



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 2020 – 16 December 2021

| 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) | <p>The HTA revised and published its Code of Practice D, to make consent expectations for the public display of imported bodies and body parts the same as for those sourced in England, Wales or Northern Ireland.</p> <p>Changes to regulatory processes From February 2021 the HTA has also introduced Virtual Regulatory Assessments (VRAs) to the Anatomy, Post Mortem, Research and Organ Donation and Transplantation sectors. A blended inspection model, combining VRAs with a site visit has also been introduced in some sectors that the HTA regulates. This approach is designed to provide greater flexibility in terms of regulatory oversight of licensed establishments and can be targeted to risk. This is intended to minimise time on-site and reduce the regulatory burden on licensed establishments.</p> |
| <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 |

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|---|--|
| Casework | <p>At the end of September 2021, 608 establishments had an HTA licence, across six diverse sectors. Of these, 328 establishments were public sector organisations and 280 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 2020 and 30 September 2021, the HTA managed:</p> <p>75 VRAs, including two with a site visit component, resulting in 232 shortfalls identified with corrective actions required. 647 incidents reported across six sectors 52 new licence applications 765 licence variations requests 54 preparation process dossier submissions 129 establishments in the Human Application sector submitted an annual activity return 1 new fixed-term emergency mortuary licence application 5 emergency mortuary licences had an extension to term 4 new fixed-term licences issued to facilities that remove samples from the deceased for testing for COVID-19 infection as part of a public-health surveillance scheme.</p> <p>The HTA made a decision on 902 living organ donors – a panel of HTA Board Members made a decision on 255 of these. 51 bone marrow/PBSC cases were also considered and approved by the HTA.</p> <p>The United Kingdom (UK) left the European Economic Area (EEA) single market and customs union which resulted in changes in HTA licensing requirements for the movement of human tissues and cells between Great Britain (GB), Northern Ireland (NI), and the EEA. 16 new licences were issued, and 31 existing licences were varied.</p> |
| Education, communications and promotion | <p>Revisions were made to Post Mortem sector policies and guidance documents for clarity. Guidance notes were also issued to regulated sectors throughout the reporting period to provide advice and guidance on how to comply with our regulatory standards and to prepare for EU exit.</p> |
| Activity related to policy development | <p>Following consideration of the exclusion category there are no measures for the reporting period that qualify for the exclusion</p> |
| Changes to management of regulator | <p>In January 2021 the office location moved from Victoria, London to Stratford, London. Staff were offered the option of home or office-based contracts.</p> |

* 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.