



UK Health
Security
Agency

Contract for the Provision of Outsourced Kitting Production

Reference: C40296

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CONDITIONS OF CONTRACT FOR THE PROVISION OF SERVICES

The Authority	THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE as part of the Crown through the UK Health Security Agency of Nobel House, 17 Smith Square, London SW1P 3HX
The Contractor	CENTRAL PHARMA CONTRACT PACKING LIMITED , a company incorporated in England & Wales with company number 05666241 and whose registered office is at Central Pharma, Caxton Road, Elm Farm Industrial Estate, Bedford, MK41 0HT.
Date	20 th October 2021

1. BACKGROUND

- 1.1 The Authority placed a contract notice in Find a Tender under the following reference C40296 on 23 July 2021 seeking tenders from providers of packing services interested in entering into an arrangement for the supply of such services to the Authority.
- 1.2 On 23 July 2021, the Authority issued an invitation to tender (the “**Invitation to Tender**”) for outsourced kitting provision services. In response to the Invitation to Tender, the Contractor submitted a tender to the Authority on 20 August 2021 (the “**Tender**”). On the basis of the Tender, the Authority selected the Contractor to enter into an agreement to provide such services to the Authority.

2. THE CONTRACT

- 2.1 This Contract is made on the date set out above subject to the terms set out in the schedules listed below (**Schedules**). The Authority and the Contractor undertake to comply with the provisions of the Schedules in the performance of this Contract.
- 2.2 The Contractor shall supply to the Authority, and the Authority shall receive and pay for, the Services on the terms of this Contract.
- 2.3 The Definitions in Schedule 3 apply to the use of all capitalised terms in this Contract.

SCHEDULES

Schedule 1	Key Provisions
Schedule 2	General Terms and Conditions
Schedule 3	Definitions and Interpretations
Schedule 4	Specification
Schedule 5	Tender
Schedule 6	Pricing
Schedule 7	Contract Monitoring

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Schedule 8	Commercially Sensitive Information
Schedule 9	Variation Form
Schedule 10	Staff Transfer
Schedule 11	Key Personnel
Schedule 12	Exit Plan and Service Transfer Arrangements
Schedule 13	Processing, Personal Data and Data Subjects
Schedule 14	Security
Schedule 15	Service Levels
Schedule 16	Implementation Phase
Schedule 17	Business Continuity and Disaster Recovery Plan
Schedule 19	Financial Reports, Open Book Data and Audit Provisions
Schedule 20	Financial Distress Events
Schedule 21	Equipment

SIGNED BY THE AUTHORISED REPRESENTATIVE OF THE AUTHORITY

Name:		Signature	
Position:			

SIGNED BY THE AUTHORISED REPRESENTATIVE OF THE CONTRACTOR

Name:		Signature	
Position:			

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SCHEDULE 1

Key Provisions

STANDARD KEY PROVISIONS

1. APPLICATION OF THE KEY PROVISIONS

- 1.1 The standard Key Provisions at Clauses 1 to 6 of this Schedule 1 shall apply to this Contract.
- 1.2 The optional Key Provisions at Clauses 7 to 15 of this Schedule 1 shall only apply to this Contract where they have been checked and information completed as applicable.

2. TERM

This Contract shall commence on the Commencement Date and the Term of this Contract shall expire on **19th October 2022** ("the **Expiry Date**"). The Term may be extended in two periods of twelve (12) Months each in accordance with Clause 2 (Extension) of Schedule 2 provided that the duration of this Contract shall be no longer than three (3) years in total.

3. AUTHORITY REPRESENTATIVE AND CONTRACTOR REPRESENTATIVE

- 3.1 The contract managers at the commencement of this Contract are:

- 3.1.1 for the Authority:

[REDACTED] Commercial Officer

- 3.1.2 for the Contractor:

[REDACTED], Chief Operating Officer

4. NAMES AND ADDRESSES FOR NOTICES

- 4.1 Notices served under this Contract are to be delivered to:

- 4.1.1 for the Authority:

Department of Health and Social Care

Finance

39 Victoria Street,

Westminster,

London SW1H 0EU

FAO: [REDACTED]

[REDACTED]

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4.1.2 for the Contractor:

Central Pharma

Caxton Road, Elms Farm Industrial Estate,

Bedford, MK41 0XZ.

FAO: [REDACTED], Chief Operating Officer

[REDACTED]

5. ORDER OF PRECEDENCE

5.1 Subject always to Clause 1.3 of Schedule 3, in the event of any conflict between any parts of this Contract the order of precedence shall be:

5.1.1 Schedule 1 (Key Provisions);

5.1.2 Schedule 4 (Specification) ;

5.1.3 Schedule 5 (Tender) (but only in respect of the Authority's requirements);

5.1.4 Schedule 2 (General Terms and Conditions);

5.1.5 Schedule 8 (Commercially Sensitive Information);

5.1.6 Schedule 10 (Staff Transfer);

5.1.7 Schedule 3 (Definitions and Interpretations); and

5.1.8 the order in which all subsequent Schedules, if any, appear.

6. APPLICATION OF TUPE AT THE COMMENCEMENT OF THE PROVISION OF SERVICES

6.1 The Parties agree that:

6.1.1 where commencement of the provision of the Services or a part of the Services does not result in a Relevant Transfer, Part C of Schedule 10 shall apply and Parts A and B of Schedule 10 shall not apply; and

6.1.2 Part D of Schedule 10 shall apply on the expiry or termination of the Services or any part of the Services.

OPTIONAL KEY PROVISIONS

7. IMPLEMENTATION PHASE ☒ (ONLY APPLICABLE TO THE CONTRACT IF THIS BOX IS CHECKED AND THE SCHEDULE INSERTED)

7.1 Prior to commencement of delivery of the Services, there is an implementation phase and therefore all references in Clause 1.3 of Schedule 2 to the Implementation Plan shall apply and the Implementation Plan is set out in Schedule 16.

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8. SERVICES COMMENCEMENT DATE (WHERE THE SERVICES ARE TO START AT A DATE AFTER THE COMMENCEMENT DATE) ☒ (ONLY APPLICABLE TO THE CONTRACT IF THIS BOX IS CHECKED AND THE DATE IS INSERTED IN CLAUSE 8.1 OF THIS SCHEDULE 1)

8.1 The Services Commencement Date shall be 1st November 2021 (being the start of the period from which the Services will be ramped up over time).

9. DIFFERENT LEVELS AND/OR TYPES OF INSURANCE ☒ (ONLY APPLICABLE TO THE CONTRACT IF THIS BOX IS CHECKED AND THE TABLE SETS OUT THE REQUIREMENTS)

9.1 The Contractor shall put in place and maintain in force the following insurances with the following minimum cover per claim:

Type of insurance required	Minimum cover
Employer's Liability	
Public Liability	
Professional Indemnity	
Cyber Liability Insurance	
Property Damage Insurance	

10. INCLUSION OF A CHANGE CONTROL PROCESS ☒ (ONLY APPLICABLE TO THE CONTRACT IF THIS BOX IS CHECKED AND THE SCHEDULE INSERTED)

10.1 Any changes to this Contract, including to the Services, may only be agreed in accordance with the Change Control Process set out in this Clause 10.

10.2 Subject to the provisions of this Clause 10, either Party may request a variation to the Contract provided that such variation does not amount to a substantial modification of the Contract within the meaning of the Regulations and the Law. Such a change once implemented is hereinafter called a "Variation".

10.3 A Party may request a Variation by completing, signing and sending the Variation Form to the other Party giving sufficient information for the receiving Party to assess the extent of the proposed Variation and any additional cost that may be incurred.

10.4 Where the Authority has so specified on receipt of a Variation Form from the Contractor, the Contractor shall carry out an impact assessment of the Variation on the Services (the "Impact Assessment"). The Impact Assessment shall be completed in good faith and shall include:

10.4.1 details of the impact of the proposed Variation on the Services and the Contractor's ability to meet its other obligations under the Contract;

10.4.2 details of the cost of implementing the proposed Variation;

10.4.3 details of the ongoing costs required by the proposed Variation when implemented, including any increase or decrease in the Contract Price, any alteration in the

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resources and/or expenditure required by either Party and any alteration to the working practices of either Party;

10.4.4 a timetable for the implementation, together with any proposals for the testing of the Variation; and

10.4.5 such other information as the Authority may reasonably request in (or in response to) the Variation request.

10.5 The Parties may agree to adjust the time limits specified in the Variation Form to allow for the preparation of the Impact Assessment.

10.6 Subject to Clause 10.4 of this Schedule 1, the receiving Party shall respond to the request within the time limits specified in the Variation Form. Such time limits shall be reasonable and ultimately at the discretion of the Authority having regard to the nature of the Services and the proposed Variation.

10.7 In the event that:

10.7.1 the Contractor fails to agree to or provide the Variation; and/or

10.7.2 the Parties are unable to agree a change to the Contract Price which may be included in a request for a Variation or response to it,

the Authority may:

(A) agree that the Contractor continues to perform its obligations under the Contract without the Variation; or

(B) terminate the Contract with immediate effect, except where the Contractor has already fulfilled part or all of the provision of the Services in accordance with the Contract or where the Contractor can show evidence of substantial work being carried out to provide the Services under the Contract,

and in such a case the Parties shall attempt to agree upon a resolution to the matter. Where a resolution cannot be reached, the matter shall be dealt with under the dispute resolution procedure set out at Clause 42 (Dispute Resolution) of Schedule 2.

10.8 If the Parties agree the Variation, the Contractor shall implement such Variation and be bound by the same provisions so far as is applicable, as though such Variation was stated in the Contract.

10.9 Within ten (10) Working Days of the Parties agreeing the Variation, the Contractor shall deliver to the Authority a copy of this Contract updated to reflect all Variations agreed in the relevant Variation Form and annotated with a reference to the Variation Form pursuant to which the relevant Variations were agreed. Upon receipt of the updated Contract from the Contractor the Authority shall review such updated Contract to verify its accuracy and shall thereafter notify the Contractor whether such updated Contract is approved. Following approval the Contractor shall provide to the Authority such further copies of the updated Contract as the Authority may from time to time request.

11. STOCK LOSS

11.1 The Contractor shall be liable for and pay to the Authority within thirty (30) days of demand, the value and/or cost of:

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- a) unaccountable losses of any components or assembled kits while in its custody or under its control;
 - b) losses caused by out of rotation stock management and non-adherence to either the Oracle WMS picking instructions or to First Expired First Out (FEFO) principles as stock moves within the Contractor's estate;
 - c) ascertainable losses, destruction of or damage to the components or assembled kits due to the Contractor's negligence or wilful acts, omissions and default, including theft, misappropriation or damage caused by the Contractor or any Contractor Personnel while the components or assembled kits are in the custody or under the control of the Contractor

together in each case with an administrative charge of ten per cent (10%) of the value and/or cost.

- 11.2 Any losses referred to in Clause 11.1 shall be determined on a Monthly basis within ten (10) Working Days of the last day of each Month.

12. TERMINATION FOR CONVENIENCE ☒ (ONLY APPLICABLE TO THE CONTRACT IF THIS BOX IS CHECKED AND CLAUSE 12 OF THIS SCHEDULE 1 IS COMPLETED)

- 12.1 The Authority may terminate this Contract at any time by giving one (1) Month's written notice to the Contractor. The Authority may extend the period of notice at any time before it expires, subject to agreement on the level of Services to be provided by the Contractor during the period of extension of such notice.

- 12.2 Subject to Clauses 19 (Liability) and 20 (Insurance) of Schedule 2, should the Authority terminate this Contract in accordance with Clause 12.1 of this Schedule 1, then the Authority shall indemnify the Contractor against any commitments, liabilities or expenditure which represent an unavoidable direct loss to the Contractor by reason of the termination of the Contract, provided that the Contractor takes all reasonable steps to mitigate such loss. Where the Contractor holds insurance, the Authority shall only indemnify the Contractor for those unavoidable direct costs that are not covered by the insurance available. The Contractor shall submit a fully itemised and costed list of unavoidable direct loss which it is seeking to recover from the Authority, with supporting evidence, of losses reasonably and actually incurred by the Contractor as a result of termination under Clause 12.1 of this Schedule 1.

- 12.3 The Authority shall not be liable under Clause 12.2 of this Schedule 1 to pay any sum which:

- 12.3.1 was claimable under insurance held by the Contractor, and the Contractor has failed to make a claim on its insurance, or has failed to make a claim in accordance with the procedural requirements of the insurance policy;
- 12.3.2 when added to any sums paid or due to the Contractor under the Contract, exceeds the total sum that would have been payable to the Contractor if the Contract had not been terminated prior to the expiry of the Term; or
- 12.3.3 is a claim by the Contractor for loss of profit, due to early termination of the Contract.

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13. MEASURES TO PROMOTE TAX COMPLIANCE ☒ (ONLY APPLICABLE TO THE CONTRACT IF THIS BOX IS CHECKED)

- 13.1 The Procurement Policy Note: Measures to Promote Tax Compliance Action 03/14 applies and therefore all references in Clause 6.2 and 23.3.3 of Schedule 2, together with the associated definitions in Schedule 3, shall apply.

14. NOT USED

15. EXIT AND SERVICE TRANSFER ☒ (ONLY APPLICABLE TO THE CONTRACT IF THIS BOX IS CHECKED)

- 15.1 In the event of the termination or expiry of the Contract for any reason, the Contractor shall provide the Transitional Assistance Services to the Authority in accordance with the requirements of the Exit Plan and both Parties shall comply with their respective obligations set out in Schedule 12. The Contractor shall co-operate with the Authority and/or the Replacement Contractor to the extent reasonably required to facilitate the smooth migration of the Services from the Contractor to the Authority or the Replacement Contractor.
- 15.2 The Authority shall pay the Transitional Services Charges in respect of the provision of the Transitional Assistance Services, except in circumstances where the Authority has terminated the Contract pursuant to Clauses 22, 23.2 or 23.3 of Schedule 2.
- 15.3 The Contractor shall, within three (3) Months after the Commencement Date, produce an Exit Plan based on the principles set out in Schedule 12 for the orderly transition of the Services from the Contractor to the Authority or any Replacement Contractor in the event of any termination or expiry of the Contract. Within ten (10) Working Days after the submission of that Exit Plan, the Parties shall meet and use all reasonable endeavours to agree the contents of that Exit Plan, based on the principles set out in Schedule 12. If the Parties are unable to agree the contents of the Exit Plan within that ten (10) Working Day period, the principles set out in Schedule 12 shall apply and either Party may refer the dispute for resolution in accordance with the dispute resolution procedure set out at Clause 42 of Schedule 2.
- 15.4 The Contractor shall update the Exit Plan no less than once during each Contract Year to reflect changes in the Services and shall keep the Exit Plan under continuous review. Following each update, the Contractor shall:
- 15.4.1 submit the revised Exit Plan to the Authority for review;
 - 15.4.2 within ten (10) Working Days after the submission of the revised Exit Plan, the Parties shall meet and use all reasonable endeavours to agree the contents of the revised Exit Plan, based on the principles set out in Schedule 12 and the changes that have occurred in the Services since the Exit Plan was last agreed; and
 - 15.4.3 if the Parties are unable to agree the contents of the revised Exit Plan within that ten (10) Working Day period, the previous version shall continue to apply and either Party may refer the dispute for resolution in accordance with the dispute resolution procedure set out at Clause 42 of Schedule 2.
- 15.5 Until the agreement of the Exit Plan, the Contractor shall provide the Transitional Assistance Services in accordance with the principles set out in Schedule 12 and the last-approved version of the Exit Plan (insofar as this still applies) to the Authority in good faith. The Contractor shall ensure that it is able to implement the Exit Plan at any time.

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15.6 Within thirty (30) days after service of a Termination Notice by either Party or six (6) Months prior to the expiration of the Contract:

15.6.1 the Contractor shall update the Exit Plan into a final form that could be implemented immediately and in doing so, provide as much detail as is appropriate given the nature of the termination or expiry and the timing of termination, so that such Exit Plan can be submitted to the Authority for review and approval; and

15.6.2 the Parties shall meet and use their respective reasonable endeavours to agree the contents of such Exit Plan based on the principles set out in Schedule 12; and

15.6.3 until the agreement of the updated Exit Plan, the Contractor shall provide the Transitional Assistance Services in accordance with the last-approved version of the Exit Plan (insofar as this still applies) to the Authority in good faith.

16. SUPPLY CHAIN VISIBILITY ☐ (ONLY APPLICABLE TO THE CONTRACT IF THIS BOX IS CHECKED)

Visibility of Sub-Contract Opportunities in the Supply Chain

16.1 The Contractor shall:

16.1.1 subject to clause 16.3, advertise on Contracts Finder all Sub-Contract opportunities arising from or in connection with the provision of the Services above a minimum threshold of £25,000 that arise during the Term;

16.1.2 within 90 days of awarding a Sub-Contract to a Sub-contractor, update the notice on Contract Finder with details of the successful Sub-contractor;

16.1.3 monitor the number, type and value of the Sub-Contract opportunities placed on Contracts Finder advertised and awarded in its supply chain during the Term;

16.1.4 provide reports on the information at clause 16.1.3 to the Authority in the format and frequency as reasonably specified by the Authority; and

16.1.5 promote Contracts Finder to its suppliers and encourage those organisations to register on Contracts Finder.

16.2 Each advert referred to at clause 16.1.1 of this Schedule 1 shall provide a full and detailed description of the Sub-Contract opportunity with each of the mandatory fields being completed on Contracts Finder by the Contractor.

16.3 The obligation on the Contractor set out at clause 16.1 shall only apply in respect of Sub-Contract opportunities arising after the Commencement Date.

16.4 Notwithstanding clause 16.1, the Authority may by giving its prior Approval, agree that a Sub-Contract opportunity is not required to be advertised by the Contractor on Contracts Finder.

Visibility of Supply Chain Spend

16.5 In addition to any other management information requirements set out in the Contract, the Contractor agrees and acknowledges that it shall, at no charge, provide timely, full, accurate and complete SME management information reports (the **"SME Management Information Reports"**) to the Authority which incorporates the data described in the Supply Chain Information Report Template which is:

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- (a) the total contract revenue received directly on the Contract;
 - (b) the total value of sub-contracted revenues under the Contract (including revenues for non-SMEs/non-VCSEs); and
 - (c) the total value of sub-contracted revenues to SMEs and VCSEs.
- 16.6 The SME Management Information Reports shall be provided by the Contractor in the correct format as required by the Supply Chain Information Report Template and any guidance issued by the Authority from time to time. The Contractor agrees that it shall use the Supply Chain Information Report Template to provide the information detailed at clause 16.5 (a)–(c) and acknowledges that the template may be changed from time to time (including the data required and/or format) by the Authority issuing a replacement version. The Authority agrees to give at least thirty (30) days' notice in writing of any such change and shall specify the date from which it must be used.
- 16.7 The Contractor further agrees and acknowledges that it may not make any amendment to the Supply Chain Information Report Template without the prior approval of the Authority.
- 16.8 Without prejudice to Clause 21 of Schedule 2, the Contractor shall:
- 16.8.1 pay any sums which are due from it to any Sub-contractor or Unconnected Sub-contractor pursuant to any invoice (or other notice of an amount for payment) on the earlier of:
 - (a) the date set out for payment in the relevant Sub-contract or Unconnected Sub-contract; or;
 - (b) the date that falls sixty (60) days after the day on which the Contractor receives an invoice (or otherwise has notice of an amount for payment); and
 - 16.8.2 include within the management information produced by it pursuant Clause 11 of Schedule 2 and Schedule 7 (Contract Monitoring) a summary of its compliance with this Clause 16.8, such data to be certified every six Months by a director of the Contractor as being accurate and not misleading.
- 16.9 If the Contractor fails to pay 95% or above of all Sub-contractor or Unconnected Sub-contractor invoices (or other notice of an amount for payment) within sixty (60) days in either of the previous two six Month periods, the Contractor shall provide to the Authority within fifteen (15) Working Days of submission of the management information required by Clause 16.8.2, above, an action plan (the “**Action Plan**”) for improvement. The Action Plan shall include, but not be limited to, the following:
- (a) identification of the primary causes of failure to pay 95% or above of all Sub-contractor or Unconnected Sub-contractor invoices (or other notice of an amount for payment) within sixty (60) days of receipt;
 - (b) actions to address each of the causes set out in sub-paragraph 16.9.1; and
 - (c) a mechanism for and commitment to regular reporting on progress to the Contractor's board of directors.
- 16.10 The Action Plan shall be certificated by a director of the Contractor and the Action Plan or a summary of the Action Plan shall be published on the Contractor's website within ten (10) Working Days of the date on which the Action Plan is provided to the Authority.

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- 16.11 Where the Contractor fails to pay any sums due to any Sub-contractor or Unconnected Sub-contractor in accordance with the terms set out in the relevant Sub-contract or Unconnected Sub-contract, the Action Plan shall include details of the steps the Contractor will take to address this.
- 16.12 The Contractor shall comply with the Action Plan or any similar action plan connected to the payment of Sub-contractors or Unconnected Sub-contractors which is required to be submitted to the Authority as part of the procurement process and such action plan shall be included as part of the Contractor's Tender (to the extent it is not already included).
- 17. BUSINESS CONTINUITY AND DISASTER RECOVERY ☒ (ONLY APPLICABLE TO THE CONTRACT IF THIS BOX IS CHECKED AND THE SCHEDULE INSERTED)**
- 17.1 Within fourteen (14) days of the Services Commencement Date the Contractor shall prepare and deliver to the Authority for the Authority's written approval a plan (a "**BCDR Plan**") in accordance with Schedule 17, which shall detail the processes and arrangements that the Contractor shall follow to:
- 17.1.1 ensure continuity of the business processes and operations supported by the Services following any failure or disruption of any element of the Services; and
- 17.1.2 the recovery of the provision of the Services in the event of a disaster.
- 17.2 Following receipt of the draft BCDR Plan from the Contractor, the Parties shall use reasonable endeavours to agree the contents of the BCDR Plan. If the Parties are unable to agree the contents of the BCDR Plan within twenty (20) Working Days of its submission, then such dispute shall be resolved in accordance with Clause 42 Schedule 242 (Dispute Resolution) of Schedule 2.
- 18. ADDITIONAL FINANCIAL PROVISIONS ☒ (ONLY APPLICABLE TO THE CONTRACT IF THIS BOX IS CHECKED AND THE RELEVANT SCHEDULES INSERTED)**
- 18.1 The finance provisions in the following Schedules shall apply:
- Schedule 19 (Financial Reports, Open Book Data and Audit Provisions)
- Schedule 20(Financial Distress Events)
- 19. SERVICE LEVELS ☒ (ONLY APPLICABLE TO THE CONTRACT IF THIS BOX IS CHECKED)**
- 19.1 In this Clause, the following definitions shall apply:
- "Service Level"**: the service levels set out in Schedule 15 (Service Levels);
- "Achieved Service Level"**: in respect of any Service in any Service Period, the standard of performance actually achieved by the Contractor in the provision of that Service in the Service Period in question (calculated and expressed in the same way as the Service Levels for that Service is calculated and expressed in Schedule 15 (Service Levels);
- "Target Service Level"**: the minimum level of performance for a Service Level which is required by the Authority as set out against the relevant Service Levels in Schedule 15 (Service Levels);

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- 19.2 The provisions of Schedule 15 (Service Levels) shall apply.
- 19.3 Where any Service is stated in Schedule 15 (Service Levels) to be subject to a specific Service Level, the Contractor shall provide that Service in such a manner as will ensure that the Achieved Service Level in respect of that Service is equal to or higher than the corresponding Target Service Level to such specific Service Level.
- 19.4 The Contractor shall monitor its performance against each Target Service Level and shall send the Authority a report detailing the Achieved Service Levels in accordance with Schedule 7 (Contract Monitoring).
- 19.5 In the event that any Achieved Service Levels falls short of the relevant Target Service Level without prejudice to any other rights the Authority may have, the Authority shall be entitled to either submit an invoice to the Supplier or make deductions from the Charges corresponding to Service Credits set out in Schedule 6 (Pricing).

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SCHEDULE 2

General Terms and Conditions

1. PROVISION OF SERVICES

- 1.1 The Authority appoints the Contractor and the Contractor agrees to provide the Services:
- 1.1.1 promptly and in any event within any time limits as may be set out in this Contract;
 - 1.1.2 in accordance with all other provisions of this Contract;
 - 1.1.3 with reasonable skill and care and in accordance with any quality assurance standards as set out in the Key Provisions;
 - 1.1.4 in accordance with the Law;
 - 1.1.5 in accordance with the Anti-slavery Policy; and
 - 1.1.6 in accordance with Good Industry Practice.
- 1.2 The Authority may inspect and examine the manner in which the Contractor supplies the Services during normal business hours on reasonable notice.
- 1.3 Immediately following the Commencement Date, the Contractor shall, if specified in the Key Provisions, implement the Services fully in accordance with the Implementation Plan. If the Implementation Plan is an outline plan, the Contractor shall, as part of implementation, develop the outline plan into a full plan and agree this with the Authority. Once this is agreed, the Contractor shall comply with the full Implementation Plan.
- 1.4 The Contractor shall commence delivery of the Services on the Services Commencement Date.
- 1.5 The Contractor shall comply fully with its obligations set out in the Specification and the Tender.
- 1.6 If the Authority informs the Contractor in writing that the Authority reasonably believes that any part of the Services does not meet the requirements and/or standards of the Contract or differs in any way from those requirements, and this is other than as a result of a Default by the Authority, the Contractor shall at its own expense re-schedule and carry out the Services in accordance with the requirements of the Contract within such reasonable time as may be specified by the Authority.
- 1.7 The Contractor shall notify the Authority as soon as it becomes aware of:
- 1.7.1 any breach, or potential breach, of the Anti-slavery Policy; or
 - 1.7.2 any actual or suspected slavery or human trafficking in a supply chain which has a connection with this Contract.
- 1.8 If required by the Authority, the Contractor shall prepare and deliver to the Authority an annual slavery and human trafficking report setting out the steps it has taken to ensure that slavery and human trafficking is not taking place in any of its supply chains or in any part of its business. The Contractor shall indemnify the Authority against any losses, liabilities,

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damages, costs (including but not limited to legal fees) and expenses incurred by, or awarded against, the Authority as a result of any breach of the Anti-slavery Policy.

2. EXTENSION

- 2.1 The Authority shall be entitled to extend the Term on one or more occasions by giving the Contractor written notice not less than one (1) Month prior to the date on which this Contract would otherwise have expired, provided that the duration of this Contract shall be no longer than the total term specified in the Key Provisions. The provisions of the Contract will apply and take effect mutatis mutandis throughout any such extended period.

3. CONTRACT PRICE

- 3.1 In consideration of the Contractor's performance of its obligations under the Contract, the Authority shall pay the Contractor the Contract Price in accordance with Clause 4 (Payment and VAT) of this Schedule 2. The Contract Price shall remain fixed for the Term and any period of extension, other than as defined in Schedule 6 (Pricing).
- 3.2 The Authority shall, in addition to the Contract Price and following receipt of a valid VAT invoice, pay the Contractor a sum equal to the VAT chargeable on the value of the Services supplied in accordance with the Contract.
- 3.3 The Contractor shall, if so requested by the Authority, furnish such information as may reasonably be required by the Authority as to the amount of VAT chargeable under the Contract and payable by the Authority to the Contractor in addition to the Contract Price. Any overpayment by the Authority to the Contractor shall be a sum of money recoverable from the Contractor under Clause 14 (Recovery of Sums Due) of this Schedule 2.
- 3.4 The Authority's right to request paper form invoicing shall be subject to procurement policy note 11/15 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/437471/PPN_e-invoicing.pdf)) in respect of the Authority's obligation to accept unstructured electronic invoices from the Contractor where and as required under that procurement policy note (as amended from time to time).

4. PAYMENT AND VAT

- 4.1 Where the Contractor submits an invoice to the Authority in accordance with Clause 4.4 of this Schedule 2 the Authority will consider and verify that invoice in a timely fashion.
- 4.2 The Authority shall pay the Contractor any sums due under such invoice no later than a period of thirty (30) days from the date on which the Authority has determined that the invoice is valid and undisputed.
- 4.3 Where the Authority fails to comply with Clause 4.1 of this Schedule 2 and there is an undue delay in considering and verifying the invoice, the invoice shall be regarded as valid and undisputed for the purposes of Clause 4.2 of this Schedule 2 after a reasonable time has passed.
- 4.4 The Contractor shall submit an invoice to the Authority Monthly in arrears. The Contractor shall ensure that each invoice contains all appropriate references and a detailed breakdown of the Services supplied and that it is supported by any other documentation as may be reasonably required by the Authority to substantiate such invoice. Where travel and subsistence is claimed, all claims must comply with the provisions set out in Schedule 6 (Pricing) and must be accompanied by appropriate receipts to cover the total amount claimed.

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- 4.5 The Authority shall be entitled to withhold payment due under Clause 4 (Payment and VAT) of this Schedule 2 for so long as the Contractor, in the Authority's reasonable opinion, has failed to comply with its obligations to pay any Sub-contractors promptly in accordance with Clause 21.11 of this Schedule 2. For the avoidance of doubt the Authority shall not be liable to pay any interest or penalty in withholding such payment.

Electronic Invoicing

- 4.6 The Authority shall accept and process for payment an electronic invoice submitted for payment by the Contractor where the invoice is undisputed and where it complies with the standard on electronic invoicing.
- 4.7 For the purposes of clause 4.6, an electronic invoice complies with the standard on electronic invoicing where it complies with the European standard and any of the syntaxes published in Commission Implementing Decision (EU) 2017/1870.

VAT

- 4.8 The Contractor shall add VAT to the Contract Price at the prevailing rate in accordance with applicable law.
- 4.9 The Contractor shall indemnify the Authority on a continuing basis against any liability, including any interest, penalties or costs incurred which is levied, demanded or assessed on the Authority at any time in respect of the Contractor's failure to account for or to pay any VAT relating to payments made to the Contractor under the Contract. Any amounts due under this Clause 4.99 shall be paid by the Contractor to the Authority not less than five (5) Working Days before the date upon which the tax or other liability is payable by the Authority.
- 4.10 The Contractor shall not suspend the supply of the Services unless the Contractor is entitled to terminate the Contract under Clause 23 (Termination on Default) of this Schedule 2 for failure to pay undisputed sums of money. Interest shall be payable by the Authority on the late payment of any undisputed sums of money properly invoiced in accordance with the Late Payment of Commercial Debts (Interest) Act 1998.
- 4.11 Where the Contractor or any Contractor Personnel are liable to be taxed in the UK or to pay national insurance contributions in respect of consideration received under the Contract, the Contractor shall:
- 4.11.1 at all times comply with the Income Tax (Earnings and Pensions) Act 2003 and all other statutes and regulations relating to income tax, and the Social Security Contributions and Benefits Act 1992 and all other statutes and regulations relating to national insurance contributions, in respect of that consideration; and
 - 4.11.2 indemnify the Authority against any income tax, national insurance and social security contributions and any other liability, deduction, contribution, assessment or claim arising from or made (whether before or after the making of a demand pursuant to the indemnity hereunder) in connection with the provision of the Services by the Contractor or any Contractor Personnel.
- 4.12 In the event that any one of the Contractor Personnel is a Worker as defined in Clause 1 (Definitions) of Schedule 3 who receives consideration relating to the Services, then, in addition to its obligations under Clause 4.9 of this Schedule 2, the Contractor shall ensure that its contract with the Worker contains the following requirements:

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- 4.12.1 that the Authority may, at any time during the Term, request that the Worker provides information which demonstrates how the Worker complies with the requirements of Clause 4.11 of this Schedule 2, or why those requirements do not apply to it. In such case, the Authority may specify the information which the Worker must provide and the period within which that information must be provided;
- 4.12.2 that the Worker's contract may be terminated at the Authority's request if:
- (a) the Worker fails to provide the information requested by the Authority within the time specified by the Authority under Clause 4.10.1 of this Schedule 2; and/or
 - (b) the Worker provides information which the Authority considers is inadequate to demonstrate how the Worker complies with Clause 4.11 of this Schedule 2 or confirms that the Worker is not complying with those requirements; and
- 4.12.3 that the Authority may supply any information it receives from the Worker to HMRC for the purpose of the collection and management of revenue for which they are responsible.

5. NO PRICE ADJUSTMENT ON EXTENSION OF TERM

- 5.1 The Contract Price shall apply for the Term and any period of extension.

6. WARRANTIES AND REPRESENTATIONS

- 6.1 The Contractor warrants and undertakes to the Authority that:
- 6.1.1 it has full capacity and authority and all necessary consents (including, where its procedures so require, the consent of its parent company) to enter into and perform its obligations under the Contract and that the Contract is executed by a duly authorised representative of the Contractor;
 - 6.1.2 in entering the Contract it has not committed any Fraud;
 - 6.1.3 as at the Commencement Date, all information contained in the Tender remains true, accurate and not misleading, save as may have been specifically disclosed in writing to the Authority prior to execution of the Contract;
 - 6.1.4 no claim is being asserted and no litigation, arbitration or administrative proceeding is presently in progress or, to the best of its knowledge and belief, pending or threatened against it or any of its assets which will or might affect its ability to perform its obligations under the Contract;
 - 6.1.5 it is not subject to any contractual obligation, compliance with which is likely to affect its ability to perform its obligations under the Contract;
 - 6.1.6 no proceedings or other steps have been taken and not discharged (nor, to the best of its knowledge, are threatened) for the winding up of the Contractor or for its dissolution or for the appointment of a receiver, administrative receiver, liquidator, manager, administrator or similar officer in relation to any of the Contractor's assets or revenue;
 - 6.1.7 it owns, has obtained or is able to obtain, valid licences for all Intellectual Property Rights that are necessary for the performance of its obligations under the Contract;

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- 6.1.8 in the three (3) years prior to the Commencement Date:
- (a) it has conducted all financial accounting and reporting activities in compliance in all material respects with the generally accepted accounting principles that apply to it in any country where it files accounts;
 - (b) it has been in full compliance with all applicable securities and tax laws and regulations in the jurisdiction in which it is established; and
 - (c) it has not done or omitted to do anything which could have a material adverse effect on its assets, financial condition or position as an ongoing business concern, ability to fulfil its obligations under the Contract or provide the Services; and
- 6.2 The Contractor warrants and undertakes to the Authority that as at the Commencement Date, it has notified the Authority in writing of any Occasions of Tax Non-Compliance or any litigation that it is involved in that is in connection with any Occasions of Tax Non Compliance. If, at any point during the Term, an Occasion of Tax Non-Compliance occurs, the Contractor shall:
- 6.2.1 notify the Authority in writing of such fact within five (5) Working Days of its occurrence; and
 - 6.2.2 promptly provide to the Authority:
 - (a) details of the steps which the Contractor is taking to address the Occasion of Tax Non-Compliance and to prevent the same from recurring, together with any mitigating factors that it considers relevant; and
 - (b) such other information in relation to the Occasion of Tax Non-Compliance as the Authority may reasonably require.
- 6.3 The Contractor warrants and undertakes to the Authority that:
- 6.3.1 its responses to the Authority's slavery and human trafficking due diligence questionnaire, if any, are complete and accurate; and
 - 6.3.2 neither the Contractor nor any of its Contractor Personnel:
 - (a) has been convicted of any offence involving slavery and human trafficking; and
 - (b) having made reasonable enquiries, so far as it is aware, has been or is the subject of any investigation, inquiry or enforcement proceedings by any governmental, administrative or regulatory body regarding any offence or alleged offence of or in connection with slavery and human trafficking; and
 - 6.3.3 it undertakes its business in a manner that is consistent with the Anti-slavery Policy.
- 6.4 The Contractor shall implement due diligence procedures for its own suppliers, Sub-contractors and other participants in its supply chains, to ensure that there is no slavery or human trafficking in its supply chains.

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- 6.5 The representations and warranties set out in this Clause 6 of this Schedule 2 shall be deemed to be repeated by the Contractor on the Services Commencement Date (if later than the date of signature of this Contract) by reference to the facts then existing.
- 6.6 Each of the representations and warranties set out in this Clause 6 of this Schedule 2 shall be construed as a separate representation and warranty and shall not be limited or restricted by reference to, or inference from, the terms of any other representation, warranty or any other undertaking in this Contract.
- 6.7 If at any time the Contractor becomes aware that a representation or warranty given by it under this Clause 6 has been breached, is untrue or is misleading, it shall immediately notify the Authority of the relevant occurrence in sufficient detail to enable the Authority to make an accurate assessment of the situation.
- 6.8 For the avoidance of doubt, the fact that any provision within this Contract is expressed as a warranty shall not preclude any right of termination which the Authority may have in respect of breach of that provision by the Contractor.
- 6.9 Except as expressly stated in this Contract, all warranties and conditions whether express or implied by statute, common law or otherwise are hereby excluded to the extent permitted by Law.

7. CHANGE CONTROL PROCESS

- 7.1 The Contractor acknowledges to the Authority that the Authority's requirements for the Services may change during the Term and the Contractor shall not unreasonably withhold or delay its consent to any reasonable variation or addition to the Specification and Tender, as may be requested by the Authority from time to time.
- 7.2 Any change to the Services or other variation to this Contract shall only be binding once it has been agreed either: (a) in accordance with the Change Control Process if the Key Provisions specify that changes are subject to a formal change control process; or (b) if the Key Provisions make no such reference, in writing and signed by an authorised representative of both Parties.

CHANGE IN LAW

- 7.3 The Contractor shall neither be relieved of its obligations to supply the Services in accordance with the terms and conditions of this Contract nor be entitled to an increase in the Contract Price as a result of a Change in Law.

8. KEY PERSONNEL

- 8.1 The Contractor acknowledges that the Key Personnel are essential to the proper provision of the Services to the Authority.
- 8.2 The Contractor shall not remove or replace any Key Personnel unless:
- 8.2.1 requested to do so by the Authority;
 - 8.2.2 the person concerned resigns, retires or dies or is on maternity or long-term sick leave;
 - 8.2.3 the person's employment or contractual arrangement with the Contractor or a Sub-contractor is terminated for material breach of contract by the employee; or

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- 8.2.4 the Contractor obtains the Authority's prior written consent.
- 8.3 The Authority shall not unreasonably withhold its consent under Clause 8.2 of this Schedule 2. Such consent shall be conditional on appropriate arrangements being made by the Contractor to minimise any adverse impact on the Contract which could be caused by a change in Key Personnel.

9. CONTRACTOR PERSONNEL

- 9.1 At all times, the Contractor shall ensure that:
- 9.1.1 each of the Contractor Personnel responsible for providing the Services is suitably qualified, adequately trained and capable of providing the applicable Services in respect of which they are engaged;
 - 9.1.2 there is an adequate number of Contractor Personnel to provide the Services properly and in accordance with the Contract;
 - 9.1.3 only those people who are authorised by the Contractor are involved in providing the Services; and
 - 9.1.4 all of the Contractor Personnel comply with all of the Authority's policies, rules, regulations and requirements (including those relating to security arrangements) as may be in force from time to time for conduct when at or outside the Premises of the Authority.
- 9.2 The Authority may refuse to grant access to and remove any of the Contractor Personnel who do not comply with Clause 9.1.4 of this Schedule 2 or if they otherwise present a security threat or the Authority reasonably determines their presence to be undesirable.
- 9.3 The Contractor shall replace any of the Contractor Personnel who the Authority reasonably decides have failed to carry out their duties with reasonable skill and care. Following the removal of any of the Contractor Personnel for any reason, the Contractor shall ensure such person is replaced promptly with another person with the necessary training and skills to meet the requirements of the Services.
- 9.4 The Contractor shall and any relevant Sub-contractor not at any time during the Term:
- 9.4.1 permanently assign any employees, including Contractor Personnel, to the Services for the majority of their working time in the provision of the Services under this Contract;
 - 9.4.2 have employees, including Contractor Personnel, working solely on the Services under this Contract;
 - 9.4.3 create an identifiable and distinguishable team or group, within the workforce employed or engaged by the Contractor or any relevant Sub-contractor, which is for the purpose of providing the Services during the Term under this Contract.
- 9.5 The Contractor confirms that all persons employed or engaged by the Contractor have the appropriate approvals or a right to work in the United Kingdom. The Contractor shall comply with the Immigration Asylum and Nationality Act 2006, the Immigration Act 2016 and other relevant UK legislation as well as any regulations or relevant codes of practice regarding the

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reporting of labour movements, concealed employment and the employment of foreign workers.

- 9.6 If the Contractor fails to comply with Clause 9.4 of this Schedule 2 within one (1) Month of the date of the request and, in the reasonable opinion of the Authority, such failure may be prejudicial to the interests of the Crown, then the Authority may terminate the Contract with immediate effect by giving written notice to the Contractor at any time after the end of that one (1) Month period, such termination shall not prejudice or affect any right of action or remedy which shall have accrued or shall thereafter accrue to the Authority.
- 9.7 The decision of the Authority as to whether any person is to be refused access to the Premises and/or as to whether the Contractor has failed to comply with Clause 9.4 of this Schedule 2 shall be final and conclusive.

10. MANNER OF CARRYING OUT THE SERVICES

- 10.1 The Contractor shall begin performing the Services on the Services Commencement Date and continue to perform them for the Term. The Authority may, by written notice, require the Contractor to execute the Services in such order as the Authority may decide. In the absence of such notice the Contractor shall submit such detailed programmes of work and progress reports as the Authority may from time to time require.
- 10.2 The Contractor shall at all times comply with the Quality Standards. To the extent that the standard of Services has not been specified in the Contract, the Contractor shall agree the relevant standard of the Services with the Authority prior to the supply of the Services and, in any event, the Contractor shall perform its obligations under the Contract in accordance with the Law and Good Industry Practice.
- 10.3 The Contractor shall ensure that all Contractor Personnel supplying the Services shall do so with all due skill, care and diligence and shall possess such qualifications, skills and experience as are necessary for the proper supply of the Services.
- 10.4 The Contractor will be responsible for providing and delivering the Services in each and every respect with all relevant provisions of the Contract at all times and will ensure continuity of supply (at no extra cost to the Authority) in accordance with Schedule 4.

11. CONTRACT MANAGEMENT AND MONITORING OF CONTRACTOR'S PERFORMANCE

- 11.1 The Parties shall each appoint a contract manager to be known respectively as the Authority Representative and the Contractor Representative. The Authority Representative and the Contractor Representative shall meet in accordance with the provisions of Schedule 7 and in any event at least Monthly (unless otherwise notified by the Authority) to discuss the Contractor's performance and other matters connected to the delivery of the Contract.
- 11.2 The Contractor shall comply, as the Authority shall require, with the monitoring arrangements set out in Schedule 7 including, but not limited to, providing such data and information as the Contractor may be required to produce under the Contract.
- 11.3 The Contractor shall comply with any and all of the monitoring arrangements that the Authority shall require from time to time. This shall include, but shall not be limited to, providing such information as the Authority may require the Contractor to produce under the Contract.
- 11.4 At the Authority's request, within five (5) Working Days of such request, the Contractor shall supply such management information to the Authority as the Authority may reasonably

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request from time to time (including without limit any information about the Contractor's supply chain and its compliance in relation to sustainability requirements).

- 11.5 The Contractor shall provide the Authority with such supporting documentation as the Authority may require to establish and verify the Contractor's levels of performance.
- 11.6 The Contractor shall meet with the Authority following the completion of the provision of the Services to discuss:
- 11.6.1 whether the Contractor believes the objectives of the Contract were achieved;
 - 11.6.2 how far the intended benefits sought in the Authority's specification in Schedule 4 and that had been forecast in the Tender were achieved; and
 - 11.6.3 to identify any lessons learnt for future projects.
- 11.7 The Authority shall be able to share and use any information arising from such meetings referred to in Clauses 11.6.1 to 11.6.3 of this Schedule 2 as it sees fit.

12. RIGHT OF AUDIT

- 12.1 The Contractor shall keep secure and maintain until six (6) years after the final payment of all sums due under the Contract, or such longer period as may be agreed between the Parties, full and accurate records of the Services, all expenditure reimbursed by the Authority and all payments made by the Authority.
- 12.2 The Contractor shall grant to the Authority, or its authorised agents, such access to those records as they may reasonably require in order to check the Contractor's compliance with the Contract.
- 12.3 For the purpose of:
- 12.3.1 the examination and certification of the Authority's accounts; or
 - 12.3.2 any examination pursuant to Section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority has used its resources

the Comptroller and Auditor General may examine such documents as he may reasonably require which are owned, held or otherwise within the control of the Contractor and may require the Contractor to provide such oral and/or written explanations as he considers necessary. This Clause does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Contractor under Section 6(3)(d) and (5) of the National Audit Act 1983.

13. PROPERTY

- 13.1 Where the Authority issues Property free of charge to the Contractor such Property shall be and remain the property of the Authority. Such Property shall include the Equipment listed in Part A of Schedule 21, title in which shall be assigned by the Contractor to the Authority immediately upon such title being assigned by the seller of such Equipment. The Contractor shall not acquire title in any of the Equipment. The Contractor irrevocably licences the Authority and its agents to enter upon any premises of the Contractor during normal business hours on reasonable notice to recover any such Property. The Contractor shall take all reasonable steps to ensure that the title of the Authority to the Property and the exclusion of

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any such lien or other interest are brought to the notice of all Sub-contractors and other appropriate persons and shall, at the Authority's request, store the Property separately and ensure that it is clearly identifiable as belonging to the Authority.

- 13.2 The Property shall be deemed to be in good condition when received by or on behalf of the Contractor unless the Contractor notifies the Authority otherwise within five (5) Working Days of receipt.
- 13.3 Upon receipt of the Property the Contractor shall subject it to:
- 13.3.1 a reasonable visual inspection, and
 - 13.3.2 such additional inspection and testing as may be necessary and practicable in order to check that the Property is not defective or deficient for the purpose for which it has been provided.
- 13.4 Within a reasonable period the Authority shall replace or re-issue issued Property agreed by the Parties to be defective provided that the Contractor shall ensure that any appropriate and relevant warranty claims are made in respect of any defective Equipment.
- 13.5 The Contractor shall ensure the security of all the Property whilst in its possession.
- 13.6 The Contractor shall be liable for all loss of, or damage to, the Property (excluding fair wear and tear), unless such loss or damage was caused by the Default of the Authority and the Contractor shall maintain such Property, at its own cost, in accordance with the manufacturer's instructions. The Contractor shall inform the Authority within two (2) Working Days of any loss of, or damage to, the Property occurring.
- 13.7 Any costs relating to the operation, repair and maintenance of any Equipment listed in Part A of Schedule 21 provided by the Authority to the Contractor shall be borne by the Contractor. The Authority shall be responsible for the repair of, and maintain, any Equipment listed in Part B of Schedule 21 provided by the Authority to the Contractor save where such Equipment has been lost or damaged as a result of the negligence or the wilful default of the Contractor or any Contractor Personnel.

14. RECOVERY OF SUMS DUE

- 14.1 The Authority may set off any amount owed by the Contractor to the Crown or any part of the Crown (including the Authority) against any amount due to the Contractor under this Contract or under any agreement between the Contractor and the Authority.

15. CONFIDENTIAL INFORMATION

- 15.1 For the purposes of this Clause, the term "**Disclosing Party**" shall mean a Party which discloses or makes available directly or indirectly its Confidential Information and "**Recipient**" shall mean the Party which receives or obtains directly Confidential Information.
- 15.2 Except to the extent set out in this Clause or where disclosure is expressly permitted elsewhere in the Contract, the Recipient shall:
- 15.2.1 treat the Disclosing Party's Confidential Information as confidential and safeguard it accordingly (which is appropriate depending on the form in which such materials are stored and the nature of the Confidential Information contained in those materials);

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- 15.2.2 not disclose the Disclosing Party's Confidential Information to any other person except as expressly set out in the Contract or without the Disclosing Party's prior written consent;
- 15.2.3 not use or exploit the Disclosing Party's Confidential Information in any way except for the purposes anticipated under the Contract; and
- 15.2.4 immediately notify the Disclosing Party if its suspects or becomes aware of any unauthorised access, copying, use or disclosure in any form of any of the Disclosing Party's Confidential Information.
- 15.3 Clause 15.1 of this Schedule 2 shall not apply to the extent that:
- 15.3.1 Law requires such disclosure by the party making the disclosure, including any requirements for disclosure under FOIA, the Regulations or the Environmental Information Regulations;
- 15.3.2 such information is required in relation to the examination and certification of the Authority's accounts (provided that the disclosure is made on a confidential basis) or for any examination pursuant to Section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority is making use of its resources;
- 15.3.3 the Recipient has reasonable grounds to believe that the Disclosing Party is involved in activity that may constitute a criminal offence under the Bribery Act 2010 and the disclosure is being made to the Serious Fraud Office;
- 15.3.4 such information was already in the public domain at the time of disclosure otherwise than by a breach of the Contract; or
- 15.3.5 it is independently developed without access to the other Party's Confidential Information.
- 15.4 If the Recipient is required by Law to make a disclosure of Confidential Information, the Recipient shall, as soon as reasonably practicable and to the extent permitted by Law, notify the Disclosing Party of the full circumstances of the required disclosure including the relevant Law and/or Regulatory Body requiring such disclosure and the Confidential Information to which such disclosure would apply.
- 15.5 The Contractor may only disclose the Confidential Information of the Authority to the Contractor Personnel directly involved in the provision of the Services and who need to know the information, and shall ensure that such Contractor Personnel are aware of and shall comply with these obligations as to confidentiality.
- 15.6 The Contractor shall not, and shall procure that the Contractor Personnel do not, use any of the Confidential Information of the Authority received otherwise than for the purposes of the Contract and the provision of the Services.
- 15.7 At the written request of the Authority, the Contractor shall procure that Contractor Personnel identified in the Authority's request shall sign a confidentiality undertaking (in a form acceptable to the Authority) prior to commencing any work in accordance with the Contract.
- 15.8 The Authority may disclose the Confidential Information of the Contractor:

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- 15.8.1 on a confidential basis to any Central Government Body for any proper purpose of the Authority or of the relevant Central Government Body;
 - 15.8.2 to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirement;
 - 15.8.3 to the extent that the Authority (acting reasonably) deems disclosure necessary or appropriate in the course of carrying out its public functions;
 - 15.8.4 on a confidential basis to a professional adviser, consultant, supplier or other person engaged by any of the entities described in Clause 15.8.1 of this Schedule 2 (including any benchmarking organisation) for any purpose relating to or connected with the Contract;
 - 15.8.5 on a confidential basis for the purpose of the exercise of its rights under the Contract; or
 - 15.8.6 on a confidential basis to a proposed successor body in connection with any assignment, novation or disposal of any of its rights, obligations or liabilities under the Contract,

and for the purposes of the foregoing, references to disclosure on a confidential basis shall mean disclosure subject to a confidentiality agreement or arrangement containing terms no less stringent than those placed on the Authority under this Clause 15 (Confidential Information).

- 15.9 The Authority shall use all reasonable endeavours to ensure that any government department, Contracting Authority, employee, third party or Sub-contractor to whom the Confidential Information of the Contractor is disclosed pursuant to Clause 15.3 of this Schedule 2 is made aware of the Authority's obligations of confidentiality.
- 15.10 Nothing in this Clause 15 (Confidential Information) shall prevent either Party from using any techniques, ideas or know-how gained during the performance of the Contract in the course of its normal business to the extent that this use does not result in a disclosure of the other Party's Confidential Information or an infringement of Intellectual Property Rights.
- 15.11 Failure by the Contractor to comply with any of its obligations under this Clause 15 (Confidential Information) shall be an irremediable material breach of this Contract and the Authority shall be entitled to terminate the Contract pursuant to Clause 23.2.1(a) of this Schedule 2.

16. AUTHORITY DATA AND SECURITY

- 16.1 The Contractor shall not delete or remove any proprietary notices contained within or relating to the Authority Data.
- 16.2 The Contractor shall not store, copy, disclose, or use the Authority Data except as necessary for the performance by the Contractor of its obligations under the Contract or as otherwise expressly authorised in writing by the Authority.
- 16.3 To the extent that Authority Data is held and/or processed by the Contractor, the Contractor shall supply that Authority Data to the Authority as requested by the Authority in the format the Authority specifies.

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- 16.4 Upon receipt or creation by the Contractor of any Authority Data and during any collection, processing, storage and transmission by the Contractor of any Authority Data, the Contractor shall take all precautions necessary to preserve the integrity of the Authority Data and to prevent any corruption or loss of the Authority Data.
- 16.5 The Contractor shall perform secure back-ups of all Authority Data. The Contractor shall ensure that such back-ups are available to the Authority at all times upon request.
- 16.6 The Contractor shall ensure that any system on which the Contractor holds any Authority Data, including back-up data, is a secure system that complies with the Security Policy Framework and Security Policy.
- 16.7 If the Authority Data is corrupted, lost or sufficiently degraded as a result of the Contractor's Default so as to be unusable, the Authority may:
- 16.7.1 require the Contractor (at the Contractor's expense) to restore or procure the restoration of the Authority Data and the Contractor shall do so as soon as practicable; and/or
- 16.7.2 itself restore or procure the restoration of the Authority Data, and shall be repaid by the Contractor any reasonable expenses incurred in doing so.
- 16.8 If at any time the Contractor suspects or has reason to believe that Authority Data has or may become corrupted, lost or sufficiently degraded in any way for any reason, then the Contractor shall notify the Authority immediately and inform the Authority of the remedial action the Contractor proposes to take.
- 16.9 The Contractor shall comply with the security requirements set out in the Schedule 14.

17. PROTECTION OF PERSONAL DATA

Status of the Controller

- 17.1 The Parties acknowledge that for the purposes of the Data Protection Legislation, the nature of the activity carried out by each of them in relation to their respective obligations under this Contract will determine the status of each Party under the Data Protection Legislation. A Party may act as:
- 17.1.1 "Controller" (where the other Party acts as the "Processor");
- 17.1.2 "Processor" (where the other Party acts as the "Controller");
- 17.1.3 "Joint Controller" (where both Parties are considered to jointly control the same Personal Data);
- 17.1.4 "Independent Controller" of the Personal Data where the other Party is also "Controller" of the same Personal Data in its own right (but there is no element of joint control);

and the Parties shall set out in Schedule 13 (Processing, Personal Data and Data Subjects) which scenario or scenarios are intended to apply under this Contract.

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Where one Party is Controller and the other Party its Processor

- 17.2 Where a Party is a Processor, the only processing that it is authorised to do is listed in Schedule 13 (Processing, Personal Data and Data Subjects) by the Controller.
- 17.3 The Processor shall notify the Controller immediately if it considers that any of the Controller's instructions infringe the Data Protection Legislation.
- 17.4 The Processor shall provide all reasonable assistance to the Controller in the preparation of any Data Protection Impact Assessment prior to commencing any processing. Such assistance may, at the discretion of the Controller, include:
- 17.4.1 a systematic description of the envisaged processing operations and the purpose of the processing;
 - 17.4.2 an assessment of the necessity and proportionality of the processing operations in relation to the Services;
 - 17.4.3 an assessment of the risks to the rights and freedoms of Data Subjects; and
 - 17.4.4 the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.
- 17.5 The Processor shall, in relation to any Personal Data processed in connection with its obligations under this Contract:
- 17.5.1 process that Personal Data only in accordance with Schedule 13 (Processing, Personal Data and Data Subjects), unless the Processor is required to do otherwise by Law. If it is so required the Processor shall promptly notify the Authority before processing the Personal Data unless prohibited by Law;
 - 17.5.2 ensure that it has in place Protective Measures, including in the case of the Controller the measures set out in Clause 16 (Authority Data), which the Controller may reasonably reject (but failure to reject shall not amount to approval by the Controller of the adequacy of the Protective Measures) having taken account of the:
 - (a) nature of the data to be protected;
 - (b) harm that might result from a Data Loss Event;
 - (c) state of technological development; and
 - (d) cost of implementing any measures;
 - 17.5.3 ensure that:
 - (a) the Processor Personnel do not process Personal Data except in accordance with this Contract (and in particular Schedule 13 (Processing, Personal Data and Data Subjects));
 - (b) it takes all reasonable steps to ensure the reliability and integrity of any Processor Personnel who have access to the Personal Data and ensure that they:

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- (i) are aware of and comply with the Processor's duties under this Clause, Clauses 15 (Confidential Information) and 16 (Authority Data);
 - (ii) are subject to appropriate confidentiality undertakings with the Processor or any Sub-processor;
 - (iii) are informed of the confidential nature of the Personal Data and do not publish, disclose or divulge any of the Personal Data to any third Party unless directed in writing to do so by the Controller or as otherwise permitted by this Contract; and (D) have undergone; and
 - (iv) adequate training in the use, care, protection and handling of Personal Data;
- (c) not transfer Personal Data outside of the EU unless the prior written consent of the Controller has been obtained and the following conditions are fulfilled:
- (i) the Controller or the Processor has provided appropriate safeguards in relation to the transfer (whether in accordance with Article 46 of the GDPR or Section 75 of the DPA 2018) as determined by the Controller;
 - (ii) the Data Subject has enforceable rights and effective legal remedies;
 - (iii) the Processor complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the Controller in meeting its obligations); and
 - (iv) the Processor complies with any reasonable instructions notified to it in advance by the Controller with respect to the processing of the Personal Data; and
- (d) at the written direction of the Controller, delete or return Personal Data (and any copies of it) to the Controller on termination of the Contract unless the Processor is required by Law to retain the Personal Data.

17.6 Subject to Clause 17.7, the Processor shall notify the Controller immediately if it:

- 17.6.1 receives a Data Subject Request (or purported Data Subject Request);
- 17.6.2 receives a request to rectify, block or erase any Personal Data;
- 17.6.3 receives any other request, complaint or communication relating to either Party's
- 17.6.4 obligations under the Data Protection Legislation; receives any communication from the Information Commissioner or any other regulatory authority in connection with Personal Data processed under this Contract;
- 17.6.5 receives a request from any third Party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law; or
- 17.6.6 becomes aware of a Data Loss Event.

17.7 The Processor's obligation to notify under Clause 17.6 shall include the provision of further information to the Controller in phases, as details become available.

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- 17.8 Taking into account the nature of the processing, the Processor shall provide the Controller with reasonable assistance in relation to either Party's obligations under Data Protection Legislation and any complaint, communication or request made under Clause 17.6 (and insofar as possible within the timescales reasonably required by the Controller) including by promptly providing:
- 17.8.1 the Controller with full details and copies of the complaint, communication or request;
 - 17.8.2 such assistance as is reasonably requested by the Controller to enable it to comply with a Data Subject Request within the relevant timescales set out in the Data Protection Legislation;
 - 17.8.3 the Controller, at its request, with any Personal Data it holds in relation to a Data Subject;
 - 17.8.4 assistance as requested by the Controller following any Data Loss Event; and/or
 - 17.8.5 assistance as requested by the Controller with respect to any request from the Information Commissioner's Office, or any consultation by the Controller with the Information Commissioner's Office.
- 17.9 The Processor shall maintain complete and accurate records and information to demonstrate its compliance with this Clause. This requirement does not apply where the Processor employs fewer than 250 staff, unless:
- 17.9.1 the Controller determines that the processing is not occasional;
 - 17.9.2 the Controller determines the processing includes special categories of data as referred to in Article 9(1) of the GDPR or Personal Data relating to criminal convictions and offences referred to in Article 10 of the GDPR; or
 - 17.9.3 the Controller determines that the processing is likely to result in a risk to the rights and freedoms of Data Subjects.
- 17.10 The Processor shall allow for audits of its Data Processing activity by the Controller or the Controller's designated auditor.
- 17.11 The Parties shall designate a Data Protection Officer if required by the Data Protection Legislation.
- 17.12 Before allowing any Sub-processor to process any Personal Data related to this Agreement, the Processor must:
- 17.12.1 notify the Controller in writing of the intended Sub-processor and processing;
 - 17.12.2 obtain the written consent of the Controller;
 - 17.12.3 enter into a written agreement with the Sub-processor which give effect to the terms set out in this Clause 17 such that they apply to the Sub-processor; and
 - 17.12.4 provide the Controller with such information regarding the Sub-processor as the Controller may reasonably require.
- 17.13 The Processor shall remain fully liable for all acts or omissions of any of its Sub-processors.
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- 17.14 The Authority may, at any time on not less than 30 Working Days' notice, revise this Clause by replacing it with any applicable controller to processor standard clauses or similar terms forming part of an applicable certification scheme (which shall apply when incorporated by attachment to this Contract).
- 17.15 The Parties agree to take account of any guidance issued by the Information Commissioner's Office. The Authority may on not less than 30 Working Days' notice to the Contractor amend this Contract to ensure that it complies with any guidance issued by the Information Commissioner's Office.

Where the Parties are Joint Controllers of Personal Data

- 17.16 In the event that the Parties are Joint Controllers in respect of Personal Data under this Contract, the Parties shall implement Clauses that are necessary to comply with Article 26 of the GDPR.

Where the Parties are Independent Controllers of Personal Data

- 17.17 With respect to Personal Data provided by one Party to another Party for which each Party acts as Controller but which is not under a Joint Controller arrangement of the Parties, each Party undertakes to comply with the applicable Data Protection Legislation in respect of their processing of such Personal Data as Controller.
- 17.18 Each Party shall process the Personal Data in compliance with its obligations under the Data Protection Legislation and not do anything to cause the other Party to be in breach of it.
- 17.19 Where a Party has provided Personal Data to the other Party in accordance with Clause 17.17, the recipient of the Personal Data will provide all such relevant documents and information relating to its data protection policies and procedures as the other Party may reasonably require.
- 17.20 The Parties shall be responsible for their own compliance with Articles 13 and 14 of the GDPR in respect of the processing of Personal Data for the purposes of this Contract.
- 17.21 The Parties shall only provide Personal Data to each other:
- 17.21.1 to the extent necessary to perform the respective obligations under this Contract;
 - 17.21.2 in compliance with the Data Protection Legislation (including by ensuring all required fair processing information has been given to affected Data Subjects); and
 - 17.21.3 where it has recorded it in Schedule 13 (Processing, Personal Data and Data Subjects).
- 17.22 Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, each Party shall, with respect to its processing of Personal Data as independent Controller, implement and maintain appropriate technical and organisational measures to ensure a level of security appropriate to that risk, including, as appropriate, the measures referred to in Article 32(1)(a), (b), (c) and (d) of the GDPR, and the measures shall, at a minimum, comply with the requirements of the Data Protection Legislation, including Article 32 of the GDPR.

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- 17.23 A Party processing Personal Data for the purposes of this Contract shall maintain a record of its processing activities in accordance with Article 30 of the GDPR and shall make the record available to the other Party upon reasonable request.
- 17.24 Where a Party receives a request by any Data Subject to exercise any of their rights under the Data Protection Legislation in relation to the Personal Data provided to it by the other Party pursuant to this Contract ("**the Request Recipient**"):
- 17.24.1 the other Party shall provide any information and/or assistance as reasonably requested by the Request Recipient to help it respond to the request or correspondence, at the cost of the Request Recipient; or
 - 17.24.2 where the request or correspondence is directed to the other party and/or relates to the other party's Processing of the Personal Data, the Request Recipient will:
 - (a) promptly, and in any event within five (5) Working Days of receipt of the request or correspondence, inform the other party that it has received the same and shall forward such request or correspondence to the other party; and
 - (b) provide any information and/or assistance as reasonably requested by the other party to help it respond to the request.
- 17.25 Each party shall promptly notify the other Party upon it becoming aware of any Personal Data Breach relating to Personal Data provided by the other party pursuant to this Contract and shall:
- 17.25.1 do all such things as reasonably necessary to assist the other Party in mitigating the effects of the Data Breach;
 - 17.25.2 implement any measures necessary to restore the security of any compromised Personal Data;
 - 17.25.3 work with the other Party to make any required notifications to the Information Commissioner's Office and affected Data Subjects in accordance with the Data Protection Legislation (including the timeframes set out therein); and
 - 17.25.4 not do anything which may damage the reputation of the other Party or that Party's relationship with the relevant Data Subjects, save as required by Law.
- 17.26 Personal Data provided by one Party to the other Party may be used exclusively to exercise rights and obligations under this Contract as specified in Schedule 13 (Processing, Personal Data and Data Subjects).
- 17.27 Personal Data shall not be retained or processed for longer than is necessary to perform each Party's obligations under this Contract which is specified in Schedule 13 (Processing, Personal Data and Data Subjects).
- 17.28 Notwithstanding the general application of Clauses 17.2 to 17.15 to Personal Data, where the Contractor is required to exercise its regulatory and/or legal obligations in respect of Personal Data, it shall act as an Independent Controller of Personal Data in accordance with Clause 17.16 to 17.27.

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18. INTELLECTUAL PROPERTY RIGHTS

- 18.1 All Intellectual Property Rights in any guidance, know-how, specifications, instructions, toolkits, plans, data, drawings, databases, patents, patterns, models, designs or other material (the "**IP Materials**"):
- 18.1.1 furnished to or made available to the Contractor by or on behalf of the Authority shall remain the property of the Authority; and
- 18.1.2 prepared by or for the Contractor on behalf of the Authority for use, or intended use, in relation to the performance by the Contractor of its obligations under the Contract shall belong to the Authority;
- and the Contractor shall not, and shall ensure that the Contractor Personnel shall not, (except when necessary for the performance of the Contract) without prior written consent, use or disclose any Intellectual Property Rights in the IP Materials.
- 18.2 The Contractor hereby assigns to the Authority, with full title guarantee, all Intellectual Property Rights which may subsist in the IP Materials prepared in accordance with Clause 18.1.2 of this Schedule 2. This assignment shall take effect on the date of the Contract or as a present assignment of future rights that will take effect immediately on the coming into existence of the Intellectual Property Rights produced by the Contractor. The Contractor shall execute all documentation necessary to execute such assignment.
- 18.3 The Authority hereby grants a royalty free, non-exclusive, licence (with no right to sub-licence) for the duration of the Term to the Contractor to use all Intellectual Property which may subsist in the IP Materials prepared in accordance with Clause 18.1.2 of this Schedule 2. This licence shall take effect on the date of the Contract.
- 18.4 The Contractor grants to the Authority a royalty-free, irrevocable and non-exclusive licence (with a right to sub-licence) to use any Intellectual Property Rights that the Contractor owned or developed prior to the Commencement Date and which the Authority reasonably requires in order to exercise its rights and take the benefit of the Contract including the Services provided.
- 18.5 The Contractor shall waive or procure a waiver of any moral rights subsisting in copyright produced by the Contract, the Services or the performance thereof.
- 18.6 The Contractor shall ensure that the third party owner of any Intellectual Property Rights that are or which may be used to perform the Contract grants to the Authority a non-exclusive licence or, if itself a licensee of those rights, shall grant to the Authority an authorised sub-licence, to use, reproduce, modify, develop and maintain such Intellectual Property Rights. Such licence or sub-licence shall be non-exclusive, perpetual, royalty free and irrevocable and shall include the right for the Authority to sub-license, transfer, novate or assign to other Contracting Authorities, the Replacement Contractor or to any other third party supplying services to the Authority.
- 18.7 The Contractor shall not infringe any Intellectual Property Rights of any third party in supplying the Services and the Contractor shall, during and after the Term, indemnify and keep indemnified and hold the Authority and the Crown harmless from and against all actions, suits, claims, demands, losses, charges, damages, costs and expenses and other liabilities which the Authority or the Crown may suffer or incur as a result of or in connection with any breach of this Clause, except where any such claim arises from:

18.7.1 items or materials based upon designs supplied by the Authority; or
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- 18.7.2 the use of data supplied by the Authority which is not required to be verified by the Contractor under any provision of the Contract.
- 18.8 The Authority shall notify the Contractor in writing of any claim or demand brought against the Authority for infringement or alleged infringement of any Intellectual Property Right in materials supplied or licensed by the Contractor.
- 18.9 The Contractor shall at its own expense conduct all negotiations and any litigation arising in connection with any claim for breach of Intellectual Property Rights in materials supplied or licensed by the Contractor, provided always that the Contractor:
- 18.9.1 shall consult the Authority on all substantive issues which arise during the conduct of such litigation and negotiations;
- 18.9.2 shall take due and proper account of the interests of the Authority; and
- 18.9.3 shall not settle or compromise any claim without the Authority's prior written consent (not to be unreasonably withheld or delayed).
- 18.10 The Authority shall at the request of the Contractor afford to the Contractor all reasonable assistance for the purpose of contesting any claim or demand made or action brought against the Authority or the Contractor by a third party for infringement or alleged infringement of any third party Intellectual Property Rights in connection with the performance of the Contractor's obligations under the Contract and the Contractor shall indemnify the Authority for all costs and expenses (including, but not limited to, legal costs and disbursements) incurred in doing so. The Contractor shall not, however, be required to indemnify the Authority in relation to any costs and expenses incurred in relation to or arising out of a claim, demand or action which relates to the matters in Clause 18.7.1 or 18.7.2 of this Schedule 2.
- 18.11 The Authority shall not make any admissions which may be prejudicial to the defence or settlement of any claim, demand or action for infringement or alleged infringement of any Intellectual Property Right by the Authority or the Contractor in connection with the performance of its obligations under the Contract.
- 18.12 If a claim, demand or action for infringement or alleged infringement of any Intellectual Property Right is made in connection with the Contract or, in the reasonable opinion of the Contractor, is likely to be made, the Contractor shall notify the Authority and, at its own expense and subject to the consent of the Authority (not to be unreasonably withheld or delayed), use its best endeavours to:
- 18.12.1 modify any or all of the Services without reducing the performance or functionality of the same, or substitute alternative Services of equivalent performance and functionality, so as to avoid the infringement or the alleged infringement, provided that the provisions herein shall apply mutates mutandis to such modified Services or to the substitute Services; or
- 18.12.2 procure a licence to use and supply the Services, which are the subject of the alleged infringement, on terms which are acceptable to the Authority; and
- 18.12.3 in the event that the Contractor is unable to comply with Clauses 18.12.1 or 18.12.2 within twenty (20) Working Days of receipt of the Contractor's notification the Authority may terminate the Contract with immediate effect by written notice.

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19. LIABILITY

19.1 Neither Party excludes or limits liability to the other Party for:

- 19.1.1 death or personal injury caused by its negligence, or that of its employees, agents or Sub-contractors;
- 19.1.2 bribery or Fraud by it or its employees;
- 19.1.3 fraudulent misrepresentation; or
- 19.1.4 any liability to the extent that it cannot be excluded or limited by any applicable law.

19.2 The Contractor does not exclude or limit its liability in respect of the indemnity at Clause 18.7 and in each case whether before or after the making of a demand pursuant to the indemnity therein.

19.3 Subject to Clauses 19.4, 19.5, 19.6 and 19.7 of this Schedule 2, the Contractor shall indemnify the Authority and keep the Authority indemnified fully against all claims, proceedings, actions, damages, costs, expenses and any other liabilities which may arise out of, or in consequence of, the supply, or the late or purported supply, of the Services or the performance or non-performance by the Contractor of its obligations under the Contract or the presence of the Contractor or any Contractor Personnel on the Premises, including in respect of any death or personal injury, loss of or damage to property, financial loss arising from any advice given or omitted to be given by the Contractor, or any other loss which is caused directly or indirectly by any act or omission of the Contractor.

19.4 The Contractor shall not be responsible for any injury, loss, damage, cost or expense if and to the extent that it is caused by the negligence or wilful misconduct of the Authority or by breach by the Authority of its obligations under the Contract.

19.5 Subject always to Clauses 19.1, 19.2, 19.6, 19.7 and 19.8 of this Schedule 2, the total liability of each Party to the other under or in connection with this Contract whether arising in contract, tort, negligence, breach of statutory duty or otherwise in respect of each Contract Year shall in no event exceed the greater of:

- 19.5.1 £5,000,000; or
- 19.5.2 one hundred per cent (100%) of the total Contract Price paid or payable by the Authority to the Contractor for the Services in that Contract Year

and for the purposes of this clause 19.5 and determining in which Contract Year a claim is made (and the applicable liability cap):

- 19.5.3 all claims notified by the Authority (or its representatives as the case maybe) to the Contractor during the duration of the Contract shall be deemed and treated by the parties as if made by the Authority in the Contract Year in which the event giving rise to the claim occurred (or where the claim relates to a series of related events in the Contract Year in which the first event of the series of related events occurred); and
- 19.5.4 all claims notified by the Authority (or its representatives as the case maybe) to the Contractor after the termination or expiry of the Agreement (post termination claims), shall be deemed and treated by the parties as if made by the Authority in the final Contract Year of the Agreement

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- 19.6 Subject always to Clause 19.1 and clause 19.7, in no event shall either Party be liable to the other for any:
- 19.6.1 loss of profits, loss of business, loss of revenue, loss of an opportunity, or loss of goodwill; and/or
 - 19.6.2 loss of savings (whether anticipated or otherwise); and/or
 - 19.6.3 indirect or consequential loss or damage.
- 19.7 For the avoidance of doubt nothing in this clause 19 shall exclude or restrict the liability of the Authority to pay the Contract Price as and when it becomes due and payable under the terms of this Contract.
- 19.8 Subject always to Clauses 19.1, 19.2, 19.6 and 19.9 of this Schedule 2 the Contractor's aggregate liability in respect of loss of or damage to Authority Data or breach of the Data Protection Legislation that is caused by Default of the Contractor occurring in each and any Contract Year shall in no event exceed £10 million;
- 19.9 Subject to clause 19.5, the Contractor acknowledges that the Authority may, amongst other things, recover from the Contractor the following losses incurred by the Authority to the extent that they arise as a result of a Default by the Contractor:
- 19.9.1 any additional operational and/or administrative costs and expenses incurred by the Authority, including costs relating to time spent by or on behalf of the Authority in dealing with the consequences of the Default;
 - 19.9.2 any wasted expenditure or charges;
 - 19.9.3 the additional costs of procuring replacement Services for the remainder of the Term, which shall include any incremental costs associated with such replacement Services above those which would have been payable under the Contract;
 - 19.9.4 any compensation or interest paid to a third party by the Authority; and
 - 19.9.5 any fine, penalty or costs incurred by the Authority pursuant to Law.
- 19.10 Each Party shall use its respective reasonable endeavours to mitigate any loss or damage suffered arising out of or connection with the Contract.
- 19.11 Where the Contractor is a consortium, for the avoidance of doubt, the organisations comprising the Contractor shall be jointly and severally liable with regard to the performance by the Contractor of any and all of its obligations under the Contract and in respect of any losses incurred by the Authority under or in connection with this Contract as a result of Defaults by the Contractor.
- 19.12 Clause 19 of this Schedule 2 shall survive the expiry of or earlier termination of this Contract for any reason.

20. INSURANCE

- 20.1 The Contractor shall effect and maintain with a reputable insurance company (or companies) the policies of insurance referred to in clause 9 of Schedule 1. Such insurance shall be maintained for the duration of the Term and for a minimum of six (6) years following the expiration or earlier termination of the Contract. For the avoidance of doubt nothing in this Contract for the provision of Outsourced Kitting Production

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Contract shall require the Contractor to obtain insurance against the risk of the Authority exercising its right to terminate for convenience.

- 20.2 The Contractor shall hold employer's liability insurance in respect of Contractor Personnel in accordance with any legal requirement from time to time in force.
- 20.3 Without limitation to any insurance arrangements as required by Law, the Contractor shall put in place and/or maintain the different types and/or levels of indemnity arrangements explicitly required by the Authority, if specified in the Key Provisions.
- 20.4 The Contractor shall from time to time and in any event within five (5) Working Days of written demand provide documentary evidence to the Authority that insurance arrangements taken out by the Contractor pursuant to Clause 20 of this Schedule 2 and the Key Provisions are fully maintained and that any premiums on them and/or contributions in respect of them (if any) are fully paid.
- 20.5 If, for whatever reason, the Contractor fails to give effect to and maintain the insurances required by the provisions of the Contract the Authority may make alternative arrangements to protect its interests and may recover the costs of such arrangements from the Contractor.
- 20.6 The provisions of any insurance or the amount of cover shall not relieve the Contractor of any liabilities under the Contract. It shall be the responsibility of the Contractor to determine the amount of insurance cover that will be adequate to enable the Contractor to satisfy any liability referred to in Clause 19 (Liability) of this Schedule 2.

21. TRANSFER AND SUB-CONTRACTING

- 21.1 The Contractor shall not assign, novate, sub-contract or otherwise dispose of or create any trust in relation to any or all of its rights, obligations or liabilities under the Contract or any part of it without the prior written consent of the Authority.
- 21.2 The Authority may assign, novate or otherwise dispose of any or all of its rights, liabilities and obligations under the Contract or any part thereof to:
- 21.2.1 any other body established by the Crown; or
 - 21.2.2 under statute in order substantially to perform any of the functions that had previously been performed by the Authority; or
 - 21.2.3 any private sector body which substantially performs the functions of the Authority, and the Contractor shall, at the Authority's request, enter into a novation agreement in such form as the Authority shall reasonably specify in order to enable the Authority to exercise its rights pursuant to this Clause 21.2.
- 21.3 A change in the legal status of the Authority shall not, subject to Clause 21.4 of this Schedule 2 affect the validity of the Contract and the Contract shall be binding on any successor body to the Authority.
- 21.4 If the Authority assigns, novates or otherwise disposes of any of its rights, obligations or liabilities under the Contract to a private sector body in accordance with Clause 21.2.3 of this Schedule 2 (the "**Transferee**" in the rest of this Clause) the right of termination of the Authority in Clause 22 (Termination on Insolvency and Change of Control) of this Schedule 2 shall be available to the Contractor in the event of insolvency of the Transferee (as if the

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references to Contractor in Clause 22 (Termination on Insolvency and Change of Control) of this Schedule 2 were references to the Transferee).

- 21.5 The Contractor shall exercise due skill and care in the selection of any Sub-contractors to ensure that the Contractor is able to:
- 21.5.1 manage any Sub-contractors in accordance with Good Industry Practice;
 - 21.5.2 comply with its obligations under the Contract in the provision of the Services; and
 - 21.5.3 assign, novate or otherwise transfer to the Authority or any Replacement Contractor any of its rights and/or obligations under each Sub-contract that relates exclusively to the Contract.
- 21.6 Prior to sub-contacting any of its obligations under the Contract, the Contractor shall notify the Authority and provide the Authority with:
- 21.6.1 the proposed Sub-contractor's name, registered office and company registration number; and
 - 21.6.2 the scope of any Services to be provided by the proposed Sub-contractor.
- 21.7 If requested by the Authority within ten (10) Working Days of receipt of the Contractor's notice issued pursuant to Clause 21.6 of this Schedule 2, the Contractor shall also provide:
- 21.7.1 a copy of the proposed Sub-contract; and
 - 21.7.2 any further information reasonably requested by the Authority.
- 21.8 The Authority may, within ten (10) Working Days of receipt of the Contractor's notice issued pursuant to Clause 21.6 of this Schedule 2 (or, if later, receipt of any further information requested pursuant to Clause 21.7 of this Schedule 2), object to the appointment of the relevant Sub-contractor if they consider that:
- 21.8.1 the appointment of a proposed Sub-contractor may prejudice the provision of the Services or may be contrary to the interests respectively of the Authority under the Contract;
 - 21.8.2 the proposed Sub-contractor is unreliable and/or has not provided reliable goods and or reasonable services to its other customers;
 - 21.8.3 the proposed Sub-contractor employs unfit persons; and/or
 - 21.8.4 the proposed Sub-contractor should be excluded in accordance with Clause 21.14 of this Schedule 2,
- in which case, the Contractor shall not proceed with the proposed appointment.
- 21.9 If the Authority has not notified the Contractor that it objects to the proposed Sub-contractor's appointment by the later of ten (10) Working Days of receipt of:
- 21.9.1 the Contractor's notice issued pursuant to Clause 21.6 of this Schedule 2; and

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- 21.9.2 any further information requested by the Authority pursuant to Clause 21.7 of this Schedule 2

the Contractor may proceed with the proposed appointment.

- 21.10 The Contractor shall ensure that all Sub-contracts (which in this sub-clause includes any contract in the Contractor's supply chain made wholly or substantially for the purpose of performing or contributing to the performance of the whole or any part of this Contract) contain provisions:
- 21.10.1 requiring the Contractor or other party receiving goods or services under the contract to consider and verify invoices under that contract in a timely fashion;
 - 21.10.2 that if the Contractor or other party fails to consider and verify an invoice in accordance with Clause 21.10.1 of this Schedule 2, the invoice shall be regarded as valid and undisputed for the purpose of Clause 21.10.3 of this Schedule 2 after a reasonable time has passed;
 - 21.10.3 requiring the Contractor or other party to pay any undisputed sums which are due from it to the Sub-contractor within a specified period not exceeding thirty (30) days of verifying that the invoice is valid and undisputed; and
 - 21.10.4 giving the Authority a right to publish the Contractor's compliance with its obligation to pay undisputed invoices within the specified payment period; and
 - 21.10.5 requiring the Sub-contractor to include a clause to the same effect as this Clause 21.10 in any contracts it enters into wholly or substantially for the purpose of performing or contributing to the performance of the whole or any part of this Contract.
- 21.11 The Contractor shall pay any undisputed sums which are due from it to a Sub-contractor within thirty (30) days of verifying that the invoice is valid and undisputed.
- 21.12 Notwithstanding any provision of Clauses 15 (Confidential Information) and 30 (Publicity) of this Schedule 2 if the Contractor notifies the Authority that the Contractor has failed to pay an undisputed Sub-contractor's invoice within thirty (30) days of receipt, or the Authority otherwise discovers the same, the Authority shall be entitled to publish the details of the late or non-payment (including on government websites and in the press).
- 21.13 Notwithstanding the Contractor's right to sub-contract pursuant to this Clause 21, the Contractor shall remain responsible for all acts and omissions of its Sub-contractors and the acts and omissions of those employed or engaged by the Sub-contractors as if they were its own.
- 21.14 Where the Authority considers whether there are grounds for exclusion of a Sub-contractor under Regulation 57 of the Regulations, then:
- 21.14.1 if the Authority finds there are compulsory grounds for exclusion, the Contractor shall replace or shall not appoint the Sub-contractor;
 - 21.14.2 if the Authority finds there are non-compulsory grounds for exclusion, the Authority may require the Contractor to replace or not appoint the Sub-contractor

and the Contractor shall comply with such a requirement.

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22. TERMINATION ON INSOLVENCY AND CHANGE OF CONTROL

- 22.1 The Authority may terminate the Contract with immediate effect by giving written notice where the Contractor is a company and in respect of the Contractor:
- 22.1.1 a proposal is made for a voluntary arrangement within Part I of the Insolvency Act 1986 or of any other composition scheme or arrangement with, or assignment for the benefit of, the Contractor's creditors; or
 - 22.1.2 a shareholders', members' or partners' meeting is convened for the purpose of considering a resolution that the Contractor be wound up or a resolution for the winding-up of the Contractor is passed (other than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation); or
 - 22.1.3 a petition is presented for the winding-up of the Contractor (which is not dismissed within five (5) Working Days of its service) or an application is made for the appointment of a provisional liquidator or a creditors' meeting is convened in respect of the Contractor pursuant to section 98 of the Insolvency Act 1986; or
 - 22.1.4 a receiver, administrative receiver or similar officer is appointed over the whole or any part of the Contractor's business or assets; or
 - 22.1.5 a creditor or encumbrancer attaches or takes possession of, or a distress, execution, sequestration or other such process is levied or enforced on or sued against, the whole or any part of the Contractor's assets and such attachment or process is not discharged within ten (10) Working Days;
 - 22.1.6 an application is made in respect of the Contractor either for the appointment of an administrator or for an administration order and an administrator is appointed, or notice of intention to appoint an administrator is given; or
 - 22.1.7 if the Contractor is or becomes insolvent within the meaning of section 123 of the Insolvency Act 1986; or
 - 22.1.8 the Contractor suspends or ceases, or threatens to suspend or cease, to carry on all or a substantial part of his business; or
 - 22.1.9 in the reasonable opinion of the Authority, there is a material detrimental change in the financial standing and/or the credit rating of the Contractor which:
 - (a) adversely impacts on the Contractor's ability to supply the Services in accordance with the Contract; or
 - (b) could reasonably be expected to have an adverse impact on the Contractor's ability to supply the Services in accordance with the Contract; or
 - 22.1.10 being a "small company" within the meaning of section 382(3) of the Companies Act 2006, a moratorium in respect of the Contractor comes into force pursuant to Schedule A1 of the Insolvency Act 1986; or
 - 22.1.11 any event similar to those listed in Clauses 22.1.1 to 22.1.10 occurs under the law of any other jurisdiction.
- 22.2 The Authority may in its sole discretion (without any obligation to provide any reasons therefor and without any obligation to pay monies arising) terminate the Contract in whole by giving Contract for the provision of Outsourced Kitting Production

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not less than three (3) Months' written notice to the Contractor if the Contractor undergoes a change of control within the meaning of sections 450 and 451 of the Corporation Tax Act 2010 ("Change of Control") which has not been agreed in advance by the Authority (such agreement not to be unreasonably withheld). It shall not be unreasonable for the Authority to withhold such agreement if the Authority reasonably expects the Change of Control to have a detrimental effect on the Supplier's performance of its obligations under the Contract.

23. TERMINATION ON DEFAULT

23.1 In the case of a breach of any of the terms of this Contract by the Contractor that is capable of remedy (including, without limitation any failure to pay any sums due under this Contract), the Authority shall, without prejudice to its other rights and remedies under this Contract, issue notice of the breach and allow the Contractor the opportunity to remedy such breach in the first instance via a remedial proposal put forward by the Contractor ("**Remedial Proposal**") before exercising any right to terminate this Contract in accordance with Clause 23.2 of this Schedule 2. Such Remedial Proposal must be agreed with the Authority (such agreement not to be unreasonably withheld or delayed) and must be implemented by the Contractor in accordance with the timescales referred to in the agreed Remedial Proposal. Once agreed, any changes to a Remedial Proposal must be approved by the Parties in writing. Any failure by the Contractor to:

23.1.1 put forward and agree a Remedial Proposal with the Authority in relation to the relevant default or breach within a period of ten (10) Working Days (or such other period as the non-breaching Party may agree in writing) from written notification of the relevant default or breach from the Authority;

23.1.2 comply with such Remedial Proposal (including, without limitation, as to its timescales for implementation, which shall be thirty (30) days unless otherwise agreed between the Parties); and/or

23.1.3 remedy the default or breach notwithstanding the implementation of such Remedial Proposal in accordance with the agreed timescales for implementation,

shall be deemed, for the purposes of Clause 23.2.1(b) of this Schedule 2, a material breach of this Contract by the Contractor not remedied in accordance with an agreed Remedial Proposal.

23.2 The Authority may terminate the Contract, or terminate the provision of any part of the Services, with immediate effect by giving written notice to the Contractor if the Contractor:

23.2.1 commits a material breach of any of the terms of this Contract which is:

(a) not capable of remedy; or

(b) in the case of a breach capable of remedy, which is not remedied in accordance with a Remedial Proposal; or

23.2.2 has been served with at least two (2) previous breach notices as a result of any material breaches which are capable of remedy within any twelve (12) Month rolling period whether or not the Contractor has remedied the breach in accordance with a Remedial Proposal. The twelve (12) Months rolling period is the twelve (12) Months immediately preceding the date of the third breach notice.

23.3 The Authority shall be entitled to terminate the Contract with immediate effect by giving written notice to the Contractor:

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- 23.3.1 if the Contractor does not commence delivery of the Services by the Services Commencement Date, if any;
- 23.3.2 pursuant to and in accordance with the Key Provisions and Clauses 9.6, 15.11, 18.12.3, 28.5, 34.5 and 41.1 of this Schedule 2;
- 23.3.3 where the warranty given by the Contractor pursuant to Clause 6.2 of this Schedule 2 is materially untrue, the Contractor commits a material breach of its obligation to notify the Authority of any Occasion of Tax Non-Compliance as required by Clause 6.2 of this Schedule 2, or the Contractor fails to provide details of proposed mitigating factors as required by Clause 6.2 of this Schedule 2 that in the reasonable opinion of the Authority are acceptable; or
- 23.3.4 if the Contractor commits a breach of the Anti-slavery Policy.
- 23.4 If the Authority fails to pay the Contractor undisputed sums of money after thirty (30) days of having received a valid invoice, the Contractor shall notify the Authority in writing of such failure to pay. If the Authority fails to pay such undisputed sums within ninety (90) Working Days of the date of such written notice, the Contractor may terminate the Contract in writing with immediate effect, save that such right of termination shall not apply where the failure to pay is due to the Authority exercising its rights under Clause 14 (Recovery of Sums Due) of this Schedule 2.

24. TERMINATION FOR BREACH OF THE REGULATIONS

- 24.1 The Authority may terminate the Contract with immediate effect by giving written notice to the Contractor on the occurrence of any of the statutory provisions contained in Regulation 73(1)(a) to (c)) of the Regulations.

25. CONSEQUENCES OF EXPIRY OR EARLIER TERMINATION

- 25.1 Where the Authority terminates the Contract under Clause 23 (Termination on Default) of this Schedule 2 and then makes other arrangements for the supply of Services, the Authority may recover from the Contractor the cost reasonably incurred of making those other arrangements and any additional expenditure incurred by the Authority throughout the remainder of the Term.

The Authority shall take all reasonable steps to mitigate such additional expenditure.

Where the Contract is terminated under Clause 23 (Termination on Default) of this Schedule 2, no further payments shall be made by the Authority to the Contractor (for Services supplied by the Contractor prior to termination and in accordance with the Contract but where the payment has yet to be made by the Authority), until the Authority has established the final cost of arranging an alternative supplier of the Services.

- 25.2 Save as otherwise expressly provided in the Contract:

25.2.1 termination or expiry of the Contract shall be without prejudice to any rights, remedies or obligations accrued under the Contract prior to termination or expiration and nothing in the Contract shall prejudice the right of either Party to recover any amount outstanding at such termination or expiry; and

25.2.2 termination of the Contract shall not affect the continuing rights, remedies or obligations of the Authority or the Contractor under Clauses 4 (Payment and VAT), 12 (Right of Audit), 14 (Recovery of Sums Due), 15 (Confidential Information), 17

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(Protection of Personal Data), 18 (Intellectual Property Rights), 19 (Liability), 20 (Insurance), 25 (Consequences of Expiry or Termination), 27 (Recovery upon Termination), 29 (Waiver and Remedies Cumulative), 31 (Official Secrets Acts and Finance Act), 32 (Prevention of Fraud and Bribery), 39 (Freedom of Information Act) and 47 (Law and Jurisdiction).

26. NOT USED

27. RECOVERY UPON EXPIRY OR EARLIER TERMINATION OF THE CONTRACT

27.1 Upon expiry or earlier termination (for any reason) of this Contract, the Contractor shall at the request of the Authority and at the Contractor's cost:

- 27.1.1 immediately return to the Authority all Confidential Information, Personal Data and IP Materials in its possession or in the possession or under the control of any permitted suppliers or Sub-contractors, which was obtained or produced in the course of providing the Services (but excluding copies of such Confidential Information, Personal Data or IP Materials that the Contractor is required to retain pursuant to the Law or for regulatory purposes);
- 27.1.2 except where the retention of Personal Data is required by Law or regulatory purposes, promptly destroy all copies of the Personal Data and provide written confirmation to the Authority that the data has been destroyed;
- 27.1.3 immediately deliver to the Authority all Property (including materials, documents, information and access keys) provided to the Contractor under Clause 13 (Property) of this Schedule 2. Such property shall be handed back in good working order (allowance shall be made for reasonable wear and tear);
- 27.1.4 vacate and procure that the Contractor Personnel vacate any premises of the Authority occupied for the purposes of providing the Services;
- 27.1.5 return to the Authority any sums prepaid in respect of the Services not provided by the date of expiry or termination (howsoever arising);
- 27.1.6 comply with its obligations under any agreed exit plan; and
- 27.1.7 promptly provide all information concerning the provision of the Services which may reasonably be requested by the Authority for the purposes of adequately understanding the manner in which the Services have been provided or for the purpose of allowing the Authority or any Replacement Contractor to conduct due diligence.

27.2 If the Contractor fails to comply with Clause 27.1.1 and 27.1.2 of this Schedule 2, the Authority may recover possession of the items mentioned in those Clauses. The Contractor shall grant, and shall procure that any Sub-contractor shall grant, a licence to the Authority for its appointed agents to enter (for the purposes of such recovery) any premises of the Contractor or its Sub-contractors where any such items may be held.

28. REMEDIES IN THE EVENT OF INADEQUATE PERFORMANCE

28.1 Where a complaint is received about the standard of Services or about the manner in which any Services have been supplied or work has been performed or about the materials or procedures used or about any other matter connected with the performance of the Contractor's obligations under the Contract, then the Authority shall notify the Contractor, and Contract for the provision of Outsourced Kitting Production

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where considered appropriate by the Authority, investigate the complaint. The Authority may, in its sole discretion, uphold the complaint and take further action in accordance with Clause 23 (Termination on Default) of this Schedule 2.

- 28.2 Should the Authority be of the view, acting reasonably, that the Contractor can no longer provide the Services, then without prejudice to the Authority's rights and remedies under this Contract, the Authority shall be entitled to exercise its Step In Rights if the Key Provisions refer to the Authority having such rights under this Contract.
- 28.3 Without prejudice to its right under Clause 14 (Recovery of Sums Due), the Authority may charge the Contractor for any costs reasonably incurred and any reasonable administration costs in respect of the supply of any part of the Services by the Authority or a third party to the extent that such costs exceed the payment which would otherwise have been payable to the Contractor for such part of the Services and provided that the Authority uses its reasonable endeavours to mitigate any additional expenditure in obtaining replacement Services.
- 28.4 If the Contractor fails to supply any of the Services in accordance with the provisions of the Contract and such failure is capable of remedy, then the Authority shall instruct the Contractor to remedy the failure and the Contractor shall, at its own cost and expense, remedy such failure (and any damage resulting from such failure) within ten (10) Working Days or such other period of time as the Authority may direct.
- 28.5 In the event that:
- 28.5.1 the Contractor fails to comply with Clause 28.4 of this Schedule 2 and the failure is materially adverse to the interests of the Authority or prevents the Authority from discharging a statutory duty; or
 - 28.5.2 the Contractor persistently fails to comply with Clause 28.4 of this Schedule 2;
- the Authority may terminate the Contract with immediate effect by giving written notice.

29. WAIVER AND CUMULATIVE REMEDIES

- 29.1 The failure of either Party to insist upon strict performance of any provision of the Contract, or the failure of either Party to exercise, or any delay in exercising, any right or remedy shall not constitute a waiver of that right or remedy and shall not cause a diminution of the obligations established by the Contract.
- 29.2 A waiver of any right or remedy arising from a breach of contract shall not constitute a waiver of any right or remedy arising from any other breach of the Contract.

30. PUBLICITY

- 30.1 The Contractor shall not and shall procure that its Sub-contractors shall not:
- 30.1.1 make any press announcements or publicise the Contract in any way; or
 - 30.1.2 use the Authority's name or brand in any promotion or marketing or announcement, without the prior written consent of the Authority.

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30.2 The Authority shall be entitled to publicise the Contract in accordance with any legal obligation upon the Authority, including any examination of the Contract, by the National Audit Office pursuant to the National Audit Act 1983 or otherwise.

30.3 The provisions of this Clause 30 (Publicity) shall apply during the Term and indefinitely after its expiry or the earlier termination of the Contract.

31. NOT USED

32. PREVENTION OF FRAUD AND BRIBERY

32.1 The Contractor warrants and undertakes to the Authority that neither it, nor to the best of its knowledge any Contractor Personnel, have at any time prior to the Commencement Date:

32.1.1 committed a Prohibited Act or been formally notified that it is subject to an investigation or prosecution which relates to an alleged Prohibited Act; and/or

32.1.2 been listed by any government department or agency as being debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for participation in government procurement programmes or contracts on the grounds of a Prohibited Act.

32.2 The Contractor shall not during the Term:

32.2.1 commit a Prohibited Act; and/or

32.2.2 do or suffer anything to be done which would cause the Authority or any of the Authority's employees, consultants, contractors, Sub-contractors or agents to contravene any of the Relevant Requirements or otherwise incur any liability in relation to the Relevant Requirements.

32.3 The Contractor shall during the Term:

32.3.1 establish, maintain and enforce, and require that its Sub-contractors establish, maintain and enforce, policies and procedures which are adequate to ensure compliance with the Relevant Requirements and prevent the occurrence of a Prohibited Act;

32.3.2 keep appropriate records of its compliance with its obligations under Clause 32.3.1 of this Schedule 2 and make such records available to the Authority on request;

32.3.3 if so required by the Authority, within twenty (20) Working Days of the Commencement Date, and annually thereafter, certify in writing to the Authority, the compliance with this Clause of all persons associated with the Contractor or its Sub-contractors who are responsible for supplying the Services in connection with the Contract. The Contractor shall provide such supporting evidence as the Authority may reasonably request; and

32.3.4 have, maintain and, where appropriate, enforce an anti-bribery policy (which shall be disclosed to the Authority on request) to prevent it and any Contractor Personnel or any person acting on the Contractor's behalf from committing a Prohibited Act.

32.4 The Contractor shall immediately notify the Authority in writing if it becomes aware of any breach of Clause 32.1 of this Schedule 2, or has reason to believe that it has or any of the Contractor Personnel has:

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- 32.4.1 been subject to an investigation or prosecution which relates to an alleged Prohibited Act;
- 32.4.2 been listed by any government department or agency as being debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for participation in government procurement programmes or contracts on the grounds of a Prohibited Act; and/or
- 32.4.3 received a request or demand for any undue financial or other advantage of any kind in connection with the performance of the Contract or otherwise suspects that any person or party directly or indirectly connected with the Contract has committed or attempted to commit a Prohibited Act.
- 32.5 If the Contractor makes a notification to the Authority pursuant to Clause 32.4, the Contractor shall respond promptly to the Authority's enquiries, co-operate with any investigation, and allow the Authority to audit any books, records and/or any other relevant documentation in accordance with Clause 12 (Right of Audit) of this Schedule 2.
- 32.6 If the Contractor breaches Clause 32.1 of this Schedule 2, the Authority may by notice:
- 32.6.1 require the Contractor to remove from the performance of the Contract any Contractor Personnel whose acts or omissions have caused the Contractor's breach; or
- 32.6.2 immediately terminate the Contract pursuant to Clause 23.2.1(a) of this Schedule 2.
- 32.7 Any notice served by the Authority under Clause 32.6 of this Schedule 2 shall specify the nature of the Prohibited Act, the identity of the party who the Authority believes has committed the Prohibited Act and the action that the Authority has elected to take (including, where relevant, the date on which the Contract shall terminate).

33. NON-SOLICITATION

- 33.1 Except in respect of any transfer of staff pursuant to Schedule 10 (, neither Party shall (except with the prior written consent of the other Party) directly or indirectly solicit or entice away (or attempt to solicit or entice away) from the employment of the other Party any person employed or engaged by such other Party in the provision of the Services or (in the case of the Authority) in the receipt of the Services at any time during the Term or for a further period of twelve (12) Months after the termination of the Contract other than by means of a national advertising campaign open to all comers and not specifically targeted at any of the employees of the other Party.
- 33.2 If either the Contractor or the Authority commits any breach of Clause 33.1 of this Schedule 2 the breaching party shall, on demand, pay to the claiming party a sum equal to one year's basic salary or the annual fee that was payable by the claiming party to that employee, worker or independent contractor plus the recruitment costs incurred by the claiming party in replacing such person.

34. CONFLICT OF INTEREST

- 34.1 The Contractor recognises that the Authority is subject to PPN 01/19: Applying Exclusions in Public Procurement, Managing Conflicts of Interest and Whistleblowing: (<https://www.gov.uk/government/publications/procurement-policy-note-0119-applying-exclusions-in-public-procurement-managing-conflicts-of-interest-and-whistleblowing>). The

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Contractor shall comply with the provision of this Clause 34 in order to assist the Authority with its compliance with its obligations under that PPN.

- 34.2 The Contractor shall take appropriate steps to ensure that neither the Contractor nor the Contractor Personnel are placed in a position where (in the reasonable opinion of the Authority) there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interest of the Contractor or the Contractor Personnel and the duties owed to the Authority and other Contracting Authorities under the provisions of the Contract.
- 34.3 The Contractor shall promptly notify and provide full particulars to the Authority or the relevant other Contracting Authority if such conflict arises or may reasonably be foreseen as arising.
- 34.4 Without prejudice to the foregoing, the Contractor shall not knowingly act at any time during the term of the Contract in any capacity for any person, firm or company in circumstances where a conflict of interest between such person, firm or company and the Authority shall thereby exist in relation to the Services. The Contractor shall immediately report to the Authority Representative any matters which involve or could potentially involve a conflict of interest as referred to in this Clause 34.4.
- 34.5 The Authority reserves the right to terminate the Contract with immediate effect by giving written notice to the Contractor and/or take such other steps it deems necessary where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Contractor and the duties owed to the Authority under the provisions of the Contract. The action of the Authority pursuant to this Clause shall not prejudice or affect any right of action or remedy which shall have accrued or shall thereafter accrue to the Authority.

35. EQUALITY AND DIVERSITY

- 35.1 The Contractor shall:
- 35.1.1 perform its obligations under the Contract (including those in relation to provision of the Services) in accordance with:
- (a) all applicable equality Law (whether in relation to race, sex, gender reassignment, religion or belief, disability, sexual orientation, pregnancy, maternity, age or otherwise); and
 - (b) any other requirements and instructions which the Authority reasonably imposes in connection with any equality obligations imposed on the Authority at any time under applicable equality Law;
- 35.1.2 take all necessary steps, and inform the Authority of the steps taken, to prevent unlawful discrimination designated as such by any court or tribunal, or the Equality and Human Rights Commission or (any successor organisation).
- 35.2 The Contractor shall not unlawfully discriminate within the meaning and scope of any law, enactment, order, or regulation relating to discrimination (whether in sex, age, race, gender, religion or belief, disability, sexual orientation, gender reassignment, maternity, pregnancy, marriage, civil partnership or otherwise) in employment.
- 35.3 The Contractor shall take all reasonable steps (at its own expense) to secure the observance of Clause 35.1 of this Schedule 2 by all of its servants, employees or agents of the Contractor engaged in performance of the Contract and shall impose on any Sub-contractor obligations substantially similar to those imposed on the Contractor by Clause 35.1 of this Schedule 2.

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- 35.4 The Contractor shall indemnify the Authority against all costs, claims, charges, demands, liabilities, damages, losses and expenses incurred or suffered by the Authority arising out of or in connection with any investigation conducted or any proceedings brought under the Equality Act 2010 due directly or indirectly to any act or omission by the Contractor, its agents, employees or Sub-contractors.
- 35.5 The Contractor shall (and shall use its reasonable endeavours to procure that the Contractor Personnel shall) at all times comply with the provisions of the Human Rights Act 1998 in the performance of the Contract.
- 35.6 The Contractor shall undertake, or refrain from undertaking, such acts as the Authority requests so as to enable the Authority to comply with its obligations under the Human Rights Act 1998.
- 35.7 Subject to Clause 19 (Liability) of this Schedule 2, the Contractor agrees to indemnify and keep indemnified the Authority against all loss, costs, proceedings or damages whatsoever arising out of or in connection with any breach by the Contractor of its obligations under this Clause 35 (Equality and Diversity).

36. HEALTH AND SAFETY

- 36.1 The Contractor shall take all measures necessary to comply with the requirements of the Health and Safety at Work etc. Act 1974 and any other Acts, orders, regulations and Codes of Practice relating to health and safety, which may apply to Contractor Personnel in the performance of the Services.
- 36.2 The Contractor shall promptly notify the Authority of any health and safety hazards which may arise in connection with the performance of the Services.
- 36.3 The Authority shall promptly notify the Contractor of any health and safety hazards which may exist or arise at the Premises of the Authority and which may affect the Contractor in the performance of the Services.
- 36.4 The Contractor shall inform all Contractor Personnel engaged in the provision of Services at the Premises of the Authority of all known health and safety hazards and shall instruct those Contractor Personnel in connection with any necessary safety measures.
- 36.5 Whilst on the Premises of the Authority, the Contractor shall comply, and shall procure that the Contractor Personnel comply, with any health and safety measures implemented by the Authority in respect of persons working on those Premises.
- 36.6 The Contractor shall notify the Authority Representative immediately in the event of any incident occurring in the performance of the Services on the Premises of the Authority where that incident causes any personal injury or any damage to property which could give rise to personal injury.
- 36.7 The Contractor shall ensure that its health and safety policy statement (as required by the Health and Safety at Work etc. Act 1974) is made available to the Authority on request.

37. RELATIONSHIP OF THE PARTIES

- 37.1 Except as expressly provided otherwise in the Contract, nothing in the Contract, nor any actions taken by the Parties pursuant to the Contract shall create a partnership, joint venture or relationship of employer and employee or principal and agent between the Parties, or

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authorise either Party to make representations or enter into any commitments for or on behalf of any other Party.

38. SERVICE OF NOTICES AND COMMUNICATIONS

- 38.1 Any notice required to be given by either Party under this Contract shall be in writing quoting the date of the Contract and shall be delivered by hand or sent by prepaid first class recorded delivery or by email to the person referred to in the Key Provisions or such other person as one Party may inform the other Party in writing from time to time.
- 38.2 A notice shall be treated as having been received:
- 38.2.1 if delivered by hand within normal business hours when so delivered or, if delivered by hand outside normal business hours, at the next start of normal business hours; or
 - 38.2.2 if sent by first class recorded delivery mail on a normal Working Day, at 9.00 am on the second Working Day subsequent to the day of posting, or, if the notice was not posted on a Working Day, at 9.00 am on the third Working Day subsequent to the day of posting; or
 - 38.2.3 if sent by email, if sent within normal business hours when so sent or, if sent outside normal business hours, at the next start of normal business hours provided the sender has either received an electronic confirmation of delivery or has telephoned the recipient to inform the recipient that the email has been sent.

39. FREEDOM OF INFORMATION ACT

- 39.1 The Contractor acknowledges that the Authority is subject to the requirements of the FOIA and the Environmental Information Regulations and shall:
- 39.1.1 provide all necessary assistance and cooperation as reasonably requested by the Authority, at the Contractor's expense, to enable the Authority to comply with its obligations under the FOIA and the Environmental Information Regulations;
 - 39.1.2 transfer to the Authority all requests for information that it receives under the FOIA and the Environmental Information Regulations ("**Requests for Information**") relating to the Contract that it receives as soon as practicable and in any event within two (2) Working Days of receipt;
 - 39.1.3 provide the Authority with a copy of all Information belonging to the Authority requested in the Request for Information which is in the Contractor's possession or control in the form that the Authority requires within five (5) Working Days (or such other period as the Authority may reasonably specify) of the Authority's request for such Information; and
 - 39.1.4 not respond directly to a Request for Information unless authorised in writing to do so by the Authority.
- 39.2 The Contractor acknowledges that the Authority may be required under the FOIA and the Environmental Information Regulations to disclose Information (including Commercially Sensitive Information) without consulting or obtaining consent from the Contractor. The Authority shall take reasonable steps to notify the Contractor of a Request For Information (in accordance with the Secretary of State's section 45 Code of Practice on the Discharge of the Functions of Public Authorities under Part 1 of the FOIA) to the extent that it is permissible Contract for the provision of Outsourced Kitting Production

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and reasonably practical for it to do so but (notwithstanding any other provision in this Contract) the Authority shall be responsible for determining in its absolute discretion whether any Commercially Sensitive Information and/or any other information is exempt from disclosure in accordance with the FOIA and/or the Environmental Information Regulations.

- 39.3 The Contractor shall ensure that all Information is retained for disclosure in accordance with Clause 12 (Right of Audit) of this Schedule 2 and shall permit the Authority to inspect such records as the Authority requests from time to time.
- 39.4 The Contractor acknowledges that the Commercially Sensitive Information is of indicative value only and that such information may be disclosed pursuant to Clause 14 (Right of Audit) of this Schedule 2.

40. TRANSPARENCY

- 40.1 The Contractor recognises that the Authority is subject to PPN 01/17: Update to Transparency Principles (<https://www.gov.uk/government/publications/procurement-policy-note-0117-update-to-transparency-principles>). The Contractor shall comply with the provision of this Clause 40 in order to assist the Authority with its compliance with its obligations under that PPN.
- 40.2 The Parties agree and acknowledge that the content of this Contract is not Confidential Information, except for:
- 40.2.1 any information which is exempt from disclosure in accordance with the provisions of the FOIA, which shall be determined by the Authority; and
- 40.2.2 Commercially Sensitive Information.
- 40.3 Notwithstanding any other provision of this Contract, the Contractor hereby gives consent for the Authority to publish to the general public this Contract in its entirety (but with any information which is exempt from disclosure in accordance with the provisions of the FOIA redacted), including any changes to this Contract agreed from time to time. The Authority may consult with the Contractor to inform its decision regarding any redactions but shall have the final decision in its absolute discretion.
- 40.4 The Contractor shall assist and cooperate with the Authority to enable the Authority to publish this Contract.

41. FORCE MAJEURE

- 41.1 Neither Party shall be liable to the other Party for any delay in performing, or failure to perform, its obligations under the Contract (other than a payment of money) to the extent that such delay or failure is a result of Force Majeure. Notwithstanding the foregoing, each Party shall use all reasonable endeavours to continue to perform its obligations under the Contract for the duration of such Force Majeure. However, if such Force Majeure prevents either Party from performing its material obligations under the Contract for a period in excess of six (6) Months, either Party may terminate the Contract with immediate effect by giving written notice.
- 41.2 Any failure or delay by the Contractor in performing its obligations under the Contract which results from any failure or delay by an agent, Sub-contractor or supplier shall be regarded as due to Force Majeure only if that agent, Sub-contractor or supplier is itself impeded by Force Majeure from complying with an obligation to the Contractor.

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- 41.3 If either Party becomes aware of Force Majeure which gives rise to, or is likely to give rise to, any failure or delay on its part as described in Clause 41.1 of this Schedule 2 it shall immediately notify the other by the most expeditious method then available and shall inform the other of the period for which it is estimated that such failure or delay shall continue.
- 41.4 If the Contractor is the affected Party, it shall not be entitled to claim relief under this Clause 41 to the extent that consequences of the relevant Force Majeure:
- 41.4.1 are capable of being mitigated, but the Contractor has failed to do so;
 - 41.4.2 should have been foreseen and prevented or avoided by a prudent provider of services similar to the Services, operating to the standards required by this Contract; or
 - 41.4.3 are the result of the Contractor's failure to comply with its BCDR Plan (except to the extent that such failure is also due to Force Majeure that affects the execution of the BCDR Plan).
- 41.5 Subject to Clause 41.6, as soon as practicable after the affected Party issues a notice of the Force Majeure under clause 41.3, and at regular intervals thereafter, the Parties shall consult in good faith and use reasonable endeavours to agree any steps to be taken and an appropriate timetable in which those steps should be taken, to enable continued provision of the Services affected by Force Majeure.
- 41.6 The Parties shall at all times following the occurrence of Force Majeure and during its subsistence use their respective reasonable endeavours to prevent and mitigate the effects of the Force Majeure. Where the Contractor is the affected Party, it shall take all steps in accordance with Good Industry Practice to overcome or minimise the consequences of Force Majeure.

42. DISPUTE RESOLUTION

- 42.1 The Authority and the Contractor shall attempt in good faith to negotiate a settlement to any dispute between them arising out of or in connection with the Contract within twenty (20) Working Days of either notifying the other party of the dispute and such efforts shall involve the escalation of the dispute to senior management of each Party.
- 42.2 Nothing in this dispute resolution procedure shall prevent the Authority or the Contractor from seeking from any court of competent jurisdiction an interim order restraining the other party from doing any act or compelling the other party to do any act.
- 42.3 If the dispute cannot be resolved by the Authority and the Contractor pursuant to Clause 42.1 of this Schedule 2, the Authority and the Contractor shall refer it to mediation pursuant to the procedure set out in Clause 47.5 of this Schedule 2 unless:
- 42.3.1 the Authority considers that the dispute is not suitable for resolution by mediation; or
 - 42.3.2 the Contractor does not agree to mediation.
- 42.4 The obligations of the Authority and the Contractor under the Contract shall not be suspended, cease or be delayed by the reference of a dispute to mediation and the Contractor and the Contractor Personnel shall comply fully with the requirements of the Contract at all times.
- 42.5 The procedure for mediation is as follows:
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- 42.5.1 a neutral adviser or mediator (the “**Contract Mediator**”) shall be chosen by agreement between the Authority and the Contractor or, if they are unable to agree upon a Contract Mediator within ten (10) Working Days after a request by one party to the other or if the Contract Mediator agreed upon is unable or unwilling to act, either Party shall within ten (10) Working Days from the date of the proposal to appoint a Contract Mediator or within ten (10) Working Days of notice to either Party that he is unable or unwilling to act, apply to the CEDR to appoint a Contract Mediator;
- 42.5.2 the Authority and the Contractor shall within ten (10) Working Days of the appointment of the Contract Mediator meet with him in order to agree a programme for the exchange of all relevant information and the structure to be adopted for negotiations to be held. If considered appropriate, the Authority and the Contractor may at any stage seek assistance from the CEDR to provide guidance on a suitable procedure;
- 42.5.3 unless otherwise agreed, all negotiations connected with the dispute and any settlement agreement relating to it shall be conducted in confidence and without prejudice to the rights of the Parties in any future proceedings;
- 42.5.4 if the Parties reach agreement on the resolution of the dispute, the agreement shall be reduced to writing and shall be binding on the Parties once it is signed by their duly authorised representatives;
- 42.5.5 failing agreement, either of the Parties may invite the Contract Mediator to provide a non-binding but informative opinion in writing. Such an opinion shall be provided on a without prejudice basis and shall not be used in evidence in any proceedings relating to the Contract without the prior written consent of both Parties; and
- 42.5.6 if the Parties fail to reach agreement in the structured negotiations within sixty (60) Working Days of the Contract Mediator being appointed, or such longer period as may be agreed by the Parties, then any dispute or difference between them may be referred to the courts.

43. SEVERABILITY

- 43.1 If any provision of the Contract is held invalid, illegal or unenforceable for any reason by any court of competent jurisdiction, such provision shall be severed and the remainder of the provisions of the Contract shall continue in full force and effect as if the Contract had been executed with the invalid, illegal or unenforceable provision eliminated. In the event of a holding of invalidity so fundamental as to prevent the accomplishment of the purpose of the Contract, the Parties shall immediately commence negotiations in good faith to remedy the invalidity.

44. ENTIRE AGREEMENT

- 44.1 The Contract constitutes the entire agreement between the Parties in respect of the matters dealt with herein. The Contract supersedes all prior negotiations between the Parties and all representations and undertakings made by one Party to the other, whether written or oral, except that this Clause shall not exclude liability in respect of any Fraud or fraudulent misrepresentation.

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45. FURTHER ASSURANCES

- 45.1 Each Party undertakes at the request of the other, and at the cost of the requesting party, to do all acts and execute all documents which may be necessary to give effect to the meaning of the Contract.

46. THE CONTRACTS (RIGHTS OF THIRD PARTIES) ACT 1999

- 46.1 A person who is not a party to the Contract shall have no right to enforce any of its provisions which, expressly or by implication, confer a benefit on him, without the prior written agreement of both Parties. This Clause does not affect any right or remedy of any person which exists or is available apart from the Contracts (Rights of Third Parties) Act 1999 and does not apply to the Crown.

47. LAW AND JURISDICTION

- 47.1 This Contract, and any dispute or claim arising out of or in connection with it or its subject matter (including any non-contractual claims), shall be governed by, and construed in accordance with, the laws of England and Wales.
- 47.2 Subject to Clause 42 of this Schedule 2, the Parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Contract or its subject matter.

SCHEDULE 3

Definitions and Interpretation

1. DEFINITIONS

- 1.1 In the Contract unless the context requires otherwise the following definitions shall be used for the purposes of interpreting the Contract. Other definitions that are not of general application are stated in the Clause where the definition first appears and shall apply only to that Clause unless otherwise shown below:

Anti-slavery Policy	the Contractor's slavery and human trafficking policy, if any.
Authority	the Secretary of State for Health acting as part of the Crown.
Authority Data	<p>the data, text, drawings, diagrams, images or sounds (together with any database made up of any of these) which are embodied in any electronic, magnetic, optical or tangible media, and which are:</p> <p>(a) supplied to the Contractor by or on behalf of the Authority; or</p> <p>(b) which the Contractor is required to generate, process, store or transmit pursuant to the Contract; or</p> <p>(c) any Personal Data for which the Authority is the Controller.</p>
Authority Representative	the person authorised to act for the Authority for the purposes of the Contract, being the person specified in the Key Provisions.
Business Continuity Event	any event or issue that could impact on the operations of the Contractor and its ability to supply the Services.
Central Government Body	<p>a body listed in one of the following sub-categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics:</p> <p>(a) Government Department;</p> <p>(b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal);</p> <p>(c) Non-Ministerial Department; or</p> <p>(d) Executive Agency.</p>
Change Control Process	the change control process, if any, referred to in the Key Provisions.
Change in Law	any change in Law which impacts on the supply of the Services (including taxation or duties of any sort affecting the Contractor) which comes into force after the Commencement Date.
Commencement Date	the date of this Contract.

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Commercially Sensitive Information	the information listed in Schedule 8 (Commercially Sensitive Information) comprising the information of a commercially sensitive nature relating to the Contractor, its business or which the Contractor has indicated to the Authority that, if disclosed by the Authority, would cause the Contractor significant commercial disadvantage or material financial loss.
Confidential Information	<p>any information which has been designated as confidential by either Party in writing or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored) including information the disclosure of which would, or would be likely to, prejudice the commercial interests of any person, trade secrets, Intellectual Property Rights and know-how of either Party and all personal data and sensitive personal data within the meaning of the GDPR. Confidential Information shall not include information which:</p> <ul style="list-style-type: none"> (a) was public knowledge at the time of disclosure (otherwise than by breach of Clause Schedule 215 (Confidential Information)); (b) was in the possession of the receiving party, without restriction as to its disclosure, before receiving it from the disclosing party (c) is received from a third party (who lawfully acquired it) without restriction as to its disclosure (d) is independently developed without access to the Confidential Information.
Contract	the form of contract at the front of this document and all schedules attached to the form of contract.
Contract Price	the price (exclusive of any applicable VAT), payable to the Contractor by the Authority under the Contract, as set out in Schedule 6 (Pricing) for the full and proper performance by the Contractor of its obligations under the Contract.
Contract Year	a period of twelve (12) Months commencing on the Commencement Date and on each anniversary of the Commencement Date.
Contracting Authority	any contracting authority as defined in Regulation 2 of the Regulations.
Contractor	the contractor named on the form of Contract on the second page.
Contractor Personnel	all directors, officers, employees, agents, consultants and contractors of the Contractor and/or of any Sub-contractor engaged in the performance of the Contractor's obligations under the Contract from time to time.
Contractor Representative	the individual authorised to act for the Contractor for the purposes of the Contract, being the person specified in the Key Provisions.

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Contracts Finder	the facility provided by the Cabinet Office to advertise contract opportunities available at https://www.gov.uk/contracts-finder and any successor facility or website.
Controller, Processor, Data Subject, Personal Data, Personal Data Breach, Data Protection Officer	take the meaning given in the GDPR.
Crown	the government of the United Kingdom (including the Northern Ireland Assembly and Executive Committee, the Scottish Executive and the National Assembly for Wales), including, but not limited to, government ministers and government departments and particular bodies, persons, commissions or agencies from time to time carrying out functions on its behalf.
Data Protection Impact Assessment	an assessment by the Controller of the impact of the envisaged processing on the protection of Personal Data.
Data Protection Legislation	<ul style="list-style-type: none"> (a) the GDPR, the Law Enforcement Directive (Directive (EU) 2016/680) and any applicable national implementing Law as amended from time to time; (b) Data Protection Act 2018 to the extent that it relates to processing of personal data and privacy; and (c) all applicable Law about the processing of personal data and privacy.
Data Subject Access Request	a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to their Personal Data.
Default	<p>any breach of the obligations of the relevant Party (including but not limited to fundamental breach or breach of a fundamental term) or any other default, act, omission, negligence or negligent statement:</p> <ul style="list-style-type: none"> (a) in the case of the Authority, of its employees, servants or agents; or (b) in the case of the Contractor, of its Sub-contractors or any Contractor Personnel, <p>in connection with or in relation to the subject matter of the Contract and in respect of which such Party is liable to the other.</p>
DOTAS	if applicable means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue & Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions by the National Insurance Contributions

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(Application of Part 7 of the Finance Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992.

Environmental Information Regulations

the Environmental Information Regulations 2004 and any guidance and/or codes of practice issued by the Information Commissioner or relevant government department in relation to such regulations.

Equipment

(a) equipment which the Authority and the Contractor agree shall be purchased by the Authority for the purposes of the Contract which is detailed in Part A of Schedule 21; and

(b) the equipment detailed in Part B of Schedule 21,

all of which form part of the Property.

Exit Day

shall have the meaning in the European Union (Withdrawal) Act 2018.

Exit Plan

the plan for the provisions of the Transitional Assistance Services in the event of the expiry or termination of the Contract, which is to be developed by the Parties pursuant to Clause 15 of Schedule 1.

Expiry Date

the date upon which the Contract shall end as specified in the Key Provisions.

FOIA

the Freedom of Information Act 2000 and any subordinate legislation made under this Act from time to time together with any guidance and/or codes of practice issued by the Information Commissioner or relevant government department in relation to such legislation.

Force Majeure

any event outside the reasonable control of either Party affecting its performance of its obligations under the Contract arising from acts, events, omissions, happenings or non-happenings beyond its reasonable control and which are not attributable to any wilful act, neglect or failure to take reasonable preventative action by that Party, including acts of God, riots, war or armed conflict, acts of terrorism, acts of government, local government or Regulatory Bodies, fire, flood, storm or earthquake, or disaster but excluding:

- (a) any industrial dispute relating to the Contractor or the Contractor Personnel
- (b) any other failure in the Contractor's or a Sub contractor's supply chain
- (c) any event or other consequence arising as a result of or in connection with the withdrawal of the United Kingdom from the European Union; or
- (d) any event or other consequence arising as a result of or in connection with the COVID 19 pandemic except for circumstances caused by or related to the COVID-19 pandemic which are changes in applicable Law and/or

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	governmental guidance which mean that the Services cannot be provided as set out in this Contract (in all material respects) without such Laws and/or government guidance being breached, or if the Contractor can reasonably demonstrate that despite all reasonable endeavours, it is unable to secure non-COVID-19 infected personnel to provide the Services due to the levels of COVID-19 infections in the population of the United Kingdom.
Fraud	any offence under Laws creating offences in respect of fraudulent acts (including the Misrepresentation Act 1967) or at common law in respect of fraudulent acts including acts of forgery.
GDPR	the General Data Protection Regulations (Regulation (EU) 2016/679).
General Anti-Abuse Rule	if applicable, means (a) the legislation in Part 5 of the Finance Act 2013; and (b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions.
Good Industry Practice	standards, practices, methods and procedures conforming to the Law and the degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled and experienced person or body engaged in a similar type of undertaking under the same or similar circumstances.
Halifax Abuse Principle	if applicable, means the principle explained in the CJEU Case C-255/02 Halifax and others.
Impact Assessment	has the meaning given to it in Clause 10.4 of Schedule 1.
Implementation Plan	the implementation plan, if any, referred to in the Key Provisions.
Information	all information of whatever nature, however conveyed and in whatever form, including in writing, orally, by demonstration, electronically and in a tangible, visual or machine-readable medium (including CD-ROM, magnetic and digital form);
Intellectual Property Rights	includes but is not limited to patents, inventions, trade marks, service marks, logos, design rights (whether registrable or otherwise), applications for any of the foregoing, copyright, rights in software programmes, database rights, domain names, trade or business names, moral rights and other similar rights or obligations whether registrable or not in any country (including but not limited to the United Kingdom) and the right to sue for passing off.
Joint Controllers	where two or more Controllers jointly determine the purposes and means of processing.
Key Personnel	those persons named in the Schedule 11 as being key personnel or such persons as shall be agreed in writing by the Authority from time to time.

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Law	any law, subordinate legislation within the meaning of Section 21(1) of the Interpretation Act 1978, bye-law, enforceable right within the meaning of Section 2 of the European Communities Act 1972, regulation, order, regulatory policy, mandatory guidance or code of practice, judgment of a relevant court of law, or directives or requirements with which the Contractor is bound to comply including but not limited to the Modern Slavery Act 2015.
Month	calendar month.
Occasion of Tax Non-Compliance	<p>if applicable:</p> <p>any tax return of the Contractor submitted to a Relevant Tax Authority on or after 1 October 2012 is found on or after 1 April 2013 to be incorrect as a result of:</p> <ul style="list-style-type: none"> (a) a Relevant Tax Authority successfully challenging the Contractor under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle; (b) the failure of an avoidance scheme which the Contractor was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or (c) any tax return of the Contractor submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Commencement Date or to a civil penalty for fraud or evasion.
Party	a party to the Contract.
Performance Monitoring Report	a report to be forwarded by the Contractor to the Authority in accordance with Paragraph 3.1 of Schedule 7 (Contract Monitoring).
Person	where the context allows, includes a corporation or an unincorporated association.
Processor Personal	all directors, officers, employees, agents, consultants and contractors of the Processor and/or of any Sub-Processor engaged in the performance of its obligations under this Contract.
Protective Measures	appropriate technical and organisational measures which may include: pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of the such measures adopted by it.

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Premises	where applicable, the location where the Services are to be supplied, as set out in the Schedule 4 (Specification).
Processing	any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.
Prohibited Act	<p>(a) to directly or indirectly offer, promise or give any person working or engaged by a Contracting Authority and/or the Authority a financial or other advantage to:</p> <p>(i) induce that person to perform improperly a relevant function or activity; or</p> <p>(ii) reward that person for improper performance of a relevant function or activity; or</p> <p>(b) committing any offence:</p> <p>(i) under the Bribery Act 2010; or</p> <p>(ii) under legislation creating offences concerning Fraud; or</p> <p>(iii) at common level concerning Fraud; or</p> <p>(iv) committing (or attempting or conspiring to commit) Fraud.</p>
Property	the property, other than real property, issued or made available to the Contractor by the Authority in connection with the Contract (including the Equipment).
pseudonymising	the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.
Quality Standards	the quality standards published by BSI British Standards, the National Standards Body of the United Kingdom, the International Organisation for Standardization or other reputable or equivalent body, (and their successor bodies) that a skilled and experienced operator in the same type of industry or business sector as the Contractor would reasonably and ordinarily be expected to comply with, and as may be further detailed in the Schedule 4 (Specification) and where applicable shall maintain accreditation with the relevant Quality Standards authorisation body.
Regulations	the Public Contracts Regulations 2015 as amended from time to time.

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Regulatory Bodies	government departments and regulatory, statutory and other entities, committees, ombudsman and bodies which, whether under statute, rules, regulations, codes of practice or otherwise, are entitled to regulate, investigate or influence the matters dealt with in the Contract and “ Regulatory Body ” shall be construed accordingly.
Relevant Requirements	all applicable Law relating to bribery, corruption and fraud, including the Bribery Act 2010 and any guidance issued by the Secretary of State for Justice pursuant to section 9 of the Bribery Act 2010.
Relevant Tax Authority	if applicable, means HM Revenue & Customs, or, if applicable, a tax authority in the jurisdiction in which the Contractor is established.
Relevant Transfer	shall have the meaning ascribed in Schedule 10 (Staff Transfer).
Replacement Contractor	any third party contractor of Replacement Services appointed by the Authority from time to time and in accordance with the terms of the Contract.
Replacement Services	any services which are identical or substantially similar to any of the Services and which the Authority receives in substitution for any of the Services following the termination or expiry of the Contract, whether those services are provided by the Authority itself or by any Replacement Contractor.
Security Policy	the Authority's security policy in force as at the Commencement Date (a copy of which has been supplied to the Contractor) as updated from time to time and notified to the Contractor.
Security Policy Framework	the HMG Security Policy Framework (April 2014) available at https://www.gov.uk/government/publications/security-policy-framework , as amended by notification to the Contractor from time to time.
Services	the services to be supplied as specified in Schedule 4 (Specification).
Services Commencement Date	the services commencement date, if any, referred to in the Key Provisions.
Sites	any premises (including the Premises, the Contractor's premises or third party premises) from, to or at which: <ul style="list-style-type: none"> (a) the Services are (or are to be) provided; or (b) the Contractor manages, organises or otherwise directs the provision or the use of the Services.
SME	an enterprise falling within the category of micro, small and medium-sized enterprises (http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en) defined by the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises;

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SME Management Information Reports	shall have the meaning set out in Clause 16 of Schedule 1.
Sub-contract	the Contractor's contract with a Sub-contractor whereby that Sub-contractor agrees to provide to the Contractor the Services (or any part thereof) or facilities or services necessary for the provision of the Services (or any part thereof) or necessary for the management, direction or control of the Services.
Sub-contractor	any person appointed by the Contractor to carry out any and/or all of the Contractor's obligations under the Contract.
Sub-processor	any third party appointed to process Personal Data on behalf of the Contractor related to this Contract.
Supply Chain Information Report Template	the template referred to in Clause 16 of Schedule 1 containing the information set out in Clauses 16.5(a) to 16.5(c) inclusive.
Tender	the tender submitted by the Contractor to the Authority and annexed to Schedule 5 (Tender).
Term	the term as set out in the Key Provisions.
Termination Notice	any notice to terminate this Contract which is given by either Party in accordance with the provisions of the Contract.
Termination Period	the period specified in the Termination Notice during which period the Authority may require the Contractor to continue to provide the Services after a Termination Notice has been given provided always that such period may not extend the Term (as extended by Clause 2 (Extension) of Schedule 2 by more than six (6) Months.
Transferring Former Contractor Employees	shall have the meaning ascribed in Schedule 10 (Staff Transfer).
Transferring Authority Employees	shall have the meaning ascribed in Schedule 10 (Staff Transfer).
Transitional Assistance Service Charges	the charges, if any, payable by the Authority to the Contractor for the provision of the Transitional Assistance Services, which shall be calculated in accordance with Schedule 6.
Transitional Assistance Services	the services to be provided by the Contractor to the Authority pursuant to Clause 15 of Schedule 1 in order to facilitate the transfer of the Services to the Authority or a Replacement Contractor.
Unconnected Sub-contract	any contract or agreement which is not a Sub-contract and is between the Contractor and a third party (which is not an Affiliate of the Contractor) and is a qualifying contract under regulation 6 of the Reporting on Payment Practices and Performance Regulations 2017.

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Unconnected Sub-contractor	any third party with whom the Contractor enters into an Unconnected Sub-contract.
Variation	has the meaning given to it in Clause 10.2 of Schedule 1.
Variation Form	the form set out in Schedule 9 (Variation Form).
VAT	value added tax in accordance with the provisions of the Value Added Tax Act 1994.
Voluntary, Community and Social Enterprise” or “VCSE	a non-governmental organisation that is value-driven and which principally reinvests its surpluses to further social, environmental or cultural objectives.
Worker	any one of the Contractor Personnel which the Authority, in its reasonable opinion, considers is an individual to which Procurement Policy Note 08/15 (Tax Arrangements of Public Appointees) applies in respect of the Services.
Working Day	any day other than a Saturday or Sunday or public holiday in England and Wales.

1.2 The interpretation and construction of the Contract shall be subject to the following provisions:

- 1.2.1 words importing the singular meaning include, where the context so admits, the plural meaning and vice versa;
- 1.2.2 words importing the masculine include the feminine and the neuter;
- 1.2.3 reference to a Clause is a reference to the whole of that Clause unless stated otherwise;
- 1.2.4 reference to any statute, enactment, order, regulation or other similar instrument shall be construed as a reference to the statute, enactment, order, regulation or instrument as amended by any subsequent enactment, modification, order, regulation or instrument as subsequently amended or re-enacted;
- 1.2.5 reference to any person shall include natural persons and partnerships, firms and other incorporated bodies and all other legal persons of whatever kind and however constituted and their successors and permitted assigns or transferees;
- 1.2.6 the words include, includes and including are to be construed as if they were immediately followed by the words without limitation; and
- 1.2.7 headings are included in the Contract for ease of reference only and shall not affect the interpretation or construction of this Contract.

1.3 Where there is any conflict between the Tender (being set out at Schedule 5) and any other part of this Contract, such other part of this Contract shall prevail.

1.4 In entering into this Contract the Authority is acting as part of the Crown.

1.5 Any reference in this Contract which immediately before Exit Day was a reference to (as it has effect from time to time):

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- 1.5.1 any EU regulation, EU decision, EU tertiary legislation or provision of the EEA agreement (EU References) which is to form part of domestic law by application of section 3 of the European Union (Withdrawal) Act 2018 shall be read on and after Exit Day as a reference to the EU References as they form part of domestic law by virtue of section 3 of the European Union (Withdrawal) Act 2018 as modified by domestic law from time to time; and
- 1.5.2 any EU institution or EU authority or other such EU body shall be read on and after Exit Day as a reference to the UK institution, authority or body to which its functions were transferred;

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SCHEDULE 4

Specification

1. SUMMARY

- 1.1 The Contractor shall design, commission and operate the kitting production solution to achieve full capacity production by 14th January 2022.
- 1.2 The Contractor shall produce test kits at its facilities and shall include all facilities, labour, maintenance and capital equipment. The Contractor's production facility, workforce and processes shall be certified to ISO 13485.
- 1.3 The Contractor shall be able to produce the PCR kit variants specified in Appendix 2.
- 1.4 The total installed capacity shall be up to [REDACTED] kits per day. The production ramp up shall be completed by 14th January 2022.
- 1.5 The Authority will provide a rolling 3-Month production plan by week to facilitate the Contractor plan and manage production at the start of each Month, which will be updated weekly. The Authority will commit to the volumes of kits for the following Month (**Month 1**) and the Contractor shall deliver the Month 1 volume. The Month 2 and 3 forecast will be for a volume commitment no lower than 50% of the initial forecast for that period. Indicative volumes are provided in Appendix 1 for information only.
- 1.6 The Contractor shall be able to vary production to quickly increase or decrease volumes in line with rapidly changing demand for tests and shall support any scale up of test-kit production in the event of any unexpected requirements, providing sufficient notice is given within a mutually agreed timeframe.
- 1.7 The Contractor shall receive, unload and store up to 3 days' production capacity of Authority free issued components.
- 1.8 The Contractor shall store up to 3 days' stock of completed test kits and shall load this onto the Authority's transportation for onwards delivery to the Authority's storage and distribution network.
- 1.9 The Contractor shall provide a "mothballing" service for the kitting production lines. The requirements of this service are laid out in Paragraph 13 of this Schedule 4.
- 1.10 The Contractor shall be compliant with MHRA visibility and traceability requirements as well as with NAO financial stock inventory reporting requirements. These are mandatory.

GENERAL REQUIREMENTS

2. DESIGN AND COMMISSIONING

- 2.1 The Contractor shall design production lines and all associated operating procedures for the Initial Kitting Production Solution production, and for Full Automation Kitting Solution production. Designs and supply chain procurement plans shall be submitted at or before the dates specified in the Implementation Plan for review and acceptance by the Authority.
- 2.2 The Contractor shall design the production lines based on a maximum Overall Equipment Effectiveness (OEE) of 85%, to allow for operational and production downtime.

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- 2.3 Speed to production is essential to mitigating risks of failing to meet wave 3 and winter peaks of testing demand. In order to de-risk the time to full production under the Initial Kitting Production Solution, and the subsequent transition to the Full Automation Kitting Solution, the Authority will, in conjunction with its manufacturing and production consultancy supplier, work with the Contractor to constructively challenge, improve and de-risk the design, project plan, and procurement plan in order to accelerate and de-risk production on stream dates. It is envisaged that this activity will be completed in the first 4 weeks of the Term, with collaborative innovation and acceleration sessions taking place at the Contractor's premises at the end of week 1 and week 3.
- 2.4 The Contractor shall demonstrate to the Authority that estimated production capacity can be achieved and that the production line, and all associated facilities, labour, training, SOPs and are in place by the required milestone dates set out in the Implementation Plan. This shall be demonstrated through the IQ / OQ / PQ acceptance process. The Authority shall attend the following acceptance tests of each production line including any amendments or additional automation modules to the production line:
- 2.4.1 Installation Qualification (IQ): the Contractor shall verify that the production line meets the requirements of the Specification as well as the production line specifications and design requirements of the Contractor.
- 2.4.2 Operational Qualification (OQ): the Contractors shall verify that the production line is able to kit all specified variants of kit design to the requirements of this Specification and that the production line meets all its design parameters. In addition, the Contractor shall demonstrate that all operational measures, including SOPs, Authority data interfaces, QMS, inventory facilities and systems are in place and operational
- 2.4.3 Performance Qualification (PQ): the Contractor shall verify that the production line is able to operate to specification for all kit variants at full production capacity.

3. TRACEABILITY

- 3.1 The Contractor shall provide full individual kit traceability and keep records enabling any individual kit to be tracked by its unique device identifier to the production run (batch), date and time. All traceability data in this section shall be recorded by the Contractor and provided to the Authority using the Authority's Oracle Inventory Management System. The Authority will free issue Oracle Inventory management on 20 December 2021. In the interim period, the Contractor shall provide its own Warehouse Management System to meet the traceability and data reporting requirements of this Schedule 4 and in particular, the reporting requirements in Appendix 4.
- 3.2 The batch number and expiry date of each vial and swab and its use in individual kits shall be recorded, with the ability to track this data from each kit's unique identifying number.
- 3.3 As defined in Appendix 2, the kit's unique bar code shall be applied to the vial in each kit. For those vials labelled with the manufacturer's batch label, the batch number, lot number and expiry date of the vial must be visible, or over printed with the kit bar code label that also replicates the batch number and expiry date of the vial. The vials may be over-labelled with the unique identifying barcode provided there is full traceability of the vial expiry date and lot details.
- 3.4 For each kit produced, the Contractor shall record and verify that the individual kit bar code applied to the components, as defined for each kit variant in the BOM, all match.

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- 3.5 Each pallet of completed kits shall be marked with a unique bar code. When completed kits are packaged into boxes and then into pallets, the Contractor must record the kit unique identifying numbers against the pallet unique identification number, such that kits can be individually tracked against pallets. The Contractor shall ensure that batches are not cross contaminated, and each pallet has Vials and Swabs from the same batch.
- 3.6 To ensure compatibility with the Authority's downstream systems, the Authority will allow printing to labels to be applied to the relevant product, but not direct printing to components. The Authority requires a minimum shelf life for bar codes. The Contractor shall provide labels which meet the following requirements which will ensure the Authority has adequate bar code shelf life:
- 3.6.1 ISO15416 to Grade 2 (C) as a minimum for Printed linear barcodes, and
- 3.6.2 ISO15415 to Grade 2 (C) as a minimum for Printed 2 D barcodes.

4. MHRA VISIBILITY AND TRACEABILITY REQUIREMENTS

- 4.1 The Contractor must be capable of:
- 4.1.1 Ascertaining where each vial and swab has been used as a component within a kit (on a per kit basis) in the manufacturing process;
- 4.1.2 Ascertaining where each manufactured kit has been stored or shipped out (on a per kit basis) from manufacturing of the initial kit out its next point in the end to end process;
- 4.2 Each kit should be uniquely numbered and traced – for example using a unique device identifier across all items within the kit and tracked to its end user;
- 4.3 Each kit must include an MHRA compliant PCR manufacturing kit label – using a specific template and having been included in the relevant Technical File and approved and authorised by the MHRA Regulatory Team within the Authority as part of a New Product Introduction Board.
- 4.4 The serial number (barcode) of each vial must be traceable to a kit and to a box (serialisation ID per box with nested details of kits) and to a pallet (serialisation ID per pallet with nested details of boxes and kits) and information on all these elements must be provided to the Authority in a searchable format to comply with traceability for recall activity.
- 4.5 No box or pallet shall contain multiple kits from multiple batches and/or production processes.

5. NAO FINANCIAL STOCK INVENTORY AND GOVERNANCE REQUIREMENTS

- 5.1 The Contractor must identify and report components have been delivered consumed within kits on a day to day basis.
- 5.2 The Contractor must identify and report which components have been consumed within each kit on a day to day basis within the manufacturing process.
- 5.3 The Contractor must identify and report any components or kits on a day to day basis which have been damaged during the manufacturing process.
- 5.4 The Contractor must not destroy or dispose of any components or kits that have been damaged without the prior permission of the Authority. The Contractor must account for and Contract for the provision of Outsourced Kitting Production

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securely package damaged components or kits and prepare to be returned to the Authority for correct disposition protocols.

- 5.5 The Contractor must identify and report any components, kits, or damaged goods that have been shipped out by the Contractor on a day to day basis.
- 5.6 The Contractor must identify and report all stock on hand on a day to day basis including components, kits, and any damaged items/goods;
- 5.7 The Contractor must always ensure Inbound stock, less out bounded stock should equal stock on hand or “in the process of being kitted”.
- 5.8 The Contractor's interim Warehouse Management Solution will provide the information specified in Appendix 4. The Authority's Oracle Fusion Inventory Management System provides the level of reporting laid out in Appendix 4.

6. OPERATIONAL CONTROL

- 6.1 The Contractor must develop and execute Standard Operating Procedures (**SOPs**) in line with the Authority's instructions that clearly describe how key kitting activities are carried out which must be approved by the Authority.
- 6.2 The Contractor shall participate in and engage with the development of new products to improve kitting efficiency.
- 6.3 The Contractor must have the ability to perform rework on damaged or incomplete test-kits at the request, and subject to the approval, of the Authority and under the required regulatory guidelines.

7. CONTINGENCY PLANNING

- 7.1 The Contractor must demonstrate that a Risk Assessment of processes has been completed.
- 7.2 The Contractor must have a Business Continuity Plan (**BCP**) in place to address risks identified through a prioritised risk assessment.
- 7.3 The Contractor shall regularly assess, test and update the BCP and share with the Authority.
- 7.4 The Contractor must be able to accommodate a minimum of two (2) Authority or 3rd party supplier staff on-site at any site, 24 hours of the day for the purposes of inspection, quality assurance and operational support activities.
- 7.5 The Contractor shall review and propose changes to or new kit designs and configuration, and confirm the impact on the production capability for that kit design, including whether or not the production lines can meet the production volumes with the amended / new design, and if not what design changes and costs would be required to accommodate the amended /new design.

8. TEST KIT SPECIFICATIONS

- 8.1 The Contractor shall produce test kits in accordance with MHRA, the Authority's and ISO 13485 requirements.

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- 8.2 The Contract covers the kitting of multiple types of test kits (PCR, Lamp etc). The current kits that the Authority will require the Contractor to kit as part of the Contract are provided in Appendix 2.
- 8.3 The Contractor's manufacturing lines (including the Equipment) shall be configured to be capable of meeting the following indicative volumes of test kit variants as specified in Appendix 2. These are indicative only and will be subject to change:
- 8.3.1 Regional Test Site (RTS) 48%
 - 8.3.2 Care home [satellite] 18%
 - 8.3.3 User agnostic 18%
 - 8.3.4 Home 16%
- 8.4 The Authority will free issue the components (detailed in Appendix 2) to the Contractor. These components will conform to the specifications, configurations and standards in Appendix 2. The Contractor shall produce test kits to the required quality and volumes using these Authority free issue components. All other components shall be provided by the Contractor and shall conform to the specifications, configurations and standards in Appendix 2.
- 8.5 The information in the test kit specification provided in Appendix 2 is current at the Commencement Date; due to the nature of the programme there is a likelihood that these will change throughout the Term. The Authority reserves the right to change the test kit specification without notification.

9. REGULATORY REQUIREMENTS

- 9.1 The Contractor must, during the whole of the Term, meet all regulatory requirements (e.g. MHRA) and quality guidelines defined by the Authority and have the necessary certifications in place. MHRA regulatory requirements include but are not limited to the below:
- 9.1.1 MHRA guidelines require that in the case of a faulty/damaged/dangerous product, the end user of the product can be contacted in a timely manner.
 - 9.1.2 The Contractor shall be certified to ISO13485:2016
- 9.2 The Contractor must allow for quality and regulatory audits by external companies given 48 hours' notice as a minimum.

10. QUALITY STANDARDS

- 10.1 The Contractor shall have in place an effective Quality Management System (**QMS**) that provides assurance that only products manufactured to the Authority's specifications are distributed, that non-compliant, defective or unsuitable medical devices can be detected, that traceability is maintained and that non-conformances and the introduction of changes are controlled.
- 10.2 The Contractor shall ensure the facility and materials used have no natural rubber latex and are free of any contaminants and must provide a declaration statement to confirm that there are no natural rubber latex contaminants in the kitting process at all.

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- 10.3 The Authority requires that in the case of a faulty/damaged/dangerous product that the end user of the product can be contacted in a timely manner; Contractor systems and records must enable this traceability.
- 10.4 The Authority requires that there remains manufacturing oversight of the test components (e.g. swabs, buffer IFUs) to a completed test batch kit; Contractor systems and records must enable this traceability.
- 10.5 The Contractor must ensure that an appropriate Quality Control inbound inspection, takes place which complies with the Authority's instructions. This covers the following activities;
- 10.5.1 Receiving components/test-kits.
 - 10.5.2 Documenting Key Information upon receipt.
 - 10.5.3 QC inspection and recording of data.
- 10.6 Non-compliant goods handling:
- 10.6.1 Non-compliant components/test-kits shall be clearly identified by the Contractor with the reasons for non-compliance recorded and stored separately for audit and traceability.
 - 10.6.2 Non-compliant goods shall be segregated from other quality approved ones electronically (using IMS/WMS) and physically to ensure components/test-kits are blocked from further entering the downstream supply chain process.
 - 10.6.3 The Contractor shall notify the Authority of non-compliant goods on a weekly basis and seek further guidance from the Authority.
 - 10.6.4 The communication and implementation of agreed corrective action shall be agreed between the Authority and the Contractor. The agreed corrective action may include the actions listed below between the Authority and Contractor:
 - (i) Return to Vendor.
 - (ii) Vendor collection of returns.
 - (iii) Goods write-off process and credit note/replacement.
 - (iv) Arrange with the Contractor for on-site resolution for non-compliant goods.
 - (v) Arrange for products to be destroyed in accordance with guidelines provided by the Authority. If goods need to be destroyed, this will need to be agreed by the Authority and must follow NHA process of destruction. Any and all information relating to the destruction including a destruction certificate must be made available to the Authority.
 - 10.6.5 The Contractor shall ensure its Quality Management Systems provide adequate management and control of the following activities:
 - (a) Maintaining traceability of bulk components in both raw material WIP and finished test-kit forms.
 - (b) Issuing production Batch Record document for each kit batch.

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- (c) Planning production of batches.
 - (d) Picking components for kit batches.
 - (e) Transforming WIP into finished goods and adherence to documenting this process.
 - (f) Completing kitting build process in line with agreed work instructions.
 - (g) Completing in process quality checks and raising non-compliant goods issues during batch manufacture.
 - (h) Completing line clearance process between batches or as defined.
 - (i) Completing document data requirements in line with Good Document Practice (**GDP**).
 - (j) Appropriate storage of finished test-kits prior to quality release.
 - (k) Create labels or similar printed identification markers for components and test-kits and apply where required from approved/release art files.
 - (l) Create shipping notes for goods out including all the agreed data.
- 10.7 The Contractor shall establish SOPs to clearly describe how key activities are carried out.
- 10.8 The Contractor's SOP shall describe the different operations which may affect the performance of the medical devices, including:
- 10.8.1 Training
 - 10.8.2 Documentation control
 - 10.8.3 Approval of Contractor and customers
 - 10.8.4 Order processing and deliveries
 - 10.8.5 Waste management
 - 10.8.6 Audits
 - 10.8.7 Change control
 - 10.8.8 Management review
 - 10.8.9 Quality risk management
 - 10.8.10 Management of Field Safety Corrective Actions/recalls
 - 10.8.11 Non-conformance management
 - 10.8.12 Corrective and preventive actions.

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- 10.9 The Quality Management System must include the Contractor's SOP and work instructions that fulfil the quality requirements of the Authority, including the following elements:
- 10.9.1 Quality Manual.
 - 10.9.2 Quality Policy.
 - 10.9.3 Record Control.
 - 10.9.4 Correction Action Preventative Action (CAPA) process.
 - 10.9.5 Document Change Control within the Quality Management System to ensure that all documents are controlled, issued at the correct revision and each employee is trained to the correct version.
- 10.10 The Contractor shall operate an internal audit programme framework to manage and control all elements of the Quality Management System, and will agree to an external audit program, conducted by the Authority or its authorised representative, that drives adherence and continuous improvements.
- 10.11 The Contractor shall ensure traceability with good record keeping.
- 10.12 All external audits shall be undertaken to an agreed schedule and shall provide the Contractor with reasonable advance notice.
- 10.13 The Contractor shall comply with the Quality/Technical Agreement (**QTA**) in Appendix 3, which will be entered in to by all parties and will outline responsibilities with respect to performing production, shipping, inspection and storage of Test kits in accordance with current good manufacturing practices. All parties will responsible for ensuring that they meet the intent of the QTA.

11. AUTHORITY DATA INTERFACE

- 11.1 The Authority has established an Oracle Inventory Management system and its Oracle Fusion Manufacturing module will be used by each Supplier to ensure that MHRA and NAO mandatory requirements can be discharged during the kitting process. The Authority will implement the Oracle Inventory Management System (including the Oracle Fusion Manufacturing module) with each supplier and at each site and will provide associated training etc. for each Supplier. The Authority will free issue licences, user training and the Equipment detailed in Part B of Schedule 21 to enable the Contractor to operate the Oracle Inventory Management System. The Contractor shall provide all generic hardware and software (including computers and Wi-Fi systems) including the requirements detailed in Appendix 6. The Contractor will be required to operate all its people and processes in line with the systems enablement to assure the regulatory requirements for this contract. This system covers the end-to-end kitting process from receiving in kit components, consuming components in kits, and serialising (nesting) of completed kits to boxes to pallets and shipping out of completed kits to fulfil the contract.
- 11.2 Any items damaged during the process must be accounted for separately within the system to ensure daily reporting compliance. This is not a warehouse management system but it covers the key inventory management activities including materials utilisation, kit production and product visibility, traceability and mandatory reporting
- 11.3 The Contractor shall ensure any access made available to the Oracle Fusion system is password protected and access to individual logins are not shared.

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12. MATERIALS HANDLING AND STORAGE

12.1 General storage

- 12.1.1 All components and test-kits are to be stored in racked pallets in accordance with the manufacturer and the Authority's requirements.
- 12.1.2 The Contractor should ensure sufficient capacity to meet loading/offloading schedules to ensure compliance with order demand and to avoid demurrage and detention of vehicles (and extended put away times).
- 12.1.3 The Contractor must agree specific delivery windows with the Authority's Bulk Component and Kitting Fulfilment Supplier to ensure deliveries and collections are made during operational hours.
- 12.1.4 The Supplier must ensure that kits are batched in no more than 150,000 kits per batch.
- 12.1.5 The Contractor must ensure that it has sufficient capacity to accept deliveries to the agreed estimated delivery requirements, during agreed delivery windows with appropriate traffic flow measures to ensure safe working procedures.
- 12.1.6 Unless further advised, pallets will not be block stacked nor be stacked on each other.
- 12.1.7 The environment in which all components and test-kits are stored and assembled must be temperature monitored and held within a temperature range of 2 -25 degrees C. Specific manufacturer and/or the Authority's requirements can be provided upon request.
- 12.1.8 The Contractor must protect product integrity at all times, including:
 - (a) Maintaining Storage locations to hygiene and pest control standards specified in this Schedule 4.
 - (b) Keeping Stock in compliance with storage conditions.
 - (c) Keeping Stock secure (physical location).
- 12.1.9 The Authority reserves the right to perform basic storage spot checks either directly or through a 3rd party representative (providing suitable notice).

12.2 Inbound Components

- 12.2.1 Incoming components will be palletised to standard heights (standard pallet height is between 1.2m and 1.6m). The Contractor must be able to accommodate this standard height as a minimum.
- 12.2.2 Pallets received will typically be UK standard dimensions.
- 12.2.3 The Contractor shall conduct a daily goods inspection and an agreed sampling plan in line with ISO 13485 requirements.
- 12.2.4 The Contractor must have the ability to quarantine components that do not meet quality standards.

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- 12.2.5 The Contractor must ensure that incorrect inbound orders are quarantined and not un-palletised.

12.3 Completed Test-kit Storage

- 12.3.1 All completed test-kits must be stored in appropriate, racked, storage locations within the storage guidelines provided by the Contractor and the Authority.
- 12.3.2 Each pallet must only contain a single Batch and SKU.
- 12.3.3 Typically, there are 50 test-kits per case and 24 cases per pallet equalling 1,200 test-kits per pallet. Volumes can vary depending on the types of test-kit and packaging requirements.
- 12.3.4 The Contractor shall perform visual inspections for paperwork, damages and broken tamper seals.
- 12.3.5 The Contractor shall quarantine completed kits that do not meet quality standards.

12.4 Inventory Management

- 12.4.1 The Contractor shall provide the following inventory management functionality using Oracle Fusion:
 - (a) Provide all data that affects stock, stock status, shipments, SKU and reports, as requested by the Authority.
 - (b) Stock records will show the associated batch details for every SKU in every location.
- 12.4.2 The Contractor must be able to track the movement of components and test-kits to adequately manage dispatch and receipt.
- 12.4.3 Inventory accuracy will be maintained through a documented process, allowing for perpetual inventory inspection (or similar) and reconciliation process for understanding all discrepancies.
- 12.4.4 The Contractor must ensure that the oldest expiry date inventory is used first.

13. MOTHBALLING SERVICE

- 13.1 The future demand for COVID testing is uncertain. . In the longer term it is predicted that COVID testing volumes will reduce. The Authority will need the flexibility to reduce testing capacity infrastructure and associated costs as it becomes confident that volumes will reduce.
- 13.2 The Authority is also in the process of developing an infrastructure to protect the nation's health and to be able to respond to a future pandemic, should one arise. The Authority will need the ability to recommission testing capacity quickly in the event of a future pandemic. As the nature of any future pandemic could vary considerably, it is likely that test kit design and associated production line design would need to change from the current COVID test kits.
- 13.3 In order to address these needs, the Authority requires the Contractor to provide a 'mothballing' service, whereby production lines can be progressively decommissioned, and if required, held in long term storage, in a manner that enables the Authority to recommission

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production lines within 2-3 months of a pandemic being detected, with redesign / reconfiguration of production Equipment.

13.4 In order to meet these requirements, the Contractor shall:

- 13.4.1 Decommission any production line with a minimum of 1 month's notification by the Authority at no additional cost;
- 13.4.2 provide confirmation of Data Retainment obligations and comply providing the Authority all requirements as part of the decommissioning
- 13.4.3 If instructed by the Authority, store, and conduct any in storage maintenance of the Authority owned production Equipment in a suitable manner to enable recommission. This shall be costed on an open book basis;
- 13.4.4 If instructed by the Authority, conduct any redesign required for the production line and associated operating / production SOPs to accommodate design changes to test kit design. This shall be costed on an open book basis.
- 13.4.5 If instructed by the Authority, recommission any production line that has been stored and / or re-designed. This shall be costed on an open book basis.

14. MANAGEMENT INFORMATION/REPORTING

14.1 The Contractor shall ensure that all MI provided in respect of the requirements under this section is in an appropriate format to be agreed with the Authority and the Contractor, within one month of the Commencement Date,

14.2 The Contractor shall provide at such times as may be required by the Authority summary reports in line with the Authority's reporting requirements as advised from time to time.

14.3 General Reporting

- 14.3.1 The Contractor shall generate and provide to the Authority a report of quarantined stock.
- 14.3.2 The Contractor shall generate and provide to the Authority a report of inventory levels of components and completed kits.
- 14.3.3 The Contractor shall generate and provide to the Authority a report of Quality Issues found.
- 14.3.4 The Contractor shall generate and provide to the Authority a report of Lost Time Inefficiencies.
- 14.3.5 The Contractor shall generate and provide to the Authority a report on Active management of performance to ensure SLAs are achieved and recovery plans in place if necessary.
- 14.3.6 The Contractor shall report on the number of outbound shipments.
- 14.3.7 The Contractor shall report on order completion rates.
- 14.3.8 The Contractor shall report on completed kit traceability to the levels defined in this Schedule.

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- 14.3.9 The Contractor shall report KPIs agreed by the Authority.
 - 14.4 Components Storage Reporting
 - 14.4.1 The Contractor shall report the volume of non-arrivals, non-scheduled arrivals, and late / early deliveries of Authority free issued raw material deliveries.
 - 14.4.2 The Contractor shall report the volume of damaged components free issued by the Authority.
 - 14.5 Kitting Production Reporting
 - 14.5.1 The Contractor must generate and provide to the Authority a report on production plan adherence.
 - 14.5.2 The Contractor shall report a 3-day rolling forecast of inventory levels along with status for alerts on low or overstocked quantities.
 - 14.5.3 The Contractor shall report on number of reworks (completed and pending).

15. RECORDS

- 15.1 The Contractor must keep records for 5 years from the last expiry date.
- 15.2 The Contractor must have a change control procedure and associated forms should be implemented and appropriately documented.
- 15.3 The purpose of the procedure should be to ensure that all changes to the operation are fully evaluated in terms of impact on the medical device's performance and traceability.

16. TRAINING

- 16.1 The Contractor shall have the appropriate personnel with suitable training and experience to adequately conduct their assigned duties.
- 16.2 The Contractor shall have documented and recorded all training.
- 16.3 The Contractor must ensure all staff in roles that perform the operations listed above and those detailed within the Quality Management System will be trained to the required level, and a competency assessment will be included in a capability assessment. All training records are to be maintained within the Quality Management System.

17. PEST CONTROL

- 17.1 The Contractor shall demonstrate adequate pest control measures are in place for the facility.
- 17.2 The Contractor shall provide a schedule of pest control for the facility and shall review its effectiveness on a periodic basis.
- 17.3 The Contractor shall take action upon information provided by the appointed pest control solution.

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18. STAFF AND CUSTOMER SERVICE

- 18.1 The Contractor shall provide a sufficient level of resource throughout the Term in order to consistently deliver a quality service.
- 18.2 The Contractor Personnel assigned to the Agreement shall have the relevant qualifications and experience to deliver the Contract to the required standard.
- 18.3 The Contractor shall ensure that the Contractor Personnel understand the Authority's vision and objectives and will provide excellent customer service to the Authority throughout the Term.

Appendix 1 – Not Used

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Appendix 2 : Test Kit Specifications

1.0 GENERAL

1.1 This document highlights the technical specification and input form of each test kit SKU that is within scope of the SOR. Each SKU will be broken down into the following levels:

- Tertiary Level - palletised
- Secondary Level - boxed
- Primary Level – individual component

1.2 Some kitting SKUs have not currently been made available for photographing. All SKUs within this document will be delivered to the Supplier in the Secondary level form for further analysis and development of the automated solution.

1.3 The test kit specification provided in this document are current at the time of issue, due to the nature of the programme there is a likelihood that these will change throughout the life of the contract. The Authority reserves the right to change the test kit specification without notification. The test kit specification will be confirmed at time of Contract Award.

2.0 INTRODUCTION

2.1 COVID Test kitting operations may be broken down into primary kitting (i.e. an individual user kit) and secondary kitting whereby the primary kits are amalgamated for onward storage and distribution.

2.2 There are 4 main variants of kit that the primary and secondary kitting solutions must produce:

- Home Test kit
- Care Home kit
- Regional Test Site kit (RTS)
- User Agnostic kit.

2.3 These kit variants are known as “channels”. The constituent parts of each primary channel kit will be referred to as “components”.

2.4 The individual components to be kitted in any given channel can vary in form. As with the overall kit type, no more than one kit component variant will be used at any one time. It should be possible to change over from one component variant to another with the minimum of disruption to the assembly of kits. Where necessary some mechanical or software reconfiguration is permissible to accommodate different component variants, however mechanical reconfiguration should be avoided wherever possible.

3.0 SYSTEM OVERVIEW: GENERAL Overview:

3.1 The diagrams below show the process flow for each channel for both primary and secondary kitting:

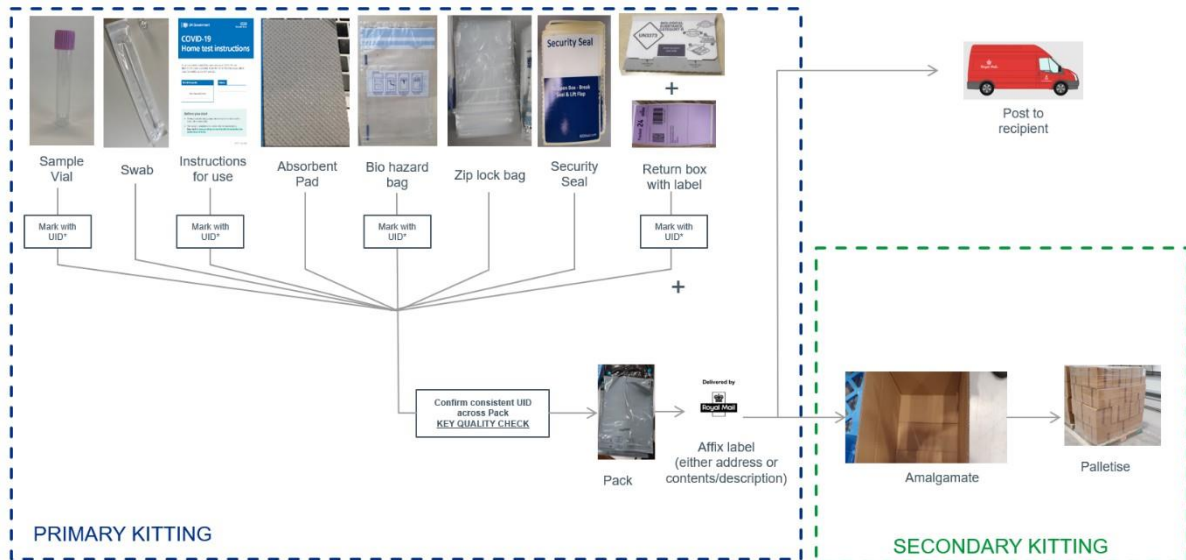


Fig.1 – Home Test Kit Contents and Format.



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Fig. 2 – Care Home Kit Contents and Format.

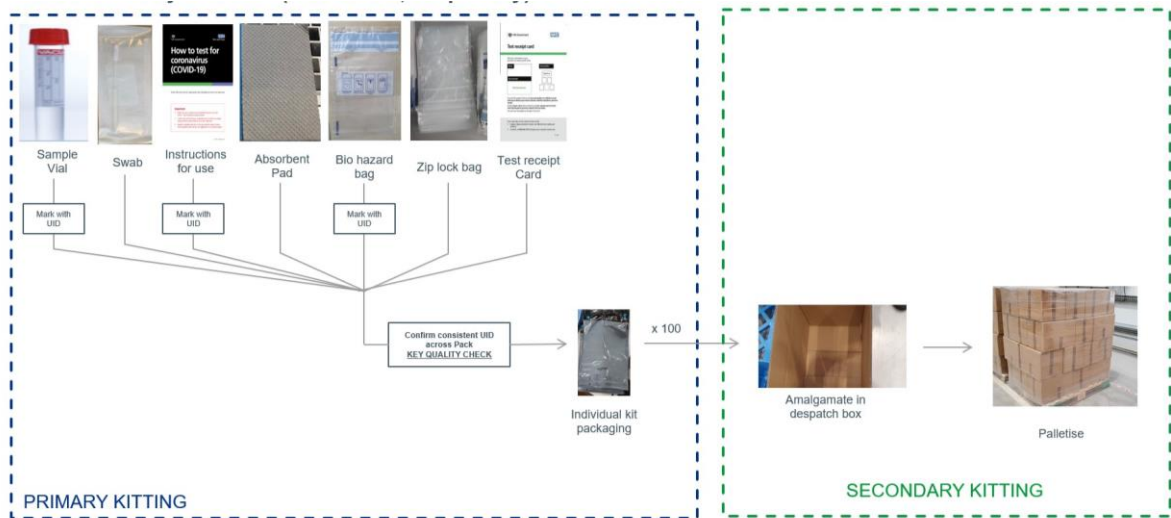


Fig. 3 – Regional Test Site Kit Contents and Format.

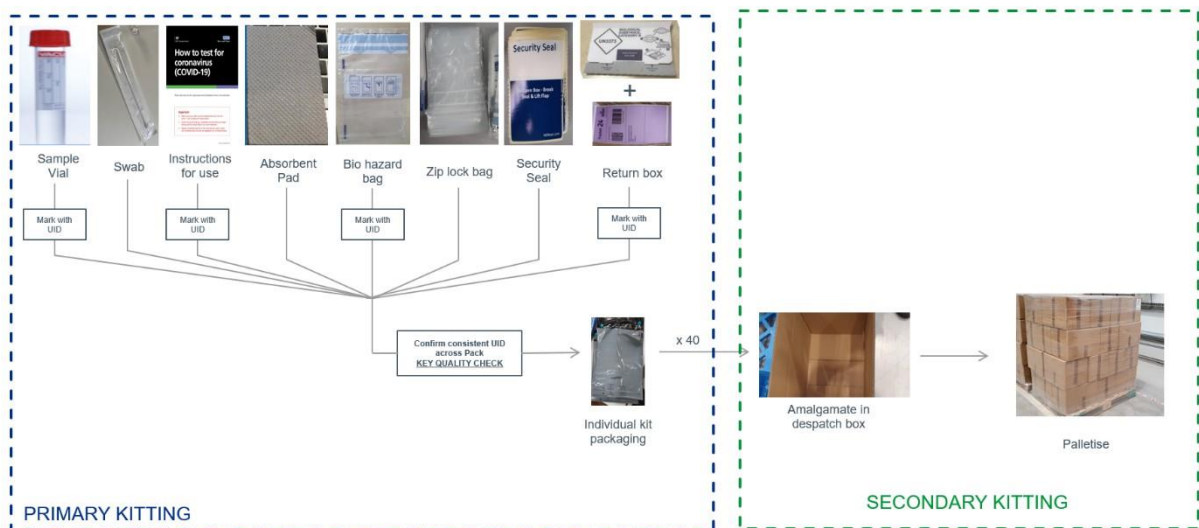


Fig. 4 – User Agnostic Kit Contents and Format.

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3.2 SYSTEM OVERVIEW: PRIMARY KITTING

- 3.2.1** It is assumed that the function of the primary kitting operation is to kit individual components into a kit and wrap for individual use. It is assumed that the secondary function will be to assemble secondary kitting amalgamated kits, for example, in Fig. 2 (above), the primary kitting solution would be capable of assembling a kit containing the components shown in the secondary kitting dashed green box.
- 3.2.2** The most complex primary kit channel (home test) contains 8 items. The simplest primary kit channel (care home) contains 5 items.
- 3.2.3** In addition to the assembly of kits, the production line process should be capable of:
- 3.2.4** Unique device identifier marking various components of the primary kit with a unique device identifier (UDI) this should be directly printed to the components or as a label.
- 3.2.5** Confirming marked components of the kit have the same UID prior to packaging.
- 3.2.6** Enveloping the primary kit in a suitably robust plastic outer packaging.
- 3.2.7** Labelling that outer packaging with a printed unique device identifying label or direct print of an MHRA required label containing the EAU, batch number, use by date and production date.
- 3.2.8** Primary kitting could be achieved by way of modular component dispensers arranged along a central conveyor. Different kit configurations are assembled by turning on/off stations along the line.

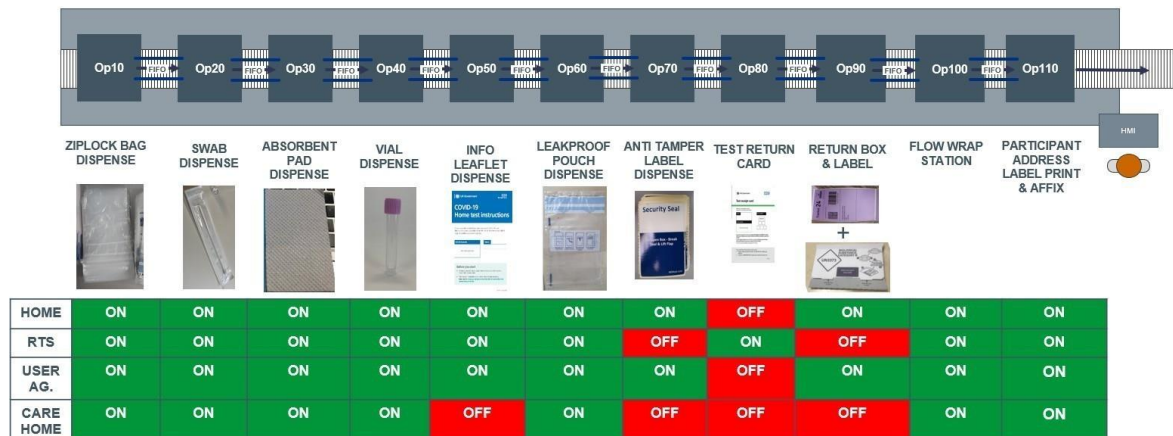


Fig.5 – Primary Kitting Cell Initial Concept.

3.3 The above concept configuration consists of eleven individual modules as shown in Figure 5 above. This diagram is for information only and the Supplier is free to design the production line configuration and design. However, the station functions in the diagram are used in this document to define the station functionality required.

3.4 Unique device identifier will be directly printed or otherwise marked via “print-on-line” self-adhesive label at Ops 40, 50, 60, 80, 90 and 110. Note that at Ops 50, the Supplier may as an alternative print or label an additional card rather than the leaflet – the purpose of this UID is to be retained by the patient as a record of the test.

3.5 Operation sequence shown is not mandatory

4.0 SYSTEM DETAIL: Op10 DISPENSE ZIPLOCK BAG

4.1 The key function of Op10 is to dispense a Ziplock bag to the central conveyor system. The Ziplock bag will be free issued by the Authority.

4.2 Op10 should pick a ziplock bag from the input delivery format outlined in appendix 1. OP10 should then process the Ziplock bag from the supply format, conveying a single item to the kit being assembled.

4.3 The zip lock bag is common to all kit channels. However, to protect for future channels omitting the bag, it must be possible to turn off this function while still running the primary kitting line.

4.4 Positive confirmation of the Ziplock bag being added to the kit should be made. The system should be able to detect a Ziplock bag addition failure, pause and alert the operator such that they can resolve the problem.

4.5 Details of the delivery format for the Ziplock bag is contained within Appendix 1.

5.0 SYSTEM DETAIL: Op20 DISPENSE OROPHARYNGEAL

5.1 The key function of Op20 is to dispense a suitable oropharyngeal swab to the central conveyor system. The oropharyngeal swab will be free issued by the Authority.

5.2 Op20 shall pick an oropharyngeal swab from the various delivery formats as detailed in Section A. Op20 shall process the swabs from the supply format, conveying a single item to the kit being assembled.

5.3 There are 7 different variants of oropharyngeal swab to be considered. Only one variant of swab will be employed during any one batch of kits produced. Some mechanical or software reconfiguration of the Op20 solution is permissible to accommodate different variants of swab. However, where possible the solution should be capable of accommodating as many variants as possible with the minimum of reconfiguration.

5.4 All variants of primary kit contain one of the variants of oropharyngeal swab. However, to protect for future channels omitting the swab, it must be possible to turn off this function while still running the primary kitting line.

5.5 Positive confirmation of the addition of the oropharyngeal swab to the kit should be made to the central control system. The system should be able to detect a

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swab addition failure, pause and alert the operator such that they can resolve the problem.

5.6 The Op20 sub-system shall provide a reservoir of oropharyngeal swabs to facilitate supply to the line for a minimum of one hour before re-stocking is required. When the supply of oropharyngeal swabs is nearing depletion, the OP20 solution shall communicate this to the central control system, warning the operator that replenishment is required.

5.7 Details of the delivery formats for the oropharyngeal swabs are contained within Appendix 1.

6.0 SYSTEM DETAIL: Op30 DISPENSE ABSORBANT PAD

6.1 The key function of OP30 is to dispense an absorbent pad to the central conveyor system. The absorbent pad will be free issued by the Authority.

6.2 Op30 shall pick an absorbent pad from a reel outlined in Section A. OP30 shall process the absorbent pad from the supply format, conveying a single item to the kit being assembled.

6.3 The absorbent pad is common to all kit channels envisaged. However, to protect for future channels omitting the absorbent pad, it must be possible to turn off this function while still running the primary kitting line.

6.4 Positive confirmation of the addition of an absorbent pad to the kit should be made to the central control system. The system should be able to detect an absorbent pad addition failure, pause and alert the operator such that they can resolve the problem.

6.5 Details of the delivery format for the absorbent pad is contained within Section A.

7.0 SYSTEM DETAIL: Op40 UID MARK AND DISPENSE SAMPLE COLLECTION VIAL

7.1 The key function of Op40 is to mark a suitable sample transport vial with the unique device identifier (UDI) and dispense the UID marked vial to the central conveyor system. The sample collection vial will be free issued by the Authority.

7.2 Op40 shall pick a sample transport vial from the various delivery formats of the different vials to be included in kits, as outlined in appendix 1. OP40 shall process the vials from the supply format, UID marking and conveying a single item to the kit being assembled.

7.3 There are 8 different variants of sample transport vial to be considered. Only one variant of vial will be employed during any one batch of kits produced. Some mechanical or software reconfiguration of the OP40 solution is permissible to accommodate different variants of vial. However, where possible the solution should be capable of accommodating as many variants as possible with the minimum of reconfiguration.

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7.4 All variants of primary kit contain one of the variants of sample transport vial. However, to protect for future channels omitting the vial, it must be possible to turn off this function while still running the primary kitting line.

7.5 Positive confirmation of the UID marking and the addition of the sample transport vial to the kit should be made to the central control system. The system should be able to detect a sample collection vial UID marking or addition failure, pause and alert the operator such that they can resolve the problem.

7.6 Details of the delivery format for the sample transport vials are contained within Section A.

8.0 SYSTEM DETAIL: Op50 UID MARK AND DISPENSE IFU LEAFLET

8.1 The key function of Op50 is to mark a suitable “instructions for use” leaflet (IFU) with the unique device identifier (UDI) and dispense it to the central conveyor system. The purpose of this UID is to be retained by the patient as a record of the test. The IFU leaflet will be free issued by the Authority.

8.2 Op50 shall pick an IFU leaflet from the delivery formats of the different IFU’s to be included in kits, as outlined in appendix 1. OP50 shall process the IFU’s from the supply format, marking with a UID and conveying a single IFU to the kit being assembled.

8.3 There are numerous variants of IFU’s to be considered, however they are all a standard A5 sized document with differing copy and language. Only one variant of IFU will be employed during any one batch of kits produced. Some mechanical or software reconfiguration of the OP50 solution is permissible to accommodate different variants of IFU. However, where possible the solution should be capable of accommodating as many variants as possible with the minimum of reconfiguration.

8.4 Not all variants of primary kit contain an IFU. It must therefore be possible to turn off this function while still running the primary kitting line.

8.5 Positive confirmation of the correct UID marking and addition of the IFU to the kit should be made to the central control system. The system should be able to detect an IFU leaflet UID marking or addition failure, pause and alert the operator such that they can resolve the problem.

8.6 Details of the delivery format for the IFU’s are contained within Section A.

9.0 SYSTEM DETAIL: Op60 UID MARK AND DISPENSE LEAK PROOF POUCH

9.1 The key function of OP60 is to mark a suitable leakproof pouch with the unique device identifier) and dispense to the central conveyor system. The leak proof pouch will be free issued by the Authority.

9.2 There are two variants of leakproof pouch to be considered. Only one variant of leakproof pouch will be employed during any one batch of kits produced. Some

mechanical or software reconfiguration of the Op60 solution is permissible to accommodate the different variants of leakproof pouch. However, where possible the solution should be capable of accommodating as many variants as possible with the minimum of reconfiguration.

9.3 The leakproof pouch is common to all kit channels envisaged. However, to protect for future channels omitting the pouch, it must be possible to turn off this function while still running the primary kitting line.

9.4 Positive confirmation of the correct UID marking and addition of the leakproof pouch the kit should be made to the central control system. The system should be able to detect a leakproof pouch UID marking or addition failure, pause and alert the operator such that they can resolve the problem.

9.5 Details of the delivery format for the leakproof pouch is contained within Section A..

10.0 SYSTEM DETAIL: Op70 SECURITY DISPENSE TAMPER PROOF LABEL

10.1 The key function of Op70 is to dispense a security tamper proof label (STPL) to the central conveyor system. The security tamper proof label will be free issued by the Authority.

10.2 Op70 shall pick a single STPL from the delivery format of the STPL, as outlined in Section A . Op70 shall process the STPL's from the supply format, conveying a single STPL to the kit being assembled.

10.3 There is only one variant of STPL.

10.4 Not all variants of primary kit contain an STPL. It must therefore be possible to turn off this function while still running the primary kitting line.

10.5 Positive confirmation of the addition of the STPL to the kit should be made to the central control system. The system should be able to detect an STPL addition failure, pause and alert the operator such that they can resolve the problem.

10.6 Details of the delivery format for the STPL is contained within Section A .

11.0 SYSTEM DETAIL: Op80 UID MARK AND DISPENSE TEST RECEIPT CARD

11.1 The key function of Op80 is to add a correctly UID marked test return card to the central conveyor. The test receipt card

11.2 Op80 shall pick a single test receipt card from the delivery format of the test receipt card, as outlined in Section A. Op80 shall process the test receipt cards from the supply format, correctly marking them with the UID, and conveying a test receipt card to the kit being assembled.

11.3 There is one variant of test return card.

11.4 Not all variants of primary kit require a test receipt card. It must therefore be

Contract for the provision of Outsourced Kitting Production

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possible to turn off this function while still running the primary test line.

11.5 Positive confirmation of the addition of the correctly UID marked test receipt card shall be communicated to the central control system. Error trapping shall exist, such that the kitting cell ceases function and warns the operator of a problem if the test receipt is not conveyed to the kit being assembled.

11.6 Details of the delivery format for the test receipt card is contained within Section A.

11.7 It is noted that Op90 and Op80 are mutually exclusive and will never be required to operate together on a single batch of primary kits.

12.0 SYSTEM DETAIL: Op90 UID MARK, APPLY ROYAL MAIL LABEL AND DISPENSE RETURN BOX

12.1 One final unique device identifier must be included as a spare

12.2 The key function of Op90 is to add a correctly labelled and UID marked cardboard return box to the central conveyor. The Royal Mail label and return box will be free issued by the Authority.

12.3 Op90 shall pick a single return box from the delivery format of the return boxes, as outlined in appendix 1. Op90 shall pick a single royal mail label from the delivery format outlined in appendix 1. OP90 shall process the return boxes and royal mail return labels from the supply format, conveying a return box, with the return label attached in a consistent and suitable orientation and position, and correctly UID marked, to the kit being assembled.

12.4 There are two variants of cardboard return box, and one variant of royal mail return label. Only one variant of return box will be employed during any one batch of kits produced. Some mechanical or software reconfiguration of the OP90 solution is permissible to accommodate the different variants of return box. However, where possible the solution should be capable accommodating both variants with the minimum of reconfiguration.

12.5 Not all variants of primary kit require a return box and royal mail return label. It must therefore be possible to turn off this function while still running the primary test line.

12.6 Positive confirmation of the addition of the correctly UID marked return box / return label combination shall be communicated to the central control system. The system shall be capable of detecting a failure to process the box and royal mail return label, and/or a failure to properly UID mark the box. In such instances the system shall pause and alert the operator such that they may resolve the issue.

12.7 It is noted that Op90 and Op80 are mutually exclusive and will never be required to operate together on a single batch of primary kits. In the event a proposal is made to combine these work packages into a single reconfigurable solution, this will be considered.

12.8 Details of the delivery format for the return boxes and royal mail return labels are contained within Appendix 1.

13.0 SYSTEM DETAIL: Op100 UID CONTINUITY CHECK AND FLOW WRAP/ Mail bags

13.1 The key functions of Op100 maybe broken down further into Op100a and Op100b. The flow wrap will be procured by the Supplier and the mail bags will be free issued by the Authority for the initial stage of semi automation, if necessary.

13.2 The key function of Op100a is to read the UID barcodes on the sample return vial, the leakproof pouch, the IFU (where included) and the return box or test receipt card (where included).

13.3 Confirmation that the UIDs match is to be communicated to the central control system.

13.4 In instances where these UIDs does not match, this is to be communicated to the central control system, such that the kitting line pauses and alerts the operator so they may resolve the issue.

13.5 Op100b function is to encapsulate the kit components into a suitable plastic wrapping. Your industry knowledge and experience shall be employed to advise on the type and weight of the suitable plastic wrapping. The solution must not include latex.

13.6 Positive confirmation of the correct wrapping of the primary kit shall be communicated to the central control system. Error trapping shall exist, such that the kitting cell ceases function and warns the operator of a problem if this does not correctly occur.

14.0 SYSTEM DETAIL: Op110 PRIMARY KIT LABELLING

14.1 Op110 function is to apply a suitable self-adhesive label to the sealed primary kit package, marked with either:

14.2 In the case of all kits produced to stock, the batch number, the use by date, the primary kit description, and the manufacturing date of the primary kit.

14.3 In the case of a home test kit for the “direct to user” application, to apply the batch number, the use by date, the primary kit description, the manufacturing date to the primary kit package.

14.4 The supply format of the self-adhesive label is to be advised from your industry knowledge and experience. No format for this input commodity has yet been determined.

14.5 The primary kitting labels are shown in Section A.

SECTION A.

1.0 GENERAL.

This document highlights the technical specification and input form of each SKU that is within scope of the Kitting Cell Automation process. Each SKU will be broken down into the following levels:

- Tertiary Level - palletised
- Secondary Level – boxed
- Primary Level – individual component

Some kitting SKUs have not currently been made available for photographing. All SKUs within this document will be delivered to suppliers in the Secondary level form for further analysis and development of the automated solution.

A.1 OP10 WORK PACKAGE: Dispense Ziplock Bag

Specification	
Description	TC1007 – PG11 PolyGrip Bag 150mm x 229mm
Packaging	Loose packed in box, orientated in opposite alternate directions.

Input Level	Image
Primary	

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Secondary	
Secondary	
Tertiary	No image available



Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.2 OP20 WORK PACKAGE: Dispense Oropharyngeal Swab

A.2.1 TC1135 – Medline swab

Specification	
Description	Individually packaged swabs, loose in zip lock bag, not perforated edges. 153mm 80mm breakpoint
Packaging	500 swabs / pk, 10 pks / secondary.

Input Level	Image
Primary	
Secondary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

	
Tertiary	No image available

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.2.2 TC1255 – Miraclean Swab

Specification	
Description	Flocked sampling swab for cell and virus specimen collection 150mm 82mm breakpoint
Packaging	Unknown – samples to follow


Input Level	Image
Primary	No image available
Secondary	No image available
Tertiary	No image available

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

TC1554 – Alphaslab (55) Swab

Specification	
Description	HHD670 - PS stick with breakpoint at 80mm, single peel pack
Packaging	Pcs per box – 1000 Pcs per pallet – 168000



Input Level	Image
Primary	No image available
Secondary	No image available
Tertiary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.2.3 TC1589 – Alphalab (54) Swab

Specification	
Description	HHD671 - PS stick with breakpoint at 78mm, single peel pack
Packaging	Pcs per box – 1000 Pcs per pallet – 168000

Input Level	Image
Primary	
Secondary	

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Contract Reference: C40296

Tertiary



Contract for the provision of Outsourced Kitting Production

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A.2.4 TC1663 – Mediwire Swab

Specification	
Description	Peelpouch dryswab consists of 1 applicator which is enclosed within a paper and polythene peel pouch. DIM: 185 x 34 x 5 mm per swab package
Packaging	Samples to follow

Input Level	Image
Primary	No image available
Secondary	No image available
Tertiary	No image available

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.3 OP30 WORK PACKAGE: Dispense Absorbent Pad

Specification	
Description	TC1623 - Lightweight absorbent pad
Packaging	Loosely packaged in plastic wrapping inside secondary box. Orientation not essential. These come loose in the box. The Authority will procure the absorbent pads on reels.

Input Level	Image
Primary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

Secondary	
Tertiary	No image available

A.4 OP40 WORK PACKAGE: UID Mark and Dispense Sample Collection Vial

A.4.1 TC1172 – Thermo saline ISS Vial

Specification	
Description	HHD654 - Vial with medium
Packaging	100 vials per secondary in upright position 4 x 4 secondaries on each pallet, wrapped in cellophane

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Contract Reference: C40296

Input Level	Image
Primary	
Secondary	 

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

Tertiary



Wrapped in cellophane when complete pallet

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.4.2 TC1476 – Thermo WASP Vial

Specification	
Description	HHD672 - Vial with medium, stacked upright in racking. DIMS: 12.9mm x 80.75mm
Packaging	100 pcs per secondary box 330 secondary per tertiary pallet

Input Level	Image
Primary	
Secondary	
Tertiary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.4.3 TC1502 – AB Science VTM Vial

Specification	
Description	No details available currently. DIMS: 17mm x 120mm
Packaging	Samples to follow.



Input Level	Image
Primary	No image available
Secondary	No image available
Tertiary	No image available

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296



A.4.4 TC1653 – Thermo WASP (Germany) Vial

Specification	
Description	HHD689 - Vial with medium, stacked upright in racking. DIMS: 12.9mm x 80.75mm
Packaging	100 pcs per secondary box 240 secondary per tertiary pallet

Input Level	Image
Primary	
Secondary	

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Contract Reference: C40296



	
Tertiary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.4.5 TK1111 – E&O Vial

Specification	
Description	Loosely packed vials in ziplock bags. DIMS: 12.6mm x 82.7mm
Packaging	16 bags per secondary box 27 secondary boxes per tertiary pallet.

Input Level	Image
Primary	
Secondary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

Tertiary



Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.4.6 TK1261 – Greiner Vial

Specification	
Description	Dimension - 13x100mm
Packaging	24 racks of 50pcs. 1200pcs in total

Input Level	Image
Primary	No image available
Secondary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

Tertiary



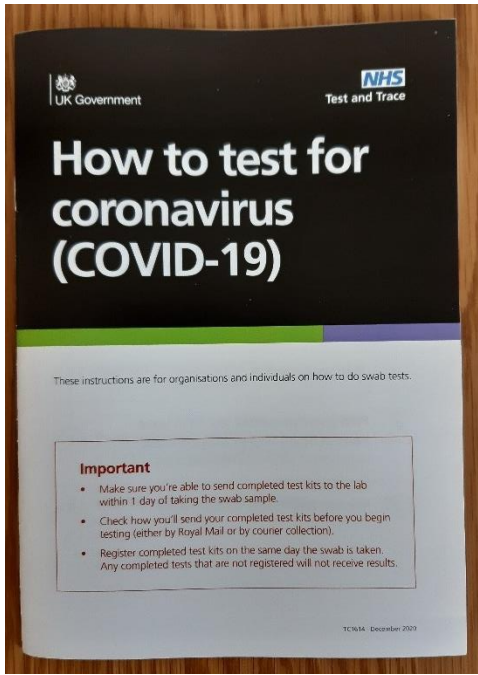
Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.5 OP50 WORK PACKAGE: UID Mark and Dispense IFU Leaflet

A.5.1 TC1614 – User Agnostic IFU

Specification	
Description	User Agnostic IFU – 28 pages, A5 with 2 staples
Packaging	

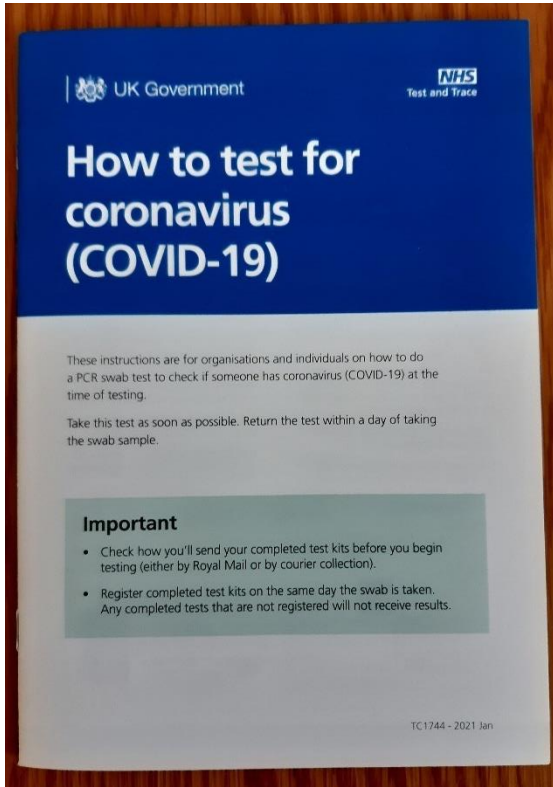
Input Level	Image
Primary	
Secondary	No image available
Tertiary	No image available

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.5.2 TC1744 – Care Home IFU

Specification	
Description	Care Home IFU – 20 pages, A5 with 2 staples
Packaging	

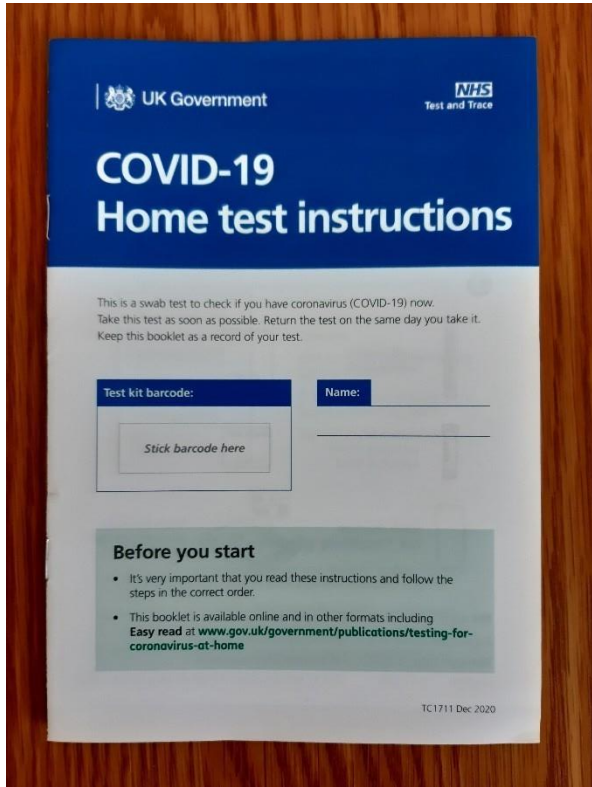
Input Level	Image
Primary	
Secondary	No image available
Tertiary	No image available

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.5.3 TC1711 – Home IFU

Specification	
Description	Home IFU – 12 pages, A5 with 2 staples
Packaging	

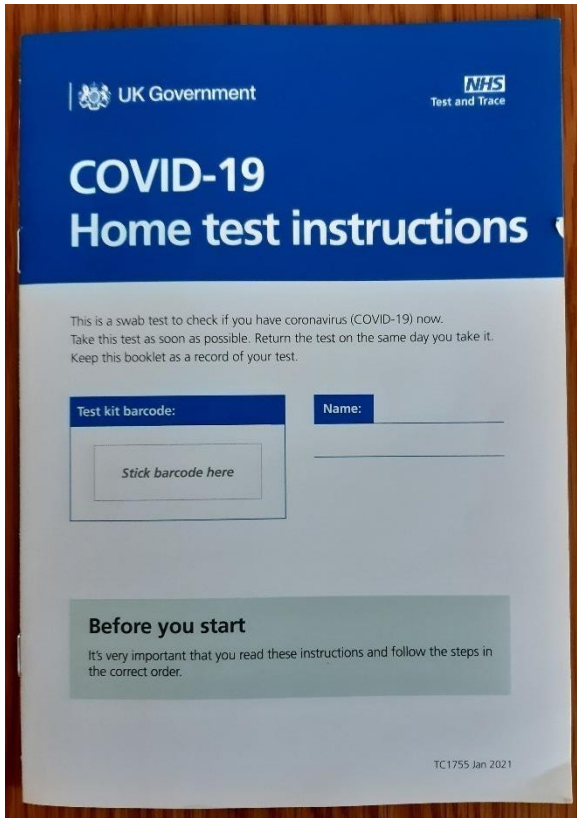
Input Level	Image
Primary	
Secondary	No image available
Tertiary	No image available

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.5.4 TC1755 – Home Test (Oxford Vaccine Trial) IFU

Specification	
Description	Home Test (Oxford Vaccine Trial) IFU – 12 pages, A5 with 2 staples
Packaging	

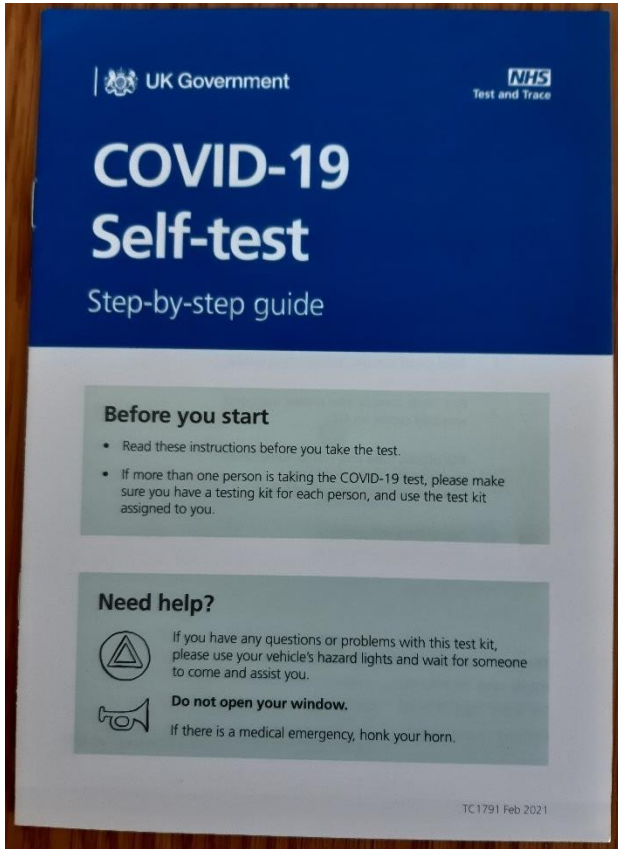
Input Level	Image
Primary	
Secondary	No image available
Tertiary	No image available

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.5.5 TC1791 – RTS IFU

Specification	
Description	RTS IFU – 8 pages, A5 with 2 staples
Packaging	

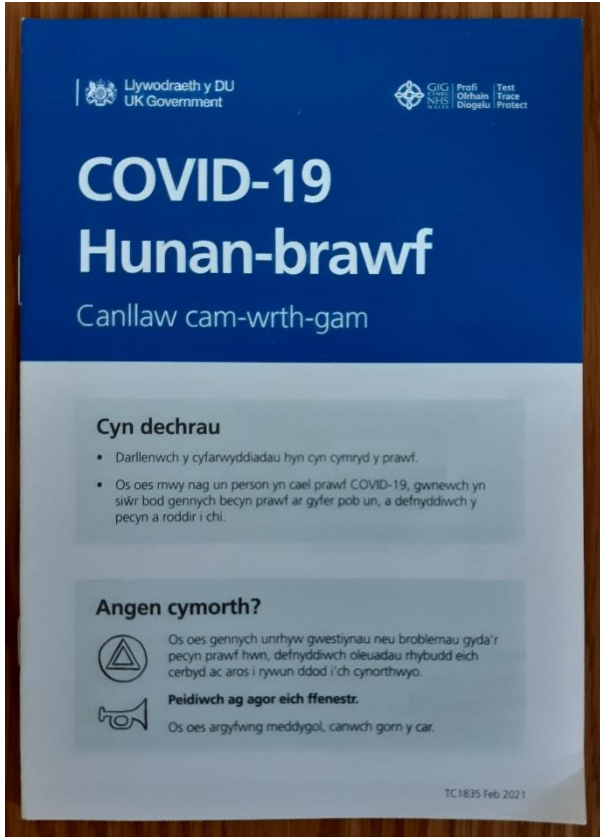
Input Level	Image
Primary	
Secondary	No image available
Tertiary	No image available

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.5.6 TC1835 – RTS (Welsh) IFU

Specification	
Description	RTS (Welsh) IFU – 16 pages, A5 with 2 staples
Packaging	

Input Level	Image
Primary	
Secondary	No image available
Tertiary	No image available



Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.6 OP60 WORK PACKAGE: UID Mark and Dispense Leakproof Pouch

A.6.1 TC1624 – FS95 Leakproof Pouch

Specification	
Description	TC1624 – FS95 Leakproof Pouch DIMS: 200mm x 330mm
Packaging	Leakproof pouch orientated in alternate opposite directions.

Input Level	Image
Primary	
Secondary	
Tertiary	No image available

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.6.2 TC1756 – FS95 (95kPa) Pouch (with Barcode Panel)

Specification	
Description	Pouches all orientated in the same direction. DIMS: 200mm x 330mm
Packaging	96 secondary boxes per tertiary pallet.

Input Level	Image
Primary	
Secondary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296



	
Tertiary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.7 OP70 WORK PACKAGE: Dispense Security Tamper Proof Label

Specification	
Description	16 x rolls per box
Packaging	Incomplete pallet seen, unknown number of secondaries per tertiary.

Input Level	Image
Primary	
Secondary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

Tertiary




Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.8 OP80 WORK PACKAGE: UID Mark and Dispense Test Receipt Card

Specification	
Description	TC1493 – Test Receipt Card DIMS: A5
Packaging	Loosely packaged in box in two separate piles, all orientated the same way. Bubble wrap loosely placed at the top of the box.

Input Level	Image
Primary	 <p>The top photograph shows a single 'Test receipt card' (TC1493) inside its cardboard sleeve. The card is white with green and blue accents. It features the NHS logo and the text 'Test receipt card'. Below the title, there are fields for 'Name', 'Test position', 'Test results', and 'Date of test'. There are also checkboxes for 'Positive', 'Negative', and 'Not tested'. At the bottom, there is a section for 'Notes' and a list of contact numbers for the customer support center.</p> <p>The bottom photograph shows two stacks of these 'Test receipt card' sleeves inside a cardboard box. The sleeves are arranged in two separate piles, and bubble wrap is visible at the top of the box.</p>

Contract for the provision of Outsourced Kitting Production

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Secondary



Tertiary




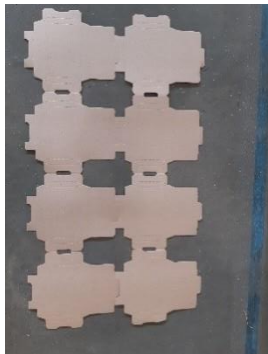

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.9 OP90 WORK PACKAGE

A.9.1 TC1557 – RF95 Easy Assemble Return Box

Specification	
Description	Return box made of thin cardboard, loosely attached to 7 others in single sheet, delicate to move. DIMS: 194mm x 125mm
Packaging	8 x return boxes bound together on perforated edge Stacked on tertiary pallet and wrapped in cellophane.



Input Level	Image
Primary	
Secondary	
Tertiary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.9.2 TC1687 – RO/1K Large Outer Cardboard Box

Specification	
Description	Flat packed cardboard box
Packaging	Laid flat on tertiary pallet and wrapped in cellophane

Input Level	Image
Primary	
Secondary	No image available
Tertiary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.9.3 TC1166 – Return Label

Specification	
Description	Royal Mail Return Label
Packaging	500 labels per roll 50 boxes per pallet

Input Level	Image
Primary	
Secondary	No image available
Tertiary	No image available

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.10 OP100 WORK PACKAGE: UID Check and Flow Wrap

Specification	
Description	TC1121 – RPS2 Outer Mailing Bag DIMS: 305mm x 405mm
Packaging	Postal bag loosely bundled and folded in half. Two bundles per box, each bundle has opposing orientation 32 secondary boxes per tertiary Any replacement of these will need to be latex free and in a latex free environment

Input Level	Image
Primary	
Secondary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

	
Tertiary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

1. INTRODUCTION.



- 1.1 This document is for an automated “**secondary** kitting cell”.
- 1.2 COVID test kitting operations may be broken down into primary kitting (i.e. an individual user kit) and secondary kitting whereby the primary kits are amalgamated into boxes of 40, 50 or 100 and palletised for onward storage and distribution.
- 1.3 The secondary kitting cell will be required to pack all the channels outlined in Schedule 4, but no more than one kit variant at a time. It should be possible to change over from one variant to another with the minimum of disruption to the assembly of kits.

2 LABELLING AND TRACEABILITY

- 2.1 For traceability purposes it is necessary to record which primary kits have been amalgamated into which despatch box and then onto which pallet.
- 2.2 Not used
- 2.3 The Supplier must ensure the equipment is designed to provide full traceability throughout the full production process by adhering to the following:
 - 2.3.1 All incoming bulk components have an assigned batch number (where applicable)
 - 2.3.2 All created test-kits have an assigned batch number and the sub-assembly and/or components within are clearly identified at the batch level.
 - 2.3.3 Any change in item status is recorded systemically and physical segregation performed as necessary.
 - 2.3.4 The Contractor must be able to track and report on the amount of stock at the kitting lines.
 - 2.3.5 All batch traced components in all finished kits must be traceable to original component batch records from the kit patient bar code.

14.5.1 TC1687 – RO/1K Large Outer Cardboard Box




Specification	
Description	Flat packed cardboard box
Packaging	Laid flat on tertiary pallet and wrapped in cellophane

Input Level	Image
Primary	
Secondary	No image available
Tertiary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

14.5.2 TC1176 – Dispatch Box




Specification	
Description	
Packaging	
Input Level	Image
Primary	
Secondary	
Tertiary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

14.6 TC1011 – Tamper Evident Security Seal

Specification	
Description	1000 seals per roll 16 x rolls per box 30 boxes per pallet
Packaging	Incomplete pallet seen, unknown number of secondaries per tertiary.

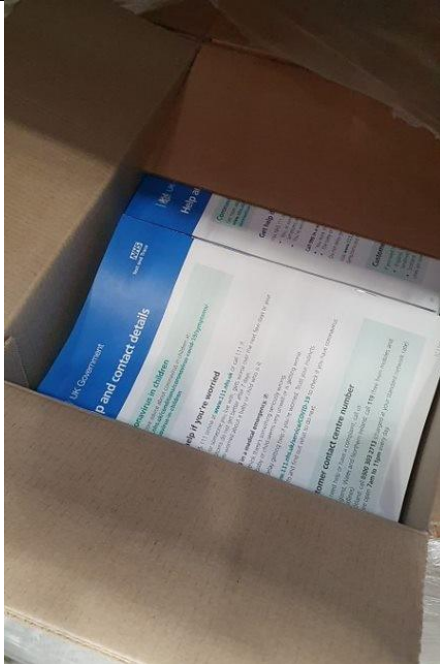
Input Level	Image
Primary	
Secondary	
Tertiary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

14.6.1 TC1545 – Instructions For Use (IFU)

Specification	
Description	440 IFUs per box 84 boxes per pallet
Packaging	Samples to follow

Input Level	Image
Primary	No image available
Secondary	
Tertiary	No image available


Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

14.7 TC1616 – Trace Label

A.11 Primary Kit Labelling

Specification	
Description	DHSC MHRA Labels Roll of labels, one sided with adhesive backing.





Input Level	
Primary	
Secondary	
Tertiary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

14.7.1 TC1545 – Instructions For Use (IFU)

Specification	
Description	Roll of traceability labels, one sided with adhesive backing.
Packaging	4 x rolls per secondary box





Input Level	Image
Primary	
Secondary	 
Tertiary	

Contract for the provision of Outsourced Kitting Production

Contract Reference: C40296

A.12 Primary Kit Labelling

Specification	
Description	TC1616 – Traceability Label Roll of traceability labels, one sided with adhesive backing.
Packaging	4 x rolls per secondary box

Input Level	Image
Primary	
Secondary	 
Tertiary	

Appendix 4



Appendix 5 – Quality/Technical Agreement (QTA)

Parties to the Agreement

Agreement Giver	Agreement Acceptor
Department of Health and Social Care	<u>Company</u> Name
39 Victoria Street, London, SW1H 0EU England	Address Post Code

Department of Health and Social Care Approvals		
Name and Position	Signature	Date
..... QA Manager		
..... Head of Programme Management		

..... Approvals		
Name and Position	Signature	Date
..... Head of Quality		
..... Head of Manufacturing		

3. Scope

4. This Quality/Technical Agreement (QTA) is made and entered into by:
- Department of Health and Social Care (hereafter referred to as **DHSC**) and
 - Company full name (hereafter referred to as Company)

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OFFICIAL

5.

The QTA outlines responsibilities with respect to performing production, shipping, inspection and storage of **DHSC** COVID19 Test kits in accordance with current good manufacturing practices. Both parties are responsible for ensuring that they meet the intent of this QTA.

The QTA takes the form of a detailed list of activities associated with the project. Responsibility for each activity is assigned to either **DHSC** or Company or assigned to both parties. Both parties work collaboratively to establish and maintain quality oversight of contracted operations and materials tested under this agreement.

The services will be provided by Company in accordance with the following applicable regulatory rules and guidance (and subsequent revisions) as applicable to the function of a manufacturing facility.

Applicable Regulatory Rules and Guidance	
The Medical Devices Regulations 2002, UK Statutory Instrument 2002 No 618 Part IV In Vitro Diagnostic Medical Device.	
6.	
7.	

8.

The programme of work will be incorporated into a project plan which shall be approved and signed by both parties.


The QTA applies to the assembly of all COVID19 test kit variants in accordance to DHSC QMS and procedures unless both parties agree in writing upon departures. If there is conflict between this QTA and the content of any other quality instruction, this document will prevail. Amendments, attachments, and additions to this QTA can only be made by mutual consent and must be in writing.

Abbreviations Table


AQL	Acceptable Quality Limit
BS	British Standard
DHSC	Department of Health and Social Care
IQ	Installation Qualification
NCR	Non-Conformance Report
OQ	Operational Qualification
POC	Proof of Concept
PQ	Production Qualification
QC	Quality Control
QTA	Quality Technical Agreement
TC	Test Component
WI	Work Instruction

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Item		Responsibilities	
		<u>Company</u>	DHSC
1	Organisation	<p>Ensure an appropriate certified quality management system is in place and defined in appropriate policies and procedures for the execution of kitting services.</p> <p>Maintain a Quality function independent from all other operations.</p>	Confirm by audit.
2	Personnel	<p>Ensure adequate numbers of personnel, which have appropriate qualifications, training and experience are in place to conduct all operations outlined within this agreement.</p> <p>Make available to DHSC, during audit, current organisational charts.</p> <p>Maintain appropriate records of training to demonstrate competency.</p> <p>Notify DHSC of any changes in key personnel (i.e. Head of Quality, Site Manager, Manufacturing Lead, Project Manager etc.).</p>	<p>Enable adequate provision for scheduling through sufficient visibility of workload.</p> <p>Confirm by audit.</p> <p>Confirm by audit.</p>

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Item	Responsibilities	
	<u>Company</u>	DHSC
3	Facilities, Utilities and Equipment	<p>Ensure the premises, environment, equipment, storage areas and utilities are correctly designed, validated, qualified, calibrated and maintained in accordance with any manufacturers and regulatory requirements to meet the production requirements of the DHSC contract.</p> <p>The facilities shall be of a suitable size and construction to meet the requirements of services and movement of stored goods to minimise disturbances that could interfere with the kitting processes.</p> <p>Ensure that work does not transfer between sites without the agreement of DHSC for whatever reason given, other than what is stipulated in the contract.</p> <p>Ensure that all work surfaces are capable of being regularly cleaned without any detrimental effect to the work surfaces or opportunity for the ingress of dirt or elements that may be detrimental to the sterile properties of the components undergoing assembly.</p> <p>Ensure appropriate controls are in place to preserve traceability of free issue components.</p> <p>Confirm by audit.</p> <p>Confirm by Audit.</p>

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Item	Responsibilities	
	<u>Company</u>	DHSC
4	Materials	<p>Only DHSC approved components can be used and the free issued components are to be utilised in the assembly of kits as identified in latest issue Bill of Materials (BOM) within DHSC documentation unless prior permission has been granted by DHSC to deviate.</p> <p>Where sourcing of a supplier is a <u>Company</u> responsibility, <u>Company</u> will review and approve vendors as suitable for use.</p> <p>Maintain appropriate stocks of materials to ensure continuity within kitting batches.</p> <p>Maintain inventory records for DHSC supplied materials and define critical quantities levels for requesting resupply to allow continuation of kitting on behalf of DHSC.</p> <p>Supply the free issue components as agreed in the latest issue BOM.</p>

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Item		Responsibilities	
		<u>Company</u>	DHSC
5	Component Management	<p>Check incoming components to ensure they correspond to the DHSC instructions.</p> <p>Ensure qualified and appropriate storage of components while in the direct custody of <u>Company</u>.</p> <p>Ensure components are stored and processed under conditions that will prevent unauthorized access, use or cross contamination.</p> <p>Ensure emergency back-up storage locations are available.</p> <p>Components are to be stored in an environment that can maintain the temperature range as stated on the component data sheets.</p> <p>Unused, quarantined and redundant components shall be retained in safe custody and disposal must not be performed without written approval from DHSC.</p>	<p>Notify <u>Company</u> of planned shipment dates. Advise <u>Company</u> of any changes to the shipment dates.</p> <p>Provide a Material Safety Data Sheet and inform <u>Company</u> of any known hazards associated with the product.</p> <p>Confirm by Audit Confirm by Audit</p> <p>Confirm by Audit</p> <p>Authorise disposal/shipment of unused/quarantined/redundant components.</p>

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Item		Responsibilities	
		<u>Company</u>	DHSC
6	Kitting assembly	<p>Perform all kitting processes according to approved/validated procedures with no deviations unless in writing from DHSC.</p> <p>Maintain agreed Work Instructions (WI) for each kit variant in a place where operatives can refer to</p> <p>Ensure that only trained operative perform kitting tasks.</p> <p>Provide Translations of instructions for those who require instructions in their own language.</p> <p>Ensure that any kit items utilised in the kitting have a minimum expiry shelf life as defined by DHSC test kit Shelf life specification before item is incorporated into any kit.</p>	<p>Provide <u>Company</u> with the “Gold” standard for finished kit ready for dispatch.</p> <p>Confirm by Audit</p>
7	Inspection	<p>Provide Quality Control (QC) checks across product assembly lines as appropriate to ensure that the risk of escapes is as low as reasonably practicable.</p> <p>Finished product will be final inspected and failure rates will be determined by the BS6001 AQL tables Inspection Level II with a sample size appropriate to the kitting batch size.</p>	<p>Review and provide feedback on the level of <u>Company</u> QC available to the kitting line.</p> <p>Provide input to the suitability to any training provided by the <u>Company</u> to their QC staff.</p> <p>Provide advice to the <u>Company</u> on the suitability of any BS6001 AQL tables sample size and the selection of defect types.</p>

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Item	Responsibilities	
	<u>Company</u>	DHSC
9	Use of Sub-Contractors	<p>For DHSC projects, <u>Company</u> will only use sub-contractors agreed in advance in writing with DHSC. Assess prior to application to DHSC for permission to outsource for legality, suitability, compliance, and competence to conduct the activity. Ensure by means of a contract that the principles of this QTA are followed. Establish a quality/technical agreement with any sub-contractor allowing provision for DHSC to evaluate. Establish an on-going documented monitoring system of evaluation, approval and maintenance of all sub-contracted work with a DHSC impact.</p>

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Item		Responsibilities	
		<u>Company</u>	DHSC
10	Non-Conformance	<p>Acknowledge a non-conformance and ensure that a Non Conformance Report (NCR) is raised in accordance with the <u>Company</u> QMS within one (1) working day.</p> <p>Complete investigation and close the NCR within thirty (30) calendar days of raising, if feasible, but in any event as soon as possible.</p> <p>Investigate the root cause(s) and implement corrective action(s) and preventative action(s) to address related non-conformance, as appropriate.</p> <p>Maintain a system for managing and recording of non-conformance investigations.</p>	<p>Promptly notify <u>Company</u> of any non-conformance that may be a result of kitting at <u>Company</u>.</p>

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Item		Responsibilities	
		<u>Company</u>	DHSC
11	Change Management	<p>Maintain a Change Control system for the management of change, which could affect kitting (including, but not limited to controlled facilities, processes, services, material storage, equipment, software and inspection).</p> <p>Notify the DHSC representative in writing of their intention to introduce a change to the kitting processes, including change in specification or suppliers use to procure components, to initiate the DHSC Change Control procedure prior to implementation.</p> <p>Raise and document any temporary change controls as required by the specific batch kitting.</p>	<p>Notify <u>Company</u> of necessary changes with regards to documentation, kitting, inspection, storage and shipping of DHSC product in writing prior to implementation. Notification will include supporting documents, justifications, rationale, supporting data and regulatory requirements, as applicable to support justification of <u>Company</u> change control.</p> <p>Review and approve proposed significant changes, such as change to specification, method or equipment and components submitted by <u>Company</u> within time manner upon receipt of such documentation unless otherwise agreed.</p>

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Item	Responsibilities	
	<u>Company</u>	DHSC
12 Customer Complaint and adverse reporting	<p><u>General complaint</u> Acknowledge receipt of a complaint within one (1) working day. Complete and issue investigation report to DHSC within ten (10) working days of receipt of the written notification of the complaint, if feasible, but in any event as soon as possible. Investigate the root cause and implement corrective actions and preventative actions to address related complaints, if appropriate. Maintain a system for managing and recording of complaint investigations.</p> <p><u>Adverse Event (i.e., patient injured)</u> The <u>Company</u> shall forthwith report any Adverse Incidents it becomes aware of, in respect of the Products to DHSC within 3 days. The <u>Company</u> agrees to provide any assistance necessary to comply with any requests made by a Competent Authority to either Party as a result of an Adverse Incident.</p>	<p>Promptly notify <u>Company</u> of any complaints that may be a result of kitting at <u>Company</u> or impact kitting at <u>Company</u>.</p> <p>Reporting of adverse events shall be managed by DHSC</p>

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Item		Responsibilities	
		<u>Company</u>	DHSC
13	Access to kitting areas	DHSC Quality and Operations teams to have full access to manufacturing and warehouse activities for the purpose of assuring adherence to the requirements of ISO 13485:2016 Provide DHSC staff access to office accommodation when required during planned visits. Agree for each kitting site who will grant or otherwise permission for the DHSC staff visit.	Ensure all requests for a visits to the <u>Company</u> are vetted to ensure they are for a valid reason and the number of visitors are kept to a minimum
14	Storage of palletised components	Ensure that the practice of double stacking of palletised components is forbidden regardless of any lack of prohibition markings on the individual pallets. Ensure that product that requires a controlled temperature is stored appropriately in a controlled environment & and notify HDSC of any breaches.	Confirm by audit.
15	Product recall	9. Without prejudice DHSC has right to recall any Products placed on the market, 10. The <u>Company</u> agrees to assist in every way to achieve a clean recall.	Confirm by audit.

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Item		Responsibilities	
		<u>Company</u>	DHSC
16	Rework	Request rework instructions from DHSC before any rework is carried out to recover non-conforming final product.	Issue approved rework Instructions to the <u>Company</u> after any investigation has concluded that rework is appropriate.
17	Quality Alerts	Comply with any Quality Alerts issued by the DHSC . Ensure that all suspect components and/or batches are placed in Quarantine. Quarantine any finished products that may contain any suspect components that are the subject of the Quality Alert. Carry out secondary inspection of quarantined components/batches/finished kits upon receipt of Inspection Instructions from DHSC . Feedback within 1 day (24 hours) the results of any action requested by a Quality Alert, including nil returns.	Review the Quality Alert and raise NCR as required.
18	Daily wastage	Report weekly to the DHSC representative the quantity by TC number of any wastage created from the daily kitting processes.	Review the wastage figures to ensure that they are acceptable for the batch quantities produced

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Item		Responsibilities	
		<u>Company</u>	DHSC
19	Records and Retention	<p>Maintain records for all DHSC kitting activities.</p> <p>Supply DHSC in a timely manner with all relevant documentation and data in order for DHSC to submit or maintain applicable registrations.</p> <p>If copies of documentation are requested by DHSC, the documentation will be labelled for information only and annotated with the following wording “This is a true copy of the original document” signed and dated.</p> <p>Retain the project and batch specific records for a minimum of ten (10) years beyond the expiry of the material.</p> <p>Contact DHSC and obtain written approval prior to destruction, deletion or shipment of DHSC kitting related documentation whether in paper or electronic format.</p>	<p>For records applicable to DHSC kitting DHSC shall authorise deletion or destruction of records at the end of their retention period or instruct transfer of records to DHSC.</p> <p>After the specified records retention period, <u>Company</u> is responsible for all costs associated with the retention, retrieval, onward transfer or destruction/disposal of these materials.</p>

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Item		Responsibilities	
		<u>Company</u>	DHSC
20	New kitting processes	<p>Conduct Design studies for any new processes that may be considered novel and contentious.</p> <p>Carry out any proof of concepts (POC) that may be required to demonstrate the viability of introducing the new process.</p> <p>Create a Project for the introduction of the new process that captures the methodology of IQ, OQ, PQ.</p> <p>Compile the required Protocols for IQ, OQ, PQ and present to DHSC for approval.</p> <p>Compile Validation reports at each stage of the IQ, OQ, PQ and present to DHSC for approval.</p>	<p>Review the <u>Company</u> proposal for the new process and approve any Design Study if suitable.</p> <p>Review the POC presented by the <u>Company</u> and approve if suitable.</p> <p>Nominate suitable DHSC staff for the Project.</p> <p>Review the Protocols presented by the <u>Company</u> and approve if suitable.</p> <p>Review the validation reports presented by the <u>Company</u> and approve if suitable</p>

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Item		Responsibilities	
		<u>Company</u>	DHSC
21	Right to Audit	<p>DHSC</p> <p>Allow DHSC, upon giving reasonable notice, access to carry out a routine quality audit to confirm <u>Company</u> compliance with the obligations defined within this agreement. This is agreed on the basis of an audit of a maximum of two (2) days a year with up to two (2) auditors.</p> <p>Provide accompanied access to all facilities, utilities, documents, records, processes, equipment, systems, raw data and personnel applicable to DHSC</p> <p>Further audits or additional auditors may be accommodated by mutual agreement.</p> <p>Allow DHSC, upon giving reasonable notice, to carry out a root cause analysis.</p> <p>Within thirty (30) days of receiving a written audit report, <u>Company</u> shall respond in writing regarding any items of noncompliance identified by DHSC.</p> <p>11.</p>	<p>Notify <u>Company</u> within a reasonable notice period of intention to audit.</p> <p>Provide a written report of all audit observations within thirty (30) calendar days to <u>Company</u>.</p> <p>Evaluate and confirm acceptability of <u>Company</u> audit response within thirty (30) calendar days of receipt of responses.</p>

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22	NB Right to Audit	<p><u>Notified Body NB</u></p> <p>12. Notified Bodies are required to carry out unannounced inspections. The <u>Company</u> will ensure that they are prepared to receive unannounced inspections and make all information as requested available. Failure to make information available may lead to the termination of this agreement. The <u>Company</u> shall accept all costs associated with hosting the unannounced audit while DHSC shall accept costs billed directly to them by the Notified Body</p> <p>13. The appropriate Competent Authority and, where necessary, the Notified Body retained by the DHSC shall have access, within 10 working days, in order to review and verify all technical documentation relating to the product, as such term is defined in applicable directives, for a term covering the supply period and for five (5) years thereafter. DHSC shall not use or disclose any proprietary information concerning the <u>Company</u>, which may be revealed to it by the Notified Body except in the case of complying with the Directives.</p> <p>14. The <u>Company</u> shall immediately communicate to DHSC, In writing, the result of audits made by the Notified Body who has released the EC mark for</p>	
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UNCONTROLLED IF PRINTED

OFFICIAL
DHSC Form: QP12-Fxx, Revision x, Change: CO-00xx, Effective Date: dd-mmm-yyyy

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Item		Responsibilities	
		<u>Company</u>	DHSC
		maintaining the prescribed condition and also the status of EC certification.	
23	Regulatory Submissions	Provide supporting data and reasonable technical support to any regulatory submission performed by DHSC .	Provide <u>Company</u> with thirty (30) calendar days of a regulatory submission where <u>Company</u> are required to provide supporting data or technical support. Allow <u>Company</u> access to sections of a regulatory support document that specifically details aspects of work performed by <u>Company</u> , where appropriate.
24	Self-Inspection	Manage a regular internal quality audits programme to monitor and ensure compliance with the agreed Applicable Regulatory Rules and Guidance listed on Page 2 of this QTA.	Confirm by audit.
25	Business Continuity	Establish documented plans to maintain integrity of the premises and process if exposed to significant risk.	Confirm by audit.

Glossary

Item	Description
Rework	Correction to Kitting contents of sealed previously sealed kits
Non-Conformance	The non-fulfilment of a specified requirement. Typically, a Non-conformity is identified before the product is released.
Change	Any planned alteration, replacement, inclusion or elimination of critical materials, facilities, equipment or document that has a reasonable potential to impact safety, identity, strength, purity or quality of drug substance or drug product.

Appendix 1

Key Contact Details	
DHSC	<u>Company</u>
Quality	
..... Quality Manager e-mail: Mob: +44 (0) Quality Manager e-mail: Tel. +44 (0)
Technical	
..... Head of Test and Trace e-mail: Mob: +44 (0) Head of e-mail: Tel. +44 (0)
Project Management	
As above for Technical Head of Project Management e-mail: Tel. +44 (0)

Review Period
Three (3) years from the date of final approval signature.

Appendix 6 : Indicative IT/Infrastructure Requirements

The Contractor shall meet the following requirements in order to facilitate use of the Oracle Fusion solution made available by the Authority to the Contractor:

INDICATIVE IT / INFRASTRUCTURE REQUIREMENTS

IT Requirements	Type	Comment
Wi-Fi connectivity	IT	<ul style="list-style-type: none"> •27x7 Wi-Fi connectivity will be required throughout the warehouse. We recommend having a site survey to assess Wi-Fi coverage within the warehouse •RF smart devices will need a static IP to connect to the wi-fi network.
BPSS Cleared staff	Infrastructure / other	•BPSS checks would be required for staff who will be accessing Oracle via browser on a desktop/laptop (e.g. shift managers)
Power at relevant locations	IT	Sufficient power points: <ul style="list-style-type: none"> •Printers •Charging bays for scanners •Laptops •Other equipment
Secure areas to store scanners / printers / accessories	Infrastructure / other	•There should be a secure designated area for storing scanner, printer and accessories. A signing in / out process is also required.
Secured laptops	IT	•Staff should secure their laptop once their shift is over; there should be a formal process for sign in and sign out of the laptop
Racking	Infrastructure / other	•Racking should be installed at the site
Barcodes on racking/ Locators	Infrastructure / other	•Barcodes should be put on the racking. Suppliers to provide locator code structure
Equipment required	Infrastructure / other	• RF Smart Scanners, Printers, Laptops. Typically DHSC provides scanners/printers but open to discussing feasibility of using existing equipment.
Phone Connectivity	Infrastructure / other	•Availability of Phone connectivity to allow support in warehouse/office

SECURITY REQUIREMENTS

DRAFT WIP

- **Physical Security**
 - Secure site complying with identified requirements
- **Network Security**
 - Secure network complying with identified requirements
- **Penetration Testing**
 - Evidence of recent Penetration testing to be presented to DHSC
- **Personnel Security**
 - BPSS cleared staff (only staff required to access Oracle via Laptop/Desktop)
- **Security Controls**
 - Below is a summary of threats for which a comprehensive set of controls and requirements have been established that would need to be met:

Threat types	Threat actors	Threat consequences
<ul style="list-style-type: none"> •Denial of Service •Tampering •Elevation of Privileges •Spoofing •Reputation •Information Disclosure 	<ul style="list-style-type: none"> •State-sponsored hackers •Physical criminals •Disgruntled employees •Cyber criminals •Untrained users •Internal employees •Process failure •Hacktivists 	<ul style="list-style-type: none"> •Comms failure •Physical theft •Unauthorised system use •Comms interception •Malicious code embed •Supply chain compromise •Data manipulation •Data leakage/loss •Operations error

Conditions of Contract for Outsourced Kitting Production

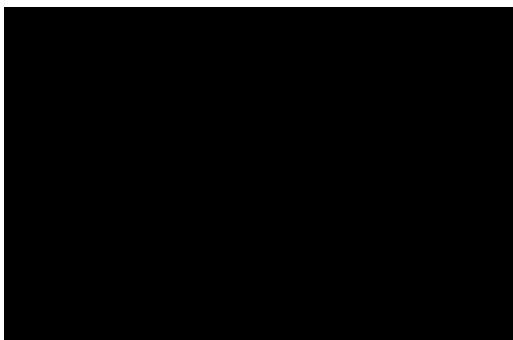
Contract Reference: C40296

Base recommendations from RF-SMART:

- Don't allow the network to use Automatic power and channel selection. The automatic selection is often based on what the Access Points see at the ceiling level, What the device see on the floor might be much different.
- Verify the Access Point power level is less than or equal to the transmit power level of the Mobile Computer. The Rugged Mobile Computers have a lower Transmit power compared to a standard Laptop computer. The Access Point power level should be matched to the device to ensure that the device has enough power to transmit back to the AP.
Usually, the max transmit power level for 2.4 is in the 50-75 Mw and for 5Ghz is 15-40 Mw.
- Verify no overlapping channels. Especially in 2.4 Ghz with limited channel selection, overlapping channels can cause interference.
- On 5Ghz, do NOT use DFS channels if possible. Because of limitations with DFS there can be slowness in how a device roams to DFS channels.
- Minimize the number of SSID's on the network to 4 or fewer. A large number of SSID's can result in more noise which will impact wireless performance.

SCHEDULE 5

Tender



SCHEDULE 6

Pricing

1. DEFINITIONS

In this schedule, the following definitions shall apply:

"Charges" means the charges forming the total Contract Price;

"Delay" means:

- a) a delay in the achievement of a Milestone by its Milestone Date; or
- b) a delay in the design, development, testing or implementation of a Service by the relevant date set out in the Implementation Plan.

"Delay Longstop Date" means forty five (45) days from the relevant Milestone Date;

"Equipment Charges" means the payments agreed between the Authority and the Contractor from time to time in respect of the purchase of Equipment and as at the Commencement Date, are detailed in Table 5 of Appendix 1;

"Facility Charges" means the weekly charge in respect of each assembly line utilised by the Contractor in the provision of the Services as detailed in Table 3 of Appendix 1;

"Fixed Price" means an all-inclusive price that will not change except as expressly stated in this Schedule using an agreed mechanism;

"Milestone" means an event or task described in the Implementation Plan which, if applicable, shall be completed by the relevant Milestone Date and as at the Commencement Date, are detailed in Table 6 of Appendix 1;

"Milestone Payment" means a payment identified in Table 6 of Appendix 1 to be made following written confirmation by the Authority to the Contractor of the achievement of a Milestone;

"Monthly Charges" means the Mothball Charge (calculated on a weekly basis but paid monthly), the Facility Charge (calculated on a weekly basis but paid monthly) and the Volume Charges;

"Mothball Charges" the charges for mothballing Equipment as requested by the Authority;

"Reimbursable Expenses" means reasonable out of pocket travel and subsistence (for example, hotel and food) expenses, properly and necessarily incurred in the performance of the Services, calculated at the rates and in accordance with the Authority's travel and expenses policy current from time to time, but not including:

- a) travel expenses incurred as a result of Contractor Personnel travelling to and from their usual place of work, or to and from the premises at which the Services are principally to be performed, unless the Authority otherwise agrees in advance in writing; and
- b) subsistence expenses incurred by Contractor Personnel whilst performing the Services at their usual place of work, or to and from the premises at which the Services are principally to be performed;

"Service Charge" means the periodic payments made in accordance with this schedule in respect of the supply of the Services designated as such under Appendix 1;

Conditions of Contract for Outsourced Kitting Production

Contract Reference: C40296

"Service Credits" means a sum which the Authority is entitled to deduct or invoice for a failure to meet the Service Levels as specified in Schedule 6 (Pricing) and Schedule 15 (Service Levels);

"Service Period" means a calendar Month, save that:

- a) the first service period shall begin on the Services Commencement Date and shall expire at the end of the calendar month in which the Service Commencement Date falls; and
- b) the final service period shall commence on the first day of the calendar month in which the Term expires or terminates and shall end on the expiry or termination of the Term;

"Supporting Documentation" means sufficient information in writing to enable the Authority reasonably to assess whether the Charges, the Monthly Charges and other sums due from the Authority detailed in the information are properly payable, including copies of any applicable receipts.

"Volume Charges" means the kitting production price per test set out in Table 2 of Appendix 1;

Part 1: Pricing

1. INTRODUCTION

- 1.1 This schedule details the Authority's requirements for the application and management of the Contract Price.
- 1.2 The Contract Price shall be calculated in accordance with the provisions of this Schedule 6.

2. APPLICABLE PRICING MECHANISM

- 2.1 Milestone Payments, Monthly Charges and Service Charges shall be calculated on the basis of the rates and prices specified in Appendix 1 as more particularly set out in this Schedule 6.
- 2.2 Table 6 of Appendix 1 sets out the Milestone Payments.
- 2.3 Table 1 of Appendix 1 sets out which pricing mechanism shall be used to calculate each Service Charge, which shall be one or more of the following:
 - 2.3.1 Not Used;
 - 2.3.2 "Volume Based" pricing, in which case the provisions of paragraph 5 shall apply; or
 - 2.3.3 "Fixed Price" in which case the provisions of paragraph 44 shall apply.

3. NOT USED

4. FIXED PRICE SERVICE CHARGES

- 4.1 Where Table 1 of Appendix 1 indicates that a Service Charge is to be calculated by reference to a Fixed Price pricing mechanism, the relevant Charge shall be the amount set out against that Charge in Tables 3, 4 and 5 respectively of Appendix 1.
- 4.2 The Contractor shall only be entitled to charge the Fixed Price in respect of the items set out in Table 3, 4 and 5 being the Facility Charges, the Mothball Charges and the Equipment Charges (including charges for set up).

Conditions of Contract for Outsourced Kitting Production

Contract Reference: C40296

5. VOLUME BASED SERVICE CHARGES

- 5.1 Where Table 1 of Appendix 1 indicates that a Service Charge is to be calculated by reference to a Volume Based pricing mechanism, the relevant Charges shall be calculated on the basis of the unit costs set out against that Service Charge in Table 2 of Appendix 1.
- 5.2 In the event that the volume of any Services that are to be calculated by reference to a Volume Based pricing mechanism fall outside the relevant volume bands set out against that Service Charge in Table 4 of Appendix 1, the relevant Service Charge shall be calculated in accordance with the Change Control Process.

6. REIMBURSABLE EXPENSES

- 6.1 Where the Authority so agrees in writing the Contractor shall be entitled to be reimbursed by the Authority for Reimbursable Expenses (in addition to being paid the relevant Charges) up to the cap (if any) specified in Schedule 4 (Specification), provided that such Reimbursable Expenses are supported by Supporting Documentation.
- 6.2 The Authority shall provide a copy of its current expenses policy to the Contractor upon request.
- 6.3 Except as expressly set out in paragraph Schedule 66.1, the Charges shall include all costs and expenses relating to the Services and/or the Contractor's performance of its obligations under this Contract and no further amounts shall be payable by the Authority to the Contractor in respect of such performance, including in respect of matters such as:
- 6.3.1 any incidental expenses that the Contractor incurs, including travel, subsistence and lodging, document and report reproduction, shipping, desktop and office equipment costs required by the Contractor Personnel, including network or data interchange costs or other telecommunications Charges; or
 - 6.3.2 any amount for any services provided or costs incurred by the Contractor prior to the Services Commencement Date.

Part 2: Charging Mechanisms

1. MILESTONE PAYMENTS

- 1.1 Subject to the provisions of paragraph 1.1 of part 3 in relation to the deduction of Delay Payments, on the achievement of a Milestone the Contractor shall be entitled to invoice the Authority for the Milestone Payment associated with that Milestone.
- 1.2 Each invoice relating to a Milestone Payment shall be supported by written confirmation from the Authority of achievement of a Milestone.

2. SERVICE CHARGE

- 2.1 Service Charges for completed test kits shall be paid monthly on the basis of the prices in Table 2 of Appendix 1.
- 2.2 Service Charges for facilities shall be paid monthly on the basis of the prices in Table 3 of Appendix 1.
- 2.3 Service Charges for mothballing shall be paid monthly on the basis of the prices in Table 4 of Appendix 1.
- 2.4 Service Charges for the capital equipment listed in Part A of Schedule 21 and set up shall be paid on the basis of the prices in Table 5 of Appendix 1 following written confirmation by the Authority to the Contractor of the achievement of a Milestone.

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- 2.5 Service Charges shall be invoiced by the Contractor for each Service Period in arrears in accordance with the requirements of the Contract.
- 2.6 If a Service Charge is to be calculated by reference to a Fixed Price pricing mechanism and the relevant Service:
- 2.6.1 commences on a day other than the first day of a month; and/or
- 2.6.2 ends on a day other than the last day of a month,
- the Service Charge for the relevant Service Period shall be pro-rated based on the proportion which the number of days in the month for which the Service is provided bears to the total number of days in that month.
- 2.7 Any Service Credits that accrue during a Service Period shall be deducted from the Service Charge payable for the next following Service Period. An invoice for a Service Charge shall not be payable by the Authority unless all adjustments (including Service Credits) for the immediately preceding Service Period have been agreed.
- 2.8 Any overpaid or underpaid amounts in accordance with this paragraph 2 shall be reconciled by an uplift or credit in respect of the applicable amount in the next invoice payable by the Authority.

Re-performance of Services

- 2.9 Where the Contractor is required to re-perform any Services that are not in accordance with applicable specifications or performance indicators, this shall be at no additional cost or expense to the Authority, and the resources required for such re-performance shall not be counted in calculating the Charges payable or resources utilised by the Authority under this Contract.

Monthly Charges

- 2.10 Monthly Charges shall be invoiced by the Contractor for each Month in arrears in accordance with the requirements of the Contract.

Part 3: Adjustments to the Charges

1. NOT USED

2. SERVICE CREDITS

- 2.1 Service Credits shall be calculated by reference to the number of Service Points accrued in any one Service Period pursuant to the provisions of Schedule 15 (Service Levels).
- 2.2 For each Service Period the Service Credit payable shall be a deduction from the Service Charge for the relevant Service Period.
- 2.3 Service Credits are a reduction of the Service Charge payable in respect of the relevant Services to reflect the reduced value of the Services actually received and are stated exclusive of any applicable sales tax.
- 2.4 Service Credits shall be shown as a deduction from the amount due from the Authority to the Contractor in the invoice for the Service Period immediately succeeding the Service Period to which they relate.

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3. CHANGES TO CHARGES

- 3.1 During the Term, any changes to the Charges shall be in accordance with clause 5 of this Contract.
- 3.2 During any extension period, any changes to the Charges shall be in accordance with the Change Control Process. The Authority may request that any Impact Assessment presents Charges without Indexation for the purposes of comparison.

APPENDIX 1: PRICING MECHANISM

1. Table 1: Fixed and volume based prices

Pricing element	Pricing type	Pricing table
Volume Charges (being the kitting production price per test)	Volume Based	2
Facility Charges	Fixed	3
Mothball Charges	Fixed	4
Equipment Charges and set up	Fixed	5

2. Table 2: Volume Charges (being the kitting production price per test)

Test kit channel	Price per test, by elapsed weeks after the Commencement Date (ex VAT)					
	Week 1 to 21	Week 22	Week 23	Week 24	Week 25 to 52	Optional extensions
Physical						
Satellite						
User Agnostic						
Home						

The price per kit includes all costs other than those in Tables 3, 4 and 5.

The price per kit shall be valid for all volumes up to the production capacity of [REDACTED] tests/day.

Optional extension prices are fixed save that the labour element may be increased to cover any increase in the national minimum wage, subject to open book validation.

3. **Table 3: Facility Charges per line**

Line type	Number of lines	Price per week, by elapsed weeks after Commencement Date (ex VAT)		
		Week 1 to 20	Week 21 to 52	Optional extensions
Semi-automated				
Automated				

4. **Table 4: Mothball Charges**

Description	Price
Mothballing Charge per week per line (ex VAT)	

The price shall include all mothballing costs including, but not limited to storage of Equipment, maintenance and servicing of Equipment and any other related costs.

5. **Table 5: Equipment Charges and charges for set up which include all installation and commissioning**

Equipment & set up description	Unit price	Number of units	Total price
Initial phase			
Coding Printers			
Scanners			
Conveyors			
Vision System			
Baging			
Serialisation			
Scara Robot			
Transition Phase			
Linear Conveyors			
Scara Robots			
Full automation phase			
Full automation equipm			

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Grand total	
Total capital equipment and set up price	██████████

6. Table 6: Milestone Payments

Initial and transition phase

Milestone	Payment, ex VAT	Milestone Date (elapsed weeks from Commencement Date)
On completion of line set up, vision system validation and printing solution validation for all lines	██████████	2 weeks
On completion of semi automation validation and pick and pack cell validation for all lines	██████████	4 weeks
On completion of linear conveyer installation and commissioning for all lines	██████████	6 weeks
Completion of IQ, OQ and PQ for all lines	██████████	8 weeks

Fully automated phase

Milestone	Payment, ex VAT	Milestone Date (elapsed weeks from Commencement Date)
On completion of submission of the detailed plan	██████████	1 week
On detailed design approval	██████████	5 weeks
On completion of assembly of all lines	██████████	12 weeks
On completion of factory acceptance testing (FAT) of all lines	██████████	15 weeks
On completion of site acceptance testing (SAT) of all lines	██████████	18 weeks

SCHEDULE 7

Contract monitoring

1. GENERAL PROVISIONS

- 1.1 The Contractor shall provide a proactive Contract manager to ensure that all Service Levels in the Contract are achieved to the highest standard throughout the Term.

2. PRINCIPAL POINTS

- 2.1 The objectives of the Service Levels and Service Credits are to:

- 2.1.1 ensure that the Services are of a consistently high quality and meet the requirements of the Authority;
- 2.1.2 provide a mechanism whereby the Authority can attain meaningful recognition of inconvenience and/or loss resulting from the Contractor's failure to deliver the level of service for which it has contracted to deliver; and
- 2.1.3 incentivise the Contractor to comply with and to expeditiously remedy any failure to comply with the Service Levels.

- 2.2 The Supplier shall attend regular Contract Management meetings as set out below:

Meeting type	Frequency	Purpose	Reporting
Production line project management	Weekly	Review and monitor the progress of the design, procurement, installation and commissioning of production capacity, and resolution or escalation of any issues, risks or delays Design Reviews	<ul style="list-style-type: none"> Weekly progress report, identifying progress against plan and RAID updates. Updated Gantt chart and RAID management plan Expediting reports for any critical path or near critical path components that are forecast for late delivery
Quality	Daily	Review and monitor all quality issues, Quality Alerts; NCR' s, CAPA' s/SCAR' s.	<ul style="list-style-type: none"> Daily QMS reports
Kit production management	Weekly	Review production output against the production plan, agree any changes to the daily and weekly production plan, and address any production issues	<ul style="list-style-type: none"> Previous week' s production KPIs Production output against plan for previous week Forward week' s production plan
Contract/ Performance	Monthly	Review and monitor the commercial aspects of the Services, including:	<ul style="list-style-type: none"> Monthly reporting pack defined in paragraph 3.3 Production reports

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		<ul style="list-style-type: none"> - Status of product line design, installation and transition to full automation - Review of previous month' s actual production against planned production - Review of the monthly submission of the Contracting Authority' s rolling 3-month production forecast - Milestones / deliverables - Performance and service levels - Risks and Issues - Payment - Change requests - Innovation / Improvement - In flight Supplier financial health 	<ul style="list-style-type: none"> • Draft invoices • In flight Supplier financial health metrics
Strategic	Quarterly	Review and monitor the overall performance of the Supplier in the provision of the Services, including strategic forward planning.	

2.3 The content, structure and attendance requirements of these meetings shall be agreed within 5 days of the Commencement Date.

2.4 Attendance at Contract Review meetings shall be at the Supplier' s own expense.

2.5 The Supplier shall produce a Monthly Reporting Pack which includes but is not limited to:

2.5.1 SLA' s/KPI' s;

2.5.2 Service delivery;

2.5.3 Financials;

2.5.4 Risk; and

2.5.5 Customer service.

2.6 The structure, format and content of the reporting pack shall be agreed between the parties.

2.7 The first Monthly Reporting Pack shall be submitted within one Month of the Commencement Date.

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3. SERVICE LEVELS

- 3.1 The Contractor shall monitor its performance of the Contract by reference to the relevant performance criteria for achieving the Service Levels shown in Schedule 15 (Service Levels) (the "Service Level Performance Criteria") and shall send the Authority a Performance Monitoring Report detailing the level of service which was achieved.
- 3.2 The Contractor shall, at all times, provide the Services in such a manner that the Service Levels Performance Measures are achieved.
- 3.3 If the level of performance of the Contractor of any element of the provision by it of the Services during the Term is likely to or fails to meet any Service Level Performance Measure the Contractor shall immediately notify the Authority in writing and the Authority, in its absolute discretion and without prejudice to any other of its rights howsoever arising under the Contract, may:
 - 3.3.1 require the Contractor to immediately take all remedial action that is reasonable to mitigate the impact on the Authority and to rectify or prevent a Service Level Failure from taking place or recurring; and
 - 3.3.2 if a Service Level Failure has occurred, deduct from the Service Charges the applicable Service Level Credits payable by the Contractor to the Authority in accordance with the calculation formula set out in Schedule 15 (Service Levels); or

4. SERVICE CREDITS

- 4.1 The Authority shall use the Performance Monitoring Reports supplied by the Contractor to verify the calculation and accuracy of the Service Credits, if any, applicable to each relevant Service Period.
- 4.2 Service Credits are a reduction of the amounts payable in respect of the Services and do not include VAT.

5. NATURE OF SERVICE CREDITS

- 5.1 The Contractor confirms that it has modelled the Service Credits and has taken them into account in setting the level of the Charges. Both parties agree that the Service Credits are a reasonable method of price adjustment to reflect poor performance.

6. SERVICE CREDIT CAP

- 6.1 For the purposes of the Contract the Service Credit Cap in each Contract Year shall be ten per cent (10%) of the aggregate Monthly Charges paid and payable by the Authority to the Contractor in such Contract Year.

7. PERFORMANCE MONITORING

- 7.1 The provisions of Paragraphs 7 to 9 inclusive provide the methodology for monitoring the provision of the Services:
 - 7.1.1 to ensure that the Contractor is complying with the Service Levels; and
 - 7.1.2 for identifying any failures to achieve Service Levels in the performance of the Contractor and/or provision of the Services ("Performance Monitoring System").
- 7.2 Within seven (7) Working Days of the Commencement Date the Contractor shall provide the Authority with details of how the process in respect of the monitoring and reporting of Service

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Levels will operate between the Parties and the Parties will endeavour to agree such process as soon as reasonably possible.

8. REPORTING OF SERVICE FAILURES

- 8.1 The Contractor shall report all failures to achieve Service Levels to the Customer in accordance with the processes agreed in Paragraph 7.2 above.

9. PERFORMANCE MONITORING AND PERFORMANCE REVIEW

- 9.1 The Contractor shall provide the Authority with performance monitoring reports ("Performance Monitoring Reports") in accordance with the process and timescales agreed pursuant to Paragraph 7.2 above which shall contain, as a minimum, the following information in respect of the relevant Service Period just ended:
- 9.1.1 for each Service Level, the actual performance achieved over the Service Level for the relevant Service Period;
 - 9.1.2 a summary of all failures to achieve Service Levels that occurred during that Service Period;
 - 9.1.3 for any repeat failures, actions taken to resolve the underlying cause and prevent recurrence;
 - 9.1.4 the Service Credits to be applied in respect of the relevant period indicating the failures and Service Levels to which the Service Credits relate; and
 - 9.1.5 such other details as the Authority may reasonably require from time to time.
- 9.2 The Parties shall attend meetings to discuss Performance Monitoring Reports ("Performance Review Meetings") on a monthly basis (unless otherwise agreed). The Performance Review Meetings will be the forum for the review by the Contractor and the Authority of the Performance Monitoring Reports. The Performance Review Meetings shall (unless otherwise agreed):
- 9.2.1 take place within one (1) week of the Performance Monitoring Reports being issued by the Contractor;
 - 9.2.2 take place at such location and time (within normal business hours) as the Authority shall reasonably require unless otherwise agreed in advance;
 - 9.2.3 be attended by the Contractor's Representative and the Authority's Representative; and
 - 9.2.4 be fully minuted by the Contractor. The prepared minutes will be circulated by the Contractor to all attendees at the relevant meeting and also to the Authority's Representative and any other recipients agreed at the relevant meeting. The minutes of the preceding month's Performance Review Meeting will be agreed and signed by both the Contractor's Representative and the Authority's Representative at each meeting.
- 9.3 The Authority shall be entitled to raise any additional questions and/or request any further information regarding any failure to achieve Service Levels.
- 9.4 The Contractor shall provide to the Authority such supporting documentation as the Authority may reasonably require in order to verify the level of the performance by the Contractor and the calculations of the amount of Service Credits for any specified Service Period.

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SCHEDULE 8

Commercially sensitive information

1. The Contractor's pricing and charges as set out in Schedule 6 (Pricing).
2. Information disclosed by the Contractor to the Authority relating to the Contractor's IT system, network and security measures.
3. Information disclosed by the Contractor to the Authority relating to the Contractor's risk management, risk matrix and risk mitigation.

SCHEDULE 9

Variation Form

No of Contract being varied:

.....

Variation Form No:

.....

BETWEEN:

[insert name of Authority] ("the **Authority**")

and

[insert name of Contract] ("the **Contractor**")

1. The Contract is varied as follows and shall take effect on the date signed by both Parties:
[Insert details of the Variation]
2. Words and expressions in this Variation shall have the meanings given to them in the Contract.
3. The Contract, including any previous Variations, shall remain effective and unaltered except as amended by this Variation.

Signed by an authorised signatory for and on behalf of the Authority

Signature

Date

Name (in Capitals)

Address

Signed by an authorised signatory to sign for and on behalf of the Contractor

Signature

Date

Name (in Capitals)

Address

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SCHEDULE 10

Staff Transfer

1. DEFINITIONS

In this Schedule, the following definitions shall apply:

Admission Contract	the agreement to be entered into by which the Contractor agrees to participate in the Schemes as amended from time to time.
Eligible Employee	any Fair Deal Employee who at the relevant time is an eligible employee as defined in the Admission Contract.
Contractor's Final Contractor Personnel List	a list provided by the Contractor of all Contractor Personnel who will transfer under the Employment Regulations on the Relevant Transfer Date.
Contractor's Provisional Contractor Personnel List	a list prepared and updated by the Contractor of all Contractor Personnel who are engaged in or wholly or mainly assigned to the provision of the Services or any relevant part of the Services which it is envisaged as at the date of such list will no longer be provided by the Contractor.
Fair Deal Employees	those Transferring Authority Employees who are on the Relevant Transfer Date entitled to the protection of New Fair Deal and any Transferring Former Contractor Employees who originally transferred pursuant to a Relevant Transfer under the Employment Regulations (or the predecessor legislation to the Employment Regulations), from employment with a public sector employer and who were once eligible to participate in the Schemes and who at the Relevant Transfer Date become entitled to the protection of New Fair Deal.
Former Contractor	a supplier supplying services to the Authority before the Relevant Transfer Date that are the same as or substantially similar to the Services (or any part of the Services) and shall include any sub-contractor of such supplier (or any sub-contractor of any such sub-contractor);
New Fair Deal	the revised Fair Deal position set out in the HM Treasury guidance: "Fair Deal for staff pensions: staff transfer from central government" issued in October 2013.
Notified Sub-contractor	a Sub-contractor identified in the Annex to this Schedule to whom Transferring Authority Employees and/or Transferring Former Contractor Employees will transfer on a Relevant Transfer Date.
Replacement Sub-contractor	a sub-contractor of the Replacement Contractor to whom Transferring Contractor Employees will transfer on a Service Transfer Date (or any sub-contractor of any such subcontractor).
Relevant Transfer	a transfer of employment to which the Employment Regulations applies.
Relevant Transfer Date	in relation to a Relevant Transfer, the date upon which the Relevant Transfer takes place.

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Schemes	the Principal Civil Service Pension Scheme available to employees of the civil service and employees of bodies under the Superannuation Act 1972, as governed by rules adopted by Parliament; the Partnership Pension Account and its (i) Ill health Benefits Scheme and (ii) Death Benefits Scheme; the Civil Service Additional Voluntary Contribution Scheme; and the 2015 New Scheme (with effect from a date to be notified to the Contractor by the Minister for the Cabinet Office).
Service Transfer	any transfer of the Services (or any part of the Services), for whatever reason, from the Contractor or any Sub-contractor to a Replacement Contractor or a Replacement Sub-contractor.
Service Transfer Date	the date of a Service Transfer.
Staffing Information	<p>in relation to all persons identified on the Contractor's Provisional Contractor Personnel List or Contractor's Final Contractor Personnel List, as the case may be, such information as the Authority may reasonably request (subject to all applicable provisions of the Data Protection Legislation), but including in an anonymised format:</p> <ul style="list-style-type: none"> (a) their ages, dates of commencement of employment or engagement and gender; (b) details of whether they are employed, self-employed contractors or consultants, agency workers or otherwise; (c) the identity of the employer or relevant contracting Party; (d) their relevant contractual notice periods and any other terms relating to termination of employment, including redundancy procedures, and redundancy payments; (e) their wages, salaries and profit sharing arrangements as applicable; (f) details of other employment-related benefits, including (without limitation) medical insurance, life assurance, pension or other retirement benefit schemes, share option schemes and company car schedules applicable to them; (g) any outstanding or potential contractual, statutory or other liabilities in respect of such individuals (including in respect of personal injury claims); (h) details of any such individuals on long term sickness absence, parental leave, maternity leave or other authorised long term absence; (i) copies of all relevant documents and materials relating to such information, including copies of relevant contracts of employment (or relevant standard contracts if applied generally in respect of such employees); and (j) any other employee liability information as such term is defined in Regulation 11 of the Employment Regulations.

Transferring Authority Employees	those employees of the Authority to whom the Employment Regulations will apply on the Relevant Transfer Date;
Transferring Former Contractor Employees	in relation to a Former Contractor, those employees of the Former Contractor to whom the Employment Regulations will apply on the Relevant Transfer Date;
Transferring Contractor Employees	those employees of the Contractor and/or the Contractor's Sub-contractors to whom the Employment Regulations will apply on the Service Transfer Date.

2. INTERPRETATION

Where a provision in this Schedule imposes an obligation on the Contractor to provide an indemnity, undertaking or warranty, the Contractor shall procure that each of its Sub-contractors shall comply with such obligation and provide such indemnity, undertaking or warranty to the Authority, Former Contractor, Replacement Contractor or Replacement Sub-contractor, as the case may be.

PART A

Not Used

PART B

Not Used

PART C

No transfer of employees at commencement of Services

1. PROCEDURE IN THE EVENT OF TRANSFER

- 1.1 The Authority and the Contractor agree that the commencement of the provision of the Services or of any part of the Services will not be a Relevant Transfer in relation to any employees of the Authority and/or any Former Contractor.
- 1.2 If any employee of the Authority and/or a Former Contractor claims, or it is determined in relation to any employee of the Authority and/or a Former Contractor, that his/her contract of employment has been transferred from the Authority and/or the Former Contractor to the Contractor and/or any Sub-contractor pursuant to the Employment Regulations or the Acquired Rights Directive then:
- 1.2.1 the Contractor shall, and shall procure that the relevant Sub-contractor shall, within five (5) Working Days of becoming aware of that fact, give notice in writing to the Authority and, where required by the Authority, give notice to the Former Contractor; and
- 1.2.2 the Authority and/or the Former Contractor may offer (or may procure that a third party may offer) employment to such person within fifteen (15) Working Days of the notification by the Contractor or the Sub-contractor (as appropriate) or take such other reasonable steps as the Authority or Former Contractor (as the case may be) considers appropriate to deal with the matter provided always that such steps are in compliance with applicable Law.
- 1.3 If an offer referred to in Paragraph 1.2(b) is accepted (or if the situation has otherwise been resolved by the Authority and/or the Former Contractor), the Contractor shall, or shall procure that the Sub-contractor shall, immediately release the person from his/her employment or alleged employment.
- 1.4 If by the end of the fifteen (15) Working Day period specified in Paragraph 1.2(b):
- 1.4.1 no such offer of employment has been made;
- 1.4.2 such offer has been made but not accepted; or
- 1.4.3 the situation has not otherwise been resolved,
- the Contractor and/or the Sub-contractor may within five (5) Working Days give notice to terminate the employment or alleged employment of such person.

2. INDEMNITIES

- 2.1 Subject to the Contractor and/or the relevant Sub-contractor acting in accordance with the provisions of Paragraphs 1.2 to 1.4 and in accordance with all applicable employment procedures set out in applicable Law and subject also to Paragraph 2.4, the Authority shall:
- 2.1.1 indemnify the Contractor and/or the relevant Sub-contractor against all Employee Liabilities arising out of the termination of the employment of any employees of the Authority referred to in Paragraph 1.2 made pursuant to the provisions of Paragraph 1.4 provided that the Contractor takes, or shall procure that the Notified Sub-contractor takes, all reasonable steps to minimise any such Employee Liabilities; and
- 2.1.2 procure that the Former Contractor indemnifies the Contractor and/or any Notified Sub-contractor against all Employee Liabilities arising out of termination of the employment of the employees of the Former Contractor made pursuant to the

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provisions of Paragraph 1.4 provided that the Contractor takes, or shall procure that the relevant Sub-contractor takes, all reasonable steps to minimise any such Employee Liabilities.

- 2.2 If any such person as is described in Paragraph 1.2 is neither re employed by the Authority and/or the Former Contractor as appropriate nor dismissed by the Contractor and/or any Sub-contractor within the fifteen (15) Working Day period referred to in Paragraph 1.4 such person shall be treated as having transferred to the Contractor and/or the Sub-contractor (as appropriate) and the Contractor shall, or shall procure that the Sub-contractor shall, comply with such obligations as may be imposed upon it under Law.
- 2.3 Where any person remains employed by the Contractor and/or any Sub-contractor pursuant to Paragraph 2.2, all Employee Liabilities in relation to such employee shall remain with the Contractor and/or the Sub-contractor and the Contractor shall indemnify the Authority and any Former Contractor, and shall procure that the Sub-contractor shall indemnify the Authority and any Former Contractor, against any Employee Liabilities that either of them may incur in respect of any such employees of the Contractor and/or employees of the Sub-contractor.
- 2.4 The indemnities in Paragraph 2.1:
- 2.4.1 shall not apply to:
- (a) any claim for:
- (i) discrimination, including on the grounds of sex, race, disability, age, gender reassignment, marriage or civil partnership, pregnancy and maternity or sexual orientation, religion or belief; or
- (ii) equal pay or compensation for less favourable treatment of part-time workers or fixed-term employees,
- in any case in relation to any alleged act or omission of the Contractor and/or any Sub-contractor; or
- (b) any claim that the termination of employment was unfair because the Contractor and/or any Sub-contractor neglected to follow a fair dismissal procedure; and
- 2.4.2 shall apply only where the notification referred to in Paragraph 1.2.1 is made by the Contractor and/or any Sub-contractor to the Authority and, if applicable, Former Contractor within six (6) Months of the Services Commencement Date.

3. PROCUREMENT OBLIGATIONS

Where in this Part C the Authority accepts an obligation to procure that a Former Contractor does or does not do something, such obligation shall be limited so that it extends only to the extent that the Authority's contract with the Former Contractor contains a contractual right in that regard which the Authority may enforce, or otherwise so that it requires only that the Authority must use reasonable endeavours to procure that the Former Contractor does or does not act accordingly.

PART D

Employment exit provisions

1. INFORMATION PROVISION OBLIGATIONS

1.1 The Contractor agrees that within twenty (20) Working Days of the earliest of:

- 1.1.1 receipt of a notification from the Authority of a Service Transfer or intended Service Transfer;
- 1.1.2 receipt of the giving of notice of early termination of this Contract;
- 1.1.3 the date which is three (3) Months before the end of the Term; and
- 1.1.4 receipt of a written request of the Authority at any time (provided that the Authority shall only be entitled to make one such request in any six (6) Month period),

it shall provide in a suitably anonymised format so as to comply with the Data Protection Legislation, the Contractor's Provisional Contractor Personnel List, together with the Staffing Information in relation to the Contractor's Provisional Contractor Personnel List and it shall provide an updated Contractor's Provisional Contractor Personnel List at such intervals as are reasonably requested by the Authority.

1.2 At least twenty (20) Working Days prior to the Service Transfer Date, the Contractor shall provide to the Authority or at the direction of the Authority to any Replacement Contractor and/or any Replacement Sub-contractor:

- 1.2.1 the Contractor's Final Contractor Personnel List, which shall identify which of the Contractor Personnel are Transferring Contractor Employees; and
- 1.2.2 the Staffing Information in relation to the Contractor's Final Contractor Personnel List (insofar as such information has not previously been provided).

1.3 The Authority shall be permitted to use and disclose information provided by the Contractor under Paragraphs 1.1 and 1.2 for the purpose of informing any prospective Replacement Contractor and/or Replacement Sub-contractor.

1.4 The Contractor warrants, for the benefit of the Authority, any Replacement Contractor, and any Replacement Sub-contractor that all information provided pursuant to Paragraphs 1.1 and 1.2 shall be true and accurate in all material respects at the time of providing the information.

1.5 From the date of the earliest event referred to in Paragraph 1.1.1, 1.1.2 and 1.1.3, the Contractor agrees, that it shall not, and agrees to procure that each Sub-contractor shall not, assign any person to the provision of the Services who is not listed on the Contractor's Provisional Contractor Personnel List and shall not without the approval of the Authority (not to be unreasonably withheld or delayed):

- 1.5.1 replace or re-deploy any Contractor Personnel listed on the Contractor Provisional Contractor Personnel List other than where any replacement is of equivalent grade, skills, experience and expertise and is employed on the same terms and conditions of employment as the person he/she replaces;
- 1.5.2 make, promise, propose or permit any material changes to the terms and conditions of employment of the Contractor Personnel (including any payments connected with the termination of employment);

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- 1.5.3 increase the proportion of working time spent on the Services (or the relevant part of the Services) by any of the Contractor Personnel save for fulfilling assignments and projects previously scheduled and agreed;
- 1.5.4 introduce any new contractual or customary practice concerning the making of any lump sum payment on the termination of employment of any employees listed on the Contractor's Provisional Contractor Personnel List;
- 1.5.5 increase or reduce the total number of employees so engaged, or deploy any other person to perform the Services (or the relevant part of the Services); or
- 1.5.6 terminate or give notice to terminate the employment or contracts of any persons on the Contractor's Provisional Contractor Personnel List save by due disciplinary process,

and shall promptly notify, and procure that each Sub-contractor shall promptly notify, the Authority or, at the direction of the Authority, any Replacement Contractor and any Replacement Sub-contractor of any notice to terminate employment given by the Contractor or relevant Sub-contractor or received from any persons listed on the Contractor's Provisional Contractor Personnel List regardless of when such notice takes effect.

- 1.6 During the Term, the Contractor shall provide, and shall procure that each Sub-contractor shall provide, to the Authority any information the Authority may reasonably require relating to the manner in which the Services are organised, which shall include:
 - 1.6.1 the numbers of employees engaged in providing the Services;
 - 1.6.2 the percentage of time spent by each employee engaged in providing the Services; and
 - 1.6.3 a description of the nature of the work undertaken by each employee by location.
- 1.7 The Contractor shall provide, and shall procure that each Sub-contractor shall provide, all reasonable cooperation and assistance to the Authority, any Replacement Contractor and/or any Replacement Sub-contractor to ensure the smooth transfer of the Transferring Contractor Employees on the Service Transfer Date including providing sufficient information in advance of the Service Transfer Date to ensure that all necessary payroll arrangements can be made to enable the Transferring Contractor Employees to be paid as appropriate. Without prejudice to the generality of the foregoing, within five (5) Working Days following the Service Transfer Date, the Contractor shall provide, and shall procure that each Sub-contractor shall provide, to the Authority or, at the direction of the Authority, to any Replacement Contractor and/or any Replacement Sub-contractor (as appropriate), in respect of each person on the Contractor's Final Contractor Personnel List who is a Transferring Contractor Employee:
 - 1.7.1 the most recent Month's copy pay slip data;
 - 1.7.2 details of cumulative pay for tax and pension purposes;
 - 1.7.3 details of cumulative tax paid;
 - 1.7.4 tax code;
 - 1.7.5 details of any voluntary deductions from pay; and
 - 1.7.6 bank/building society account details for payroll purposes.

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2. EMPLOYMENT REGULATIONS EXIT PROVISIONS

- 2.1 The Authority and the Contractor acknowledge that subsequent to the commencement of the provision of the Services, the identity of the provider of the Services (or any part of the Services) may change (whether as a result of termination of this Contract or otherwise) resulting in the Services being undertaken by a Replacement Contractor and/or a Replacement Sub-contractor.
- 2.2 The Authority and the Contractor agree that such change in the identity of the supplier of such services shall not constitute a Relevant Transfer to which the Employment Regulations and/or the Acquired Rights Directive will apply.
- 2.3 If, contrary to the understanding and intention of the parties, it is found or alleged that there is a Relevant Transfer which means that the contract of employment of any Transferring Contractor Employee shall transfer to the Authority and/or any Replacement Contractor and/or a Replacement Sub-contractor, the Contractor shall subject also to paragraph 2.4 below indemnify the Authority and/or any Replacement Contractor and/or a Replacement Sub-contractor against all and any Employee Liabilities arising out of the termination of the employment of any such Transferring Contractor Employee provided that the Authority takes and procures as applicable that the Replacement Contractor and/or a Replacement Sub-contractor take all reasonable steps to minimise any such Employee Liabilities.
- 2.4 The indemnity in Paragraph 2.3:
- 2.4.1 shall not apply to:
- (a) any claim for:
- (iii) discrimination, including on the grounds of sex, race, disability, age, gender reassignment, marriage or civil partnership, pregnancy and maternity or sexual orientation, religion or belief; or
- (iv) equal pay or compensation for less favourable treatment of part-time workers or fixed-term employees,
- in any case in relation to any alleged act or omission of the Authority and/or any Replacement Contractor and/or a Replacement Sub-contractor; or
- (b) any claim that the termination of employment was unfair because the Authority and/or any Replacement Contractor and/or a Replacement Sub-contractor; neglected to follow a fair dismissal procedure; and
- 2.4.2 shall apply in respect of claims to be indemnified made within six (6) Months of the date of the Relevant Transfer.

ANNEX: LIST OF NOTIFIED SUB-CONTRACTORS

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SCHEDULE 11

Key Personnel

Key Role	Name of Key Personnel	Responsibilities / Authorities	Minimum period in Key Role
Contract/ Account manager	██████████	COO	
Service Delivery Manager	██████████	COO	
Director/ CEO	██████████	CEO	

SCHEDULE 12

Exit plan and service transfer arrangements

1. DEFINITIONS

In this Schedule, the following definitions shall apply:

Registers	the registers and database referred to in Paragraph 4.2.1 and Paragraph 4.2.2 of this Schedule 12;
Transitional Assistance Notice	has the meaning set out in Paragraph 5.1 of this Schedule 12;
Transitional Period	has the meaning set out in Paragraph 5.1.3 of this Schedule 12.

2. PURPOSE OF SCHEDULE

- 2.1** The Contractor is required to ensure the orderly transition of the Services from the Contractor to the Authority or any Replacement Contractor in the event of any termination (including partial termination) or expiry of this Contract. This Schedule sets out the principles of the exit and service transition arrangements which are intended to achieve this and upon which the Exit Plan shall be based.
- 2.2** For the avoidance of doubt the Contractor is responsible for the overall management of the exit and Service transfer arrangements.

3. EXIT

- 3.1** The Exit Plan shall:
- 3.1.1** address each of the issues set out in this Schedule 12 to facilitate the transition of the Services from the Contractor to the Replacement Contractor and/or the Authority and shall ensure that there is no disruption in the supply of the Services and no deterioration in the quality of delivery of the Services;
 - 3.1.2** detail how the Services will transfer to the Replacement Contractor and/or the Authority including details of the processes, documentation, data transfer, systems migration, security and the segregation of the Authority's technology components from any technology components run by the Contractor or any of its Sub-contractors (where applicable);
 - 3.1.3** specify the scope of the Transitional Assistance Services that may be required by the Authority, any charges that would be payable for the provision of Transitional Assistance Services and detail how such services would be provided (if required) during the Termination Period;
 - 3.1.4** provide a timetable and identify critical issues for carrying out the Transitional Assistance Services; and
 - 3.1.5** set out the management structure to be put in place and employed during the Termination Period.
- 3.2** The Supplier shall provide to the Authority within two (2) Months of the Commencement Date a comprehensive Exit Plan which shall address each of the issues set out in Paragraph 3.1 above.

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4. OBLIGATIONS DURING THE TERM

- 4.1 The Contractor and the Authority shall each appoint an exit manager and provide written notification of such appointment to each other within six (6) Months after the Commencement Date. The Contractor's exit manager shall be responsible for ensuring that the Contractor and its employees, agents and Sub-contractors comply with this Schedule. The Contractor shall ensure that its exit manager has the requisite authority to arrange and procure any resources of the Contractor as are reasonably necessary to enable the Contractor to comply with this Paragraph 4.1. The exit managers shall liaise with one another in relation to all issues relevant to termination or expiry and all matters connected with this Schedule 12 and each Party's compliance with it.
- 4.2 During the Term, the Contractor shall:
- 4.2.1 create and maintain a register of:
 - (a) all assets, detailing their ownership status; and
 - (b) all Sub-contracts and other agreements required to perform the Services;
 - 4.2.2 create and maintain a database setting out the Contractor's technical infrastructure through which the Services are delivered. Such database shall be capable of allowing staff of the Replacement Contractor and/or the Authority to acquire sufficient technical understanding of how the Contractor provides the Services to ensure the smooth transition of the Services with the minimum of disruption; and
 - 4.2.3 at all times keep the Registers up to date and shall maintain copies of any agreements referred to in any Register.
- 4.3 The Parties shall agree the format of the Registers as part of the process of agreeing the first Exit Plan.
- 4.4 At the same time as the Contractor submits a revised Exit Plan, it shall also submit to the Authority up-to-date Registers.
- 4.5 On reasonable notice, the Contractor shall provide to the Authority and/or to its Replacement Contractor (subject to the Replacement Contractor entering into reasonable written confidentiality undertakings with the Contractor), such material and information as the Authority shall reasonably require in order to facilitate the preparation by the Authority of any invitation to tender and/or to facilitate any potential Replacement Contractor undertaking due diligence.

5. TRANSITIONAL ASSISTANCE SERVICES

- 5.1 The Authority shall be entitled to require the provision of Transitional Assistance Services by sending the Contractor a notice to that effect (**Transitional Assistance Notice**) at any time prior to termination or expiry. The Transitional Assistance Notice shall specify:
- 5.1.1 the date from which Transitional Assistance Services are required;
 - 5.1.2 the nature and extent of the Transitional Assistance Services required; and
 - 5.1.3 the period during which it is anticipated that Transitional Assistance Services will be required (**Transitional Period**) (which shall continue no longer than one (1) Month after the date that the Contractor ceases to provide the Services or, in the event that a Termination Period is specified by the Authority, no longer than the end of the Termination Period).

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- 5.2 The Authority shall have an option to extend the Transitional Period beyond the period specified in the Transitional Assistance Notice by written notice to the Contractor provided that such extension shall not extend beyond one (1) Month after the expiry of the period referred to in Paragraph 5.1.3 of this Schedule 12.
- 5.3 The Authority shall have the right to terminate its requirement for Transitional Assistance Services by serving not less than twenty (20) days' notice upon the Contractor to such effect.
- 5.4 The Transitional Assistance Services shall be provided in good faith and in accordance with Good Industry Practice.
- 5.5 During the Transitional Period, the Contractor shall, in addition to providing the Services and the Transitional Assistance Services, provide to the Authority any reasonable assistance requested by the Authority to allow the Services to continue without interruption and to facilitate the orderly transfer of the Services. The Contractor shall use all reasonable endeavours to reallocate resources to provide these services without additional costs. However if this is not possible, any additional reasonable costs incurred by the Contractor in this regard which are not already in the scope of the Transitional Assistance Services or the Exit Plan shall be provided on a time-and-materials basis in accordance with the applicable rates set out in **Error! Reference source not found.** and subject to agreement under the Change Control Process.
- 5.6 The Authority and the Contractor acknowledge that the transition of the Services to the Replacement Contractor may be phased over a period of time so that certain identified Services are transferred to the Replacement Contractor before others.
- 5.7 The Authority shall, at the Contractor's reasonable request, require the Replacement Contractor and any agent or personnel of the Replacement Contractor, to enter into an appropriate confidentiality undertaking with the Contractor.
- 5.8 The Contractor shall comply with all of its obligations contained in the Exit Plan.
- 5.9 From the date six (6) Months before expiry or from the service by either Party of any Termination Notice (whichever is the earlier) and during any Termination Period, the Contractor shall not terminate or vary in any material respect any Transferable Contract without the Authority's prior written consent, such consent not to be unreasonably withheld or delayed.
- 5.10 The Contractor shall comply with all of its obligations regarding its personnel in accordance with Paragraph 6 of Schedule 1 and **Error! Reference source not found.**
- 5.11 Upon termination or expiry (as the case may be) or upon expiration of the Termination Period or, provided that it does not have an adverse impact on the ability of the Contractor to provide the Services or the Transitional Assistance Services at any time during the Termination Period (as the Authority shall require):
 - 5.11.1 the Contractor shall cease to use the Authority Data and, at the direction of the Authority either:
 - (a) provide the Authority or Replacement Contractor with a complete and uncorrupted version of the Authority Data in electronic form (or such other format as reasonably required by the Authority); or
 - (b) destroy (including removal from any hard disk) or return (at the Authority's option) all copies of the Authority Data not required to be retained by the Contractor for statutory compliance purposes and confirm in writing that such destruction has taken place;

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- 5.11.2 the Contractor shall erase from any computers, storage devices and storage media that are to be retained by the Contractor after the end of the Termination Period any software containing the Intellectual Property Rights owned by the Authority;
- 5.11.3 the Contractor shall return to the Authority such of the following as are in the Contractor's possession or control:
 - (a) all materials created by the Contractor under this Contract, the Intellectual Property Rights in which are owned by the Authority;
 - (b) the Equipment together with any other equipment which belongs to the Authority; and
 - (c) any items that have been on-charged to the Authority, such as consumables;
- 5.11.4 the Contractor shall vacate any Authority's Premises; and
- 5.11.5 each Party shall return to the other Party all Confidential Information of the other Party and shall certify that it does not retain the other Party's Confidential Information.
- 5.12 The Transitional Assistance Services to be provided by the Contractor shall include (without limitation) such of the following services as the Authority may specify:
 - 5.12.1 providing assistance and expertise as necessary to examine all operational and business processes (including all supporting documentation) in place and re-writing and implementing processes and procedures such that they are appropriate for use by the Authority or Replacement Contractor after the end of the Termination Period;
 - 5.12.2 providing details of work volumes and staffing requirements over the preceding twelve (12) Months;
 - 5.12.3 analysing and providing information about capacity and performance requirements, processor requirements and bandwidth requirements, and known planned requirements for capacity growth;
 - 5.12.4 transferring all training material and providing appropriate training to those Authority and/or Replacement Contractor staff responsible for internal training in connection with the provision of the Services;
 - 5.12.5 providing for transfer to the Authority and/or the Replacement Contractor of all knowledge reasonably required for the provision of the Services which may, as appropriate, include information, records and documents; and
- 5.13 answering all reasonable questions from the Authority and/or the Replacement Contractor regarding the Services.

SCHEDULE 13

Processing, Personal Data and Data Subjects

Annex 1 – Processing Personal Data

This Schedule shall be completed by the Controller, who may take account of the view of the Processors, however the final decision as to the content of this Schedule shall be with the Controller at its absolute discretion.

- 1.1.1 The contact details of the Authority's Data Protection Officer are: Lee Cramp (ODPO@dhsc.gov.uk)
- 1.1.2 The contact details of the Contractor's Data Protection Officer are: Karen Nicol
- 1.1.3 The Processor shall comply with any further written instructions with respect to processing by the Controller.
- 1.1.4 Any such further instructions shall be incorporated into this Schedule.

Description	Details
Identity of Controller for each Category of Personal Data	<p><i>The Authority is Controller and the Contractor is Processor</i></p> <p><i>The Parties are Independent Controllers of Personal Data</i></p> <p><i>The Parties acknowledge that they are Independent Controllers for the purposes of the Data Protection Legislation in respect of:</i></p> <ul style="list-style-type: none">• <i>Business contact details of Contractor Personnel,</i>• <i>Business contact details of any directors, officers, employees, agents, consultants and contractors of the Authority (excluding the Contractor Personnel) engaged in the performance of the Authority's duties under this Agreement).</i>
Subject matter of the processing	<i>Business contact details are required for operation purposes and review Service Levels</i>
Duration of the processing	<i>Processing will take place for the duration of the Term</i>
Nature and purposes of the processing	<i>Collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of data (whether or not by automated means).</i>
Type of Personal Data being Processed	<i>Name, work email address and work telephone number</i>

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Categories of Data Subject	<i>Staff of the Contractor and the Authority (including volunteers, agents and temporary workers)</i>
Plan for return and destruction of the data once the processing is complete	<i>The data will be retained and destroyed in accordance with instructions provided by the Authority.</i>

SCHEDULE 14

Security

1. DEFINITIONS

In this Schedule, the following definitions shall apply:

"Breach of Security" means the occurrence of:

- (a) any unauthorised access to or use of the Services, the Sites and/or any Information and Communication Technology ("ICT"), information or data (including the Confidential Information and the Authority Data) used by the Authority and/or the Contractor in connection with this Contract; and/or
- (b) the loss and/or unauthorised disclosure of any information or data (including the Confidential Information and the Authority Data), including any copies of such information or data, used by the Authority and/or the Contractor in connection with this Contract;

in either case as more particularly set out in the Security Policy;

"ICT Policy" means the Authority's policy in respect of information and communications technology which is in force as at the Commencement Date (a copy of which has been supplied to the Contractor), as updated from time to time in accordance with the Change Control Process; and

"Security Management Plan" means the Contractor's security management plan prepared pursuant to paragraph 4 of this Schedule a draft of which has been provided by the Contractor to the Authority in accordance with paragraph 4 of this Schedule and as updated from time to time.

2. INTRODUCTION

2.1 The purpose of this Schedule is to ensure a good organisational approach to security under which the specific requirements of this Contract will be met.

2.2 This Schedule covers:

- 2.2.1 principles of protective security to be applied in delivering the Services;
- 2.2.2 the creation and maintenance of the Security Management Plan; and
- 2.2.3 obligations in the event of actual or attempted Breaches of Security.

3. PRINCIPLES OF SECURITY

3.1 The Contractor acknowledges that the Authority places great emphasis on the reliability of the performance of the Services, confidentiality, integrity and availability of information and consequently on security.

3.2 The Contractor shall be responsible for the effective performance of its security obligations and shall at all times provide a level of security which:

- 3.2.1 is in accordance with the Law and this Contract;
- 3.2.2 as a minimum demonstrates Good Industry Practice;

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- 3.2.3 complies with the Security Policy;
- 3.2.4 meets any specific security threats of immediate relevance to the Services and/or the Authority Data; and
- 3.2.5 complies with the Authority's ICT Policy.
- 3.3 The references to standards, guidance and policies contained or set out in paragraph 3.2 of this Schedule shall be deemed to be references to such items as developed and updated and to any successor to or replacement for such standards, guidance and policies, as notified to the Contractor from time to time.
- 3.4 In the event of any inconsistency in the provisions of the above standards, guidance and policies, the Contractor should notify the Authority's Representative of such inconsistency immediately upon becoming aware of the same, and the Authority's Representative shall, as soon as practicable, advise the Contractor which provision the Contractor shall be required to comply with.

4. SECURITY REQUIREMENTS

- 4.1 The Contractor shall have in place a proportionate and considered protective security plan that effectively protects raw material and completed test-kit storage.
- 4.2 The Contractor shall provide evidence and assurance of its processes and standards that apply to the storage of goods and the storage of information.
- 4.3 The Contractor shall conduct a comprehensive security risk assessment, which:
 - 4.3.1 Identifies a senior risk owner;
 - 4.3.2 Accounts for physical, personnel, cyber and information security risks;
 - 4.3.3 Outlines threats that would hinder business continuity;
 - 4.3.4 Outlines a risk mitigation plan for the identified risks; and
 - 4.3.5 Is a mutually agreed and shared document between the Supplier and the Authority's expert security advice.
- 4.4 A significant security breach or change in structure shall prompt the re-evaluation of risk assessments and mitigation plans.
- 4.5 The Contractor must continually share information relating to the security and integrity of the Authority's supply chain, including:
 - 4.5.1 Internal security Standard Operating Procedures (SOP) that are mutually agreeable and satisfy expert security advice;
 - 4.5.2 Contingency plans, detailing response processes in the event of a security incident;
 - 4.5.3 Organisational and environmental changes that could affect the security of the Authority's assets and the following of Security Requirement's;
 - 4.5.4 Vulnerabilities, incidents and risks that were not foreseeable at the risk assessment stage.

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- 4.6 The Contractor must ensure that all visitors are escorted when on site and denied the opportunity for indirect access to the Authority's assets. Additionally, all Contractor staff must be reminded of the need to guard against compromising the Authority's assets.

5. SECURITY REPORTING

- 5.1 The Contractor must report security incidents in a timely manner as set out by the Authority's guidelines for reporting such incidents.
- 5.2 The Contractor must report risks and vulnerabilities as they arise.
- 5.3 The Contractor must report any internal changes that could impact the security of the Authority's assets and the following of Security Requirements.

6. SECURITY BREACHES AND CORRECTIVE ACTION

- 6.1 The Contractor must ensure that any breach in security is thoroughly investigated and corrective action for any vulnerabilities identified is taken in a timely manner.
- 6.2 The Contractor agrees that any breaches in key Security Requirements will trigger a review and/or corrective action by an independent party.
- 6.3 The Contractor shall allow the Authority, or an independent party on behalf of the Authority, to audit the entirety of the Contractor's supply chain processes and security standards that relate to the Authority's assets (including the Equipment) , at a time convenient to the Authority.

7. SECURITY MANAGEMENT PLAN

- 7.1 The Contractor shall develop and maintain a Security Management Plan in accordance with this Schedule. The Contractor shall thereafter comply with its obligations set out in the Security Management Plan.
- 7.2 The Security Management Plan shall:
- 7.2.1 comply with the principles of security set out in paragraph 3 of this Schedule and any other provisions of this Contract relevant to security;
 - 7.2.2 identify the necessary delegated organisational roles defined for those responsible for ensuring it is complied with by the Contractor;
 - 7.2.3 detail the process for managing any security risks from Sub-Contractors and third parties authorised by the Authority with access to the Services, processes associated with the provision of the Services, the Authority Premises, the Sites and any ICT, information and data (including the Authority's Confidential Information and the Authority Data) and any system that could directly or indirectly have an impact on that information, data and/or the Services;
 - 7.2.4 unless otherwise specified by the Authority in writing, be developed to protect all aspects of the Services and all processes associated with the provision of the Services, including the Authority Premises, the Sites, and any ICT, information and data (including the Authority's Confidential Information and the Authority Data) to the extent used by the Authority or the Contractor in connection with this Contract or in connection with any system that could directly or indirectly have an impact on that Information, data and/or the Services;
 - 7.2.5 set out the security measures to be implemented and maintained by the Contractor in relation to all aspects of the Services and all processes associated with the provision of

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the Services and shall at all times comply with and specify security measures and procedures which are sufficient to ensure that the Services comply with the provisions of this Contract;

- 7.2.6 set out the plans for transitioning all security arrangements and responsibilities for the Contractor to meet the full obligations of the security requirements set out in this Contract and the Security Policy; and
- 7.2.7 be written in plain English in language which is readily comprehensible to the staff of the Contractor and the Authority engaged in the provision of the Services and shall only reference documents which are in the possession of the Parties or whose location is otherwise specified in this Schedule.

8. DEVELOPMENT OF THE SECURITY MANAGEMENT PLAN

- 8.1 Within twenty (20) Working Days after the Commencement Date (or such other period agreed by the Parties in writing) and in accordance with paragraph 9, the Contractor shall prepare and deliver to the Authority for approval a fully complete and up to date Security Management Plan which will be based on the draft Security Management Plan.
- 8.2 If the Security Management Plan submitted to the Authority in accordance with paragraph 4.3(a), or any subsequent revision to it in accordance with paragraph 9, is approved it will be adopted immediately and will replace the previous version of the Security Management Plan and thereafter operated and maintained in accordance with this Schedule. If the Security Management Plan is not approved, the Contractor shall amend it within ten (10) Working Days or such other period as the Parties may agree in writing of a notice of non-approval from the Authority and re-submit to the Authority for approval. The Parties will use all reasonable endeavours to ensure that the approval process takes as little time as possible and in any event no longer than fifteen (15) Working Days (or such other period as the parties may agree in writing) from the date of its first submission to the Authority. If the Authority does not approve the Security Management Plan following its resubmission, the matter will be resolved in accordance with the dispute resolution procedure as set out at clause 42 of Schedule 2.
- 8.3 The Authority shall not unreasonably withhold or delay its decision to approve or not the Security Management Plan pursuant to paragraph 8.2. However a refusal by the Authority to approve the Security Management Plan on the grounds that it does not comply with the requirements set out in paragraph 7.2 shall be deemed to be reasonable.
- 8.4 Approval by the Authority of the Security Management Plan pursuant to paragraph 8.2 of this Schedule or of any change to the Security Management Plan in accordance with paragraph 9 shall not relieve the Contractor of its obligations under this Schedule.

9. AMENDMENT AND REVISION OF THE SECURITY MANAGEMENT PLAN

- 9.1 The Security Management Plan shall be fully reviewed and updated by the Contractor at least annually to reflect:
 - 9.1.1 emerging changes in Good Industry Practice;
 - 9.1.2 any change or proposed change to the Services and/or associated processes;
 - 9.1.3 any change to the Security Policy;
 - 9.1.4 any new perceived or changed security threats; and
 - 9.1.5 any reasonable change in requirements requested by the Authority.

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- 9.2 The Contractor shall provide the Authority with the results of such reviews as soon as reasonably practicable after their completion and amendment of the Security Management Plan at no additional cost to the Authority. The results of the review shall include, without limitation:
- 9.2.1 suggested improvements to the effectiveness of the Security Management Plan;
 - 9.2.2 updates to the risk assessments; and
 - 9.2.3 suggested improvements in measuring the effectiveness of controls.
- 9.3 Subject to paragraph 9.4, any change or amendment which the Contractor proposes to make to the Security Management Plan (as a result of a review carried out in accordance with paragraph 9.1, a request by the Authority or otherwise) shall be subject to the Change Control Process and shall not be implemented until approved by the Authority.
- 9.4 The Authority may, where it is reasonable to do so, approve and require changes or amendments to the Security Management Plan to be implemented on timescales faster than set out in the Change Control Process but, without prejudice to their effectiveness, all such changes and amendments shall thereafter be subject to the Change Control Process for the purposes of formalising and documenting the relevant change or amendment for the purposes of this Contract.

10. BREACH OF SECURITY

- 10.1 Either party shall notify the other in accordance with the agreed security incident management process (as detailed in the Security Management Plan if one exists) upon becoming aware of any Breach of Security or any potential or attempted Breach of Security.
- 10.2 Without prejudice to the security incident management process, upon becoming aware of any of the circumstances referred to in paragraph 10.1, the Contractor shall:
- 10.3 immediately take all reasonable steps(which shall include any action or changes reasonably required by the Authority) necessary to:
- (a) minimise the extent of actual or potential harm caused by any Breach of Security;
 - (b) remedy such Breach of Security to the extent possible and protect the integrity of the Authority and the provision of the Services to the extent within its control against any such Breach of Security or attempted Breach of Security;
 - (c) prevent an equivalent breach in the future exploiting the same root cause failure; and
- as soon as reasonably practicable provide to the Authority, where the Authority so requests, full details (using the reporting mechanism defined by the Security Management Plan if one exists) of the Breach of Security or attempted Breach of Security, including a root cause analysis where required by the Authority.
- 10.4 In the event that any action is taken in response to a Breach of Security or potential or attempted Breach of Security that demonstrates non-compliance of the Security Management Plan with the Security policy or the requirements of this Schedule, then any required change to the Security Management Plan shall be at no cost to the Authority.

SCHEDULE 15

Service Levels

The Service Levels which the Parties have agreed shall be used to measure the performance of the Services by the Contractor are contained in the below table. The Contractor shall monitor its performance against each Target Service Level and shall send the Authority a report detailing the Achieved Service Level in accordance with Schedule 7 (Contract Monitoring).

Service Level Performance Criterion	Key Indicator	Measure	Target Service Level Performance Measure at all times	Minimum Service Level	Service Credit payable after failure to meet Minimum Service Level	Service Credit Threshold	Measurement Period
1. Production vs Plan	Percentage of plan achieved number of test kits	Number Kits produced to quality standards/ number of kits volume agreed in rolling forecast plan	100%	99.5%	1.125% of the total weekly Charge (kit price per kit x total number of kits + weekly service charge) per % point below the minimum service level for the week in which the failure occurred	95%	Weekly
2. Quality Output	% of kits that fail to meet the Quality Standards set out by the Authority	Kits that fail to meet the standard / total kits produced	100%	99%	0.25% of the total Monthly Charges (kit price per kit x total number of kits) per 1% below the minimum service level for month in which the failure occurred	95%	Monthly
3. Change Management	Provision of a completed Impact Assessment for Changes requested by the Authority in a timely manner	% of completed Impact Assessments provided to the Authority within 7 days of any Variation being requested (unless otherwise agreed in writing in advance with the Authority	100%	n/a	n/a	n/a	Monthly

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SCHEDULE 16

Implementation Phase

- 1.1 In this Schedule, the following definitions shall apply:
- 1.1.1 **“Delay”**: a delay in the successful achievement of a Milestone.
 - 1.1.2 **“Detailed Implementation Plan”**: the detailed plan for the implementation of the Services that is developed in accordance with Paragraph 1.3 of this Schedule, **as** amended from time to time in accordance with the Change Control Process.
 - 1.1.3 **“Implementation Plan”**: the Outline Implementation Plan unless and until it is superseded by the Detailed Implementation Plan.
 - 1.1.4 **“Key Milestone”**: any Milestone which is identified as "key" in the Implementation Plan or by operation of the Change Control Process.
 - 1.1.5 **“Key Milestone Date”**: the date for completion of any Key Milestone as set out in the Implementation Plan.
 - 1.1.6 **“Milestone”**: an event or task described in the Implementation Plan which, if applicable, shall be **completed** by the **relevant** Milestone Date.
 - 1.1.7 **“Milestone Date”**: the date set against the relevant Milestone in the Implementation Plan by which the **Milestone** shall be completed.
 - 1.1.8 **“Outline Implementation Plan”**: the outline plan set out in Annex 1 to this Schedule for the implementation of **the** Services

Development of the Detailed Implementation Plan

- 1.2 Prior to commencement of delivery of the Services, there is an implementation phase and therefore all references in Paragraph 1.3 (Provision of Services) of Schedule 2 to the Implementation Plan shall apply.
- 1.3 The Detailed Implementation Plan shall be agreed as follows:
- 1.3.1 the Contractor shall prepare and deliver to the Authority for the Authority's approval a draft of the Detailed Implementation Plan within seven (7) Working Days of the Commencement Date;
 - 1.3.2 the Contractor shall not be entitled to propose any Variation to the Key Milestone Dates set out in the Outline Implementation Plan;
 - 1.3.3 the Authority shall review and comment on the draft Detailed Implementation Plan as soon as reasonably practicable.
 - 1.3.4 following such review and consultation, the Authority shall formally approve or reject the draft Detailed Implementation Plan no later than ten (10) Working Days after the date on which the draft Detailed Implementation Plan is first delivered to the Authority. If the Authority rejects the draft Detailed Implementation Plan, the provision of Paragraph 1.4 (Rejection of Detailed Implementation Plan) of this Schedule shall apply.

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- 1.3.5 Once the draft Detailed Implementation Plan is approved, it shall replace the Outline Implementation Plan.

Rejection of Detailed Implementation Plan

- 1.4 The following shall apply if the Authority rejects the draft Detailed Implementation Plan:

- 1.4.1 the Authority shall inform the Contractor in writing of its reasons for its rejection.

- 1.4.2 The Contractor shall then revise the draft Detailed Implementation Plan (taking reasonable account of the Authority's comments) and shall re-submit a revised draft Detailed Implementation Plan to the Authority for the Authority's approval within ten (10) Working Days of the date of the Authority's notice of rejection.

The provisions of Paragraph 1.3 (Development of the Implementation Plan) of this Schedule and this Paragraph 1.4 (Rejection of Detailed Implementation Plan) shall apply again to any resubmitted draft Detailed Implementation Plan, provided that either party may refer any disputed matters for resolution in accordance with Paragraph Schedule 242 (Dispute Resolution) of Schedule 2 at any time.

Implementation

- 1.5 The Contractor shall perform each of the tasks identified in the Implementation Plan by the applicable Milestone Date assigned to the particular task in the Implementation Plan.
- 1.6 If the Contractor is relying on a dependency to be performed by the Authority in order to achieve a Milestone or Key Milestone, the Contractor shall ensure that any such dependency is:
- 1.6.1 incorporated into the Implementation Plan; and
- 1.6.2 notified to the Authority at least ten (10) days prior to the date when the Contractor requires the dependency to be performed and completed by the Authority.
- 1.7 In the event that the Contractor fails to comply with Paragraph 1.6, above, any non-performance of a dependency by the Authority shall not be treated as a Default by the Authority and the Authority shall use reasonable endeavours to complete such dependency as soon as reasonably practicable.
- 1.8 If, at any time, the Contractor becomes aware that it will not (or is unlikely to) successfully achieve any Milestone by the applicable Milestone Date, it shall immediately notify the Authority of the fact of the Delay, the reasons for the Delay, the consequences of the Delay for the rest of the Implementation Plan and how the Contractor proposes to mitigate the Delay.
- 1.9 Subject to Paragraph 1.10.2 of this Schedule, the Parties acknowledge that the Contract Price shall not be increased as a result of a Delay.
- 1.10 The Parties acknowledge that:
- 1.10.1 where a Delay is caused by a Default of the Contractor, the Authority shall be entitled to claim any direct loss and/or expense that cannot be mitigated that it incurs as a result of the Default of the Contractor; and
- 1.10.2 where a Delay is caused by a Default of the Authority (and for the purposes of this Paragraph 1.10.2, a Delay caused by a failure of the Authority to perform a dependency specified in the Implementation Plan shall only be treated as a Default of the Authority in accordance with the provisions of Paragraphs 1.6 and 1.7 of this Schedule) and the Contractor has demonstrated to the Authority's satisfaction that it

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has incurred a direct loss and/or expense as a result of the Default of the Authority, in which circumstance the Contractor shall be entitled to compensation to the extent that it cannot mitigate that loss or expense.

- 1.11 Any disputes about or arising out of Delays shall be resolved through the dispute resolution procedure set out in Paragraph Schedule 242 (Dispute Resolution) of Schedule 2. Pending the resolution of the dispute, both parties shall continue to work together to resolve the causes of, and mitigate the effects of, the Delay.

Annex 1: Implementation Plan

The following key Milestones and deliverables shall be incorporated in the Implementation Plan:

Milestone /Deliverable	Description	Timeframe or Delivery Date
1	Project Plan showing the mobilisation to full Initial Kitting Production Solution capacity and subsequent plan to transition to Full Automation Kitting Solution. This shall be in Gantt chart format, and shall show the critical path and near critical path activities	1 week after the Commencement Date and thereafter updated weekly
2	RAID Management Plan laying out the risks and issues associated with delivering the requirements and the mitigation and management activities required to manage these	1 week after the Commencement Date and thereafter updated weekly
3	Initial Kitting Production Solution production line design, detailing the design, layout, space required, number of operators. The design shall include: a description and the specification of all component items of equipment; shall identify which items of equipment the Supplier currently has available, which items require procurement; and shall include calculations and assumptions used in the design to demonstrate that maximum production volumes can be achieved.	1 week after the Commencement Date
4	Initial Kitting Production Solution production line facility layout drawing, detailing the location of the production lines in the Supplier's facility, including working areas required.	1 week after the Commencement Date
5	Initial Kitting Production Solution Supply Chain Management Plan detailing, for all procured components, the component description, number procured, supplier, required delivery date and forecast delivery date.	1 week after the Commencement Date for long lead items, and thereafter, updated weekly

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6	Business Continuity Plan detailing the business continuity risks and risk mitigation in place for the Services	Within 2 weeks of the Commencement Date
7	Initial and Full Automation Kitting Solution production line design, detailing the design, layout, space required, number of operators. The design shall include a description and the specification of all component items of equipment and shall identify which items of equipment the Supplier currently has available, which items require procurement.	Within 3 weeks of the Commencement Date
8	Initial and Full Automation Kitting Solution production line facility layout drawing, detailing the location of the production lines in the Supplier's facility, including working areas required.	Within 3 weeks of the Commencement Date
9	Initial and Full Automation Kitting Solution Supply Chain Management Plan detailing for all procured components, the component description, number procured, supplier, required delivery date and forecast delivery date.	Within 3 weeks of the Commencement Date for long lead items, and thereafter, updated weekly
10	Exit Plan detailing the transition plan, timeline, stage gates, key documentation (equipment manuals and documentation, maintenance plans, handover documentation and open purchase orders) key personnel, key suppliers and Business Continuity plans	Within 4 weeks of the Commencement Date
11	Initial Kitting Production Solution Production Quality Management Plan in accordance with the requirements of this Statement of Requirements, including all proposed production and quality SOPs	Within 4 weeks of the Commencement Date
12	Implementation plan for Oracle systems, identify requirements installation dates and training.	Within 4 weeks of Commencement Date
13	Installation Qualification completed for all Initial Kitting Production Solution production lines	To be agreed within 4 weeks of Commencement Date
14	Operational Qualification completed for all Initial Kitting Production Solution production lines	To be agreed within 4 weeks of Commencement Date
15	Performance Qualification completed for all Initial Kitting Production Solution production lines	To be agreed within 4 weeks of Commencement Date
16	Initial and Full Automation Kitting Solution Production Quality Management Plan in accordance with the requirements of this Statement of Requirements, including all proposed production and quality SOPs	Within 8 weeks of the Commencement Date

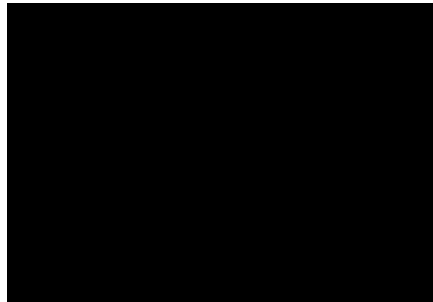
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17	Installation Qualification completed for all Initial and Full Automation Kitting Solution production lines	To be agreed within 4 weeks of Commencement Date
18	Operational Qualification completed for all Initial and Full Automation Kitting Solution production lines	To be agreed within 4 weeks of Commencement Date
18	Performance Qualification completed for all Initial and Full Automation Kitting Solution production lines	To be agreed within 4 weeks of Commencement Date

All documents and designs shall be subject to Authority review. The Authority shall have 5 Working Days to review and provide comments and the Contractor shall incorporate all reasonable Authority requirements and resubmit within 5 Working Days.

The Contractor's Outline Implementation plan is included below:



SCHEDULE 17

Business Continuity and Disaster Recovery Plan

1. BUSINESS CONTINUITY AND DISASTER RECOVERY PLAN

1.1 The Contractor shall ensure that the BCDR Plan shall include:

- 1.1.1 details of how the Contractor will implement the BCDR Plan;
- 1.1.2 details of how the BCDR Plan inter-operates with any other disaster recovery and business continuity plan of the Authority (as notified by the Authority from time to time);
- 1.1.3 details as to how the invocation of any element of the BCDR Plan may impact on the operation of the Services and a full analysis of the risks to the operation of the services; and
- 1.1.4 identification of all reasonably possible failures of or disruptions to the Services.

1.2 The Contractor shall ensure that the BCDR Plan shall also include:

- 1.2.1 back-up methodology;
- 1.2.2 data verification procedures;
- 1.2.3 identification of all potential disaster recovery scenarios;
- 1.2.4 provision of appropriate levels of spares, maintenance equipment and test equipment;
- 1.2.5 responsibilities of the Sub-contractors in the event of a disaster;
- 1.2.6 hardware configuration details, network planning and invocation rules and procedures;
- 1.2.7 data centre site audits;
- 1.2.8 Authority obligations and dependencies.

1.3 The BCDR Plan shall be designed so as to ensure that:

- 1.3.1 the Services are provided in accordance with this Contract at all times during and after the invocation of the BCDR Plan;
- 1.3.2 the adverse impact of any disaster is minimised as far as reasonably possible;
- 1.3.3 it complies with the relevant provisions of ISO/IEC 27002; ISO22301/ISO22313 and all other industry standards from time to time in force; and
- 1.3.4 it details a process for the management of disaster recovery testing.

1.4 The Contractor shall also ensure that the BCDR Plan defines the processes, activities and responsibilities relating to the application of emergency fixes in business-critical emergency situations. It shall also define the rules for storing data, the required availability for that data and the mechanisms for making that data available. It shall also include:

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- 1.4.1 risk analysis (including failure scenarios, assessments, identification of single points of failure and ways to manage such failure and business impact analysis);
 - 1.4.2 possible areas where system critical elements can be "dual sourced" so as to eliminate or minimise single points of failure;
 - 1.4.3 business continuity maintenance;
 - 1.4.4 documentation of business processes, procedures and responsibilities;
 - 1.4.5 a communications strategy; and
 - 1.4.6 procedures for reverting to normal service.
- 2. REVIEW AND AMENDMENT OF THE DISASTER RECOVERY AND BUSINESS CONTINUITY PLAN**
- 2.1 The Contractor shall review and test the BCDR Plan:
- 2.1.1 On a regular basis and as a minimum once every twelve (12) Months; and
 - 2.1.2 within three (3) calendar Months of the BCDR plan (or any part of it having been invoked).
- 2.2 The Contractor shall test its BCDR Plan in accordance with this Schedule taking into account the criticality of this Contract to the Authority and the size and scope of the Contractor's business operations. The Contractor shall promptly provide to the Authority, at the Authority's written request, copies of its BCDR Plan, reasonable and proportionate documentary evidence that the Contractor tests its BCDR Plan in accordance with the requirements of this Paragraph 2 and reasonable and proportionate information regarding the outcome of such tests. The Contractor shall provide to the Authority a copy of any updated or revised BCDR Plan within fourteen (14) Working Days of any material update or revision to the BCDR Plan.
- 2.3 The Authority may suggest reasonable and proportionate amendments to the Contractor regarding the BCDR Plan at any time. Where the Contractor, acting reasonably, deems such suggestions made by the Authority to be relevant and appropriate, the Contractor will incorporate into the BCDR Plan all such suggestions made by the Authority in respect of such BCDR Plan. Should the Contractor not incorporate any suggestion made by the Authority into such BCDR Plan it will explain the reasons for not doing so to the Authority.
- 2.4 Should a Business Continuity Event occur at any time, the Contractor shall implement and comply with its BCDR Plan and provide regular written reports to the Authority on such implementation. During and following a Business Continuity Event, the Contractor shall use reasonable endeavours to continue to supply the Services in accordance with this Contract.

SCHEDULE 18

Not Used

SCHEDULE 19

Financial Reports, Open Book Data and Audit Provisions

In this Schedule, the following definitions shall apply:

"Contractor Profit" means in relation to a period or a milestone (as the context requires), the difference between the total Contract Price (in nominal cash flow terms but excluding any deductions) and total costs (in nominal cash flow terms) for the relevant period or in relation to the relevant milestone;

"Contractor Profit Margin" means in relation to a period or a milestone (as the context requires), the Contractor Profit for the relevant period or in relation to the relevant milestone divided by the total Contract Price over the same period or in relation to the relevant milestone and expressed as a percentage;

"Financial Report" means the financial reports to be provided by the Contractor to the Authority pursuant to paragraph 1; and

"Financial Representative" means a reasonably skilled and experienced member of the Contractor's staff who has specific responsibility for preparing, maintaining, facilitating access to, discussing and explaining the Financial Reports.

"Open Book Data" means complete and accurate financial and non-financial information which is sufficient to enable the Authority to verify the Contract Price already paid or payable and the Contract Price forecast to be paid during the remainder of the Term, including details and all assumptions relating to:

(a) the Contractor's costs broken down against each Service, including actual capital expenditure (including capital replacement costs) and the unit cost and total actual costs of all hardware and software;

(b) operating expenditure relating to the provision of the Services including an analysis showing:

(i) the unit costs and quantity of consumables and bought-in services;

(ii) manpower resources broken down into the number and grade/role of all Contractor Personnel (free of any contingency) together with a list of agreed rates against each manpower grade;

(iii) a list of costs underpinning those rates for each manpower grade, being the agreed rate less the Contractor's Profit Margin; and

(iv) Reimbursable Expenses;

(c) overheads;

(d) all interest, expenses and any other third party financing costs incurred in relation to the provision of the Services;

(e) the Contractor Profit achieved over the Term and on an annual basis;

(f) confirmation that all methods of cost apportionment and overhead allocation are consistent with and not more onerous than such methods applied generally by the Contractor;

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(g) an explanation of the type and value of risk and contingencies associated with the provision of the Services, including the amount of money attributed to each risk and/or contingency; and

(h) the actual costs profile for each Service Period.

"Reimbursable Expenses" means reasonable out of pocket travel and subsistence (for example, hotel and food) expenses, properly and necessarily incurred in the performance of the Services, calculated at the rates and in accordance with the Authority's expenses policy current from time to time, but not including:

(a) travel expenses incurred as a result of Contractor Personnel travelling to and from their usual place of work, or to and from the premises at which the Services are principally to be performed, unless the Authority otherwise agrees in advance in writing; and

(b) subsistence expenses incurred by Contractor Personnel whilst performing the Services at their usual place of work, or to and from the premises at which the Services are principally to be performed; and

"Service Period" means a calendar month, save that:

(a) the first service period shall begin on the first Services Commencement Date and shall expire at the end of the calendar month in which the first Services Commencement Date falls; and

(b) the final service period shall commence on the first day of the calendar month in which the Term expires or terminates and shall end on the expiry or termination of the Term.

1. Provision of the Financial Reports

1.1 The Contractor shall provide during the Term the following financial reports to the Authority, in the frequency specified below:

Financial Report	When to be provided
Contract Financial Report	Monthly
Monthly management Accounts	Monthly

1.2 The Contractor shall provide to the Authority the Contract Financial Report in the same layout and format as provided in the template form as set out in Annex 1 to this Schedule. The Authority shall be entitled to modify the template for the Contract Financial Report by giving written notice to the Contractor, including a copy of the updated template.

1.3 If applicable, the Contractor shall provide to the Authority the Management Accounts in the same layout and format as provided in the template form as set out in Annex 2 to this Schedule. The Authority shall be entitled to modify the template for any Management Accounts by giving written notice to the Contractor, including a copy of the updated template.

1.4 A copy of each Financial Report shall be held by both the Authority and the Contractor. If there is a dispute regarding a Financial Report, the Authority's copy of the relevant Financial Report shall be authoritative.

1.5 Each Financial Report shall:

(a) be completed by the Contractor using reasonable skill and care;

(b) incorporate and use the same defined terms as are used in this Contract;

(c) quote all monetary values in pounds sterling;

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- (d) quote all costs as exclusive of any sales tax; and
 - (e) quote all costs and charges based on current prices.
- 1.6 Each Financial Report shall be certified by the Contractor as:
- (a) being accurate and not misleading;
 - (b) having been prepared in conformity with generally accepted accounting principles within the United Kingdom;
 - (c) being a true and fair reflection of the costs and charges incurred and forecast by the Contractor; and
 - (d) if applicable, being a true and fair reflection of the information included within the Contractor's management accounts.
- 1.7 During the Term, and for a period of 18 months following the end of the Term, the Contractor shall make available the Financial Representative at reasonable times and on reasonable notice to answer any queries that the Authority may have on any of the Financial Reports.
- 1.8 If the Contractor becomes aware of the occurrence, or the likelihood of the future occurrence, of an event which will or may have a material effect on the following:
- (a) the costs incurred (or those forecast to be incurred) by the Contractor; and/or
 - (b) the forecast charges for the remainder of the Term,
- the Contractor shall, as soon as practicable, notify the Authority in writing of the event in question detailing the actual or anticipated effect. For the avoidance of doubt, notifications provided in accordance with this paragraph 1.8 shall not have the effect of amending any provisions of this Contract.

2. Response to Audits

- 2.1 If an audit undertaken pursuant to clause 12 of schedule 2 identifies that:
- (a) the Contractor has committed a Default, the Authority may (without prejudice to any rights and remedies the Authority may have) issue notice of the breach and allow the Contractor to remedy such breach, in the first instance via a Remedial Proposal, before exercising any right to terminate the Contract;
 - (b) there is an error in a Financial Report, the Contractor shall promptly rectify the error;
 - (c) the Authority has overpaid any charges, the Contractor shall pay to the Authority:
 - (i) the amount overpaid;
 - (ii) interest on the amount overpaid at the applicable rate under the Late Payment of Commercial Debts (Interest) Act 1998, accruing on a daily basis from the date of overpayment by the Authority up to the date of repayment by the Contractor; and
 - (iii) the reasonable costs incurred by the Authority in undertaking the audit,

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provided that the Authority may exercise its right to deduct such amount from the Contract Price if it prefers; and

- (d) the Authority has underpaid any charges, the Contractor shall not be entitled to increase the charges paid or payable by the Authority.

- 2.2 Any overpaid or underpaid amounts in accordance with paragraph 2.1(c) or 2.1(d) shall be reconciled by an uplift or credit in respect of the applicable amount in the next invoice payable by the Authority.

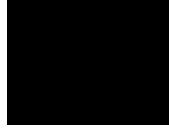
3. Open Book Data

- 3.1 The Contractor acknowledges the Authority's need for complete transparency in the way in which the Contract Price is calculated.

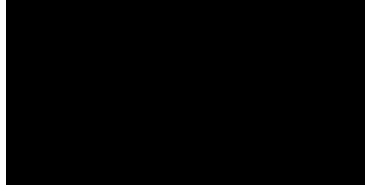
- 3.2 During the Term, and for a period of 7 years following the end of the Term, the Contractor shall:

- (a) maintain and retain the Open Book Data; and
- (b) disclose and allow the Authority and/or auditors access to the Open Book Data.

APPENDIX 1: FINANCIAL REPORT TEMPLATE



APPENDIX 1: MANAGEMENT ACCOUNTS TEMPLATE



SCHEDULE 20

Additional provisions in respect of Financial Distress

1. Definitions

In this schedule, the following definitions shall apply:

"Accounting Reference Date" means in each year the date to which the Contractor prepares its annual audited financial statements;

"Associates" means, in relation to an entity, an undertaking in which the entity owns, directly or indirectly, between 20% and 50% of the voting rights and exercises a degree of control sufficient for the undertaking to be treated as an associate under generally accepted accounting principles;

"Assurance" means written confirmation from a Relevant Authority to the Contractor that the CRP Information is approved by the Relevant Authority;

"Board" means the Contractor's board of directors;

"Board Confirmation" means written confirmation from the Board in accordance with paragraph 7 of this schedule;

"Class 1 Transaction" has the meaning set out in the listing rules issued by the UK Listing Authority;

"Contractor Group" means the Contractor, its Dependent Parent Undertakings and all Subsidiary Undertakings and Associates of such Dependent Parent Undertakings;

"Control" means the possession by person, directly or indirectly, of the power to direct or cause the direction of the management and policies of the other person (whether through the ownership of voting shares, by contract or otherwise) and **"Controls"** and **"Controlled"** shall be interpreted accordingly;

"Corporate Change Event" means

- (a) any change of Control of the Contractor or a Parent Undertaking of the Contractor;
- (b) any change of Control of any member of the Contractor Group which, in the reasonable opinion of the Authority, could have a material adverse effect on the Services;
- (c) any change to the business of the Contractor or any member of the Contractor Group which, in the reasonable opinion of the Authority, could have a material adverse effect on the Services;
- (d) a Class 1 Transaction taking place in relation to the shares of the Contractor or any Parent Undertaking of the Contractor whose shares are listed on the main market of the London Stock Exchange plc;
- (e) an event that could reasonably be regarded as being equivalent to a Class 1 Transaction taking place in respect of the Contractor or any Parent Undertaking of the Contractor;
- (f) payment of dividends by the Contractor or the ultimate Parent Undertaking of the Contractor Group exceeding 25% of the Net Asset Value of the Contractor or the ultimate Parent Undertaking of the Contractor Group respectively in any 12 month period;
- (g) an order is made or an effective resolution is passed for the winding up of any member of the Contractor Group;

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- (h) any member of the Contractor Group stopping payment of its debts generally or becoming unable to pay its debts within the meaning of section 123(1) of the Insolvency Act 1986 or any member of the Contractor Group ceasing to carry on all or substantially all its business, or any compromise, composition, arrangement or agreement being made with creditors of any member of the Contractor Group;
- (i) the appointment of a receiver, administrative receiver or administrator in respect of or over all or a material part of the undertaking or assets of any member of the Contractor Group; and/or
- (j) any process or events with an effect analogous to those in paragraphs (e) to (g) inclusive above occurring in a jurisdiction outside England and Wales;

"Credit Rating Level" means a credit rating level as specified in appendix of this schedule;

"Credit Rating Threshold" means the minimum Credit Rating Level for each entity in the FDE Group as set out in appendix of this schedule;

"Dependent Parent Undertakings" means any Parent Undertaking which provides any of its Subsidiary Undertakings and/or Associates, whether directly or indirectly, with any financial, trading, managerial or other assistance of whatever nature, without which the Contractor would be unable to continue the day to day conduct and operation of its business in the same manner as carried on at the time of entering into this Contract, including for the avoidance of doubt the provision of the Services in accordance with the terms of this Contract;

"Dispute Resolution Procedure" means the dispute resolution procedure set out in clause 42 of Schedule 2;

"FDE Group" means the Contractor, the Sub-contractors and any guarantor of the Contractor in accordance with clause 11 of Schedule 1;

"Financial Distress Event" means the occurrence of one or more of the events listed in paragraph 3 of this schedule;

"Financial Distress Remediation Plan" means a plan setting out how the Contractor will ensure the continued performance and delivery of the Services in accordance with this Contract in the event that a Financial Distress Event occurs;

"Group Structure Information and Resolution Commentary" means the information relating to the Contractor's group to be provided by the Contractor in accordance with paragraphs **Error! Reference source not found.** to 4 and annex 1 of Part 2 of this schedule;

"Parent Undertaking" has the meaning set out in section 1162 of the Companies Act 2006;

"Rating Agencies" means the rating agencies listed in appendix of this schedule;

"Relevant Authority" or "Relevant Authorities" means the Authority and the Cabinet Office Markets and Suppliers Team or, where the Contractor is a Strategic Supplier, the Cabinet Office Markets and Suppliers Team;

"Subsidiary Undertakings" has the meaning set out in section 1162 of the Companies Act 2006;

2. Warranties and duty to notify

- 2.1 The Contractor warrants and represents to the Authority for the benefit of the Authority that as at the Commencement Date:

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- 2.2 The long-term credit ratings issued for each entity in the FDE Group by each of the Rating Agencies are as set out in appendix of this schedule.
- 2.3 The Contractor shall promptly notify (or shall procure that its auditors promptly notify) the Authority in writing if there is any downgrade in the credit rating issued by any Rating Agency for any entity in the FDE Group (and in any event within five (5) Working Days of the occurrence of the downgrade).
- 2.4 The Contractor shall:
- (a) regularly monitor the credit ratings of each entity in the FDE Group with the Rating Agencies;
 - (b) promptly notify (or shall procure that its auditors promptly notify) the Authority in writing following the occurrence of a Financial Distress Event or any fact, circumstance or matter which could cause a Financial Distress Event (and in any event, ensure that such notification is made within 10 Working Days of the date on which the Contractor first becomes aware of the Financial Distress Event or the fact, circumstance or matter which could cause a Financial Distress Event).
- 2.5 For the purposes of determining whether a Financial Distress Event has occurred pursuant to the provisions of paragraph 3, and for the purposes of determining relief under paragraph 6.1, the credit rating of an FDE Group entity shall be deemed to have dropped below the applicable Credit Rating Threshold if:
- (a) any of the Rating Agencies have given a Credit Rating Level for that entity which is below the applicable Credit Rating Threshold; or
 - (b) a Rating Agency that is specified as holding a Credit Rating for an entity as set out at appendix of this schedule ceases to hold a Credit Rating for that entity.

3. Financial Distress Events

The following shall be Financial Distress Events:

- 3.1 the credit rating of an FDE Group entity dropping below the applicable Credit Rating Threshold;
- 3.2 an FDE Group entity issuing a profits warning to a stock exchange or making any other public announcement, in each case about a material deterioration in its financial position or prospects;
- 3.3 there being a public investigation into improper financial accounting and reporting, suspected fraud or any other impropriety of an FDE Group entity;
- 3.4 an FDE Group entity committing a material breach of covenant to its lenders;
- 3.5 a Sub-contractor notifying the Authority that the Contractor has not satisfied any material sums properly due under a specified invoice and not subject to a genuine dispute;
- 3.6 any of the following:
 - (a) commencement of any litigation against an FDE Group entity with respect to financial indebtedness greater than £5m or obligations under a service contract with a total contract value greater than £5m;
 - (b) non-payment by an FDE Group entity of any financial indebtedness;

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- (c) any financial indebtedness of an FDE Group entity becoming due as a result of an event of default;
- (d) the cancellation or suspension of any financial indebtedness in respect of an FDE Group entity; or
- (e) the external auditor of an FDE Group entity expressing a qualified opinion on, or including an emphasis of matter in, its opinion on the statutory accounts of that FDE entity;

in each case which the Authority reasonably believes (or would be likely reasonably to believe) could directly impact on the continued performance and delivery of the Services in accordance with this Contract.

4. Consequences of Financial Distress Events

4.1 Immediately upon notification by the Contractor of a Financial Distress Event (or if the Authority becomes aware of a Financial Distress Event without notification and brings the event to the attention of the Contractor), the Contractor shall have the obligations and the Authority shall have the rights and remedies as set out in paragraphs 4.3 to 4.5.

4.2 In the event of a late or non-payment of a Sub-contractor pursuant to paragraph 3.4, the Authority shall not exercise any of its rights or remedies under paragraph 4.3 without first giving the Contractor 10 Working Days to:

- (a) rectify such late or non-payment; or
- (b) demonstrate to the Authority's reasonable satisfaction that there is a valid reason for late or non-payment.

4.3 The Contractor shall (and shall procure that any Sub-contractor shall):

- (a) at the request of the Authority, meet the Authority as soon as reasonably practicable (and in any event within three (3) Working Days of the initial notification (or awareness) of the Financial Distress Event or such other period as the Authority may permit and notify to the Contractor in writing) to review the effect of the Financial Distress Event on the continued performance and delivery of the Services in accordance with this Contract; and
- (b) where the Authority reasonably believes (taking into account the discussions and any representations made under paragraph 4.3(a) that the Financial Distress Event could impact on the continued performance and delivery of the Services in accordance with this Contract:
 - (i) submit to the Authority for its approval, a draft Financial Distress Remediation Plan as soon as reasonably practicable (and in any event, within 10 Working Days of the initial notification (or awareness) of the Financial Distress Event or such other period as the Authority may permit and notify to the Contractor in writing); and
 - (ii) to the extent that it is legally permitted to do so and subject to paragraph 4.7, provide such information relating to the Contractor or Sub-contractors as the Authority may reasonably require in order to understand the risk to the Services, which may include forecasts in relation to cash flow, orders and profits and details of financial measures being considered to mitigate the impact of the Financial Distress Event.

4.4 The Authority shall not withhold its approval of a draft Financial Distress Remediation Plan unreasonably. If the Authority does not approve the draft Financial Distress Remediation Plan, it

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shall inform the Contractor of its reasons and the Contractor shall take those reasons into account in the preparation of a further draft Financial Distress Remediation Plan, which shall be resubmitted to the Authority within five (5) Working Days of the rejection of the first draft. This process shall be repeated until the Financial Distress Remediation Plan is approved by the Authority or referred to the Dispute Resolution Procedure under paragraph 4.4.

- 4.5 If the Authority considers that the draft Financial Distress Remediation Plan is insufficiently detailed to be properly evaluated, will take too long to complete or will not ensure the continued performance of the Contractor's obligations in accordance with the Contract, then it may either agree a further time period for the development and agreement of the Financial Distress Remediation Plan or escalate any issues with the draft Financial Distress Remediation Plan using the Dispute Resolution Procedure.
- 4.6 Following approval of the Financial Distress Remediation Plan by the Authority, the Contractor shall:
- (a) on a regular basis (which shall not be less than fortnightly):
 - (i) review and make any updates to the Financial Distress Remediation Plan as the Contractor may deem reasonably necessary and/or as may be reasonably requested by the Authority, so that the plan remains adequate, up to date and ensures the continued performance and delivery of the Services in accordance with this Contract; and
 - (ii) provide a written report to the Authority setting out its progress against the Financial Distress Remediation Plan, the reasons for any changes made to the Financial Distress Remediation Plan by the Contractor and/or the reasons why the Contractor may have decided not to make any changes;
 - (b) where updates are made to the Financial Distress Remediation Plan in accordance with paragraph 4.6(a), submit an updated Financial Distress Remediation Plan to the Authority for its approval, and the provisions of paragraphs 4.4 and 4.4 shall apply to the review and approval process for the updated Financial Distress Remediation Plan; and
 - (c) comply with the Financial Distress Remediation Plan (including any updated Financial Distress Remediation Plan) and ensure that it achieves the financial and performance requirements set out in the Financial Distress Remediation Plan.
- 4.7 Where the Contractor reasonably believes that the relevant Financial Distress Event under paragraph 4.1 (or the circumstance or matter which has caused or otherwise led to it) no longer exists, it shall notify the Authority and the Parties may agree that the Contractor shall be relieved of its obligations under paragraph 4.5.
- 4.8 The Contractor shall use reasonable endeavours to put in place the necessary measures to ensure that the information specified at paragraph (ii) is available when required and on request from the Authority and within reasonable timescales. Such measures may include:
- (a) obtaining in advance written authority from Sub-contractors authorising the disclosure of the information to the Authority and/or entering into confidentiality agreements which permit disclosure;
 - (b) agreeing in advance with the Authority, Sub-contractors a form of confidentiality agreement to be entered by the relevant parties to enable the disclosure of the information to the Authority;
 - (c) putting in place any other reasonable arrangements to enable the information to be lawfully disclosed to the Authority (which may include making price sensitive information available

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to Authority nominated personnel through confidential arrangements, subject to their consent); and

- (d) disclosing the information to the fullest extent that it is lawfully entitled to do so, including through the use of redaction, anonymization and any other techniques to permit disclosure of the information without breaching a duty of confidentiality.

5. Termination Rights

5.1 The Authority shall be entitled to terminate this Contract under clause 23 of schedule 2 if:

- (a) the Contractor fails to notify the Authority of a Financial Distress Event in accordance with paragraph (b);
- (b) the Parties fail to agree a Financial Distress Remediation Plan (or any updated Financial Distress Remediation Plan) in accordance with paragraphs 4.3 to 4.4; and/or
- (c) the Contractor fails to comply with the terms of the Financial Distress Remediation Plan (or any updated Financial Distress Remediation Plan) in accordance with paragraph (c).

6. Primacy of Credit Ratings

6.1 Without prejudice to the Contractor's obligations and the Authority's rights and remedies under paragraph 2, if, following the occurrence of a Financial Distress Event pursuant to any of paragraphs 3.1 to 3.5, the Rating Agencies review and report subsequently that the credit ratings for the FDE Group entities do not drop below the relevant Credit Rating Thresholds specified for those entities in appendix of this schedule, then:

- (a) the Contractor shall be relieved automatically of its obligations under paragraphs 4.3 to 4.5; and
- (b) the Authority shall not be entitled to require the Contractor to provide financial information in accordance with paragraph (ii).

7. Board Confirmation

7.1 Subject to paragraph 7.3 of this schedule, the Contractor shall within 120 days after each Accounting Reference Date or within 15 months of the previous Board Confirmation (whichever is the earlier) provide a Board Confirmation to the Authority in the form set out at appendix 2 of this schedule, confirming that to the best of the Board's knowledge and belief, it is not aware of and has no knowledge:

- (a) that a Financial Distress Event has occurred since the later of the Commencement Date or the previous Board Confirmation or is subsisting; or
- (b) of any matters which have occurred or are subsisting that could reasonably be expected to cause a Financial Distress Event.

7.2 The Contractor shall ensure that in its preparation of the Board Confirmation it exercises due care and diligence and has made reasonable enquiry of all relevant Contractor Personnel and other persons as is reasonably necessary to understand and confirm the position.

7.3 In respect of the first Board Confirmation to be provided under this Contract, the Contractor shall provide the Board Confirmation within 15 months of the Commencement Date if earlier than the timescale for submission set out in paragraph 7.1 of this schedule.

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- 7.4 Where the Contractor is unable to provide a Board Confirmation in accordance with paragraphs 7.1 to 7.3 of this schedule due to the occurrence of a Financial Distress Event or knowledge of subsisting matters which could reasonably be expected to cause a Financial Distress Event, it will be sufficient for the Contractor to submit in place of the Board Confirmation, a statement from the Board of Directors to the Authority setting out full details of any Financial Distress Events that have occurred and/or the matters which could reasonably be expected to cause a Financial Distress Event.

APPENDIX 1: Rating Agencies and their Standard Rating System

Dun and Bradstreet Failure Score

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APPENDIX 1: CREDIT RATINGS AND CREDIT RATING THRESHOLDS

Entity	Credit Rating (long term)	Credit Rating Threshold
Contractor	Contractor to confirm D&B Failure Score at commencement date	D&B Failure Score of [REDACTED]
[Guarantor]	n/a	n/a

APPENDIX 2: BOARD CONFIRMATION

Contractor Name: u

Contract Reference Number: u

The Board of Directors acknowledge the requirements set out at paragraph 1 of schedule u and confirm that the Contractor has exercised due care and diligence and made reasonable enquiry of all relevant Contractor Personnel and other persons as is reasonably necessary to enable the Board to prepare this statement.

The Board of Directors confirms, to the best of its knowledge and belief, that as at the date of this Board Confirmation it is not aware of and has no knowledge:

- 1 that a Financial Distress Event has occurred since the later of the previous Board Confirmation and the Commencement Date or is subsisting; or
- 2 of any matters which have occurred or are subsisting that could reasonably be expected to cause a Financial Distress Event.

On behalf of the Board of Directors:

Chair

Signed

Date

Director

Signed

Date

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SCHEDULE 21

Equipment

PART A

Equipment to be paid for by the Authority and used by the Contractor in the provision of the Services

Set up and semi automation phase

Setup and semi Automated Lines	Item	Equipment Specification
	Coding Printers	
	Pallet and Shipper printers	
	Scanners	
	Conveyors	
	Vision System	
	Friction Feeders	
	Pallet lyft	
	Work Benches	
	Chairs	
	Bins	
	Stainless Steel Trolleys	
	Serialisation and aggregation Laptop	
	Bagging	
	Serialisation	
	Scara Robot	
	Pallet Transport	
	Linear Conveyors	

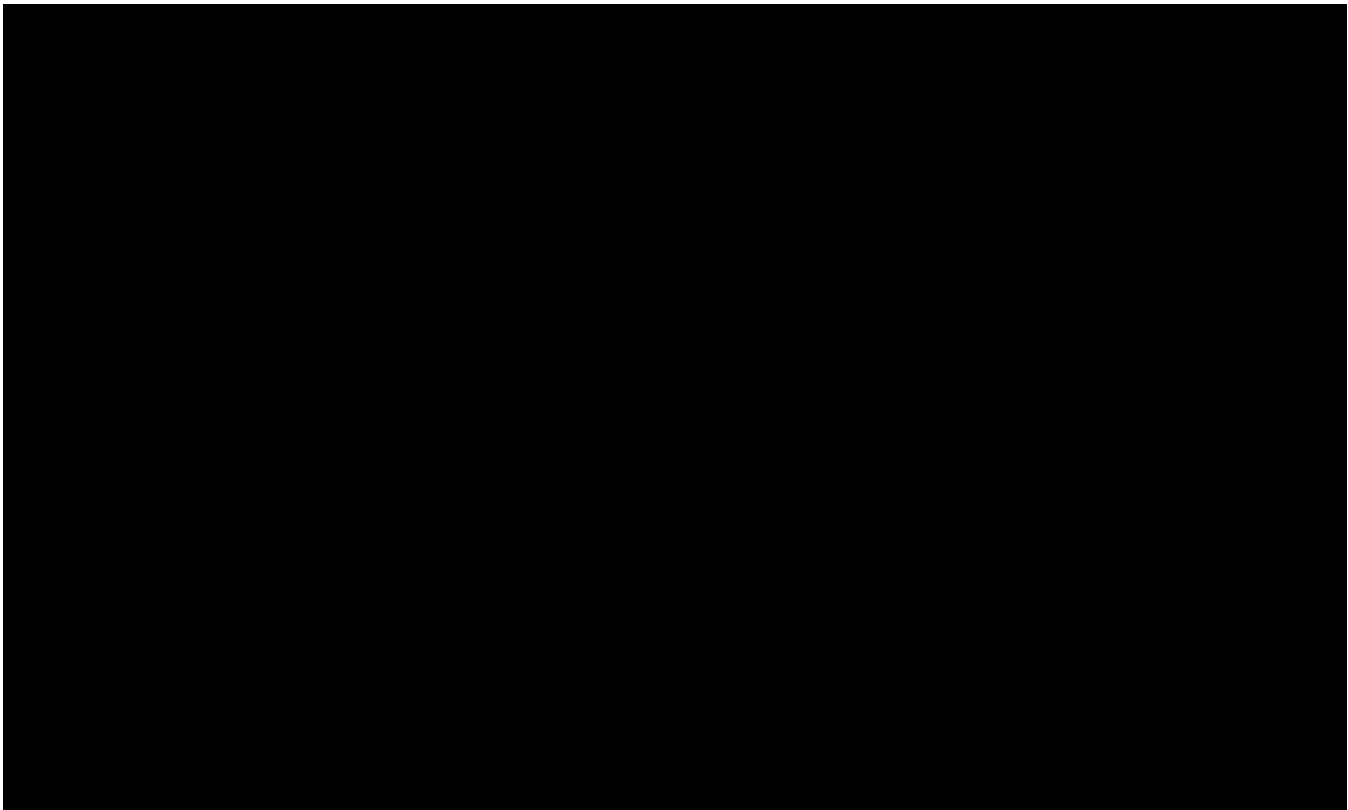
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Scara Robots	
Lockers	

Full automation phase

Automated Solution

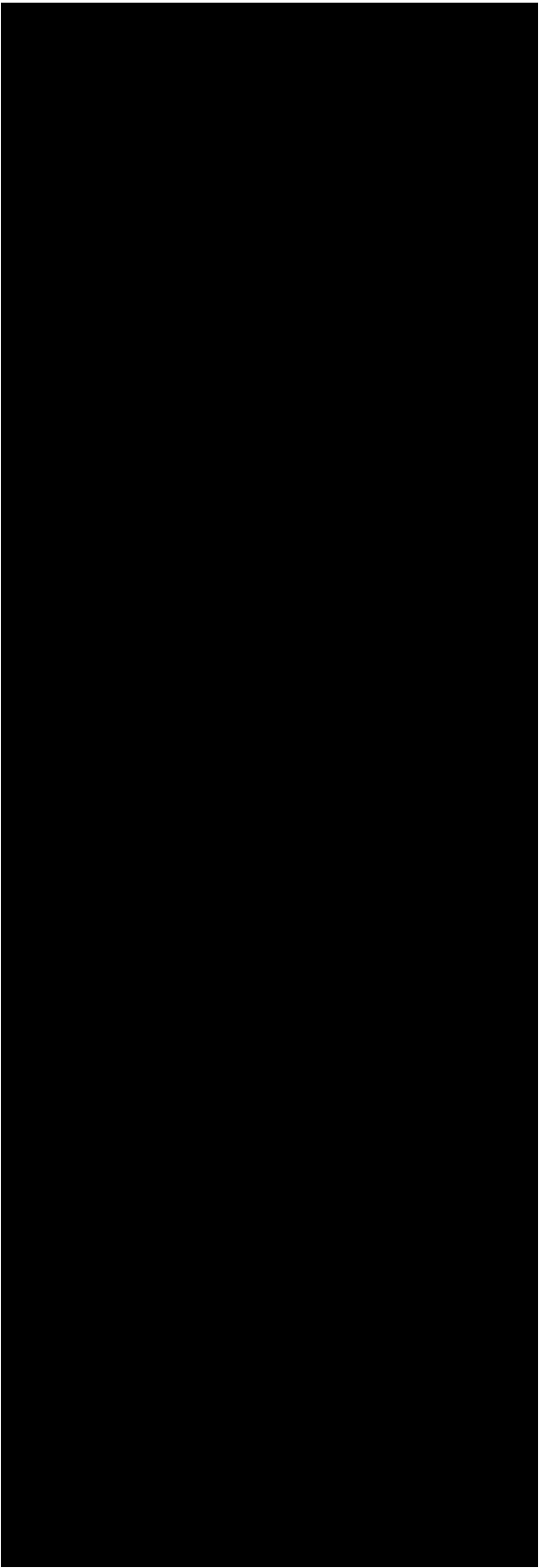


The Modular elements will be configurable to handle a variety of elements and will also be interchangeable, so that completely new units can be rolled into the production line to handle new or changed components. The modules will also be used, tested, and refined during the semi-automated packing phase so that the performance and timeline risk could virtually be eliminated once the integration phase of the project starts.

The specification of the equipment is:

Automated Lines	Item	
	Guarding	
	Machine frame	

Manufactured part treatment
Electrical cabinets
Cable conduit
Electrical protection
PLC
HMI
Servo motors
Servo drives
Field bus
AC Motors
Inverters
Guard switches
Sensors
Vision
Code reading
Actuators
Safety dump valve
Air pressure switch
Vacuum Pump
Vacuum Switch
Electrical power



Pneumatics

The modular cell details are contained in the following section:

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PART B

Free Issue Equipment to be provided by the Authority

Category			No. of
Device			
Accessory			
Battery			
Accessory			
Charger			
Accessory			
Accessory			
Accessory			
Printer			
Accessory			
Printer			
Battery			
Charger			
Accessory			
Accessory			