

Dear Colleague

General Directions 002/2011 given under the Human Tissue Act 2004 (HT Act)

The HTA has issued new General Directions for the Anatomy, Public Display and Research sectors today. The Directions require all licensed establishments to complete a self assessment against HTA standards and to provide some supplementary information by **Thursday 30 June 2011**. The submission should be completed via the online form HTA01-002/2011 on the HTA website, where you will also find information to guide you.

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/htalegaldirections.cfm>

Why are we asking you to complete a self assessment?

As part of the move to continuous licensing in April 2009, rather than a fixed licence period, we informed establishments that they would be required to provide an update of their performance against HTA standards, to assure the HTA that they continue to be suitable to be licensed to undertake activities under the HT Act. These General Directions initiate the two-yearly (biennial) self assessment process.

As well as information about how they meet HTA standards, we are asking establishments for some additional details about the licensable activities being undertaken and some sector-specific questions which will inform our risk assessments. The HTA will use the information gathered to inform the scheduling of site-visit inspections. It will also be used to guide our regulatory approach to each sector.

What should you do if you have been inspected recently / are due to be inspected in the near future?

To ensure parity, all establishments are required to complete the exercise, regardless of whether they have just been inspected by the HTA or are due to be inspected, so that the HTA has the most up to date information available.

Is completion of the self assessment compulsory?

Yes; however, the HTA acknowledges that staff at our licensed establishments are very busy and may have limited resources. We have tried to minimise the time required to complete the self assessment through the use of multiple choice questions. This is not just a paper exercise, it is essential in order for us to maintain oversight of the sectors we regulate and ensure public confidence in the safe and ethical use of human tissue.

It is not the intention of the HTA to use the results of the self assessment required by these General Directions to target establishments for regulatory action. Where there are shortfalls in meeting HTA standards, the HTA will provide advice to individual establishments and to sectors as a whole where necessary, and would take regulatory action only if critical shortfalls against HTA standards make this necessary.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Craig Muir', written in a cursive style.

Craig Muir
Chief Executive
Human Tissue Authority