



Department for
Business, Energy
& Industrial Strategy

BUSINESS IMPACT TARGET: SUMMARY TEMPLATE

Non-qualifying Regulatory Provisions
(NQRP) summary reporting template



Regulator: Human Tissue Authority (HTA)

Business Impact Target Reporting Period Covered: 13 December 2019 – 16 December 2020

Excluded Category*	Summary of measure(s), including any impact data where available**
<p>Measures certified as being below de minimis (measures with an EANDCB below +/- £5 million)</p>	<p>Casework</p> <p>At the end of September 2020, the HTA licenced 579 establishments across six sectors. Of these, 327 establishments were public sector organisations and 252 were classified as businesses.</p> <p>Casework figures have been determined for an annual period deemed representative of the reporting period.</p> <p>Between 1st October 2019 – 30th September 2020, the HTA managed:</p> <ul style="list-style-type: none">71 site visits of licensed premises, resulting in 297 shortfalls identified with corrective action required.575 incidents reported across six sectors27 new licence applications833 licence variations requests82 preparation process dossiers submissions <p>129 establishments in the Human Application sector submitted an annual activity return.</p> <p>Between 1st October 2019 – 30th September 2020, the HTA made a decision on 872 organ donation cases from living donors – a panel of HTA Authority Members made a decision on 233 of these.</p> <p>Advice and guidance</p> <p>The Organ Donation (Deemed Consent) Act 2019 introduced a system of deemed consent for organ and tissue donation in England. To coincide with the law change, the HTA published a revised Code of Practice, providing advice and guidance to transplant professionals in England on how the new deemed consent system will affect their practice.</p> <p>Updated guidance for emergency mortuary licensing in a pandemic scenario and on consent and licensing for removing samples from the deceased for testing.</p>

Excluded Category*	Summary of measure(s), including any impact data where available**
	<p data-bbox="547 237 979 271">Changes to regulatory processes</p> <p data-bbox="547 309 1321 495">Change to the management of processes for relating to the publication of data relating to incidents reported in three sectors. This change decreased the time spent on agreeing incident closure statements and is intended to streamline publication processes.</p> <p data-bbox="547 539 1321 611">Introduction of fixed-term licences to facilities that remove samples from the deceased for testing.</p> <p data-bbox="547 656 1394 808">The HTA introduced Virtual Regulatory Assessments (VRAs), with 10 carried out in the reporting period. These allow regulatory oversight and assessment of establishment compliance without an on-site inspection and can be targeted to risk.</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
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

Excluded Category*	Summary of measure(s), including any impact data where available**
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 full, legal definitions of these exclusion categories, please see

<https://www.parliament.uk/business/publications/written-questions-answers-statements/written-statement/Commons/2018-06-20/HCWS776/>

** 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.