

<b>POL reference</b>	HTA/POL/035 Regulatory Enforcement Policy	<b>Approved by</b>	HTA Authority
<b>Version number</b>	V0.5	<b>Date:</b>	01/10/2008
<b>Author(s)</b>	Caroline Browne	<b>Review Date</b>	6 months from date of approval and annually thereafter
<b>Owner</b>	Sandy Mather	<b>Distribution</b>	HTA staff, Designated Individuals, Licence Holders and other interested stakeholders

## Regulatory enforcement policy

### Background

1. The HTA's functions include superintending compliance with the requirements of the Human Tissue Act 2004 (HT Act) and the HTA's codes of practice. In addition, the HTA also has duties under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 to ensure that the requirements of the European Union Tissue and Cells Directive and its technical Directives are met. As part of its statutory remit, the HTA licenses establishments, carries out inspections, conducts investigations and seeks to help establishments improve standards by providing advice and guidance. Where regulatory breaches are identified, appropriate regulatory action is taken in line with this enforcement policy.
2. It is a statutory duty of the HTA to have regard to the principles of best regulatory practice, including the need to act in a proportionate and consistent way and to target regulatory action where it is most needed. To this end, the HTA regulates according to risk by focusing on establishments whose non-compliance with the HTA's standards has, or is likely to have, the most significant impact. The HTA also has regard to the Better Regulation Executive's (BRE) Statutory Code of Practice for Regulators in carrying out its functions. In keeping with the BRE's Code, the primary aims of this enforcement policy are to reduce the likelihood of future non-compliance and to ensure that regulatory enforcement action is proportionate to the nature of the offence and the harm caused.

## **The HTA's approach**

### **Licensed establishments**

3. If the HTA becomes aware of a possible regulatory breach or potential offence under the HT Act or associated Regulations by an establishment licensed by the HTA, the Regulation Directorate will carry out an investigation and provide advice and guidance to the establishment concerned to assist it in complying with our standards and any licence conditions attached to its licences. Where appropriate, we may also give guidance to all Designated Individuals and Licence Holders in the sector by way of a Regulatory Alert, and may also develop or revise our policies and provide further information via the HTA website, e-newsletter or in other suitable ways.
4. The HTA works as a compliance-based regulator, which means we place a strong emphasis on the value of providing advice and guidance to professionals working within the sector so that they understand the regulatory requirements and are better equipped to meet our standards. The provision of advice and guidance can be reactive or proactive, and it can be verbal – for example during on-site inspection or at training events for Designated Individuals – or in written format, for example via letter, email, the website and e-newsletter.
5. Where enforcement through regulatory action is also necessary, we aim to make evidence-based, justifiable and proportionate decisions. Where a potential offence is identified, the Criminal Prosecution Policy will be triggered.

### **Unlicensed establishments**

6. If the HTA receives information that licensable activities are being carried out without a licence, we undertake an investigation and if necessary issue both advice and warning. The HTA normally requires the establishment to suspend activities, apply for a licence and to transfer material to alternative licensed premises pending the grant of a licence. In some cases, where a breach of the licensing requirements is also a criminal offence, the HTA will consider referring the case to the police, in line with its Criminal Prosecutions Policy.

### **Regulatory Action**

7. Where the HTA finds that a standard is not being met (or a licence condition is not being complied with), formal regulatory action may be taken where the non-compliance triggers the HTA's power to revoke and therefore vary a licence. There are several different types of regulatory action that may be considered by the HTA: variation of licences through, for example, the imposition of additional conditions; issue of special directions; suspension of a licence or revocation of a licence. In the majority of cases,

the HTA will take regulatory action by varying a licence to impose additional conditions. Additional conditions are time-bound and Designated Individuals (DIs) are required to inform the HTA when they have taken appropriate action to comply with them. The HTA then assesses this information to decide whether the establishment has met the condition or whether further regulatory action should be taken.

### **Regulatory Action Panel (RAP)**

8. The RAP is non-statutory and is set up as an internal panel by the HTA to consider complex regulatory issues. The purpose of the RAP is to ensure that all relevant considerations are taken into account and that a fair, proportionate and justifiable licensing decision is made. Regulatory action resulting from a RAP can be statutory and non-statutory. The statutory action includes inspection (which in this case the HTA would describe as a heightened risk inspection - see below), licence suspensions, revocations, variations and Special Directions. The non-statutory action is typically in the form of verbal and written advice and guidance and/or advice and warning.
9. All licensing decisions made following a RAP are reasoned. They are also intended to be consistent with decisions made where similar circumstances existed although any exceptional circumstances, which may warrant a departure from previous similar decisions, will be considered.
10. Where the HTA considers that there has been an increase in the establishment's risk, we may choose to carry out a previously unscheduled inspection, possibly unannounced (a heightened risk inspection). Following a heightened risk inspection the findings are normally considered by a RAP and further regulatory action may be taken.
11. For each establishment the HTA maintains a licensing record. This ensures that any regulatory action taken is fully informed and based on a good understanding of the establishment's particular circumstances and regulatory history.

### **Representations Panel**

12. A Representations Panel is non-statutory but is set up to comply with the statutory process enabling establishments to seek a review by the HTA of certain proposed licensing decisions. The panel considers oral and/or written representations by the holder of a licence and where different the Designated Individual (or the applicant for a licence). The Representations Panel consists of HTA staff and includes the original licensing decision maker and a member of the senior management team. It is attended by a legal adviser and may also have other external advisers. There is a detailed standard operating procedure in place for this process. Establishments have a statutory period of 28 days (from the date the establishment is notified of the proposed decision) to indicate that they wish to make representations against certain

proposed licensing decisions such as refusal to grant a licence, licence variations and revocations. Representations are a means by which usually the Licence Holder, or, where different, the Designated Individual has an opportunity to state their case as to why a proposed licensing decision should not be made.

### **Appeals Committee**

13. An Appeals Committee is a statutory committee and is maintained under section 20 of the HT Act (and as applied by the Human Tissue (Quality and Safety for Human Application) Regulations 2007) for the HTA to reconsider certain licensing decisions. The Appeals Committee is comprised of not less than five members of the Authority and the quorum for it is three. It is important to note that this Appeals Committee comprises Members of the Authority as opposed to Executive staff of the HTA. Establishments have a statutory period of 28 days (from the date the establishment is notified of the licensing decision) to indicate that they wish the HTA to reconsider that decision.

### **Review**

14. This policy will be reviewed in six months and annually thereafter.

### **Revision History**

<b>Date</b>	<b>Version</b>	<b>Comments</b>
26 March 08	V0.1	Initial draft, SG
11 August 08	V0.2	Revised draft, CB
19 August 08	V0.3	Reviewed by RMG and minor amendments made
18 September 08	V0.4	Reviewed by Authority and minor amendments made
24 September 08	V0.5	Reviewed by SG, SJM and minor amendments made

### **Linked documents - Policies**

HTA/POL/23 Criminal Prosecution Process

### **Linked documents - Standard Operating Procedures (SOPs)**

REG/SOP/22 Enforcement action in response to unlicensed establishments carrying out licensable activities

REG/SOP/26 Regulatory Action Panels

REG/SOP/14 Representations