



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:** 17 December 2021 – 16 December 2022

Excluded Category*	Summary of measure(s), including any impact data where available**
Measures certified as being below <i>de minimis</i> (measures with an EANDCB below +/- £5 million)	The HTA revised and published (2 September 2022) its <b>Code of Practice F part 2</b> , to reflect the introduction, in Spring 2023, of deemed consent for deceased organ and tissue donation for the purpose of transplantation in Northern Ireland (NI). The code is currently laid before the UK parliament and will come into force in NI in Spring 2023.
<i>EU Regulations, Decisions and Directives and other international obligations, including the implementation of the EU Withdrawal Bill and EU Withdrawal Agreement</i>	-
<i>Measures certified as concerning EU Withdrawal Bill operability measures</i>	-
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
Casework	As of 21 October 2022, 614 establishments had an HTA licence across six diverse sectors. Of these, 328 establishments were public sector organisations and 286

Excluded Category*	Summary of measure(s), including any impact data where available**
	<p>were classified as businesses.</p> <p>Casework figures have been determined for an annual period deemed representative of the reporting period.</p> <p>Between 1 October 2021 and 21 October 2022, the HTA delivered:</p> <p>224 inspections, of which 45 inspections were site based, 63 were entirely virtual and 116 had both a site visit and virtual component.</p> <p>The HTA continues to utilise a hybrid model of assessments using Virtual Regulatory Assessments (VRAs) with an onsite inspection component for establishments conducting higher risk activities.</p> <p>This resulted in 835 shortfalls identified with corrective actions required.</p> <p>In addition:  818 incidents were reported  36 new licence applications were submitted  899 licence variation requests were received  58 preparation process dossier submissions  144 establishments in the Human Application sector submitted an annual activity return.</p> <p>The HTA made a decision on 1021 living organ donation cases – a panel of HTA Board Members made a decision on 230 of these. 85 bone marrow/Peripheral Blood Stem Cell cases were also considered and approved by the HTA.</p>
Education, communications and promotion	The HTA revised and published (27 September 2022) <b>Code B Standards and Guidance: Post Mortem examination</b> guidance to reinforce the importance of establishments considering all risks to the dignity of the deceased.
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	On 1 January 2022 the HTA appointed Dr Colin Sullivan as Chief Executive Officer. Lynne Berry, Chair of the HTA Board, was reappointed to 2025.

\* 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.