



Department for  
Business, Energy  
& Industrial Strategy

# BUSINESS IMPACT TARGET: SUMMARY TEMPLATE

Non-qualifying Regulatory Provisions  
(NQRP) summary reporting template

**Regulator:** Human Tissue Authority

**Business Impact Target Reporting Period Covered:** 21 June 2018 to 20 June 2019

<b>Excluded Category*</b>	<b>Summary of measure(s), including any impact data where available**</b>
<p>Measures certified as being below <i>de minimis</i> (measures with an EANDCB below +/- £5 million)</p>	<p><u>Casework</u> Figures cover the 2018/19 business year. This is considered as representative of a 12 month period.</p> <p>As of June 2019, the HTA licensed 564 establishments across six sectors. Of these, 322 establishments were public sector organisations and 242 were classified as businesses.</p> <p>For this reporting period, the HTA's casework did not introduce any new measures, or changes to activity, that would change the burden of regulation placed on business.</p> <p>Between 1 April 2018 and 31 March 2019, the HTA managed:</p> <ul style="list-style-type: none"><li>• 223 site visits of licensed premises, resulting in 1,533 shortfalls.</li><li>• 568 incidents reported across six sectors.</li><li>• 15 new licence applications.</li><li>• 639 licence variation requests.</li><li>• Information submissions for 35 preparation process dossiers.</li></ul> <p>In January 2019, 136 establishments in the Human Application sector were required to submit an annual activity return. This information is collected annually to fulfil EU legislative requirements. Information was also requested on the import and export of tissues and cells from, and to, EU Member States.</p> <p>The HTA has a statutory duty to make a decision on whether or not to approve every proposed case of living organ donation. This is to ensure that every donation takes place with valid consent, and to ensure that the donor is acting free from duress, coercion and reward. In 2018/19, the HTA made a decision on 1,228 organ donation cases from living donors – a panel of HTA Authority Members made a decision on 322 of these.</p> <p><u>Education, communications activities and promotional campaigns</u></p> <p>The HTA produces a newsletter for professional stakeholders every two months. This contains general information about the HTA's activities, and signposts to latest news, updated guidance and policies.</p>

<b>Excluded Category*</b>	<b>Summary of measure(s), including any impact data where available**</b>
	<p>A quarterly newsletter is sent to Independent Assessors.</p> <p>During the reporting period, the HTA published guidance for each of its sectors on how to meet existing regulatory requirements.</p> <p>It also published guidance for establishments on how to prepare for EU Exit.</p> <p>In March 2019, the HTA launched online tests on HTA legislation. These were publicised to stakeholders, but are not mandatory.</p> <p>A blog on HTA regulatory activity was launched in May 2019.</p> <p>The HTA updated its guidance on incident reporting in the Post Mortem sector. This included a minor modification to certain reporting categories.</p>
EU Regulations, Decisions and Directives and other international obligations, including the implementation of the EU Withdrawal Bill and EU Withdrawal Agreement	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion
Measures certified as concerning EU Withdrawal Bill operability measures	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion
Pro-competition	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion
Systemic Financial Risk	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion
Civil Emergencies	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion
Fines and Penalties	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion
Misuse of Drugs	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion
Measures certified as relating to the safety of tenants, residents and occupants in response to the Grenfell tragedy	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion

Excluded Category*	Summary of measure(s), including any impact data where available**
Casework	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion
Education, communications and promotion	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion
Activity related to policy development	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion
Changes to management of regulator	Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion

\* For detailed guidance on the exclusion categories, please see <https://www.gov.uk/government/publications/better-regulation-framework>

\*\* Complete the summary box as 'Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion.' where this is appropriate.