresh the list and email an updated copy to the contact person in the HTA. Any changes that are made on the master list to CQC providers or to CQC compliance inspectors' allocations will be automatically updated by CQC's Data management team and included in their monthly refresh of the list.

A routine updating and emailing of the list will be carried out by CQC in the first week of every month, where new information has been provided by the HTA or in the preceding month, or changes to CQC information have been made, so the list is continually up-to-date.

The HTA should send any updated information for the master list to the CQC Data Management Team and copied to the CQC MoU manager:

- CQC Data Management team: datamanagement@cqc.org.uk
- CQC MoU Manager: gemma.rafferty@cqc.org.uk

Updated versions of the master list will be sent to:

- CQC: gemma.rafferty@cqc.org.uk
- HTA: anthony.wright@hta.gov.uk

Any CQC compliance inspector who is affected by changes to the master list will also be notified.

2. Sharing information

2.1 Who will share information?

Information will generally be shared at an operational level, between HTA inspectors and CQC compliance inspectors and registration assessors. The information shared will relate to an organisation which is licensed or registered by both regulators.

2.2 Situations in which information will be shared

We will aim to foster a culture of information-sharing, in which inspectors are empowered to pick up the phone to their counterpart to discuss an organisation in their portfolio which is causing them concern. The email details of the CQC lead for the provider will be included in the master list so HTA inspectors can contact them directly. CQC inspectors will contact the single point of contact for the HTA set out in the master list, rather than individual inspectors. These contact details are:

- HTA: anthony.wright@hta.gov.uk

In order to record the volume and type of joint working activity between the CQC and the HTA, the CQC MoU Manager should be copied into correspondence relevant correspondence:

- CQC MoU Manager: gemma.rafferty@cqc.org.uk

There will be a two way sharing of information, which may be volunteered by one regulator to the other, or provided in response to a particular request. Information will only be shared where the organisation is regulated by, or carrying out activities which should be regulated or licensed by, both regulators.

Under certain circumstances, there will be an **expectation** that information held by one regulator will be shared with the other. These circumstances are as follows:

CQC	HTA
<ul style="list-style-type: none"> • Whistle-blowing event as defined by CQC 	<ul style="list-style-type: none"> • Whistle-blowing event as defined by HTA
<ul style="list-style-type: none"> • A notification is submitted by the provider which triggers a responsive inspection 	<ul style="list-style-type: none"> • Serious Untoward incident or SEAR reported that has the potential to cause a reputational risk to the establishment
<ul style="list-style-type: none"> • A responsive inspection is being undertaken 	<ul style="list-style-type: none"> • A non-routine inspection is arranged
<ul style="list-style-type: none"> • Registration is suspended or cancelled or conditions of registration are imposed by CQC to restrict the activities permitted. 	<ul style="list-style-type: none"> • Licence is suspended or revoked or steps are taken to restrict licensable activities.
<ul style="list-style-type: none"> • Enforcement powers are used, including issuing a warning notice, simple caution or fixed penalty notice 	<ul style="list-style-type: none"> • Significant regulatory sanctions are imposed
<ul style="list-style-type: none"> • Referral is made to another agency, for example the HSE or the MHRA 	<ul style="list-style-type: none"> • Referral is made to another agency, for example the HSE or the MHRA
<ul style="list-style-type: none"> • Media interest in an organisation, which may give rise to concerns which need further consideration. 	<ul style="list-style-type: none"> • Media interest in an organisation, which may give rise to concerns which need further consideration

In the circumstances listed above, the inspector will be expected to contact their counterpart in the other organisation, both to pass on the information and to ascertain whether there is any additional information held by the other regulator which should be taken into account. Contact may occur in other circumstances where it is considered to be appropriate and proportionate, and if necessary agreed with a relevant manager.

Each regulator should record the information shared, who it was shared with and when, and any outcomes. The manner in which this is done is up to individual regulators to determine.

3. What information will be shared?

The information to be shared in the situations listed above will include:

- background information about the organisation concerned and its compliance history
- information about regulatory action taken to date and the effect it has had
- the steps in place for on-going monitoring of compliance or follow up of required improvement or enforcement actions.

Only non-patient identifying information will be shared between the regulators under this protocol. Sharing patient identifiable information is subject to legal restrictions in both regulators. Account must also be taken of the Data Protection Act when information is shared about registered or licensed individuals and people who work for the provider.

Any proposed sharing of patient identifiable data should follow the policies and guidance of the disclosing organisation, and must be lawful and proportionate.

Where needed, case management meetings will be arranged between the regulators. This would be in exceptional circumstances only and subject to the agreement of the relevant senior managers.

4. FOI requests for information shared between the regulators

Any request under the FOI Act relating to information which was all or in part provided by the other regulator will not be released without first seeking advice from the organisation that provided the information. This includes information or data relating to serious incidents, which may include information about individuals. For example, if a CQC inspector informs an HTA inspector about allegations made by a whistle-blower, following which an FOI request is received by the HTA for information held about the organisation concerned, no information relating to the incident would be released without discussion with the CQC about whether the information which had been shared is subject to any exemptions under the FOI Act or Data Protection Act.

Legal responsibility for responding to an FOI Act request – including final responsibility for making any decision to withhold information under exemption - remains with the organisation receiving that request.

5. Press enquires

Where inspectors share information about regulatory non-compliance within an organisation, and that organisation becomes the subject of press interest, the regulators will co-ordinate their press responses, while ensuring that the judgement or position of each is adequately reflected.

Joint management arrangements

This JWP will have effect for a period of 12 months commencing on the date on which the MoU was signed by the Chief Executives of the two organisations. The JWP may be reviewed at any time at the request of either party.

The formal review date will be: 2 January 2014

1. Review of master list

The efficacy of using the master list will be reviewed by the SWG of the JWG every six months. The SWG will canvas views and experiences of inspectors in each of the regulators and the CQC Data Management team to establish whether the list is working well, or improvements to the process need to be made.

The SWG will make recommendations to the JWG depending on the findings of the review.

2. Review of operational protocols and joint working arrangements

The efficacy of implementing the protocols for sharing information will be reviewed by the SWG every six months. The SWG will undertake an audit of when and under what circumstances information has been shared, the impact of that on regulatory responses, and whether any improvements to the process or changes to the scope of information sharing need to be implemented.

The SWG will make recommendations to the JWG depending on the findings of the review.

The Chief Executives of the CQC and the HTA will meet annually; the meeting will include consideration of joint working arrangements. Additional meetings may be called at any time if required.

Annex C: Contact details

Care Quality Commission Finsbury Tower 103 – 105 Bunhill Row London EC1Y 8TG Telephone: 03000 616161	Human Tissue Authority 151 Buckingham Palace Road, Victoria, London SW1W 9SZ Telephone 020 7269 1900
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There will be named contacts between the CQC and the HTA as follows:

Chief Executives (internal escalating policies should be followed before referral to Chief Executives)	
David Behan Chief Executive Email: david.behan@cqc.org.uk	Alan Clamp Chief Executive Email: alan.clamp@hta.gov.uk
MoU management (including strategic issues)	
Gemma Rafferty Regulatory Policy Manager Email: gemma.rafferty@cqc.org.uk Direct lines: 020 7448 0878	Caroline Browne Head of Regulation Email: caroline.browne@hta.gov.uk Direct line: 020 7269 1927