# WRITTEN STATEMENT

# BY

# THE WELSH GOVERNMENT

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| **TITLE** | **Human Tissue Authority report relating to an inspection of mortuary facilities within the Cardiff and Vale University Health Board** |
| **DATE** | **8 November 2017** |
| **BY** | **Vaughan Gething AM, Cabinet Secretary for Health and Social Services** |

Today, the Human Tissue Authority (HTA) has published their report relating to an inspection of mortuary facilities within the Cardiff and Vale University Health Board at University Hospital of Wales (UHW) which took place on 9 and 10 August 2017.

The report identifies significant shortfalls against a number of standards which include traceability, premises and governance. Cardiff and Vale University Health Board has been actively working, over the past few weeks, to address these. Whilst I have been unable to make a public statement prior to the HTA publication of the report, I have discussed this matter directly with the Chair; in addition, my officials have had a number of discussions with the chief executive and executive team.

The HTA is a regulatory agency, which licences and inspects organisations that store and use human tissue for purposes such as research, patient treatment, post-mortem examination, teaching and public exhibitions.

As part of their regulatory function the HTA carries out inspections of licensed establishments. Under the Human Tissue Act 2004, the HTA has a statutory responsibility to make judgments about the suitability of the designated individual (DI); licence applicant (Holder); premises and practices in relation to the licensed activities.

The HTA publishes 13 standards that licensed establishments must meet, inspect against these standards and check that appropriate procedures are being followed. They inspect establishments on a cyclical basis, usually every three to five years, according to the potential risk of establishments, focusing on those posing the higher risk, owing to the nature of activity and impact on patients and families if things were to go wrong.

All licensed establishments must appoint a DI who has a legal duty to ensure that statutory and regulatory requirements are met. They are responsible for supervising licensed activities and ensuring suitable practices are taking place.

The HTA inspection reports are exception-based: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as ‘Critical’, ‘Major’ or ‘Minor’. Where HTA standards are met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

The latest routine inspection of mortuary facilities at UHW highlighted deficiencies against a number of the standards tested, including traceability, premises and governance. It identified three critical, 14 major and nine minor shortfalls against the standards. The three critical shortfalls related to traceability, audit, and management of post mortem samples.

The HTA set the health board a timeframe to undertake a number of actions to address the issues identified.

Significant work has been undertaken by Cardiff and Vale University Health Board since the inspection and receipt of the draft inspection report on 6 September. An improvement action plan has been implemented and they have met all HTA deadlines so far. A longer term action plan is in place to address the remaining issues. Actions taken include replacing the DI, an audit of all post-mortem material currently being held at the mortuary and work is ongoing to address the facilities issues.

The HTA has already revisited the site to undertake a follow up inspection and are satisfied with the progress on actions being implemented to meet the shortfalls identified during the initial inspection.

I am deeply disappointed in the failings identified and there is still further work required to ensure the site is fully compliant. All NHS Chief Executives have been reminded of health boards’ responsibilities in relation to compliance with the Human Tissue Act 2004, its associated regulations, codes of practice and standards. The Chief Medical Officer’s office will continue to monitor the corrective and preventative actions being implemented to provide the assurances about progress on the shortfalls identified during the inspection.

A copy of the inspection report is available on the Human Tissue Authority website.

[https://www.hta.gov.uk/sites/default/files/2017-08-09%2012163%20University%20Hospital%20of%20Wales%20inspection%20report%20FINAL.pdf](https://emea01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hta.gov.uk%2Fsites%2Fdefault%2Ffiles%2F2017-08-09%252012163%2520University%2520Hospital%2520of%2520Wales%2520inspection%2520report%2520FINAL.pdf&data=02%7C01%7CCaroline.Lewis%40gov.wales%7C84910fcad1ed4166137b08d52687573c%7Ca2cc36c592804ae78887d06dab89216b%7C0%7C1%7C636457285095247615&sdata=BPo6QcSeEyaqQ7KUZWuVtHUZz3FDqBbLJtH7CVOaBRE%3D&reserved=0)

<http://www.cardiffandvaleuhb.wales.nhs.uk/news/46632>