

# **SPECIFICATIONS:** Tar Nicotine and Carbon Monoxide (TNCO) Testing in cigarettes Services



1.	Executive Summary	2
2.	Definitions	2
3.	The Contract Requirement	3
4.	The Provider Requirements	3
	Expected Outputs	
6.	Authority Responsibilities	5
7.	Provider Responsibilities	5
8.	Detailed specification of Survey	5
9.	Key Performance Indicators	9
10.	Additional Responsibilities	9
11.	Timetable	
12.	Skills and Knowledge Transfer	10
13.	Intellectual Property	10
14.	Indicative Costs	10

#### 1. EXECUTIVE SUMMARY

- 1.1 As part of the overarching objective of the Government to protect the health of the public, there is an effective comprehensive tobacco control programme in place in the UK, which contributes to reducing smoking prevalence and the health harms of smoking. This programme, which is based on tried and tested global tobacco control strategies, includes smoking cessation, media and education campaigns, a high tax policy, reducing exposure to second-hand smoke, reducing tobacco advertising and legislation governing the contents, packaging and labelling of tobacco products. The latter is regulated by a number of UK laws, which were transposed from the <a href="EU Tobacco Products Directive 2014/40/EU">EU Tobacco Products Directive 2014/40/EU</a> a statutory obligation that places tobacco product regulation obligations on Member States of the European Union (EU).
- 1.2 Under the Northern Ireland Protocol, December 2020, this statutory obligation continues to apply to Northern Ireland (NI), which is subject to EU regulations related to the Single Market for goods and the Customs Union. Under Article 6 and 7, the market in Northern Ireland shall be governed by the law of the United Kingdom (UK).
- 1.3 The responsibility for meeting Tar, Nicotine and Carbon Monoxide (TNCO) testing obligation has been conferred to the Office for Health Improvement and Disparities (OHID), Department of Health and Social Care (DHSC) as the UK Competent Authority for Tobacco and Related Products Regulations. The UK meets the obligation to test for TNCO by appointing an accredited testing laboratory, which is able to demonstrate independence from the tobacco industry (hereafter known as the Industry), and has the capacity to fulfil the requirements as set out in the relevant UK tobacco control regulations; the Tobacco and Related Products Regulations 2016/507, The Standardised Packaging of Tobacco Products Regulations 2015/829 and The Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020/1316.
- 1.4 The UK Tobacco and Related Products Regulations 2016 (TRPR 2016) necessitates that TNCO emissions from cigarettes sold in the UK must be measured in accordance with standards: ISO 4387 for tar, ISO 10315 for nicotine, ISO 8454 for carbon monoxide and ISO 8243 for accurate measurements of TNCO emission levels. Also must meet, the visual surveillance of standardised packaging of tobacco products (SPoT) requirements. Additionally, spot-check emission testing for other cigarette chemicals may be required, in line with regulations.
- 1.5 This applies to the four home countries of the UK: England, Northern Ireland, Scotland and Wales that make up the UK. In order to fulfil UK statutory requirements, this specification sets out the requirements for a regular survey of all cigarette brand variants on sale in the UK and those intended for sale in the UK through the travel retail sector must undergo TNCO testing. This includes all brands that are produced, even those that are only imported twice a year. Any products found to be in non-compliance with TNCO standards will be removed from sale in the UK.
- 1.6 The current TNCO testing contract expires on 31 December 2022. Initially the new contract will befor a period of three years from 1 January 2023 to 31 December 2025, with a standard break clause at the end of each year and an option to extend for a maximum of two years from 1 January 2026. Therefore, applicants should clearly state their pricing for each of the next three years and the additional two-year extension period.
- 1.8 Payment will be made by The Office for Health improvement and Disparities (OHID) upon receipt of an accurate invoice, following the agreed completion of all KPIs and receipt of accurate reports in each testing period, and in accordance with the Civil Service 30-day payment policy.

# 2. **DEFINITIONS**

- 2.1 'The Survey' refers to the specific content of this specification as delivered over each twelve-month annual period. This includes the testing of TNCO and the requirements for the monitoring of labelling and packaging of cigarettes at various points throughout the year. For the purposes of this contract, the annual survey will consist of 6 discrete testing periods a year, each lasting two months.
- 2.2 'The Authority' refers to OHID, the designated authority of the Secretary of State for the management of this process.

- 2.3 'The Producer' takes the meaning provided in Regulation 3(1) of Statutory Instrument 2016/507 and Statutory Instrument 2020/1316:
  - "A person produces a tobacco product or related product if in the course of a business and with a view to the product being supplied for consumption in any part of the United Kingdom or through the travel retail sector, the person;
- (a) manufactures the product (as defined in Regulation 13(2));
- (b) puts a name, trademark or other distinguishing mark on it by which the person is held out to be its manufacturer or originator; or
- (c) imports it into the United Kingdom.
- 2.4 'The Provider' refers to the successful applicant to this process.
- 2.5 'Skill requirement' refers to any skill identified in this specification that is required for the successful delivery of this contract.

#### 3. THE CONTRACT REQUIREMENT

- 3.1 The Provider will provide expertise in the area of testing tobacco emissions and will deliver the testing of TNCO emission levels in cigarettes and the surveillance of SPoT requirements. The Provider will test samples of cigarettes provided to it by Producers, on behalf of the Authority. and provide expertise in the area of testing tobacco and related products.
- Following the UK's exit from the European Union on 31 December 2020, the Tobacco Industry is required to notify cigarette products to be sold in Northern Ireland (NI) separately to those products being sold in Great Britain (GB). For the purposes of TNCO yield testing, any identical products sold in both NI and GB should be treated as one product. However, any products sold uniquely in NI or GB are tested as separate products.
- 3.3 The Service Provider must generate electronic reports for OHID at two-month intervals, in a format to be agreed with OHID, and in compliance with ISO 8243 standard. Reports must highlight any cigarette brands that are above the maximum yields stipulated in regulation 13 of SI 2016/507. This data will ensure the effective monitoring of TNCO smoke yields in accordance with ISO standards as well as the limits set in EU and UK regulations and will allow the necessary enforcement steps to be taken should there be any instances of non-compliance.
- The Provider is also required to monitor compliance of producers with regulations 5, 6, 7, 8, 9, 11, 12 and 15 of SI 2016/507, and regulations 3, 4, 5, 6, 10, 11 and 12 of SI 2015/829 and regulations 2,3,5,6 and 7 in SI 2020/1316. These relate to the labelling and packaging of cigarettes, including requirements on combined health warnings, general warnings and information messages, general conditions applicable to all health warnings, images on tobacco products targeted to consumers and the appearance, packaging and product presentation, and where practicably possible flavouring.
- The Provider must note the two different regulatory requirements applicable to GB and NI around rotation of the different sets of graphic picture warning photographs for different production years (and subsequent years), as set out in regulation 6 of SI 507/2016 for cigarettes to be sold in NI and regulations 5 and 6 of SI 1316/2020 for cigarettes to be sold in GB. The Provider must note the requirement to rotate the sets of graphic warnings for the different production years (and subsequent years), as set out in Regulation 6 of SI 2016/507. A production year is a period of 12 months beginning with 20 May and ending with 19 May.
- The Provider may also be required to undertake occasional cigarette emission testing for chemicals other than Tar, Nicotine and Carbon Monoxide, to ascertain compliance with other regulatory requirements. This might include independent laboratory analysis of the yields of menthol (or menthol analogue alternatives) in specified cigarette brands, in pursuance of Regulation 15 of the TRPR 2016 <a href="http://www.legislation.gov.uk/uksi/2016/507/regulation/15/made">http://www.legislation.gov.uk/uksi/2016/507/regulation/15/made</a> in accordance with relevant ISO standards. Such testing will be randomised spot-checks on an ad-hoc basis, at the specific request of the Authority, and will not exceed more than one testing cycle per brand each year.

# 4. THE PROVIDER REQUIREMENTS

- 4.1 Demonstrate non-controllability and independence from the tobacco industry.
- 4.2 Have the capacity to carry out the skill requirement in terms of human resources, technical expertise, quality systems, smoking and analytical instruments, electronic reporting systems, and provide evidence to show that it is capable of executing a programme of work of the magnitude required.
- 4.3 Hold national accreditation, listed in Section 8.7.2 of this specification in respect of the relevant smoke yield analysis, as required.
- 4.4 Demonstrate expertise in analytical procedures related to tobacco emissions.
- 4.5 Fulfil the requirements set out by the <u>European Commission in the Practical Guide for 'Cigarette yield measurement and some basic steps for laboratory approval'</u>, published on 11 September 2007.
- 4.6 Comply with the standards required by the European Commission and <u>The Tobacco and Related Products Regulations</u> 2016 in relation to the testing of tobacco and related products.

- 4.7 Demonstrate practical experience of tobacco (in particular cigarette) technology and the principles of cigarette manufacture.
- 4.8 Demonstrate an up-to-date knowledge of the main types of instrumental chemical analysis, smoking methodologies, and their limitations.
- 4.9 Demonstrate experience in collaborative (round robin) testing and participation in recognised annual collaborative tests.
- 4.10 Have comprehensive knowledge of quality procedures, demonstrated expertise in the use of quality systems and comply with Global Laboratory Practice or national equivalent, as far as reasonably practicable.
- 4,11 Be aware of European and International activity in relation to the testing of tobacco and related products

#### 5. EXPECTED OUTPUTS

- 5.1 Undertake the annual survey of all cigarette brand variants of each brand of cigarette for TNCO yields throughout the 12-month calendar year.
- In addition to the annual survey of all cigarette brand variants, testing will also include 'one point in time' analyses of new brand variants launched, in the UK domestic market or UK travel retail sector. This testing will constitute 20 determinations of one production batch of individual cigarette brand variants and may be required at any point in time during the year.
- 5.3 One point in time analysis may also be required to be undertaken on any batch of product where;
  - a) the mean levels of TNCO over four testing periods are greater than 115% of maximum emission levels identified in Regulation 13 of SI 2016/507; or
  - b) TNCO levels for a single measurement point greater than 120% maximum emission levels identified in Regulation 13 of SI 2016/507.

As with regular testing; the smoke yields will be measured against the requirements of Regulation 13 of SI 2016/507 and from data derived from information declared to the Secretary of State in accordance to Regulation 20 of SI 2016/507.

- 5.4 Be responsible for obtaining test samples from the Industry. Additionally, the Provider will make enquiries in the first instance for samples not received or received late and promptly notify the Authority of any problems encountered with sample receipt and/or with the Industry. The Industry must provide official samples to the testing laboratory is in accordance with ISO 8243:2013 rules. The cost of transporting the samples to the test laboratory is to be borne by the Industry and not the Provider.
- Provide electronic reports to the Authority every two months, as set out in Section 8.9 of this document 'Periodic reporting of data', detailing the results of each period (6 periods in total each year). Subsequent tables are to be supplied on a cumulative basis; four results after test period 1, eight results after test period 2, twelve results after period 3 as so forward. (Appendix: Tables 1 and 2).
- Provide an annual commentary report, as set out in Section 8.10 of this document, 'Annual reporting of data,' in a portable document format (pdf), detailing comments and data relating to the full reporting year.
- 5.7 Send an electronic table to producers, based on samples supplied for testing during the survey at the end of each period. Each producer will receive cigarette brand data pertinent to its own company (Appendix, Example 3 Table 3). This will include a copy of the TNCO results for all the brand variants tested for this period, and only those brand variants supplied by that producer.
- 5.8 Provide a 'Customer Satisfaction Survey Form' to be completed by the Authority at the end of each testing period, to allow the Authority to provide timely feedback to the Provider on its performance.
- Raise sampling and testing issues with producers in the first instance and inform the Authority promptly. Issues will be logged and presented to the Authority either at review meetings or as requested.
- 5.10 Complete all actions by the dates set in the timetable in Section 11 of this document.
- 5.11 Provide the Authority with information on any new products on the UK market through active surveillance of products on the UK market.
- 5.12 Deliver quarterly presentations to demonstrate how each Key Performance Indicator (KPI) as set out in Section 9 of this specification, has been met.
- 5.13 Attend meetings every two periods (every 4 months, usually held after periods 2, 4 and 6) or as deemed necessary to review progress against the deliverables. The meetings will take place at either the Authority's offices, at other premises specified by the Authority or as a video/teleconference.
- 5.14 Participate in discretionary audits conducted by the Authority at the laboratory premises and provide the necessary documents to facilitate this.

- 5.15 Attend an annual review meeting with the Authority, between May and July in every year to discuss all aspects of the service in the previous year. This may be held at the Authority's offices, or as video/teleconference.
- 5.16 Attend a post-contract review meeting with the Authority following the culmination of the contract, to review whether the objectives of the contract were met, to review the benefits realised and to identify any lessons learnt for future projects following the initial three-year period of the contract.

#### 6. AUTHORITY RESPONSIBILITIES

- 6.1 Appoint a Tobacco Programme Manager as the Project Manager from within the team. That person will manage the relationship and ongoing communications with the Provider, hold meetings, and where necessary, review delivery against the specification with the Provider.
- 6.2 Provide a guidance document and a reference table for the required SPoT compliance checks.
- At the commencement of the contract, the Authority will provide the Provider with a list of the brand variants for which test results are required, together with the contact name and email address of the producer of each brand variant.
- 6.4 Provide appropriate representation at the meetings indicated in this specification.
- 6.5 Provide timely indication as to contract breaks or extension.
- 6.6 Provide prompt payment in accordance with the Civil Service 30-day payment policy.

#### 7. PROVIDER RESPONSIBILITIES

- 7.1 Designate a Contract Manager to oversee the work as set out below, liaise with and report to the Authority; the identity of the Contract Manager must be notified to the Authority in writing, within one week, of a successful bid.
- 7.2 Perform quality assurance on all aspects of the service being provided to the Authority. The provider shall also provide reports of accreditation, information on quality assurance procedures, international studies and data relating to the provision of the skill requirement, on request and at review meetings.
- 7.3 Provide the Authority with timely and ongoing evaluation information relating to the service.
- 7.4 Describe its proposals for any additional liaison requirements with the Industry which it considers necessary to deliver the contract.
- 7.5 Provide information on any quality assurance measures, including documentation on the competence/training staff involved with this contract.
- 7.6 Provide information on compliance checks in relation to labelling and SPoT requirements for cigarettes (Appendix: Table 4).
- 7.7 Fulfil EU and UK statutory obligations in the area of testing and SPoT in compliance with the EU Tobacco Products Directive 2014/40/EU and UK tobacco laws (2016/507 and 2015/829), reporting any anomalies to the Authority in a timely manner.
- 7.8 Maintain a high level of scientific expertise and provide technical advice, when needed, on tobacco products/technology.
- 7.9 Ensure that the most appropriate testing and measuring methods are proposed and employed for the evaluation of tobacco products for research or other purposes.
- 7.10 Cooperate with any requests by the Authority in relation to the annual audit and any other audit as required.
- 7.11 Develop an audit tool to ensure that SPoT checks are made correctly and reported, which is agreed with the Authority.

#### 8. DETAILED SPECIFICATION OF SURVEY

# 8.1. Number of test brands

The number of variant brands to be tested during the survey will vary depending on the number of producers` brand variants, deletions and introductions during the survey period. There is a low estimate of 350 cigarette brand variants and a high estimate of 650 cigarette brand variants produced for sale in the UK market and the travel retail sector each year. Therefore, we estimate a mean figure of approximately500 cigarette brand variants will be in the UK market every year. This is subject to change based on discontinuations and introductions of brand variants and may also be subject to change in line with the exit of the UK from the EU, and the potential divergence of the GB and NI markets.

#### 8.2 Number of tests per brand

The official sampling protocol in use, which is in line with ISO 8243:2013 requirements, consists of six equal sampling periods a year, each of two months duration. The sampling period commences on 1 January in every calendar year. Four samples of each cigarette brand will be received for testing in each sampling period. Assuming fully compliant sampling this makes 24 samples tested each year for each brand, and results obtained. Whilst this protocol is expected to be followed,

consideration will be given to other sampling protocols that are compliant with ISO 8243:2013. For brands introduced midyear, it is expected that they will be tested from the relevant period in which they are introduced; and will continue to be tested in subsequent periods, providing that the brand continues to be produced.

8.3 Number of tests for new brands and infrequent brands

A 'one-time' analysis of 20 determinations may be required by the Authority on new brand variants which are produced infrequently and made available for sale to the UK market. This may occur once a year and must be reported within the period in which samples are supplied, as well as, in the annual commentary and executive reports, in a portable document format (pdf), detailing comments and data relating to the full reporting year. For this, 20 samples of each of these brand variants shall be tested annually. All sampling must be undertaken in line with the procedures set out in ISO 8243:2013.

- 8.4 Reporting time scale
- 8.4.1 The test laboratory will receive samples from the Producer for the first sampling period, January to February 2023, by the specified date in March. These are to be processed, in line with the requirements of this technical specification and appropriate ISO standards, and results reported to the Authority for the first time within two months, or by 8 May 2023.
- 8.4.2 Test results for samples from the remaining five periods will then be reported sequentially at two-monthly intervals on 8 July, 8 September, 8 November, 8 January and 8 March. This means that the last bimonthly data report, received for period 6, will be made available by 8 March 2024. A detailed timeframe for this is provided in Section 11 of this specification. Where any of these dates falls on a weekend or bank holiday the report will be due the next working day.
- 8.5 Sampling responsibilities
- 8.5.1 The Provider is responsible for dispatching sample labels to each Producer prior to each testing period so that;
  - a) the Producer will know which brand variant(s) it is required to send for testing; and
  - b) on receipt, the samples will be accurately identified.
- 8.5.2 Labels should be dispatched to arrive at least seven working days before the start of each sampling period.
- 8.6 Receipt of samples
- 8.6.1 Manufacturing dates of samples must be recorded on receipt of samples by the testing laboratory. This requires cigarette producers to provide information, in confidence to the test laboratory, to enable manufacture dates to be determined.
- 8.6.2 If samples have not arrived by the allotted time, Producers must be contacted by the Provider to ensure compliance as quickly as possible. The laboratory has the full authority of the Authority to request official samples and is responsible for informing the Authority of non-compliance with the sampling protocol.
- 8.7 Testing requirements
- 8.7.1 Determinations of water and nicotine in the extract of smoke particulate matter will be made using gas chromatographic methods as detailed in the ISO standards identified in Section 8.7.2 of this specification.
- 8.7.2 All aspects of the conditioning, smoking and subsequent analytical procedures used must comply with all the relevant standards issued by the International Organisation for Standardisation (ISO)

ISO 3308:2012

Machine Smoking Parameters: Routine analytical cigarette-smoking machine – Definitions and standard conditions

ISO 3402:1999

Environmental Conditions: Tobacco and tobacco products - Atmosphere for conditioning and testing

ISO 4387:1999 (2000 version has been withdrawn)

Tar Yield (mg per cigarette): Determination of total and nicotine-free dry particulate matter (NFDPM) using a routine analytical smoking machine.

ISO 8454:2007/ Amd 1:2009/AMD 2: 2019

Cigarettes - Carbon Monoxide Yield (vapour phase) (mg per cigarette): Determination of carbon monoxide in vapour phase of cigarette smoke -(NDIR method)

ISO 10315:2021 (withdrawn)

Nicotine Yield (mg per Cigarettes)- : Determination of nicotine in total particulate matter from the mainstream smoke - condensates – Gas chromatographic method

ISO 10362-1: 1999 (withdrawn)/Amd 1:20112019

Water yield (mg per cigarettes-): Determination of water in total particulate matter from the mainstream smoke condensates – Part 1: Gas chromatographic method.

8.7.3 These standards are subject to regular reviews by ISO. Therefore, it is the responsibility of the Provider to monitor activities in ISO, inform the Authority of the most up-to-date standard(s) and to ensure that the latter is used for the work specified in this contract.

#### 8.8 Quality control procedures

Each smoking run made in pursuance of this skill requirement will contain at least one channel of a quality control monitor cigarette such as the appropriate Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) monitor or a Kentucky Reference Cigarette. Data for the monitor cigarette will not be supplied, but will be made available upon request. A summary of such activities in the specified periods should be included in the updates given at review meetings with the Authority.

#### 8.9 Periodic reporting of data

The report provided every two months must be presented as an excel file and comply with the format presented in Appendix: Table 3.

#### 8.9.1 Periodic reports must detail;

- a) Manufacturers' compliance with;
  - i. Provision of samples
  - ii. Identifications of introductions and discontinuations
  - iii. Brand name changes
  - iv. Notification of split declarations; changes to declarations; illegible codes; and reporting of duty-free brands
  - v. TNCO limits
  - vi. Packaging regulations.

#### b) Laboratory performance;

- Timeliness of reports delivered
- ii. Timeliness of label dispatch
- iii. Number of total tests delivered
- iv. Compliance with ISO standards 4387, 8243, 8454 and 10315
- v. Compliance with ISO standards 3308, 3402 and 10362-1
- vi. Compliance with sampling protocols
- vii. Staff training to ensure compliance with latest test, packaging and sampling requirements
- viii. Summary of organisational changes including those to laboratory form or function, or staffing and skill levels, that may impact on the laboratory's ability to deliver the requirements of this contract, either at that time, or those planned for the future.

#### c) Test outputs;

- i. the number of tests undertaken in each testing period
- ii. the number of non-compliances with regard to the above-mentioned UK tobacco laws and EU Tobacco Products Directive 2014/40/EC;
- iii. the nature of these non-compliances, including any remedial action taken and the results of these actions;
- iv. proof that the tests have all been carried out to appropriate ISO/BSI standards and confirmation of the accuracy of all results.
- d) Monitoring of risks identified throughout the survey.
- e) Issues or problems encountered during the reporting period and recommendations for actions to be taken to address sampling, testing or other issues.
- f) Records of labelling and packaging of cigarettes compliance checks, conducted in every period, must be kept in hard copy and these may be requested by the Authority for audit purposes.
- g) Any other issues arising that are not covered in this specification and are relevant to the accurate delivery against KPI Indicators detailed in Section 9.

#### 8.9.2 The following non-analytical information will be displayed for each data entry:

- a) The sampling period identifier
- b) Sample number
- c) Manufacturing date (week) as identified from the batch code
- d) Age of the sample (in weeks) with reference to the first week of the sampling period
- e) Pack size
- f) Smoking run/channel number.

#### 8.9.3 The following analytical information will be displayed for each data entry:

- a) Puff number (to one decimal place)
- b) Total Particulate Matter yield in mg (to two decimal places)
- c) Water yield in mg (to two decimal places)
- d) Nicotine yield in mg (to two decimal places)
- e) Nicotine Free Dry Particulate Matter (NFDPM) yield in mg (to two decimal places)
- f) Carbon monoxide yield in mg (to two decimal places)
- g) Carbon monoxide concentration corrected for STP (% v/v to two decimal places)
- h) Ratio of NFDPM yield to nicotine yield (to two decimal places).

# 8.9.4 In respect of each entry and for both the latest period reported and the total data set to date, as a minimum, the following statistical criteria shall be calculated:

- a) mean
- b) standard deviation

- c) coefficient of variation
- d) 95% confidence levels
- e) standard error
- f) variance.
- 8.9.5 Results must be reported on a one page per variant brand basis. By the end of the sixth period, all the results obtained for a particular brand variant during the survey should be displayed on this page.
- 8.10 Annual reporting of data

At the end of each survey period; present an annual commentary report, in a portable document format (pdf), detailing comments and data relating to the full reporting year, to the Authority by the 6th April immediately following each year of the contract.

As well as detailing how each KPI has been achieved, the report must cover;

- a) Each Producer's overall compliance with the official sampling, labelling and coding requirements throughout the year.
- b) Cigarette brand variants with test results above the maximum allowed smoke yields as stated in EU Directive 2014/40/EU and SI 2016/507. These brands must be clearly highlighted.
- All declaration changes, brand introductions, split declarations, missing packs and brand withdrawals that have occurred during the Survey.
- d) A summary of the test results of collaborative studies in which the testing laboratory participated.
- e) A summary of organisational changes and the Provider's performance based on customer satisfaction survey forms<sup>1</sup> for the 6 periods and feedback received from the Authority.
- f) Monitoring of risks throughout the survey.
- g) Issues or problems encountered during a testing year and recommendations for actions to be taken to address sampling, testing or other issues.
- h) SPoT requirements as monitored by the Provider.
- 8.10.1 The annual report will include details of results of all the tests conducted throughout the testing year (periods 1 to 6). Assuming fully compliant sampling, 24 sets of test results will be determined and reported for each brand in any given year. Test results will be reported in the stated format described in this specification, or an equivalent format subject to approval by the Authority.
- 8.10.2 The Provider will provide the Authority with an annual executive report by 6 April each year, summarising the results of all the tests conducted throughout the previous testing year. This will be a condensed form of the commentary report, and also in a portable document format (pdf), detailing comments and data relating to the full reporting year, providing a summary of the details specified in 8.10.
- 8.11 Additional data presentation

At the end of each period, a report should be generated with information on the number of brand variant(s) tested and any problems associated with receipt of samples. The report will include tables highlighting brands that have exceeded the limits specified for the end of survey report (Appendix: Example 5 - Table 5).

- 8.11.1 In addition to, and at the same time as, the report described above, electronic copies of the tables will be supplied with subsequent tables being supplied on a cumulative basis (e.g. four results after test period 1, eight results after test period 2, twelve results after period 3 etc. (Appendix: Example 1).
- 8.11.2 Further, at the end of each period, the report will include a table listing all brand variants comparing their respective yields (on an accumulating basis) to the TNCO yields notified to the Authority by Producers highlighting those that have exceeded the tolerance limits specified in ISO 8243:2013, either over a period of time, or at one point in time (Appendix: Example 1 Table 1).
- 8.11.3 At the end of each period, the Provider must present a table showing, for each brand, the mean value to date for all the criteria listed sorted alphabetically by brand variant name (Appendix: Table 2).
- 8.11.4 An electronic table, based on samples supplied for testing during the Survey and as specified under the 'reporting of data', must be sent to Producers at the end of each period. Each producer will receive cigarette brand variant data pertinent ONLY to its own company (Appendix Example 3 Table 3).
- 8.11.5 The reporting requirements can be modified or changed by the Authority during the course of the contract when this is required to meet regulatory obligations.
- 8.11.7 All quality control monitoring results obtained during the course of testing and any other documentation which provide assurance that the contract obligations have been met must also be made available to the Authority should they be requested.
- 8.12 Sample retention
- 8.12.1 All samples received under this contract for 2023 shall be retained until 30 June 2024.

- 8.12.2 All samples received under this contract for 2024 shall be retained until 30 June 2025.
- 8.12.3 All samples received under this contract for 2025 shall be retained until 30 June 2026.

#### 9. **KEY PERFORMANCE INDICATORS**

- 9.1 The following are the key performance indicators (KPIs), for each testing period, which will form the basis of a reporting dashboard, to be used to measure successful delivery of the contract. An example of how these may be reported is given as Table 6 in the Appendix.
- 9.1.1 The number of labels sent to manufacturers, and the percentage and number of those labels which result in a brand submitted for testing.
- 9.1.2 The total quantity of brands submitted and tested.
- 9.1.5 The number and percentage of submitted samples received late.
- 9.1.6 The number and percentage of samples missing.
- 9.1.7 The number and percentage of submitted brands failing to comply with SPoT regs.
- 9.1.8 The number and percentage of submitted brands failing to comply with any of the regulations.
- 9.1.9 The number and percentage of submitted brands falling outside of expected limits for;
  - a) Tar
  - b) Nicotine
  - c) Carbon Monoxide.
- 9.1.10 The number and percentage of non-compliant test runs and brands where tests required repeating due to control monitor failure.

### 10. ADDITIONAL RESPONSIBILITIES

- 10.1 Be responsible for the accuracy and content of all presentations and reports made to the Authority, delivery of inaccurate reports or presentations may affect the achievement of related KPIs.
- 10.2 Promptly notify the Authority of any structural/organisational changes that may affect the smooth delivery of the contract.
- 10.3 Provide the Authority with copies of all correspondence with producers in relation with issues pertaining to the contract.
- OHID is vigilant in its duty to reduce inequalities and to promote equity and equality. It is therefore vital that all work undertaken on behalf of OHID can demonstrate how it supports this agenda and where appropriate/required an Equality Impact Assessment (EIA) is carried out. It is also important to consider the <a href="Equalities Act 2010">Equalities Act 2010</a> and ensure compliance with this and the protected characteristics within are considered.
- 10.5 Completion of all tests required in an accurate and timely manner, for all products identified by the Authority.
- 10.6 Accurate and timely monitoring of Producer's compliance with the relevant stated UK tobacco laws and the /EU Tobacco Products Directive 2014/40/EU and official sampling requirements, taking actions as appropriate.
- 10.7 Provision of accurate and timely periodic reporting as specified in the timetable detailed in section 11.
- 10.8 Accurate record keeping of quality assurance checks and quality control measures and provision to the Authority, when requested.
- 10.9 Prompt escalation of issues with testing or compliance to enable the Authority to take prompt action.
- 10.10 Timely submission of the customer satisfaction survey form.
- 10.11 Timely provision of an accurate, signed commentary and executive report checked by two officials of the Provider and delivered at each year end.
- 10.12 Accurate and timely identification of risks as they arise, application of monitoring activities in relation to these risks and reporting of actions taken to mitigate the risks.
- 10.13 Accurate and timely invoicing, where payment will be made in GBP Sterling.

# 11. TIMETABLE

11.1 The 12-month timetable for the 2023 Survey is shown below as an example. The contract will follow this pattern for subsequent years:

Sampling Period	Sampling Period No.	Approx. Dispatch Date for Dispatch of Labels	Latest Date for Sample Receipt	Date for Receipt of Data report
Jan – Feb 2023	1	20 Jan 2023	8 March 2023	8 May 2023
Mar – April 2023	2	10 Feb 2023	8 May 2023	8 Jul 2023
May – June 2023	3	10 April 2023	8 July 2023	8 Sept 2023
July – Aug 2023	4	10 June 2023	8 Sept 2023	8 Nov 2023
Sept – Oct 2023	5	10 Aug 2023	8 Nov 2023	8 Jan 2024
Nov – Dec 2023	6	10 Oct 2023	8 Jan 2024	8 Mar 2024
Final Reports – Executive and Commentary reports (2023)				8 Apr 2024

- 11.2 Subject to the end of year review meeting between May and July 2026, the 2025 survey will be completed through receipt and review of the final report by 6 April 2025. This constitutes Phase 1 of the contract.
- 11.3 Subsequently, Phase 2 will be completed subject to the receipt/review of the final report in 2027 (2026 Survey).
- 11.4 Phase 3, will be completed subject to the receipt/review of the final report in 2027 (2028 Survey).

#### 12. SKILLS AND KNOWLEDGE TRANSFER

- 12.1 The Authority will be in regular contact with the successful Provider throughout the lifetime of the contract to enable the realisation of benefits, identification of any lessons learnt for future projects and all samples will be kept for the duration specified by the Authority (as a minimum), to allow further investigations to be made if necessary.
- 12.2 Copies of correspondence with Producers in relation to the delivery of the skill requirement shall be kept.
- 12.3 All data generated is owned by the Authority and will not be divulged to a third party, unless approved by the Authority.
- 12.4 The Authority will be kept up to date on progress and skills/knowledge relating to the skill requirement will be transferred to the Authority, through meetings every three months and by the Provider responding to queries/addressing issues relating to the testing of tobacco and its products.
- 12.5 The Provider will conduct tours of their facilities and accommodate visits, as necessary, and as requested by the Authority. The Authority retains all copyrights of any information produced as part of the contract.

#### 13. INTELLECTUAL PROPERTY

- 13.1 All items published on gov.uk at Intellectual Property Office GOV.UK (www.gov.uk) are crown copyright.
- 13.2 "Background Intellectual Property" means any Intellectual Property and Intellectual Property Rights, other than Foreground Intellectual Property, that is used in connection with any part of the Services.
- All Background Intellectual Property owned by either Party shall remain the property of that Party but the Contractor shall, where it has the right to do so, grant the Authority and any Beneficiary a non-exclusive, perpetual, royalty free, global license to use any Background Intellectual Property to the extent necessary for the purpose of the Services and for the use or exploitation of any Foreground Intellectual Property.
- 13.4 "Foreground Intellectual Property" means any Intellectual Property and Intellectual Property Rights that arises or is obtained or developed by, or by the contractor on behalf of, either party in the course of or in connection with the performance of the Services.
- 13.5 All Foreground Intellectual Property shall vest in and be owned absolutely by the Authority and the Contractor agrees to execute all documents and assignments and do all such things as may be necessary to perfect the Authority's title to the Intellectual Property or to register the Authority as owner of registrable rights.
- 13.6 The Authority shall be entitled to negotiate and agree provisions for the ownership of Intellectual Property Rights which deviate from the above to the extent that such other provisions, in the authority's opinion, are more suitable for the services under that Order.

# 14. INDICATIVE COSTS

- 14.1 All prices must be stated in GBP Sterling and be inclusive of VAT (if applicable) and your stated price should be fixed and firm for the duration of each year of the contract.
- 14.2 An excel spreadsheet with a breakdown of how the costs are calculated per year for option 14.2.1 and 14.2.2 must be provided.
- 14.2.1 The original bulk delivery with minimum level of activity guaranteed, with a break clause at the end of each year.

14.2.2 A cost per unit tested, with no minimum level of activity guaranteed, with a break clause at the end of each year.

## 15. SOCIAL VALUE

15.1 The Authority has set out what they see as the priority Social Value areas for this contract.

The contract will support Social Value Theme Fighting climate change, Effective stewardship of the environment MAC 4.1 Deliver additional environmental benefits in the performance of the contract including working towards net zero greenhouse gas emissions.

The supplier will require to provide metrics as part of their KPIs that demonstrate the delivery of the social value:

#### Annual:

- o Reduction in emissions of greenhouse gases arising from the performance of the contract, measured in metric tonnes carbon dioxide equivalents (MTCDE).
- o Reduction in water use arising from the performance of the contract, measured in litres.
- o Reduction in waste to landfill arising from the performance of the contract, measured in metric tonnes.



# Appendix: Examples of Tables for reporting purposes

All tables are provided as examples of how reports may be made. The Authority welcomes suggestions from Providers as to improvements if these improve clarity.

#### Example 1

This electronic table, for each brand, presents the integer experimental NFDPM yield, NFDPM yield declared, experimental nicotine yield (to one decimal place), nicotine yield declared, experimental integer CO yield and CO yield declared. This table should be sorted on yield and within that, alphabetically on brand name.

It compares the respective yields (on an accumulating basis) to the limits set in law. Those exceeding these limits will be highlighted.

Table 1 shows data for NFDPM only, similar data is required for Nicotine (± 15 %) and CO ± 20 %)

Table 1 – Nicotine-free dry particulate matter (Survey X, Year Y)

<b>Brands Sorted</b>	on Brand Va	riant Name						
OHID Survey P	eriod X	Results for	NOVEMBER/I	DECEMBER,	Year 20XX			
Brand Variant Name	Brand Variant Code		Laboratory measured NFDPM	Tolerance limit (low)	Tar notified to the Authority	Tolerance limit (high)	Pass/Fail Status	Number of months of a single
	Duty Free/		Yield	-15%		15%	Pass/Fail	dec.
	Duty Paid							
Name of Manufacturer								
Brand 1	Duty Free	1143	11.04	8.5	10	11.5	Р	6
Brand 2	Duty Paid	1145	<mark>11.8</mark>	8.5	10	11.5	F	6
Brand 3	Duty Free	1162	7.64	6.8	8	9.2	Р	6
Brand 4	Duty Paid	1163	10.51	8.5	10	11.5	Р	6
Brand 5	Duty Paid	1164	10.56	8.5	10	11.5	P	6
Brand 6	Duty Paid	1213	10.62	8.5	10	11.5	Р	6
Brand 7	Duty Paid	1216	9.49	8.5	10	11.5	P	6
Brand 8	Duty Free	1360	1.53	0	1	2	Р	6
Brand 9	Duty Paid	1361	5.33		5	6	Р	6

Table 2 - mean value to date for all the criteria listed sorted alphabetically by brand variant name

<b>Brands So</b>	rted on Brand \	/ariant Name							
OHID Surv	ey Period X	Results for	NOVEMBER	/DECEMBER	R, Year 20YY				
Brand	Brand			<	Yield In M	illigrams Per	r Cigarette	>	
Code	" Variant	Puffs Per Cig	%VV CO	СО	ТРМ	Water	Nicotine	NFDPM	NFDPM / NIC Ratio
5886	Brand 1	7.13	3.76	10.88	12.3	1.57	0.84	9.89	11.78
5885	Brand 2	8.9	2.83	10.26	12.59	0.9	0.98	10.7	10.9
8548	Brand 3	6.6	4.09	11.01	13.65	2.19	0.69	10.77	15.62
8551	Brand 4	6.95	2.84	8.08	7.74	0.76	0.47	6.51	13.94
8586	Brand 5	7.95	3.24	10.47	10.73	1.03	0.64	9.06	14.21
8590	Brand 6	8.8	1.56	5.57	6.02	0.34	0.45	5.23	11.58
8534	Brand 7	6.55	4.17	11.12	12.16	1.74	0.63	9.79	15.54
8521	Brand 8	7.48	2.37	7.24	6.9	0.49	0.46	5.95	12.91
8576	Brand 9	8.28	3.12	10.53	10.71	0.83	0.69	9.18	13.26
8861	Brand 10	8.4	1.76	6.01	6.87	0.42	0.48	5.97	12.38

# Example 3

One report should be prepared for each brand, for each 6 rolling period

Table 3 - electronic table to producers, based on samples supplied for testing during the survey at the end of each period

SURVEY P	ERIOD					NOVEM	BER/DECEN	/IBER 20XX to 9	SPETEMBE	R/OCTO	BER 20	YY			
1143 Bra		d 6 11	l									Min Lalin			
	sults use				I	l	l		1	<	I		mg per cig		NFDPM/Nic
Period	Factory	Sample	Date	Age	Pack size	Run	Channel	Puffs per Cig	%W CO	СО	TPM	Water	Nicotine	NFDPM	Ratio
AAA		1													
AAA		2													
AAA		3													
AAA		4													
BBB		1													
BBB		2													
BBB		3													
BBB		4													
CCC		1													
CCC		2													
CCC		3													4
CCC		4													
DDD		1													
DDD		2													
DDD		3													
DDD		4													
EEE		1													
EEE		2													
EEE		3													
EEE		4													
FFF		1													
FFF		2													
FFF		3													
FFF		4													
						ı									
Periods	Mean	95%	Standard	Coef.	Standard	Variance			Period	Mean	95%	Standard	Coef.	Standard	Variance
AAA-FFF	Value	Conf.	Dev.	Variable	Error	variance			FFF	Value	Conf.	Dev.	Variable	Error	variance
Puffs									Puffs						
со									со						
TPM									TPM						[
Water									Water						
Ratio									Ratio						
Co Yield									Co Yield						
									Nic	l				1	
Nic															

Table 4 – Example of reporting for Standardised Packaging of Tobacco requirements

Brands Name V	ariant:				
OHID Survey Po	eriod X				
Period	Relevant requirements checked by Technician	Specified requirements checked by the laboratory's Contract Manager	Dates or Period Checked	Records filed by/Date	
Period 1	Technician X	Contract Manager A	xx/04/2018 yy/04/2018	By X on xx/04/2018	
Period 2	Technician Y	Contract Manager B	xx/04/2018 yy/04/2018	By X on xx/04/2018	
Period 3	Technician X	Contract Manager A	xx/04/2018 yy/04/2018	By X on xx/04/2018	
Period 4	Technician Y	Contract Manager	xx/04/2018	By V on xx/04/20	
	rechnician f	В	yy/04/2018	By X on xx/04/2018	
Period 5	Technician X	Contract Manager	xx/04/2018	D. V an and 0.412040	
	i ecnnician X	A	yy/04/2018	By X on xx/04/20	
Davis d C	Taskaisian V	Contract Manager	xx/04/2018	Du V an am/04/2045	
Period 6	Technician Y	В	yy/04/2018	By X on xx/04/20	

#### Example 5

Reporting of brands with experimental yield in excess of 10 mg/cigarette tar, or 1.0 mg/cigarette nicotine, or 10 mg/cigarette carbon monoxide expressed in an accumulating period report format (Table 5 shows specimen data for 2 consecutive periods, X – Y).

The highlighted yields in yellow are those that lie above the 10 1 10 EU regulation for Tar, Nicotine and CO in cigarettes as shown above but not outside limits set by ISO 8243. Yield results with Tar, Nicotine and CO values outside of ISO 8243 tolerance limits should be highlighted, as indicated in Table 5.

Table 5 - Highlight of brands that have exceeded the limits specified for the end of survey report

Brands So	rted on Brand V	ariant Name					
OHID Surv	ey Period X	Results for N	NOVEMBER/DI	ECEMBER, Ye	ar 20XX		
Brand Variant Name	Brand Variant Code	Tar notified to the Authority	Laboratory measured Tar Yield	Nicotine notified to the Authority	Laboratory measured Nicotine Yield	CO notified to the Authority	Laboratory measured CO Yield
Brand 1	5886	10	<mark>10</mark>	0.8	0.8	10	1
Brand 2	5885	10	<mark>11</mark>	0.8	1	10	10
Brand 3	8548	10	10	0.8	0.7	10	1
Brand 4	8534	10	<mark>10</mark>	0.8	0.6	10	1
Brand 5	5263	10	11	0.9	1	10	1
Brand 6	5273	10	<mark>10</mark>	0.9	0.9	10	1
Brand 7	5473	10	11	0.9	1	10	1
OHID Surv	ey Period Y	Results for N	NOVEMBER/DI	ECEMBER, Ye	ar 20XX		
Brand 1	5886	10	<mark>10</mark>	0.8	0.8	10	11
Brand 2	5885	10	<mark>11</mark>	0.8	1	10	10
Brand 3	8548	10	10	0.8	0.7	10	11
Brand 4	8534	10	<mark>10</mark>	0.8	0.6	10	1
Brand 5	5263	10	<mark>11</mark>	0.9	1	10	1
Brand 6	5273	10	10	0.9	0.9	10	11
Brand 7	5473	10	11	0.9	1	10	1

Table 6 – Example of monitoring of contract deliverables

HE Survey	Year 20XX/YY						
Period	Labels sent (n)	Labels resulting brand submission (n)	Total brands submitted (n)	Brands discontinued (n)	Brands introduced (n)	Samples recived late (n)	Samples missing (n)
1							
2							
3							
4							
5							
6							
Period	Brands failing to comply with SPoT regs (n)	Brands failing to comply with any Regs (n)		ng outside expect	Tests counted as failures (n)	Non-compliant test runs and control monito failures (n)	
1			Tar	Nicotine	CO		
2							
3							
4							
5							
6							