

DATED

2022

**THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE AS PART OF THE
CROWN**

AND

B. BRAUN AVITUM (UK) LTD.

**CALL OFF CONTRACT FOR THE PROVISION OF RENAL REPLACEMENT THERAPIES
SERVICES, AND CONSUMABLES**

The Authority	Secretary of State for Health and Social Care, acting as part of the Crown Supply Resilience Team Medical Technology Directorate 39 Victoria Street Westminster London SW1H 0EU
The Supplier	B. Braun Avitum (UK) Ltd. Brookdale Road Thorncliffe Park Sheffield S35 2PW
Commencement Date	As set out in the Order Form
Type of Goods	Renal Replacement
Framework Agreement Name	Renal Replacement Therapies Services, Technologies, and Consumables
Framework Agreement Number	2019/S 205-499640

The Contract is subject to the Order Form and the terms set out in the schedules of these Call-off Terms and Conditions listed below ("**Schedules**").

The Authority and the Supplier undertake to comply with the provisions of the Schedules in the performance of the Contract.

The Supplier shall supply to the Authority, and the Authority shall receive and pay for, the Goods and/or Services on the terms of the Contract.

For the avoidance of doubt, any actions or work undertaken by the Supplier prior to the receipt of an Order Form covering the relevant Goods and/or Services shall be undertaken at the Supplier's risk and expense and the Supplier shall only be entitled to invoice for Goods or Services covered by a valid Order Form.

The Definitions in Schedule 4 of these Call-off Terms and Conditions apply to the use of all capitalised terms in the Contract.

Schedules

Schedule 1 of these Call-off Terms and Conditions	Key Provisions
Schedule 1A of these Call-Off Terms and Conditions	Order Form
Schedule 2 of these Call-off Terms and Conditions	General Terms and Conditions
Schedule 3 of these Call-off Terms and Conditions	Information and Data Provisions
Schedule 4 of these Call-Off Terms and Conditions	Definitions and Interpretations
Schedule 5 of these Call-Off Terms and Conditions	Additional Terms
Schedule 6 of these Call-Off Terms and Conditions	Operational Requirements for Suppliers
Schedule 7 of these Call-Off Terms and Conditions	Supplier Code of Conduct

Signed by an authorised representative of the Authority

Name:	.. Redacted Under FOIA Section 40, Personal Information	Signature:	Redacted Under FOIA Section 40, Personal Information
Position:	.Senior Manager VMC Team...	Date:	23 Mar 2023

Signed by an authorised representative of the Supplier

Name:	Redacted Under FOIA Section 40, Personal Information	Signature	Redacted Under FOIA Section 40, Personal Information
Position:	Head of Infusion & Renal Therapies	Date:	10.11.2022
Name:	Redacted Under FOIA Section 40, Personal Information	Signature	Redacted Under FOIA Section 40, Personal Information
Position:	UK Group Legal Counsel	Date:	11.11.2022

Schedule 1A of these call off terms and conditions

Order Form

[ORDER FORM TO BE INSERTED]

Schedule 1

Key Provisions

Standard Key Provisions

1 Application of the Key Provisions

- 1.1 The standard Key Provisions at Clauses 1 to 7 of this Schedule 1 of these Call-off Terms and Conditions shall apply to this Contract.
- 1.2 Extra Key Provisions shall only apply to this Contract where such provisions are set out as part of the Order Form.

2 Term

- 2.1 This Contract shall commence on the Commencement Date.
- 2.2 The Term of this Contract shall be as set out in the Order Form.
- 2.3 The Term may be extended in accordance with Clause 15.2 of Schedule 2 of these Call-off Terms and Conditions provided that the duration of this Contract shall be no longer than any maximum applicable to the Contract if such maximum duration is set out in the Framework Agreement (including any options to extend).

3 Contract Managers

- 3.1 The Contract Managers at the commencement of this Contract shall be as set out in the Order Form or as otherwise agreed between the Parties in writing.

4 Names and addresses for notices

- 4.1 Unless otherwise agreed by the Parties in writing, notices served under this Contract are to be delivered to such persons at such addresses as referred to in the Order Form.

5 Management levels for escalation and dispute resolution

- 5.1 Unless otherwise agreed by the Parties in writing, the management levels at which a Dispute will be dealt with are as follows:

Level	Authority representative	Supplier representative
1	Contract Manager	Contract Manager
2	Assistant Director or equivalent	Assistant Director or equivalent
3	Director or equivalent	Director or equivalent

6 Order of precedence

- 6.1 Subject always to Clause 1.10 of Schedule 4 of these Call-off Terms and Conditions, should there be a conflict between any other parts of this Contract the order of priority for construction purposes shall be:
- 6.1.1 the Order Form
 - 6.1.2 the applicable provisions of the Framework Agreement other than the Specification and Tender Response Document;
 - 6.1.3 the provisions on the front page of these Terms and Conditions for the Supply of Goods and the Provision of Services (Purchase Order Version);
 - 6.1.4 Schedule 1 of these Call-off Terms and Conditions: Key Provisions;
 - 6.1.5 the Specification and Tender Response Document (but only in respect of the requirements);
 - 6.1.6 Schedule 2 of these Call-off Terms and Conditions: General Terms and Conditions;
 - 6.1.7 Schedule 3 of these Call-off Terms and Conditions: Information Governance Provisions;
 - 6.1.8 Schedule 4 of these Call-off Terms and Conditions: Definitions and Interpretations;
 - 6.1.9 the order in which all subsequent schedules, if any, appear; and
 - 6.1.10 any other documentation forming part of the Contract in the date order in which such documentation was created with the more recent documentation taking precedence over older documentation to the extent only of any conflict.

7 Application of TUPE at the commencement of the provision of Services

- 7.1 The Parties agree that at the commencement of the provision of Services by the Supplier, TUPE and the Cabinet Office Statement shall not apply so as to transfer the employment of any employees of the Authority or a Third Party to the Supplier.
- 7.2 If any person who is an employee of the Authority or a Third Party claims or it is determined that their contract of employment has been transferred from the Authority or Third Party to the Supplier or a Sub-contractor pursuant to TUPE, or claims that their employment would have so transferred had they not resigned, then:
- 7.2.1 the Supplier will, within seven (7) days of becoming aware of that fact, give notice in writing to the Authority;
 - 7.2.2 the Authority or Third Party may offer employment to such person within twenty-eight (28) days of the notification by the Supplier;
 - 7.2.3 if such offer of employment is accepted, the Supplier or a Sub-contractor shall immediately release the person from their employment;

- 7.2.4 if after that period specified in Clause 7.2.2 of this Schedule 1 of these Call-off Terms and Conditions has elapsed, no offer of employment has been made by the Authority or Third Party, or such offer has been made by the Authority or Third Party but not accepted within a reasonable time, the Supplier or Sub-contractor shall employ that person in accordance with its obligations and duties under TUPE and shall be responsible for all liabilities arising in respect of any such person and shall (where relevant) be bound to apply Fair Deal for Staff Pensions in respect of any such person in accordance with the requirements of Part D of Schedule 7 of the NHS Terms and Conditions for the Provision of Services (Contract Version) (January 2018).

Schedule 2

General Terms and Conditions

Contents

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1 Supply of Goods and the provision of Services

1.1 The Supplier shall supply the Goods ordered by the Authority and provide the Services under this Contract:

- 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 the provisions of the Framework Agreement as applicable and/or the provisions of the Order Form;
- 1.1.4 in accordance with the Law and with Guidance;
- 1.1.5 in accordance with Good Industry Practice;
- 1.1.6 in accordance with the Policies; and
- 1.1.7 in a professional and courteous manner.

In complying with its obligations under this Contract, the Supplier shall, and shall procure that all Staff shall, act in accordance with the NHS values as set out in the NHS Constitution from time to time.

1.2 The Supplier shall comply with the Implementation Requirements (if any) in accordance with any timescales as may be set out in the Specification and Tender Response Document. Without limitation to the foregoing provisions of this Clause 1.2 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall, if specified in the Order Form, carry out all implementation activities fully in accordance with the Implementation Plan. If the Implementation Plan is an outline plan, the Supplier shall, as part of implementation, develop the outline plan into a full plan and agree this with the Authority. Once this is agreed, the Supplier shall comply with the full Implementation Plan.

1.3 Where the Supplier is providing services, the Supplier shall commence delivery of the Services on the Services Commencement Date.

1.4 The Supplier shall comply fully with its obligations set out in the Specification and Tender Response Document and/or the Order Form, including, without limitation, the KPIs and all obligations in relation to the quality, performance characteristics, supply, delivery, installation and training in relation to the Goods and their use.

1.5 Unless otherwise agreed by the Parties in writing, the Goods shall be new, consistent with any sample, and shall comply with any applicable specification set out in this Contract (to include, without limitation, the provisions of the Authority's requirements set out in the Specification and Tender Response Document and the Supplier's response to such requirements) and any applicable manufacturers' specifications.

1.6 The Supplier shall ensure that all relevant consents, authorisations, licences and accreditations:

- 1.6.1 required to supply the Goods are in place prior to the delivery of any Goods to the Authority; and

- 1.6.2 required to provide the Services are in place at the Actual Services Commencement Date and are maintained throughout the Term.
- 1.7 If there are any incidents that in any way relate to or involve the use of the Goods by the Authority, the Supplier shall cooperate fully with the Authority in relation to the Authority's application of the Policies on reporting and responding to all incidents, including serious incidents requiring investigation, and shall respond promptly to any reasonable and proportionate queries, questions and/or requests for information that the Authority may have in this context in relation to the Goods.
- 1.8 If there are any quality, performance and/or safety related reports, notices, alerts or other communications issued by the Supplier or any regulatory or other body in relation to the Goods, the Supplier shall promptly provide the Authority with a copy of any such reports, notices, alerts or other communications.
- 1.9 Upon receipt of any such reports, notices, alerts or other communications pursuant to Clause 1.8 of this Schedule 2 of these Call-off Terms and Conditions, the Authority shall be entitled to request further information from the Supplier and/or a meeting with the Supplier, and the Supplier shall cooperate fully with any such request.

2 Delivery of the Goods and passing of risk and ownership in the Goods

- 2.1 The Supplier shall deliver the Goods in accordance with any delivery timescales, delivery dates and delivery instructions (to include, without limitation, as to delivery location and delivery times) set out in the Specification and Tender Response Document, the Order Form or as otherwise agreed with the Authority in writing.
- 2.2 Delivery shall be completed when the Goods have been unloaded at the location specified by the Authority and such delivery has been received by a duly authorised agent, employee, or location representative of the Authority. The Authority shall procure that such duly authorised agent, employee or location representative of the Authority is at the delivery location at the agreed delivery date and times to accept such delivery. Any arrangement by which the Goods are collected by the Authority in return for a discount on the Contract Price shall be agreed by the Parties in writing (where due to an emergency such arrangements cannot be committed to writing prior to collection, the Parties shall confirm such arrangements in writing as soon as possible following collection). Where the Authority collects the Goods, collection is deemed delivery for the purposes of the Contract.
- 2.3 The Supplier shall ensure that a delivery note shall accompany each delivery of the Goods. Such delivery note shall contain the information specified in the Specification and Tender Response Document or as otherwise agreed with the Authority in writing. Where such information requirements as to the content of delivery notes are not specified or separately agreed, such delivery notes shall, as a minimum, contain the Authority's order number, the name and address of the Authority, a description and quantity of the Goods, and shall show separately any extra agreed charges for containers and/or any other item not included in the Contract Price or, where no charge is made, whether the containers are required to be returned.
- 2.4 Part deliveries and/or deliveries outside of the agreed delivery times/dates may be refused unless the Authority has previously agreed in writing to accept such deliveries. Where delivery of the Goods is refused by the Authority in accordance with this Clause 2.4 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall be responsible for all risks, costs and expenses associated with the re-delivery of the Goods in accordance with the agreed delivery times/dates. Where the Authority

accepts delivery more than five (5) days before the agreed delivery date, the Authority shall be entitled to charge the Supplier for the costs of insurance and storage of the Goods until the agreed date for delivery.

- 2.5 Unless otherwise set out in the Specification and Tender Response Document or agreed with the Authority in writing, the Supplier shall be responsible for carriage, insurance, transport, all relevant licences, all related costs, and all other costs associated with the delivery of the Goods to the delivery location and unloading of the Goods at that location. Without limitation to the foregoing provision of this Clause 2.5 of this Schedule 2 of these Call-off Terms and Conditions, unless otherwise stated in the Specification and Tender Response Document or agreed with the Authority in writing, the Supplier shall be responsible for obtaining all export and import licences for the Goods and shall be responsible for any delays to the delivery time due to such licences not being available when required. In the case of any Goods supplied from outside the United Kingdom, the Supplier shall ensure that accurate information is provided to the Authority as to the country of origin of the Goods and shall be liable to the Authority for any extra duties or taxes for which the Authority may be accountable should the country of origin prove to be different from that set out in the Specification and Tender Response Document.
- 2.6 All third-party carriers engaged to deliver the Goods shall at no time be an agent of the Authority and accordingly the Supplier shall be liable to the Authority for the acts and omissions of all third-party carriers engaged to deliver the Goods to the Authority.
- 2.7 Risk in the Goods shall pass to the Authority when the Goods are delivered as specified in this Contract or, in the case of Goods which require installation by the Supplier, when that installation process is complete.
- 2.8 Ownership of the Goods shall pass to the Authority on the earlier of:
- 2.8.1 full payment for such Goods; or
 - 2.8.2 where the goods are consumables or are non-recoverable (e.g., used in clinical procedures), at the point such Goods are taken into use. For the avoidance of doubt, where ownership passes in accordance with this Clause 2.8.2 of this Schedule 2 of these Call-off Terms and Conditions, then the full Contract Price for such Goods shall be recoverable by the Supplier from the Authority as a debt if there is non-payment of a valid undisputed invoice issued by the Supplier to the Authority in relation to such Goods.
- 2.9 All tools, equipment and materials of the Supplier required in the performance of the Supplier's obligations under this Contract shall be and remain at the sole risk of the Supplier, whether or not they are situated at a delivery location.

3 Inspection, rejection, return and recall of the Goods

- 3.1 As relevant and proportionate to the Goods in question and subject to reasonable written notice, the Supplier shall permit any person authorised by the Authority, to inspect work being undertaken in relation to the Goods and/or the storage facilities used in the storage of the Goods at all reasonable times at the Supplier's premises or at the premises of any Sub-contractor or agent of the Supplier in order to confirm that the Goods are being manufactured and/or stored in accordance with Good Industry Practice and in compliance the requirements of this Contract and/or that stock holding and quality assurance processes are in accordance with the requirements of this Contract.

- 3.2 Without prejudice to the provisions of Clause 3.6 of this Schedule 2 of these Call-off Terms and Conditions and subject to Clause 3.7 of this Schedule 2 of these Call-off Terms and Conditions, the Authority shall visually inspect the Goods within a reasonable time following delivery (or such other period as may be set out as part of the Authority's requirements in the Specification and Tender Response Document, if any) and may by written notice reject any Goods found to be damaged or otherwise not in accordance with the requirements of this Contract ("**Rejected Goods**"). The whole of any delivery may be rejected if a reasonable sample of the Goods taken indiscriminately from that delivery is found not to conform in all material respects to the requirements of the Contract.
- 3.3 Without prejudice to the provisions of Clause 3.5 of this Schedule 2 of these Call-off Terms and Conditions, upon the rejection of any Goods in accordance with Clauses 3.2 and/or 3.6 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall at the Authority's written request:
- 3.3.1 collect the Rejected Goods at the Supplier's risk and expense within ten (10) Business Days of issue of written notice from the Authority rejecting the Goods; and
 - 3.3.2 without extra charge, promptly (and in any event within twenty (20) Business Days or such other time agreed by the Parties in writing acting reasonably) supply replacements for the Rejected Goods to the Authority subject to the Authority not cancelling its purchase obligations in accordance with Clause 3.5 of this Schedule 2 of these Call-off Terms and Conditions.
- If the Supplier requests and the Authority accepts that the Rejected Goods should be disposed of by the Authority rather than returned to the Supplier, the Authority reserves the right to charge the Supplier for the costs associated with the disposal of the Rejected Goods and the Supplier shall promptly pay any such costs.
- 3.4 Risk and title in respect of any Rejected Goods shall pass to the Supplier on the earlier of: (a) collection by the Supplier in accordance with Clause 3.3 of this Schedule 2; or (b) immediately following the expiry of ten (10) Business Days from the Authority issuing written notification rejecting the Goods. If Rejected Goods are not collected within ten (10) Business Days of the Authority issuing written notification rejecting the Goods, the Authority may return the Rejected Goods at the Supplier's risk and expense and charge the Supplier for the cost of storage from the expiry of ten (10) Business Days from the date of notification of rejection.
- 3.5 Where the Authority rejects any Goods in accordance with Clauses 3.2 and/or 3.6 of this Schedule 2 of these Call-off Terms and Conditions and the Authority no longer requires replacement Goods, the Authority may by written notice cancel its purchase obligations in relation to such quantity of Rejected Goods. Should the Authority have paid for such Rejected Goods the Supplier shall refund such payment to the Authority within thirty (30) days of the Authority cancelling such purchase obligations and informing the Supplier that the Authority does not require replacements for such Rejected Goods.
- 3.6 Without prejudice to any other provisions of this Contract or any other warranties or guarantees applicable to the Goods supplied and subject to Clause 3.7 of this Schedule 2 of these Call-off Terms and Conditions, if at any time following the date of the delivery of any Goods, all or any part of such Goods are found to be defective or otherwise not in accordance with the requirements of this Contract ("**Defective Goods**"), the Supplier shall, at the Authority's discretion:

- 3.6.1 upon written request and without charge, promptly (and in any event within twenty (20) Business Days or such other time agreed by the Parties in writing acting reasonably) remedy the deficiency by repairing such Defective Goods; or
 - 3.6.2 upon written notice of rejection from the Authority, treat such Defective Goods as Rejected Goods in accordance with Clauses 3.2 to 3.5 of this Schedule 2 of these Call-off Terms and Conditions.
- 3.7 The Supplier shall be relieved of its liabilities under Clauses 3.2 to 3.5 (inclusive) and/or Clause 3.6 of this Schedule 2 of these Call-off Terms and Conditions to the extent only that the Goods are damaged, there are defects in the Goods and/or the Goods fail to comply with the requirements of this Contract due, in each case, to any acts or omissions of the Authority.
- 3.8 The Authority's rights and remedies under Clause 3.6 of this Schedule 2 of these Call-off Terms and Conditions shall cease within a reasonable period of time from the date on which the Authority discovers or might reasonably be expected to discover that the Goods are Defective Goods or within such other period as may be set out as part of the requirements in the Specification and Tender Response Document, if any. For the avoidance of doubt, Goods not used before their expiry date shall in no event be considered Defective Goods following the date of expiry provided that at the point such Goods were delivered to the Authority, they met any shelf -life requirements set out in the Specification and Tender Response Document.
- 3.9 Where the Supplier is required by Law, Guidance, and/or Good Industry Practice to order a product recall ("**Requirement to Recall**") in respect of the Goods, the Supplier shall:
 - 3.9.1 promptly (taking into consideration the potential impact of the continued use of the Goods on patients, service users and the Authority as well as compliance by the Supplier with any regulatory requirements) notify the Authority in writing of the recall together with the circumstances giving rise to the recall.
 - 3.9.2 from the date of the Requirement to Recall treat the Goods the subject of such recall as Defective Goods in accordance with Clause 3.6 of this Schedule 2 of these Call-off Terms and Conditions;
 - 3.9.3 consult with the Authority as to the most efficient method of executing the recall of the Goods and use its reasonable endeavors to minimise the impact on the Authority of the recall; and
 - 3.9.4 indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such Requirement to Recall.

4 Operation of the Services

- 4.1 The Services shall be provided at such Authority premises and at such locations within those premises, as may be set out in the Order From or as otherwise agreed by the Parties in writing ("**Premises and Locations**").

- 4.2 Subject to the Supplier and its Staff complying with all relevant Policies applicable to such Premises and Locations, the Authority shall grant reasonable access to the Supplier and its Staff to such Premises and Locations to enable the Supplier to provide the Services.
- 4.3 Subject to Clause 4.4 of this Schedule 2 of these Call-off Terms and Conditions, any access granted to the Supplier and its Staff under Clause 4.2 of this Schedule 2 of these Call-off Terms and Conditions shall be non-exclusive and revocable. Such access shall not be deemed to create any greater rights or interest than so granted (to include, without limitation, any relationship of landlord and tenant) in the Premises and Locations. The Supplier warrants that it shall carry out all such reasonable further acts to give effect to this Clause 4.3 of this Schedule 2 of these Call-off Terms and Conditions.
- 4.4 Where, in order to provide the Services, the Supplier requires any greater rights to use or occupy any specific Premises and Locations over and above such reasonable access rights granted in accordance with Clause 4.2 and Clause 4.3 of this Schedule 2 of these Call-off Terms and Conditions, such further rights shall be limited to any rights granted to the Supplier by the Authority in accordance with any licence and/or lease entered into by the Supplier as referred to in any Order Form.
- 4.5 Where it is provided for by a specific mechanism set out in the Specification and Tender Response Document and/or the Order Form, the Authority may increase, reduce or otherwise vary the Premises and Locations in accordance with such mechanism subject to the provisions of any licence or lease entered into by the Parties as referred to at Clause 4.4 of this Schedule 2 of these Call-off Terms and Conditions. Where there is no such specific mechanism set out in the Specification and Tender Response Document and/or the Order Form, any variations to the Premises and Locations where the Services are to be provided shall be agreed by the Parties in accordance with Clause 21 of this Schedule 2 of these Call-off Terms and Conditions. If agreement cannot be reached the matter shall be referred to, and resolved in accordance with, the dispute resolution process set out in Clause 5 of the Key Provisions and Clause 22.3 of this Schedule 2 of these Call-off Terms and Conditions.
- 4.6 Unless otherwise set out in the Specification and Tender Response Document or otherwise agreed by the Parties in writing, any equipment or other items provided by the Authority for use by the Supplier:
- 4.6.1 shall be provided at the Authority's sole discretion;
 - 4.6.2 shall be inspected by the Supplier in order that the Supplier can confirm to its reasonable satisfaction that such equipment and/or item is fit for its intended use and shall not be used by the Supplier until it has satisfied itself of this;
 - 4.6.3 must be returned to the Authority within any agreed timescales for such return or otherwise upon the request of the Authority; and
 - 4.6.4 shall be used by the Supplier at the Supplier's risk and the Supplier shall upon written request by the Authority reimburse the Authority for any loss or damage relating to such equipment or other items caused by the Supplier (fair wear and tear exempted).
- 4.7 If the Services, or any part of them, are regulated by any regulatory body, the Supplier shall ensure that at the Actual Services Commencement Date it has in place all

relevant registrations and shall maintain such registrations during the Term. The Supplier shall notify the Authority forthwith in writing of any changes to such registration or any other matter relating to its registration that would affect the delivery or the quality of Services.

4.8 The Supplier shall notify the Authority forthwith in writing:

4.8.1 of any pending inspection of the Services, or any part of them, by a regulatory body immediately upon the Supplier becoming aware of such inspection; and

4.8.2 of any failure of the Services, or any part of them, to meet the quality standards required by a regulatory body, promptly and in any event within two (2) Business Days of the Supplier becoming aware of any such failure. This shall include without limitation any informal feedback received during or following an inspection raising concerns of any nature regarding the provision of the Services.

4.9 Following any inspection of the Services, or any part of them, by a regulatory body, the Supplier shall provide the Authority with a copy of any report or other communication published or provided by the relevant regulatory body in relation to the provision of the Services.

4.10 Upon receipt of notice pursuant to Clause 4.8 of this Schedule 2 of these Call-off Terms and Conditions or any report or communication pursuant to Clause 4.9 of this Schedule 2 of these Call-off Terms and Conditions, the Authority shall be entitled to request further information from the Supplier and/or a meeting with the Supplier, and the Supplier shall cooperate fully with any such request.

4.11 Where applicable, the Supplier shall implement and comply with the Policies on reporting and responding to all incidents and accidents, including serious incidents requiring investigation, shall complete the Authority's incident and accident forms in accordance with the Policies and provide reasonable support and information as requested by the Authority to help the Authority deal with any incident or accident relevant to the Services. The Supplier shall ensure that its Contract Manager informs the Authority's Contract Manager in writing forthwith upon (a) becoming aware that any serious incidents requiring investigation and/or notifiable accidents have occurred; or (b) the Supplier's Contract Manager having reasonable cause to believe any serious incidents and/or notifiable accidents requiring investigation have occurred. The Supplier shall ensure that its Contract Manager informs the Authority's Contract Manager in writing within forty-eight (48) hours of all other incidents and/or accidents that have or may have an impact on the Services.

4.12 The Supplier shall, as reasonably required by the Authority, cooperate with any other service providers to the Authority and/or any other third parties as may be relevant in the provision of the Services.

4.13 To the extent relevant to the Services, the Supplier shall have in place and operate a complaints procedure which complies with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009.

4.14 Each Party shall inform the other of all complaints from or on behalf of patients or other service users arising out of or in connection with the provision of the Services within twenty-four (24) hours of receipt of each complaint and shall keep the other Party updated on the manner of resolution of any such complaints.

- 4.15 The Supplier shall be relieved from its obligations under this Contract to provide the Services to the extent that it is prevented from complying with any such obligations due to any acts, omissions, or defaults of the Authority. To qualify for such relief, the Supplier must notify the Authority promptly (and in any event within five (5) Business Days) in writing of the occurrence of such act, omission, or default of the Authority together with the potential impact on the Supplier's obligations.

5 Staff and Lifescience Industry Accredited Credentialing Register

- 5.1 Subject to the requirements of this Contract and any Law, the Supplier shall be entirely responsible for the employment and conditions of service of Staff. The Supplier shall ensure that such conditions of employment are consistent with its obligations under this Contract.
- 5.2 The Supplier will employ sufficient Staff to ensure that it complies with its obligations under this Contract. This will include, but not be limited to, the Supplier providing a sufficient reserve of trained and competent Staff to supply the Goods and/or provide the Services during Staff holidays or absence.
- 5.3 The Supplier shall use reasonable endeavours to ensure the continuity of all Staff in the provision of the Services and, where any member of Staff is designated as key to the provision of the Services as set out in the Specification and Tender Response Document, the Order Form or as otherwise agreed between the Parties in writing, any redeployment and/or replacement of such member of Staff by the Supplier shall be subject to the prior written approval of the Authority, such approval not to be unreasonably withheld or delayed.
- 5.4 The Supplier shall ensure that all Staff are aware of, and at all times comply with, the Policies.
- 5.5 The Supplier shall:
- 5.5.1 employ only those Staff who are careful, skilled and experienced in the duties required of them;
 - 5.5.2 ensure that every member of Staff is properly and sufficiently trained and instructed;
 - 5.5.3 ensure all Staff have the qualifications to carry out their duties;
 - 5.5.4 maintain throughout the Term all appropriate licences and registrations with any relevant bodies (at the Supplier's expense) in respect of the Staff; and
 - 5.5.5 ensure all Staff comply with such registration, continuing professional development and training requirements or recommendations appropriate to their role including those from time to time issued by the Department of Health or any relevant regulatory body or any industry body in relation to such Staff; and
 - 5.5.6 comply with the Authority's staff vetting procedures and other staff protocols, as may be relevant to this Contract and which are notified to the Supplier by the Authority in writing.
- 5.6 The Supplier shall not deploy in the provision of the Services any person who has suffered from, has signs of, is under treatment for, or who is suffering from any medical

condition which is known to, or does potentially, place the health and safety of the Authority's staff, patients, service users or visitors at risk unless otherwise agreed in writing with the Authority.

- 5.7 The Supplier shall ensure that all potential Staff or persons performing any of the Services during the Term who may reasonably be expected in the course of performing any of the Services under this Contract to have access to or come into contact with children or other vulnerable persons and/or have access to or come into contact with persons receiving health care services:
 - 5.7.1 are questioned concerning their Convictions; and
 - 5.7.2 obtain appropriate disclosures from the Disclosure and Barring Service (or other appropriate body) as required by Law and/or the Policies before the Supplier engages the potential staff or persons in the provision of the Services.
- 5.8 The Supplier shall take all necessary steps to ensure that such potential staff or persons obtain standard and enhanced disclosures from the Disclosure and Barring Service (or other appropriate body) and shall ensure all such disclosures are kept up to date. The obtaining of such disclosures shall be at the Supplier's cost and expense.
- 5.9 The Supplier shall ensure that no person is employed or otherwise engaged in the provision of the Services without the Authority's prior written consent if:
 - 5.9.1 the person has disclosed any Convictions upon being questioned about their Convictions in accordance with Clause 5.7.1 of this Schedule 2 of these Call-off Terms and Conditions;
 - 5.9.2 the person is found to have any Convictions following receipt of standard and/or enhanced disclosures from the Disclosure and Barring Service (or other appropriate body) in accordance with Clause 5.7.2 of this Schedule 2 of these Call-off Terms and Conditions; or
 - 5.9.3 the person fails to obtain standard and/or enhanced disclosures from the Disclosure and Barring Service (or other appropriate body) upon request by the Supplier in accordance with Clause 5.7.2 of this Schedule 2 of these Call-off Terms and Conditions.
- 5.10 In addition to the requirements of Clause 5.7 to Clause 5.9 of this Schedule 2 of these Call-off Terms and Conditions, where the Services are or include regulated activities as defined by the Safeguarding Vulnerable Groups Act 2006 the Supplier:
 - 5.10.1 warrants that it shall comply with all requirements placed on it by the Safeguarding Vulnerable Groups Act 2006;
 - 5.10.2 warrants that at all times it has and will have no reason to believe that any member of Staff is barred in accordance with the Safeguarding Vulnerable Groups Act 2006; and
 - 5.10.3 shall ensure that no person is employed or otherwise engaged in the provision of the Services if that person is barred from carrying out, or whose previous conduct or records indicate that they would not be suitable to carry out, any regulated activities as defined by the Safeguarding Vulnerable

Groups Act 2006 or may present a risk to patients, service users or any other person.

- 5.11 The Supplier shall ensure that the Authority is kept advised at all times of any member of Staff who, subsequent to their commencement of employment as a member of Staff receives a Conviction or whose previous Convictions become known to the Supplier or whose conduct or records indicate that they are not suitable to carry out any regulated activities as defined by the Safeguarding Vulnerable Groups Act 2006 or may present a risk to patients, service users or any other person. The Supplier shall only be entitled to continue to engage or employ such member of Staff with the Authority's written consent and with such safeguards being put in place as the Authority may reasonably request. Should the Authority withhold consent the Supplier shall remove such member of Staff from the provision of the Services forthwith.
- 5.12 The Supplier shall immediately provide to the Authority any information that the Authority reasonably requests to enable the Authority to satisfy itself that the obligations set out in Clause 5.7 to Clause 5.11 of this Schedule 2 of these Call-off Terms and Conditions have been met.
- 5.13 The Authority may at any time request that the Supplier remove and replace any member of Staff from the provision of the Services, provided always that the Authority will act reasonably in making such a request. Prior to making any such request the Authority shall raise with the Supplier the Authority's concerns regarding the member of Staff in question with the aim of seeking a mutually agreeable resolution. The Authority shall be under no obligation to have such prior discussion should the Authority have concerns regarding patient or service user safety.
- 5.14 Unless otherwise confirmed by the Authority in writing, the Supplier shall ensure full compliance (to include with any implementation timelines) with any Guidance issued by the Department of Health and Social Care and/or any requirements and/or Policies issued by the Authority (to include as may be set out as part of any procurement documents leading to the award of this Contract) in relation to the adoption of, and compliance with, any scheme or schemes to verify the credentials of Supplier representatives that visit NHS premises (to include use of the Lifescience Industry Accredited Credentialing Register). Once compliance with any notified implementation timelines has been achieved by the Supplier, the Supplier shall, during the Term, maintain the required level of compliance in accordance with any such Guidance, requirements and Policies.

6 Business continuity

- 6.1 Throughout the Term, the Supplier will ensure its Business Continuity Plan provides for continuity during a Business Continuity Event. The Supplier confirms and agrees such Business Continuity Plan details and will continue to detail robust arrangements that are reasonable and proportionate to:
- 6.1.1 the criticality of this Contract to the Authority; and
- 6.1.2 the size and scope of the Supplier's business operations,
- regarding continuity of the supply of the Goods and the provision of the Services during and following a Business Continuity Event.
- 6.2 The Supplier shall test its Business Continuity Plan at reasonable intervals, and in any event no less than once every twelve (12) months or such other period as may be

agreed between the Parties taking into account the criticality of this Contract to the Authority and the size and scope of the Supplier's business operations. The Supplier shall promptly provide to the Authority, at the Authority's written request, copies of its Business Continuity Plan, reasonable and proportionate documentary evidence that the Supplier tests its Business Continuity Plan in accordance with the requirements of this Clause 6.3 of this Schedule 2 of these Call-off Terms and Conditions and reasonable and proportionate information regarding the outcome of such tests. The Supplier shall provide to the Authority a copy of any updated or revised Business Continuity Plan within fourteen (14) Business Days of any material update or revision to the Business Continuity Plan.

- 6.3 Should a Business Continuity Event occur at any time, the Supplier shall implement and comply with its Business Continuity Plan and provide regular written reports to the Authority on such implementation.
- 6.4 During and following a Business Continuity Event, the Supplier shall use reasonable endeavours to continue to supply the Goods and provide the Services in accordance with this Contract.

7 The Authority's obligations

- 7.1 Subject to the Supplier supplying the Goods and providing the Services in accordance with this Contract, the Authority will pay the Supplier for the Goods and/or Services in accordance with Clause 9 of this Schedule 2 of these Call-off Terms and Conditions.
- 7.2 The Authority shall, as appropriate, provide copies of or give the Supplier access to such of the Policies that are relevant to the supply of the Goods and the provision of the Services.
- 7.3 The Authority shall comply with the Authority's Obligations.
- 7.4 The Authority shall provide the Supplier with any reasonable and proportionate cooperation necessary to enable the Supplier to comply with its obligations under this Contract. The Supplier shall at all times provide reasonable advance written notification to Authority of any such cooperation necessary in circumstances where such cooperation will require the Authority to plan for and/or allocate specific resources in order to provide such cooperation.

8 Contract management

- 8.1 Each Party shall appoint and retain a Contract Manager who shall be the primary point of contact for the other Party in relation to matters arising from this Contract. Should the Contract Manager be replaced, the Party replacing the Contract Manager shall promptly inform the other Party in writing of the name and contact details for the new Contract Manager. Any Contract Manager appointed shall be of sufficient seniority and experience to be able to make decisions on the day-to-day operation of the Contract. The Supplier confirms and agrees that it will be expected to work closely and cooperate fully with the Authority's Contract Manager.
- 8.2 Each Party shall ensure that its representatives (to include, without limitation, its Contract Manager) shall attend review meetings on a regular basis to review the performance of the Supplier under this Contract and to discuss matters arising generally under this Contract. Each Party shall ensure that those attending such meetings have the authority to make decisions regarding the day-to-day operation of

the Contract. Review meetings shall take place at the frequency specified in the Specification and Tender Response Document. Should the Specification and Tender Response Document not state the frequency, then the first such meeting shall take place on a date to be agreed on or around the end of the first month after the Commencement Date. Subsequent meetings shall take place at monthly intervals or as may otherwise be agreed in writing between the Parties.

- 8.3 The Supplier shall, on a weekly basis, submit the completed and up to date Performance Monitoring Tool to the Authority to the Renal Email Inbox.
- 8.4 Two weeks prior to each review meeting (or at such time and frequency as may be specified in the Specification and Tender Response Document) the Supplier shall provide a written contract management report to the Authority regarding the supply of the Goods, the provision of the Services and the operation of this Contract. Unless otherwise agreed by the Parties in writing, such contract management report shall contain:
 - 8.4.1 details of the performance of the Supplier when assessed in accordance with the KPIs since the last such performance report;
 - 8.4.2 details of any complaints by the Authority regarding the supply of Goods or provision of Services and any complaints from or on behalf of patients or other service users, their nature and the way in which the Supplier has responded to such complaints since the last review meeting written report;
 - 8.4.3 the information specified in the Specification and Tender Response Document;
 - 8.4.4 a status report in relation to the implementation of any current Remedial Proposals by either Party; and
 - 8.4.5 such other information as reasonably required by the Authority.
- 8.5 Unless specified otherwise in the Specification and Tender Response Document, the Authority shall take minutes of each review meeting and shall circulate draft minutes to the Supplier within a reasonable time following such review meeting. The Supplier shall inform the Authority in writing of any suggested amendments to the minutes within five (5) Business Days of receipt of the draft minutes. If the Supplier does not respond to the Authority within such five (5) Business Days the minutes will be deemed to be approved. Where there are any differences in interpretation of the minutes, the Parties will use their reasonable endeavors to reach agreement. If agreement cannot be reached the matter shall be referred to, and resolved in accordance with, the dispute resolution process set out in Clause 5 of the Key Provisions and Clause 22.3 of this Schedule 2 of these Call-off Terms and Conditions.
- 8.6 The Supplier shall provide such management information as the Authority may request from time to time within seven (7) Business Days of the date of the request. The Supplier shall supply the management information to the Authority in such form as may be specified by the Authority and, where requested to do so, the Supplier shall also provide such management information to another Contracting Authority, whose role it is to: (a) analyse such management information in accordance with UK government policy (to include, without limitation, for the purposes of analysing public sector expenditure and planning future procurement activities); or (b) manage the Framework Agreement with the Supplier ("**Third Party Body**"). The Supplier confirms and agrees that the Authority may itself provide the Third Party Body with management information

relating to the Goods and Services purchased, any payments made under this Contract, and any other information relevant to the operation of this Contract.

8.7 Upon receipt of management information supplied by the Supplier to the Authority and/or the Third Party Body, or by the Authority to the Third Party Body, the Parties hereby consent to the Third Party Body and the Authority:

8.7.1 storing and analysing the management information and producing statistics; and

8.7.2 sharing the management information or any statistics produced using the management information with any other Contracting Authority.

8.8 If the Third Party Body and/or the Authority shares the management information or any other information provided under Clause 8.6 of this Schedule 2 of these Call-off Terms and Conditions, any Contracting Authority receiving the management information shall, where such management information is subject to obligations of confidence under this Contract and such management information is provided direct by the Authority to such Contracting Authority, be informed of the confidential nature of that information by the Authority and shall be requested by the Authority not to disclose it to any body that is not a Contracting Authority (unless required to do so by Law).

8.9 The Authority may make changes to the type of management information which the Supplier is required to supply and shall give the Supplier at least one (1) month's written notice of any changes.

9 Price and payment

9.1 The Contract Price shall be calculated in accordance with the provisions of the Framework Agreement, as confirmed in the Order Form.

9.2 Unless otherwise stated in the Framework Agreement and/or the Order Form, the Contract Price:

9.2.1 shall remain fixed during the Term; and

9.2.2 in respect of the Goods, is the entire price payable by the Authority to the Supplier in respect of the provision of the Goods and includes, without limitation:

- (i) packaging, packing materials, addressing, labelling, loading, delivery to and unloading at the delivery location, the cost of any import or export licences, all appropriate taxes (excluding VAT), duties and tariffs, any expenses arising from import and export administration, any installation costs and associated works, the costs of all associated documentation and information supplied or made accessible to the Authority in any media, and any training in relation to the use, storage, handling or operation of the Goods;
- (ii) any royalties, licence fees or similar expenses in respect of the making, use or exercise by the Supplier of any Intellectual Property Rights for the purposes of performing this Contract, and any licence rights granted to the Authority in accordance with Clause 11 of this Schedule 2 of these Call-off Terms and Conditions; and

- (iii) costs and expenses in relation to supplies and materials used by the Supplier or any third party in the manufacture of the Goods, and any other costs incurred by the Supplier in association with the manufacture, supply or installation of the Goods; and

9.2.3 in respect of the Services:

- (i) shall be payable from the Actual Services Commencement Date; and
- (ii) is the entire price payable by the Authority to the Supplier in respect of the Services and includes, without limitation, any royalties, licence fees, supplies and all consumables used by the Supplier, travel costs, accommodation expenses, the cost of Staff and all appropriate taxes (excluding VAT), duties and tariffs and any expenses arising from import and export administration.

9.3 Unless stated otherwise in the Framework Agreement and/or the Order Form:

9.3.1 where the Framework Agreement and/or the Order Form confirms that the payment profile for this Contract is monthly in arrears, the Supplier shall invoice the Authority, within fourteen (14) days of the end of each calendar month, the Contract Price in respect of the Goods supplied or the Services provided in compliance with this Contract in the preceding calendar month; or

9.3.2 where Clause 9.3.1 of this Schedule 2 of these Call-off Terms and Conditions does not apply, the Supplier shall invoice the Authority for the Goods or Services at any time following completion of the supply of the Goods or the provision of the Services in compliance with this Contract.

Each invoice shall contain such information and be addressed to such individual as the Authority may inform the Supplier from time to time.

9.4 The Contract Price is exclusive of VAT, which, if properly chargeable, the Authority shall pay at the prevailing rate subject to receipt from the Supplier of a valid and accurate VAT invoice. Such VAT invoices shall show the VAT calculations as a separate line item.

9.5 Where the Contract Price is or may become subject to any pricing requirements of any voluntary and/or statutory pricing regulation schemes, the Parties shall comply with such pricing requirements as required by Law from time to time and specifically as required by the statutory pricing regulation scheme (and any future regulation) or to the extent applicable to the Supplier from time to time as an industry member of a voluntary scheme, including any reductions in price by reason of the application of such schemes.

9.6 The Authority shall verify and pay each valid and undisputed invoice received in accordance with Clause 9.3 of this Schedule 2 of these Call off Terms and Conditions within thirty (30) days of receipt of such invoice at the latest. However, the Authority shall use its reasonable endeavours to pay such undisputed invoices sooner in accordance with any applicable government prompt payment targets. If there is undue delay in verifying the invoice in accordance with this Clause 9.6 of this Schedule 2, the invoice shall be regarded as valid and undisputed for the purposes this Clause 9.6 after a reasonable time has passed.

- 9.7 Where the Authority raises a query with respect to an invoice the Parties shall liaise with each other and agree a resolution to such query within thirty (30) days of the query being raised. If the Parties are unable to agree a resolution within thirty (30) days the query shall be referred to dispute resolution in accordance with Clause 22 of this Schedule 2 of these Call off Terms and Conditions. For the avoidance of doubt, the Authority shall not be in breach of any of any of its payment obligations under this Contract in relation to any queried or disputed invoice sums unless the process referred to in this Clause 9.7 of this Schedule 2 has been followed and it has been determined that the queried or disputed invoice amount is properly due to the Supplier and the Authority has then failed to pay such sum within a reasonable period following such determination.
- 9.8 The Supplier shall pay to the Authority any service credits and/or other sums and/or deductions (to include, without limitation, deductions relating to a reduction in the Contract Price) that may become due in accordance with the provisions of the Specification and Tender Response Document and/or the Order Form. For the avoidance of doubt, the Authority may invoice the Supplier for such sums or deductions at any time in the event that they have not automatically been credited to the Authority in accordance with the provisions of the Specification and Tender Response Document and/or Order Form. Such invoice shall be paid by the Supplier within 30 days of the date of such invoice.
- 9.9 The Authority reserves the right to set-off:
- 9.9.1 any monies due to the Supplier from the Authority as against any monies due to the Authority from the Supplier under this Contract; and
- 9.9.2 any monies due to the Authority from the Supplier as against any monies due to the Supplier from the Authority under this Contract.
- 9.10 Where the Authority is entitled to receive any sums (including, without limitation, any costs, charges or expenses) from the Supplier under this Contract, the Authority may invoice the Supplier for such sums. Such invoices shall be paid by the Supplier within 30 days of the date of such invoice.
- 9.11 If a Party fails to pay any undisputed sum properly due to the other Party under this Contract, the Party due such sum shall have the right to charge interest on the overdue amount at the applicable rate under the Late Payment of Commercial Debts (Interest) Act 1998, accruing on a daily basis from the due date up to the date of actual payment, whether before or after judgment.

10 Warranties

- 10.1 The Supplier warrants and undertakes that:
- 10.1.1 it shall comply with the Framework Agreement;
- 10.1.2 the Goods shall be suitable for the purposes and/or treatments as referred to in the Specification and Tender Response Document, be of satisfactory quality, fit for their intended purpose and shall comply with the standards and requirements set out in this Contract;
- 10.1.3 unless otherwise confirmed by the Authority in writing (to include, without limitation, as part of the Specification and Tender Response Document), it will ensure that the Goods and any products purchased by the Supplier

partially or wholly for the purpose of providing the services comply with requirements five (5) to eight (8), as set out in Annex 1 of the Cabinet Office Procurement Policy Note – Implementing Article 6 of the Energy Efficiency Directive (Action Note 07/14 3rd June 2014), to the extent such requirements apply to the relevant Goods;

- 10.1.4 it shall ensure that prior to actual delivery to the Authority the Goods are manufactured, stored and/or distributed using reasonable skill and care and in accordance with Good Industry Practice;
- 10.1.5 without prejudice to the generality of the warranty at 10.1.4 of this Schedule 2 of these Call-off Terms and Conditions, it shall ensure that, the Goods are manufactured, stored and/or distributed in accordance with good manufacturing practice and/or good warehousing practice and/or good distribution practice, as may be defined under any Law, Guidance and/or Good Industry Practice relevant to the Goods, and in accordance with any specific instructions of the manufacturer of the Goods;
- 10.1.6 it shall ensure that all facilities used in the manufacture, storage and distribution of the Goods are kept in a state and condition necessary to enable the Supplier to comply with its obligations in accordance with this Contract;
- 10.1.7 it has, or the manufacturer of the Goods has, manufacturing and warehousing capacity sufficient to comply with its obligations under this Contract;
- 10.1.8 it will ensure sufficient stock levels to comply with its obligations under this Contract;
- 10.1.9 it shall ensure that the transport and delivery of the Goods mean that they are delivered in good and useable condition;
- 10.1.10 where the Goods are required to be stored at a certain temperature, it shall provide, or shall procure the provision of, complete and accurate temperature records for each delivery of the Goods during the period of transport and/or storage of the Goods from the point of manufacture to the point of delivery to the Authority;
- 10.1.11 where there is any instruction information, including without limitation patient information leaflets, that accompany the Goods, it shall provide a sufficient number of copies to the Authority and provide updated copies should the instruction information change at any time during the Term;
- 10.1.12 all Goods delivered to the Authority shall comply with any shelf life requirements set out in the Specification and Tender Response Document;
- 10.1.13 it shall not make any significant changes to the Goods without the prior written consent of the Authority, such consent not to be unreasonably withheld or delayed;
- 10.1.14 any equipment it uses in the manufacture, delivery, or installation of the Goods shall comply with all relevant Law and Guidance, be fit for its intended purpose and maintained fully in accordance with the manufacturer's specification;

- 10.1.15 it has and shall as relevant maintain all rights, consents, authorisations, licences and accreditations required to supply the Goods;
- 10.1.16 it has, and shall ensure its Staff shall have, and shall maintain throughout the Term, all appropriate licences and registrations with the relevant bodies to fulfil its obligations under this Contract;
- 10.1.17 it has all rights, consents, authorisations, licences and accreditations required to provide the Services and shall maintain such consents, authorisations, licences and accreditations throughout the Term;
- 10.1.18 it has and shall maintain a properly documented system of quality controls and processes covering all aspects of its obligations under this Contract and/or under Law and/or Guidance and shall at all times comply with such quality controls and processes;
- 10.1.19 it shall not make any significant changes to its system of quality controls and processes in relation to the Goods and/or Services without notifying the Authority in writing at least twenty one (21) days in advance of such change (such notice to include the details of the consequences which follow such change being implemented);
- 10.1.20 where any act of the Supplier requires the notification to and/or approval by any regulatory or other competent body in accordance with any Law and Guidance, the Supplier shall comply fully with such notification and/or approval requirements;
- 10.1.21 receipt of the Goods and/or Services by or on behalf of the Authority and use of the Goods and/or deliverables or of any other item or information supplied or made available to the Authority will not infringe any third party rights, to include without limitation any Intellectual Property Rights;
- 10.1.22 it will comply with all Law, Guidance, Policies and the Supplier Code of Conduct in so far as is relevant to the supply of the Goods and/or the provision of the Services;
- 10.1.23 it will provide the Services using reasonable skill and care and in accordance with Good Industry Practice and shall fulfil all requirements of this Contract using appropriately skilled, trained and experienced staff;
- 10.1.24 unless otherwise set out in the Specification and Tender Response Document and/or as otherwise agreed in writing by the Parties, it has and/or shall procure all resources, equipment, consumables and other items and facilities required to provide the Services;
- 10.1.25 without limitation to the generality of Clause 10.1.22 of this Schedule 2 of these Call-off Terms and Conditions, it shall comply with all health and safety processes, requirements safeguards, controls, and training obligations in accordance with its own operational procedures, Law, Guidance, Policies, Good Industry Practice, the requirements of the Specification and Tender Response Document and any notices or instructions given to the Supplier by the Authority and/or any competent body, as relevant to the supply of the Goods, the provision of the Services and the Supplier's access to the Premises and Locations in accordance with this Contract;

- 10.1.26 without prejudice to any specific notification requirements set out in this Contract, it will promptly notify the Authority of any health and safety hazard which has arisen, or the Supplier is aware may arise, in connection with the Goods and/or the performance of the Services and take such steps as are reasonably necessary to ensure the health and safety of persons likely to be affected by such hazards;
- 10.1.27 any equipment it uses in the provision of the Services shall comply with all relevant Law and Guidance, be fit for its intended purpose and maintained fully in accordance with the manufacturer's specification and shall remain the Supplier's risk and responsibility at all times;
- 10.1.28 it shall use Good Industry Practice to ensure that any information and communications technology systems and/or related hardware and/or software it uses are free from corrupt data, viruses, worms and any other computer programs or code which might cause harm or disruption to the Authority's information and communications technology systems;
- 10.1.29 it will fully and promptly respond to all requests for information and/or requests for answers to questions regarding this Contract, the Goods, the provision of the Services, any complaints and any Disputes at the frequency, in the timeframes and in the format as requested by the Authority from time to time (acting reasonably);
- 10.1.30 all information included within the Supplier's responses to any documents issued by the Authority as part of the procurement relating to the award of this Contract (to include, without limitation, as referred to in the Specification and Tender Response Document and/or Order Form) and all accompanying materials is accurate;
- 10.1.31 it has the right and authority to enter into this Contract and that it has the capability and capacity to fulfil its obligations under this Contract;
- 10.1.32 it is a properly constituted entity and it is fully empowered by the terms of its constitutional documents to enter into and to carry out its obligations under this Contract and the documents referred to in this Contract;
- 10.1.33 all necessary actions to authorise the execution of and performance of its obligations under this Contract have been taken before such execution;
- 10.1.34 there are no pending or threatened actions or proceedings before any court or administrative agency which would materially adversely affect the financial condition, business or operations of the Supplier;
- 10.1.35 there are no material agreements existing to which the Supplier is a party which prevent the Supplier from entering into or complying with this Contract;
- 10.1.36 it has and will continue to have the capacity, funding and cash flow to meet all its obligations under this Contract; and
- 10.1.37 it has satisfied itself as to the nature and extent of the risks assumed by it under this Contract and has gathered all information necessary to perform its obligations under this Contract and all other obligations assumed by it.

- 10.2 Where the sale, manufacture, assembly, importation, storage, distribution, supply, delivery, or installation of the Goods under this Contract relates to medical devices and/or medicinal products (both as defined under any relevant Law and Guidance), the Supplier warrants and undertakes that it will comply with any such Law and Guidance relating to such activities in relation to such medical devices and/or medicinal products. In particular, but without limitation, the Supplier warrants that:
- 10.2.1 at the point such Goods are supplied to the Authority, all such Goods which are medical devices shall have valid CE marking as required by Law and Guidance and that all relevant marking, authorisation, registration, approval and documentation requirements as required under Law and Guidance relating to the sale, manufacture, assembly, importation, storage, distribution, supply, delivery, or installation of such Goods shall have been complied with. Without limitation to the foregoing provisions of this Clause 10.2 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall, upon written request from the Authority, make available to the Authority evidence of the grant of such valid CE marking, and evidence of any other authorisations, registrations, approvals or documentation required;
 - 10.2.2 at the point such Goods are supplied to the Authority, all such Goods which are medicinal products shall have a valid marketing authorisation as required by Law and Guidance in order to supply the Goods to the Authority and that all relevant authorisation, labelling, registration, approval and documentation requirements as required under Law and Guidance relating to the sale, manufacture, assembly, importation, storage, distribution, supply or delivery of such Goods shall have been complied with. Without limitation to the foregoing provisions of this Clause 10.2 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall, upon written request from the Authority, make available to the Authority evidence of the grant of any required valid marketing authorisation, and evidence of any other authorisations, labelling, registrations, approvals or documentation required; and
 - 10.2.3 it shall maintain, and no later than any due date when it would otherwise expire, obtain a renewal of, any authorisation, registration or approval (including without limitation CE marking and/or marketing authorisation) required in relation to the Goods in accordance with Law and Guidance until such time as the Goods expire or the Authority notifies the Supplier in writing that it has used or disposed of all units of the Goods supplied under this Contract.
- 10.3 If the Supplier is in breach of Clause 10.2 of this Schedule 2 of these Call-off Terms and Conditions, then, without prejudice to any other right or remedy of the Authority, the Authority shall be entitled to reject and/or return the Goods and the Supplier shall, subject to Clause 13.2 of this Schedule 2 of these Call-off Terms and Conditions, indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such breach.
- 10.4 The Supplier agrees to use reasonable endeavours to assign to the Authority upon request the benefit of any warranty, guarantee or similar right which it has against any third party manufacturer or supplier of the Goods in full or part.

- 10.5 The Supplier warrants that all information, data and other records and documents required by the Authority as set out in the Specification and Tender Response Document shall be submitted to the Authority in the format and in accordance with any timescales set out in the Specification and Tender Response Document.
- 10.6 Without prejudice to the generality of Clause 10.5 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier acknowledges that a failure by the Supplier to submit accurate invoices and other information on time to the Authority may result in the commissioner of health services, or other entity responsible for reimbursing costs to the Authority, delaying or failing to make relevant payments to the Authority. Accordingly, the Supplier warrants that it shall submit accurate invoices and other information on time to the Authority.
- 10.7 The Supplier warrants and undertakes to the Authority that it shall comply with any eProcurement Guidance as it may apply to the Supplier and shall carry out all reasonable acts required of the Supplier to enable the Authority to comply with such eProcurement Guidance.
- 10.8 The Supplier 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 Supplier shall:
- 10.8.1 notify the Authority in writing of such fact within five (5) Business Days of its occurrence; and
- 10.8.2 promptly provide to the Authority:
- (i) details of the steps which the Supplier 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
- (ii) such other information in relation to the Occasion of Tax Non-Compliance as the Authority may reasonably require.
- 10.9 The Supplier further warrants and undertakes to the Authority that it will inform the Authority in writing immediately upon becoming aware that any of the warranties set out in Clause 10 of this Schedule 2 of these Call-off Terms and Conditions have been breached or there is a risk that any warranties may be breached.
- 10.10 Any warranties provided under this Contract are both independent and cumulative and may be enforced independently or collectively at the sole discretion of the enforcing Party.

11 Intellectual property

- 11.1 Unless specified otherwise in the Specification and Tender Response Document, the Supplier hereby grants to the Authority, for the life of the use of Goods by the Authority, an irrevocable, royalty-free, non-exclusive licence of any Intellectual Property Rights required for the purposes of receiving and using, and to the extent necessary to receive and use, the Goods (to include any associated technical or other documentation and information supplied or made accessible to the Authority in any media) in accordance with this Contract.

- 11.2 Unless specified otherwise in the Specification and Tender Response Document, the Supplier hereby grants to the Authority, for the life of the use by the Authority of any deliverables, material or any other output supplied to the Authority in any format as part of the Services, an irrevocable, royalty-free, non-exclusive licence to use, modify, adapt or enhance such items in the course of the Authority's normal business operations. For the avoidance of doubt, unless specified otherwise in any Key Provisions and/or the Specification and Tender Response Document, the Authority shall have no rights to commercially exploit (e.g. by selling to third parties) any deliverables, matter or any other output supplied to the Authority in any format as part of the Services.

12 Indemnity

- 12.1 The Supplier shall be liable to the Authority for, and shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings in respect of:

- 12.1.1 any injury or allegation of injury to any person, including injury resulting in death;
- 12.1.2 any loss of or damage to property (whether real or personal);
- 12.1.3 any breach of Clause 10.1.20 and/or Clause 11 of this Schedule 2 of these Call-off Terms and Conditions; and/or
- 12.1.4 any failure by the Supplier to commence the delivery of the Services by the Services Commencement Date;

that arise or result from the Supplier's negligent acts or omissions or breach of contract in connection with the performance of this Contract including the supply of Goods and provision of the Services, except to the extent that such loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings have been caused by any act or omission by, or on behalf of, or in accordance with the instructions of, the Authority.

- 12.2 Liability under Clauses 12.1.1, 12.1.3 and 17.13 of this Schedule 2 of these Call-off Terms and Conditions and Clause 2.6 of Schedule 3 of these Call-off Terms and Conditions shall be unlimited. Liability under Clauses 3.9.4, 10.3, 12.1.2 and 12.1.4 of this Schedule 2 of these Call-off Terms and Conditions shall be subject to the limitation of liability set out in Clause 13 of this Schedule 2 of these Call-off Terms and Conditions.
- 12.3 In relation to all third party claims against the Authority, which are the subject of any indemnity given by the Supplier under this Contract, the Authority shall use its reasonable endeavours, upon a written request from the Supplier, to transfer the conduct of such claims to the Supplier unless restricted from doing so. Such restrictions may include, without limitation, any restrictions:
- 12.3.1 relating to any legal, regulatory, governance, information governance, or confidentiality obligations on the Authority; and/or
 - 12.3.2 relating to the Authority's membership of any indemnity and/or risk pooling arrangements.

Such transfer shall be subject to the Parties agreeing appropriate terms for such conduct of the third party claim by the Supplier (to include, without limitation, the right of the Authority to be informed and consulted on the ongoing conduct of the claim following such transfer and any reasonable cooperation required by the Supplier from the Authority).

13 Limitation of liability

13.1 Nothing in this Contract shall exclude or restrict the liability of either Party:

13.1.1 for death or personal injury resulting from its negligence;

13.1.2 for fraud or fraudulent misrepresentation; or

13.1.3 in any other circumstances where liability may not be limited or excluded under any applicable law.

13.2 Subject to Clauses 12.2, 13.1, 13.3 and 13.5 of this Schedule 2 of these Call-off Terms and Conditions, 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 shall be limited in aggregate to the greater of: (a) five million GBP (£5,000,000); or (b) one hundred and twenty five percent (125%) of the total Contract Price paid or payable by the Authority to the Supplier for the Goods and Services.

13.3 There shall be no right to claim losses, damages and/or other costs and expenses under or in connection with this Contract whether arising in contract (to include, without limitation, under any relevant indemnity), tort, negligence, breach of statutory duty or otherwise to the extent that any losses, damages and/or other costs and expenses claimed are in respect of loss of production, loss of business opportunity or are in respect of indirect loss of any nature suffered or alleged. For the avoidance of doubt, without limitation, the Parties agree that for the purposes of this Contract the following costs, expenses and/or loss of income shall be direct recoverable losses (to include under any relevant indemnity) provided such costs, expenses and/or loss of income are properly evidenced by the claiming Party:

13.3.1 extra costs incurred purchasing replacement or alternative goods and/or services;

13.3.2 costs incurred in relation to any product recall;

13.3.3 costs associated with advising, screening, testing, treating, retreating or otherwise providing healthcare to patients;

13.3.4 the costs of extra management time; and/or

13.3.5 loss of income due to an inability to provide health care services,

in each case to the extent to which such costs, expenses and/or loss of income arise or result from the other Party's breach of contract, negligent act or omission, breach of statutory duty, and/or other liability under or in connection with this Contract.

13.4 Each Party shall at all times take all reasonable steps to minimise and mitigate any loss for which that Party is entitled to bring a claim against the other pursuant to this Contract.

- 13.5 If the total Contract Price paid or payable by the Authority to the Supplier over the Term:
- 13.5.1 is less than or equal to one million pounds (£1,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 of these Call-off Terms and Conditions shall be replaced with one million pounds (£1,000,000);
 - 13.5.2 is less than or equal to three million pounds (£3,000,000) but greater than one million pounds (£1,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 of these Call-off Terms and Conditions shall be replaced with three million pounds (£3,000,000);
 - 13.5.3 is equal to, exceeds or will exceed ten million pounds (£10,000,000), but is less than fifty million pounds (£50,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 of these Call-off Terms and Conditions shall be replaced with ten million pounds (£10,000,000) and the figure of one hundred and twenty five percent (125%) at Clause 13.2 of this Schedule 2 of these Call-off Terms and Conditions shall be deemed to have been deleted and replaced with one hundred and fifteen percent (115%); and
 - 13.5.4 is equal to, exceeds or will exceed fifty million pounds (£50,000,000), then the figure of five million pounds (£5,000,000) at Clause 13.2 of this Schedule 2 of these Call-off Terms and Conditions shall be replaced with fifty million pounds (£50,000,000) and the figure of one hundred and twenty five percent (125%) at Clause 13.2 of this Schedule 2 of these Call-off Terms and Conditions shall be deemed to have been deleted and replaced with one hundred and five percent (105%).
- 13.6 Clause 13.5 of this Schedule 2 of these Call-off Terms and Conditions shall survive the expiry of or earlier termination of this Contract for any reason.

14 Insurance

- 14.1 Subject to Clauses 14.2 and 14.3 of this Schedule 2 of these Call-off Terms and Conditions and unless otherwise confirmed in writing by the Authority, as a minimum level of protection, the Supplier shall put in place and/or maintain in force at its own cost with a reputable commercial insurer, insurance arrangements in respect of employer's liability, public liability, product liability and professional indemnity in accordance with Good Industry Practice with the minimum cover per claim of the greater of five million pounds (£5,000,000) or any sum as required by Law unless otherwise agreed with the Authority in writing. These requirements shall not apply to the extent that the Supplier is a member and maintains membership of each of the indemnity schemes run by the NHS Litigation Authority.
- 14.2 Without limitation to any insurance arrangements as required by Law, the Supplier shall put in place and/or maintain the different types and/or levels of indemnity arrangements specified in the Framework Agreement, if any.
- 14.3 Provided that the Supplier maintains all indemnity arrangements required by Law, the Supplier may self insure in order to meet other relevant requirements referred to at Clauses 14.1 and 14.2 of this Schedule 2 of these Call-off Terms and Conditions on condition that such self insurance arrangements offer the appropriate levels of

protection and are approved by the Authority in writing prior to the Commencement Date.

- 14.4 The amount of any indemnity cover and/or self insurance arrangements shall not relieve the Supplier of any liabilities under this Contract. It shall be the responsibility of the Supplier to determine the amount of indemnity and/or self insurance cover that will be adequate to enable it to satisfy its potential liabilities under this Contract. Accordingly, the Supplier shall be liable to make good any deficiency if the proceeds of any indemnity cover and/or self insurance arrangement is insufficient to cover the settlement of any claim.
- 14.5 The Supplier warrants that it shall not take any action or fail to take any reasonable action or (in so far as it is reasonable and within its power) permit or allow others to take or fail to take any action, as a result of which its insurance cover may be rendered void, voidable, unenforceable, or be suspended or impaired in whole or in part, or which may otherwise render any sum paid out under such insurances repayable in whole or in part.
- 14.6 The Supplier shall from time to time and in any event within five (5) Business Days of written demand provide documentary evidence to the Authority that insurance arrangements taken out by the Supplier pursuant to Clause 14 of this Schedule 2 of these Call-off Terms and Conditions and/or the provisions of the Framework Agreement are fully maintained and that any premiums on them and/or contributions in respect of them (if any) are fully paid.
- 14.7 Upon the expiry or earlier termination of this Contract, the Supplier shall ensure that any ongoing liability it has or may have arising out of this Contract shall continue to be the subject of appropriate indemnity arrangements for the period of twenty one (21) years from termination or expiry of this Contract or until such earlier date as that liability may reasonably be considered to have ceased to exist.

15 Term and termination

- 15.1 This Contract shall commence on the Commencement Date and, unless terminated earlier in accordance with the terms of this Contract or the general law, shall continue until the end of the Term.
- 15.2 The Authority shall be entitled to terminate the Contract by providing at least 3 months' written notice to the Supplier, such termination to take effect on either 30 September 2023, 30 September 2024 or such other date as the parties shall agree.
- 15.3 In the case of a breach of any of the terms of this Contract by either Party that is capable of remedy (including, without limitation any breach of any KPI and, subject to Clause 9.7 of this Schedule 2 of these Call-off Terms and Conditions, any breach of any payment obligations under this Contract), the non-breaching Party may, without prejudice to its other rights and remedies under this Contract, issue a Breach Notice and shall allow the Party in breach the opportunity to remedy such breach in the first instance via a remedial proposal put forward by the Party in breach ("**Remedial Proposal**") before exercising any right to terminate this Contract in accordance with Clause 15.4(ii) of this Schedule 2 of these Call-off Terms and Conditions. Such Remedial Proposal must be agreed with the non-breaching Party (such agreement not to be unreasonably withheld or delayed) and must be implemented by the Party in breach 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 Party in breach to:

- 15.3.1 put forward and agree a Remedial Proposal with the non-breaching Party in relation to the relevant default or breach within a period of ten (10) Business 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 non-breaching Party;
- 15.3.2 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
- 15.3.3 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 15.4(ii) of this Schedule 2 of these Call-off Terms and Conditions, a material breach of this Contract by the Party in breach not remedied in accordance with an agreed Remedial Proposal.

- 15.4 Either Party may terminate this Contract by issuing a Termination Notice to the other Party if such other Party commits a material breach of any of the terms of this Contract which is:
 - (i) not capable of remedy; or
 - (ii) in the case of a breach capable of remedy, which is not remedied in accordance with a Remedial Proposal.
- 15.5 The Authority may terminate this Contract by issuing a Termination Notice to the Supplier if:
 - 15.5.1 the Supplier does not commence supply of the Goods and/or delivery of the Services by any Long Stop Date;
 - 15.5.2 the Supplier, or any third party guaranteeing the obligations of the Supplier under this Contract, ceases or threatens to cease carrying on its business; suspends making payments on any of its debts or announces an intention to do so; is, or is deemed for the purposes of any Law to be, unable to pay its debts as they fall due or insolvent; enters into or proposes any composition, assignment or arrangement with its creditors generally; takes any step or suffers any step to be taken in relation to its winding-up, dissolution, administration (whether out of court or otherwise) or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) otherwise than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation; has a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, administrator or similar officer appointed (in each case, whether out of court or otherwise) in respect of it or any of its assets; has any security over any of its assets enforced; or any analogous procedure or step is taken in any jurisdiction;
 - 15.5.3 the Supplier undergoes a change of control within the meaning of sections 450 and 451 of the Corporation Tax Act 2010 (other than for an intra-group change of control) without the prior written consent of the Authority and the Authority shall be entitled to withhold such consent if, in the reasonable opinion of the Authority, the proposed change of control will have a material impact on the performance of this Contract or the reputation of the Authority;

- 15.5.4 the Supplier purports to assign, Sub-contract, novate, create a trust in or otherwise transfer or dispose of this Contract in breach of Clause 28.1 of this Schedule 2 of these Call-off Terms and Conditions;
 - 15.5.5 pursuant to and in accordance with any termination rights set out in any Key Provisions and Clauses 15.6, 23.8; 25.2; 25.4 and 29.2 of this Schedule 2 of these Call-off Terms and Conditions; or
 - 15.5.6 the warranty given by the Supplier pursuant to Clause 10.8 of this Schedule 2 of these Call-off Terms and Conditions is materially untrue, the Supplier commits a material breach of its obligation to notify the Authority of any Occasion of Tax Non-Compliance as required by Clause 10.8 of this Schedule 2 of these Call-off Terms and Conditions, or the Supplier fails to provide details of proposed mitigating factors as required by Clause 10.8 of this Schedule 2 of these Call-off Terms and Conditions that in the reasonable opinion of the Authority are acceptable.
- 15.6 If the Authority, acting reasonably, has good cause to believe that there has been a material deterioration in the financial circumstances of the Supplier and/or any third party guaranteeing the obligations of the Supplier under this Contract and/or any material Sub-contractor of the Supplier when compared to any information provided to and/or assessed by the Authority as part of any procurement process or other due diligence leading to the award of this Contract to the Supplier or the entering into a Sub-contract by the Supplier, the following process shall apply:
- 15.6.1 the Authority may (but shall not be obliged to) give notice to the Supplier requesting adequate financial or other security and/or assurances for due performance of its material obligations under this Contract on such reasonable and proportionate terms as the Authority may require within a reasonable time period as specified in such notice;
 - 15.6.2 a failure or refusal by the Supplier to provide the financial or other security and/or assurances requested in accordance with Clause 15.6 of this Schedule 2 of these Call-off Terms and Conditions in accordance with any reasonable timescales specified in any such notice issued by the Authority shall be deemed a breach of this Contract by the Supplier and shall be referred to and resolved in accordance with the Dispute Resolution Procedure; and
 - 15.6.3 a failure to resolve such breach in accordance with such Dispute Resolution Procedure by the end of the escalation stage of such process (as set out in Clause 22.3 of this Schedule 2 of these Call-off Terms and Conditions) shall entitle, but shall not compel, the Authority to terminate this Contract in accordance with Clause 15.4(i) of this Schedule 2 of these Call-off Terms and Conditions.

In order that the Authority may act reasonably in exercising its discretion in accordance with Clause 15.6 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall provide the Authority with such reasonable and proportionate up-to-date financial or other information relating to the Supplier or any relevant third party entity upon request.

- 15.7 The Authority may terminate this Contract by issuing a Termination Notice to the Supplier where:

- 15.7.1 the Contract has been substantially amended to the extent that the Public Contracts Regulations 2015 require a new procurement procedure;
 - 15.7.2 the Authority has become aware that the Supplier should have been excluded under Regulation 57(1) or (2) of the Public Contracts Regulations 2015 from the procurement procedure leading to the award of this Contract;
 - 15.7.3 the Contract should not have been awarded to the Supplier in view of a serious infringement of obligations under European law declared by the Court of Justice of the European Union under Article 258 of the Treaty on the Functioning of the EU; or
 - 15.7.4 there has been a failure by the Supplier and/or one its Sub-contractors to comply with legal obligations in the fields of environmental, social or labour Law. Where the failure to comply with legal obligations in the fields of environmental, social or labour Law is a failure by one of the Supplier's Sub-contractors, the Authority may request the replacement of such Sub -contractor and the Supplier shall comply with such request as an alternative to the Authority terminating this Contract under this Clause 15.7.4
- 15.8 If the Authority novates this Contract to any body that is not a Contracting Authority, from the effective date of such novation, the rights of the Authority to terminate this Contract in accordance with Clause 15.5.2 to Clause 15.5.4 of this Schedule 2 of these Call-off Terms and Conditions shall be deemed mutual termination rights and the Supplier may terminate this Contract by issuing a Termination Notice to the entity assuming the position of the Authority if any of the circumstances referred to in such Clauses apply to the entity assuming the position of the Authority.
- 15.9 Within three (3) months of the Commencement Date the Supplier shall develop and agree an exit plan with the Authority consistent with the Exit Requirements, which shall ensure continuity of the Services on expiry or earlier termination of this Contract. The Supplier shall provide the Authority with the first draft of an exit plan within one (1) month of the Commencement Date. The Parties shall review and, as appropriate, update the exit plan on each anniversary of the Commencement Date of this Contract. If the Parties cannot agree an exit plan in accordance with the timescales set out in this Clause 15.9 of this Schedule 2 of these Call-off Terms and Conditions (such agreement not to be unreasonably withheld or delayed), such failure to agree shall be deemed a Dispute, which shall be referred to and resolved in accordance with the Dispute Resolution Procedure.

16 Consequences of expiry or early termination of this Contract

- 16.1 Subject to the provision set out in Clause 16.5 of this Schedule 2 of these Call-off Terms and Conditions, upon expiry or earlier termination of this Contract, the Authority agrees to pay the Supplier for:
- 16.1.1 the Goods which have been supplied by the Supplier and not rejected by the Authority in accordance with this Contract prior to the expiry or earlier termination of this Contract; and
 - 16.1.2 the Services which have been completed by the Supplier in accordance with this Contract prior to expiry or earlier termination of this Contract.
- 16.2 Immediately following expiry or earlier termination of this Contract and/or in accordance with any timescales as set out in the agreed exit plan:

- 16.2.1 the Supplier shall comply with its obligations under any agreed exit plan;
- 16.2.2 all data, excluding Personal Data, documents and records (whether stored electronically or otherwise) relating in whole or in part to the Services, including without limitation relating to patients or other service users, and all other items provided on loan or otherwise to the Supplier by the Authority shall be delivered by the Supplier to the Authority provided that the Supplier shall be entitled to keep copies to the extent that: (a) the content does not relate solely to this Contract; (b) the Supplier is required by Law and/or Guidance to keep copies; or (c) the Supplier was in possession of such data, documents and records prior to the Commencement Date; and
- 16.2.3 any Personal Data Processed by the Supplier on behalf of the Authority shall be returned to the Authority or destroyed in accordance with the relevant provisions of the Data Protection Protocol.
- 16.3 The Supplier shall retain all data relating to the provision of the Services that are not transferred or destroyed pursuant to Clause 16.2 of this Schedule 2 of these Call-off Terms and Conditions for the period set out in Clause 24.1 of this Schedule 2 of these Call-off Terms and Conditions.
- 16.4 The Supplier shall cooperate fully with the Authority or, as the case may be, any replacement supplier during any re-procurement and handover period prior to and following the expiry or earlier termination of this Contract. This cooperation shall extend to providing access to all information relevant to the operation of this Contract, as reasonably required by the Authority to achieve a fair and transparent re-procurement and/or an effective transition without disruption to routine operational requirements.
- 16.5 If the Authority terminates the Contract in accordance with Clause 15.5.1 of this Schedule 2 of these Call-off Terms and Conditions, the Authority shall be entitled to a refund of any sums paid under this Contract provided the Authority informs the Supplier in writing of its intention to claim such refund no later than thirty (30) days of the effective date of such termination. Should the Authority seek a refund in respect of Goods already delivered, the Authority shall return such Goods to the Supplier at the Supplier's written request and at the Supplier's cost and expense.
- 16.6 Immediately upon expiry or earlier termination of this Contract any license or lease entered into in accordance with any Order Form shall automatically terminate.
- 16.7 The expiry or earlier termination of this Contract for whatever reason shall not affect any rights or obligations of either Party which accrued prior to such expiry or earlier termination.
- 16.8 The expiry or earlier termination of this Contract shall not affect any obligations which expressly or by implication are intended to come into or continue in force on or after such expiry or earlier termination.
- 16.9 The expiry or earlier termination of the Framework Agreement shall not affect this Contract. For the avoidance of doubt, any obligations set out in the Framework Agreement that form part of this Contract shall continue to apply for the purposes of this Contract notwithstanding any termination of the Framework Agreement.

17 Staff information and the application of TUPE at the end of the Contract

- 17.1 Upon the day which is no greater than nine (9) months before the expiry of this Contract or as soon as the Supplier is aware of the proposed termination of the Contract, the Supplier shall, within twenty eight (28) days of receiving a written request from the Authority and to the extent permitted by Law, supply to the Authority and keep updated all information required by the Authority as to the terms and conditions of employment and employment history of any Supplier Personnel (including all employee liability information identified in regulation 11 of TUPE) and the Supplier shall warrant such information is full, complete and accurate.
- 17.2 No later than twenty eight (28) days prior to the Subsequent Transfer Date, the Supplier shall or shall procure that any Sub-contractor shall provide a final list to the Successor and/or the Authority, as appropriate, containing the names of all the Subsequent Transferring Employees whom the Supplier or Sub-contractor expects will transfer to the Successor or the Authority and all employee liability information identified in regulation 11 of TUPE in relation to the Subsequent Transferring Employees.
- 17.3 If the Supplier shall, in the reasonable opinion of the Authority, deliberately not comply with its obligations under Clauses 17.1 and 17.2 of this Schedule 2 of these Call-off Terms and Conditions, the Authority may withhold payment under Clause 9 of this Schedule 2 of these Call-off Terms and Conditions.
- 17.4 The Supplier shall be liable to the Authority for, and shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings that arise or result from any deficiency or inaccuracy in the information which the Supplier is required to provide under Clauses 17.1 and 17.2 of this Schedule 2 of these Call-off Terms and Conditions.
- 17.5 Subject to Clauses 17.6 and 17.7 of this Schedule 2 of these Call-off Terms and Conditions, during the period of nine (9) months preceding the expiry of this Contract or after notice of termination of this Contract has been served by either Party, the Supplier shall not, and shall procure that any Sub-contractor shall not, without the prior written consent of the Authority, such consent not to be unreasonably withheld or delayed:
- 17.5.1 make, propose or permit any material changes to the terms and conditions of employment or other arrangements of any of the Supplier Personnel;
- 17.5.2 increase or seek to increase the emoluments (excluding cost of living increases awarded in the ordinary course of business) payable to any of the Supplier Personnel;
- 17.5.3 replace any of the Supplier Personnel or increase the total number of employees providing the Services;
- 17.5.4 deploy any person other than the Supplier Personnel to perform the Services;
- 17.5.5 terminate or give notice to terminate the employment or arrangements of any of the Supplier Personnel;
- 17.5.6 increase the proportion of working time spent on the Services by any of the Supplier Personnel; or

- 17.5.7 introduce any new contractual term or customary practice concerning the making of any lump sum payment on the termination of employment of any of the Supplier Personnel.
- 17.6 Clause 17.5 of this Schedule 2 of these Call-off Terms and Conditions shall not prevent the Supplier or any Sub-contractor from taking any of the steps prohibited in that Clause in circumstances where the Supplier or Sub-contractor is required to take such a step pursuant to any changes in legislation or pursuant to a collective agreement in force at that time.
- 17.7 Where the obligations on the Supplier under Clause 17 of this Schedule 2 of these Call-off Terms and Conditions are subject to the Data Protection Legislation, the Supplier will, and shall procure that any Sub-contractor will, use its best endeavours to seek the consent of the Supplier Personnel to disclose any information covered under the Data Protection Legislation and utilise any other exemption or provision within the Data Protection Legislation which would allow such disclosure.
- 17.8 Having as appropriate gained permission from any Sub-contractor, the Supplier hereby permits the Authority to disclose information about the Supplier Personnel to any Interested Party provided that the Authority informs the Interested Party in writing of the confidential nature of the information.
- 17.9 The Parties agree that where a Successor or the Authority provides the Services or services which are fundamentally the same as the Services in the immediate or subsequent succession to the Supplier or Sub-contractor (in whole or in part) on expiry or early termination of this Contract (howsoever arising) TUPE, the Cabinet Office Statement and Fair Deal for Staff Pensions may apply in respect of the subsequent provision of the Services or services which are fundamentally the same as the Services. If TUPE, the Cabinet Office Statement and Fair Deal for Staff Pensions apply then Clause 17.11 to Clause 17.14 of this Schedule 2 of these Call-off Terms and Conditions and (where relevant) the requirements of Clause 1.5 of Part D of Schedule 7 of the NHS Terms and Conditions for the Provision of Services (Contract Version) (December 2016) shall apply.
- 17.10 If on the termination or at the end of the Contract TUPE does not apply, then all Employment Liabilities and any other liabilities in relation to the Supplier Personnel shall remain with the Supplier or Sub-contractor as appropriate. The Supplier will, and shall procure that any Sub-contractor shall, indemnify and keep indemnified the Authority in relation to any Employment Liabilities arising out of or in connection with any allegation or claim raised by any Supplier Personnel.
- 17.11 In accordance with TUPE, and any other policy or arrangement applicable, the Supplier shall, and will procure that any Sub-contractor shall, comply with its obligations to inform and consult with the appropriate representatives of any of its employees affected by the subsequent transfer of the Services or services which are fundamentally the same as the Services.
- 17.12 The Supplier will and shall procure that any Sub-contractor will on or before any Subsequent Transfer Date:
- 17.12.1 pay all wages, salaries and other benefits of the Subsequent Transferring Employees and discharge all other financial obligations (including reimbursement of any expenses and any contributions to retirement benefit schemes) in respect of the period between the Transfer Date and the Subsequent Transfer Date;

- 17.12.2 account to the proper authority for all PAYE, tax deductions and national insurance contributions payable in respect of the Subsequent Transferring Employees in the period between the Transfer Date and the Subsequent Transfer Date;
 - 17.12.3 pay any Successor or the Authority, as appropriate, the amount which would be payable to each of the Subsequent Transferring Employees in lieu of accrued but untaken holiday entitlement as at the Subsequent Transfer Date;
 - 17.12.4 pay any Successor or the Authority, as appropriate, the amount which fairly reflects the progress of each of the Subsequent Transferring Employees towards achieving any commission, bonus, profit share or other incentive payment payable after the Subsequent Transfer Date wholly or partly in respect of a period prior to the Subsequent Transfer Date; and
 - 17.12.5 subject to any legal requirement, provide to the Successor or the Authority, as appropriate, all personnel records relating to the Subsequent Transferring Employees including, without prejudice to the generality of the foregoing, all records relating to national insurance, PAYE and income tax. The Supplier shall for itself and any Sub-contractor warrant that such records are accurate and up to date.
- 17.13 The Supplier will and shall procure that any Sub-contractor will indemnify and keep indemnified the Authority and/or a Successor in relation to any Employment Liabilities arising out of or in connection with any claim arising from:
- 17.13.1 the Supplier's or Sub-contractor's failure to perform and discharge its obligations under Clause 17.2 of this Schedule 2 of these Call-off Terms and Conditions;
 - 17.13.2 any act or omission by the Supplier or Sub-contractor in respect of the Subsequent Transferring Employees occurring on or before the Subsequent Transfer Date;
 - 17.13.3 any allegation or claim by any person who is not a Subsequent Transferring Employee but who alleges that their employment should transfer or has transferred to the Successor or the Authority, as appropriate;
 - 17.13.4 any emoluments payable to a person employed or engaged by the Supplier or Sub-contractor (including without limitation all wages, accrued holiday pay, bonuses, commissions, PAYE, national insurance contributions, pension contributions and other contributions) payable in respect of any period on or before the Subsequent Transfer Date;
 - 17.13.5 any allegation or claim by any of the Subsequent Transferring Employees on the grounds that the Successor or Authority, as appropriate, has failed to continue a benefit provided by the Supplier or Sub-contractor as a term of such Subsequent Transferring Employee's contract as at the Subsequent Transfer Date where it was not reasonably practicable for the Successor or Authority, as appropriate, to provide an identical benefit but where the Successor or Authority, as appropriate, has provided (or offered to provide where such benefit is not accepted by the Subsequent Transferring Employee) an alternative benefit which, taken as a whole, is no less favourable to such Subsequent Transferring Employee; and

- 17.13.6 any act or omission of the Supplier or any Sub-contractor in relation to its obligations under regulation 13 of TUPE, or in respect of an award of compensation under regulation 15 of TUPE except to the extent that the liability arises from the Successor's or Authority's failure to comply with regulation 13(4) of TUPE.
- 17.14 The Supplier will, or shall procure that any Sub-contractor will, on request by the Authority provide a written and legally binding indemnity in the same terms as set out in Clause 17.13 of this Schedule 2 of these Call-off Terms and Conditions to any Successor in relation to any Employment Liabilities arising up to and including the Subsequent Transfer Date.
- 17.15 The Supplier will indemnify and keep indemnified the Authority and/or any Successor in respect of any Employment Liabilities arising from any act or omission of the Supplier or Sub-contractor in relation to any other Supplier Personnel who is not a Subsequent Transferring Employee arising during any period whether before, on or after the Subsequent Transfer Date.
- 17.16 If any person who is not a Subsequent Transferring Employee claims or it is determined that their contract of employment has been transferred from the Supplier or any Sub-contractor to the Authority or Successor pursuant to TUPE or claims that their employment would have so transferred had they not resigned, then:
 - 17.16.1 the Authority will, or shall procure that the Successor will, within seven (7) days of becoming aware of that fact, give notice in writing to the Supplier;
 - 17.16.2 the Supplier may offer (or may procure that a Sub-contractor may offer) employment to such person within twenty eight (28) days of the notification by the Authority or Successor;
 - 17.16.3 if such offer of employment is accepted, the Authority will, or shall procure that the Successor will, immediately release the person from their employment; and
 - 17.16.4 if after the period in Clause 17.16.2 of this Schedule 2 of these Call-off Terms and Conditions has elapsed, no such offer of employment has been made or such offer has been made but not accepted, the Authority will, or shall procure that the Successor will (whichever is the provider of the Services or services of the same or similar nature to the Services), employ that person in accordance with its obligations and duties under TUPE and shall be responsible for all liabilities arising in respect of any such person after the Subsequent Transfer Date.

18 Packaging, identification, end of use and coding requirements

- 18.1 The Supplier shall comply with all obligations imposed on it by Law relevant to the Goods in relation to packaging, identification, and obligations following end of use by the Authority.
- 18.2 Unless otherwise specified in the Specification and Tender Response Document or otherwise agreed with the Authority in writing, the Goods shall be securely packed in trade packages of a type normally used by the Supplier for deliveries of the same or similar goods in the same quantities within the United Kingdom.

- 18.3 The Supplier shall comply with any labelling requirements in respect of the Goods: (a) specified in the Specification and Tender Response Document; (b) agreed with the Authority in writing; and/or (c) required to comply with Law or Guidance.
- 18.4 The Supplier shall ensure that all Goods that are required by Law or Guidance to bear any safety information, environmental information, any mark, tab, brand, label, serial numbers or other device indicating place of origin, inspection by any government or other body or standard of quality at the point such Goods are delivered shall comply with such requirements at the point of delivery.
- 18.5 Unless otherwise set out in the Specification and Tender Response Document or agreed with the Authority in writing, the Supplier shall collect without charge any returnable containers and/or packages (including pallets) within twenty one (21) days of the date of the relevant delivery. Empty containers and/or packages not so removed may be returned by the Authority at the Supplier's expense or otherwise disposed of at the Authority's discretion. The Supplier shall credit the Authority in full for any containers for which the Authority has been charged upon their collection, return and/or disposal by the Authority in accordance with Clause 18.5 of this Schedule 2 of these Call-off Terms and Conditions.
- 18.6 Unless otherwise confirmed and/or agreed by the Authority in writing and subject to Clause 18.7 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall ensure full compliance with any Guidance issued by the Department of Health in relation to the adoption of GS1 and PEPPOL standards (to include, without limitation, any supplier compliance timeline and other policy requirements published by the Department of Health in relation to the adoption of GS1 and PEPPOL standards for master data provision and exchange, barcode labelling, and purchase -to-pay transacting).
- 18.7 Once compliance with any published timelines has been achieved by the Supplier pursuant to Clause 18.6 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall, during the Term, maintain the required level of compliance relating to the Goods in accordance with any such requirements and Guidance referred to as part of this Contract.
- 18.8 Once product information relating to Goods is placed by the Supplier into a GS1 certified data pool, the Supplier shall, during the Term, keep such information updated with any changes to the product data relating to the Goods.

19 Sustainable development

- 19.1 The Supplier shall comply in all material respects with applicable environmental, social and labour Law requirements in force from time to time in relation to the Goods and Services. Where the provisions of any such Law are implemented by the use of voluntary agreements, the Supplier shall comply with such agreements as if they were incorporated into English law subject to those voluntary agreements being cited in the Specification and Tender Response Document. Without prejudice to the generality of the foregoing, the Supplier shall:
- 19.1.1 comply with all Policies and/or procedures and requirements set out in the Specification and Tender Response Document in relation to any stated environmental, social and labour requirements, characteristics and impacts of the Goods and Services and the Supplier's supply chain;

- 19.1.2 maintain relevant policy statements documenting the Supplier's significant labour, social and environmental aspects as relevant to the Goods and Services being supplied and provided and as proportionate to the nature and scale of the Supplier's business operations; and
 - 19.1.3 maintain plans and procedures that support the commitments made as part of the Supplier's significant labour, social and environmental policies, as referred to at Clause 19.1.2 of this Schedule 2 of these Call-off Terms and Conditions.
- 19.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of Clause 19 of this Schedule 2 of these Call-off Terms and Conditions.

20 Electronic product and services information

- 20.1 Where requested by the Authority, the Supplier shall provide the Authority the Product Information and the Services Information in such manner and upon such media as agreed between the Supplier and the Authority from time to time for the sole use by the Authority.
- 20.2 The Supplier warrants that the Product Information and the Services Information is complete and accurate as at the date upon which it is delivered to the Authority and that the Product Information and the Services Information shall not contain any data or statement which gives rise to any liability on the part of the Authority following publication of the same in accordance with Clause 20 of this Schedule 2 of these Call-off Terms and Conditions.
- 20.3 If the Product Information and/or the Services Information ceases to be complete and accurate, the Supplier shall promptly notify the Authority in writing of any modification or addition to or any inaccuracy or omission in the Product Information and/or the Services Information.
- 20.4 The Supplier grants the Authority a perpetual, non-exclusive, royalty free licence to use and exploit the Product Information and the Services Information and any Intellectual Property Rights in the Product Information and the Services Information for the purpose of illustrating the range of goods and services (including, without limitation, the Goods and Services) available pursuant to the Authority's contracts from time to time. Subject to Clause 20.5 of this Schedule 2 of these Call-off Terms and Conditions, no obligation to illustrate or advertise the Product Information or the Services Information is imposed on the Authority, as a consequence of the licence conferred by this Clause 20.4 of this Schedule 2 of these Call-off Terms and Conditions.
- 20.5 The Authority may reproduce for its sole use the Product Information and the Services Information provided by the Supplier in the Authority's product and/or services catalogues from time to time which may be made available on any NHS communications networks in electronic format and/or made available on the Authority's external website and/or made available on other digital media from time to time.
- 20.6 Before any publication of the Product Information and the Services Information (electronic or otherwise) is made by the Authority, the Authority will submit a copy of the relevant sections of the Authority's product and/or services catalogues to the Supplier for approval, such approval not to be unreasonably withheld or delayed. For the avoidance of doubt the Supplier shall have no right to compel the Authority to exhibit the Product Information and/or the Services Information in any product and/or

services catalogues as a result of the approval given by it pursuant to this Clause 20.6 of this Schedule 2 of these Call-off Terms and Conditions or otherwise under the terms of this Contract.

- 20.7 If requested in writing by the Authority, and to the extent not already agreed as part of the Specification and Tender Response Document, the Supplier and the Authority shall discuss and seek to agree in good faith arrangements to use any Electronic Trading System.

21 Change management

- 21.1 The Supplier acknowledges to the Authority that the Authority's requirements for the Goods and/or Services may change during the Term and the Supplier shall not unreasonably withhold or delay its consent to any reasonable variation or addition to the Specification and Tender Response Document, as may be requested by the Authority from time to time.
- 21.2 Subject to Clause 21.3 of this Schedule 2 of these Call-off Terms and Conditions, any change to the Goods and/or Services or other variation to this Contract shall only be binding once it has been agreed (a) in accordance with any Change Control Process if any 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.
- 21.3 Any change to the Data Protection Protocol shall be made in accordance with the relevant provisions of that protocol.

22 Dispute resolution

- 22.1 During any Dispute, including a Dispute as to the validity of this Contract, it is agreed that the Supplier shall continue its performance of the provisions of the Contract (unless the Authority requests in writing that the Supplier does not do so).
- 22.2 In the case of a Dispute arising out of or in connection with this Contract the Supplier and the Authority shall make every reasonable effort to communicate and cooperate with each other with a view to resolving the Dispute and follow the procedure set out in Clause 22.3 of this Schedule 2 of these Call-off Terms and Conditions as the first stage in the Dispute Resolution Procedure.
- 22.3 If any Dispute arises out of the Contract either Party may serve a notice on the other Party to commence formal resolution of the Dispute. The Parties shall first seek to resolve the Dispute by escalation in accordance with the management levels as set out in Clause 5 of the Key Provisions. Respective representatives at each level, as set out in Clause 5 of the Key Provisions, shall have five (5) Business Days at each level during which they will use their reasonable endeavours to resolve the Dispute before escalating the matter to the next level until all levels have been exhausted. Level 1 will commence on the date of service of the Dispute Notice. The final level of the escalation process shall be deemed exhausted on the expiry of five (5) Business Days following escalation to that level unless otherwise agreed by the Parties in writing.
- 22.4 If the procedure set out in Clause 22.3 of this Schedule 2 of these Call-off Terms and Conditions above has been exhausted and fails to resolve such Dispute, as part of the Dispute Resolution Procedure, the Parties will attempt to settle it by mediation. The Parties shall, acting reasonably, attempt to agree upon a mediator. In the event that the Parties fail to agree a mediator within five (5) Business Days following the

exhaustion of all levels of the escalation procedure at Clause 22.3 of this Schedule 2 of these Call-off Terms and Conditions, the mediator shall be nominated and confirmed by the Centre for Effective Dispute Resolution, London.

- 22.5 The mediation shall commence within twenty eight (28) days of the confirmation of the mediator in accordance with Clause 22.4 of this Schedule 2 of these Call-off Terms and Conditions or at such other time as may be agreed by the Parties in writing. Neither Party will terminate such mediation process until each Party has made its opening presentation and the mediator has met each Party separately for at least one hour or one Party has failed to participate in the mediation process. After this time, either Party may terminate the mediation process by notification to the other party (such notification may be verbal provided that it is followed up by written confirmation). The Authority and the Supplier will cooperate with any person appointed as mediator providing them with such information and other assistance as they shall require and will pay their costs, as they shall determine, or in the absence of such determination such costs will be shared equally.
- 22.6 Nothing in this Contract shall prevent:
- 22.6.1 the Authority taking action in any court in relation to any death or personal injury arising or allegedly arising in connection with the supply of the Goods and/or the provision of the Services; or
- 22.6.2 either Party seeking from any court any interim or provisional relief that may be necessary to protect the rights or property of that Party or that relates to the safety of patients and other service users or the security of Confidential Information, pending resolution of the relevant Dispute in accordance with the Dispute Resolution Procedure.
- 22.7 Clause 22 of this Schedule 2 of these Call-off Terms and Conditions shall survive the expiry of or earlier termination of this Contract for any reason.

23 Force majeure

- 23.1 Subject to Clause 23.2 of this Schedule 2 of these Call-off Terms and Conditions neither Party shall be liable to the other for any failure to perform all or any of its obligations under this Contract nor liable to the other Party for any loss or damage arising out of the failure to perform its obligations to the extent only that such performance is rendered impossible by a Force Majeure Event.
- 23.2 The Supplier shall only be entitled to rely on a Force Majeure Event and the relief set out in Clause 23 of this Schedule 2 of these Call-off Terms and Conditions and will not be considered to be in default or liable for breach of any obligations under this Contract if:
- 23.2.1 the Supplier has fulfilled its obligations pursuant to Clause 6 of this Schedule 2 of these Call-off Terms and Conditions;
- 23.2.2 the Force Majeure Event does not arise directly or indirectly as a result of any wilful or negligent act or default of the Supplier; and
- 23.2.3 the Supplier has complied with the procedural requirements set out in Clause 23 of this Schedule 2 of these Call-off Terms and Conditions.

- 23.3 Where a Party is (or claims to be) affected by a Force Majeure Event it shall use reasonable endeavours to mitigate the consequences of such a Force Majeure Event upon the performance of its obligations under this Contract, and to resume the performance of its obligations affected by the Force Majeure Event as soon as practicable.
- 23.4 Where the Force Majeure Event affects the Supplier's ability to perform part of its obligations under the Contract the Supplier shall fulfil all such contractual obligations that are not so affected and shall not be relieved from its liability to do so.
- 23.5 If either Party is prevented or delayed in the performance of its obligations under this Contract by a Force Majeure Event, that Party shall as soon as reasonably practicable serve notice in writing on the other Party specifying the nature and extent of the circumstances giving rise to its failure to perform or any anticipated delay in performance of its obligations.
- 23.6 Subject to service of such notice, the Party affected by such circumstances shall have no liability for its failure to perform or for any delay in performance of its obligations affected by the Force Majeure Event only for so long as such circumstances continue and for such time after they cease as is necessary for that Party, using its best endeavours, to recommence its affected operations in order for it to perform its obligations.
- 23.7 The Party claiming relief shall notify the other in writing as soon as the consequences of the Force Majeure Event have ceased and of when performance of its affected obligations can be resumed.
- 23.8 If the Supplier is prevented from performance of its obligations as a result of a Force Majeure Event, the Authority may at any time, if the Force Majeure Event subsists for thirty (30) days or more, terminate this Contract by issuing a Termination Notice to the Supplier.
- 23.9 Following such termination in accordance with Clause 23.8 of this Schedule 2 of these Call-off Terms and Conditions and subject to Clause 23.10 of this Schedule 2 of these Call-off Terms and Conditions, neither Party shall have any liability to the other.
- 23.10 Any rights and liabilities of either Party which have accrued prior to such termination in accordance with Clause 23.8 of this Schedule 2 of these Call-off Terms and Conditions shall continue in full force and effect unless otherwise specified in this Contract.

24 Records retention and right of audit

- 24.1 Subject to any statutory requirement and Clause 24.2 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall keep secure and maintain for the Term and six (6) years afterwards, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Contract.
- 24.2 Where any records could be relevant to a claim for personal injury such records shall be kept secure and maintained for a period of twenty one (21) years from the date of expiry or earlier termination of this Contract.
- 24.3 The Authority shall have the right to audit the Supplier's compliance with this Contract. The Supplier shall permit or procure permission for the Authority or its authorised representative during normal business hours having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and

records reasonably required to audit the Supplier's compliance with its obligations under this Contract.

- 24.4 Should the Supplier Sub-contract any of its obligations under this Contract, the Authority shall have the right to audit and inspect such third party. The Supplier shall procure permission for the Authority or its authorised representative during normal business hours no more than once in any twelve (12) months, having given advance written notice of no less than five (5) Business Days, access to any premises and facilities, books and records used in the performance of the Supplier's obligations under this Contract that are Sub-contracted to such third party. The Supplier shall cooperate with such audit and inspection and accompany the Authority or its authorised representative if requested.
- 24.5 The Supplier shall grant to the Authority or its authorised representative, such access to those records as they may reasonably require in order to check the Supplier's compliance with this Contract for the purposes of:
- 24.5.1 the examination and certification of the Authority's accounts; or
- 24.5.2 any examination pursuant to section 6(1) of the National Audit Act 1983 of the economic efficiency and effectiveness with which the Authority has used its resources.
- 24.6 The Comptroller and Auditor General may examine such documents as they may reasonably require which are owned, held or otherwise within the control of the Supplier and may require the Supplier to provide such oral and/or written explanations as they consider necessary. Clause 24 of this Schedule 2 of these Call-off Terms and Conditions does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Supplier under sections 6(3)(d) and 6(5) of the National Audit Act 1983.
- 24.7 The Supplier shall provide reasonable cooperation to the Authority, its representatives and any regulatory body in relation to any audit, review, investigation or enquiry carried out in relation to the subject matter of this Contract.
- 24.8 The Supplier shall provide all reasonable information as may be reasonably requested by the Authority to evidence the Supplier's compliance with the requirements of this Contract.

25 Conflicts of interest and the prevention of fraud

- 25.1 The Supplier shall take appropriate steps to ensure that neither the Supplier nor any Staff 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 interests of the Supplier and the duties owed to the Authority under the provisions of this Contract. The Supplier will disclose to the Authority full particulars of any such conflict of interest which may arise.
- 25.2 The Authority reserves the right to terminate this Contract immediately by notice in writing and/or to 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 Supplier and the duties owed to the Authority under the provisions of this Contract. The actions of the Authority pursuant to this Clause 25.2 of this Schedule 2 of these Call-off Terms and Conditions shall not

prejudice or affect any right of action or remedy which shall have accrued or shall subsequently accrue to the Authority.

- 25.3 The Supplier shall take all reasonable steps to prevent Fraud by Staff and the Supplier (including its owners, members and directors). The Supplier shall notify the Authority immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.
- 25.4 If the Supplier or its Staff commits Fraud the Authority may terminate this Contract and recover from the Supplier the amount of any direct loss suffered by the Authority resulting from the termination.

26 Equality and human rights

26.1 The Supplier shall:

26.1.1 ensure that (a) it does not, whether as employer, a supplier of Goods or as provider of the Services, engage in any act or omission that would contravene the Equality Legislation, and (b) it complies with all its obligations as an employer, a supplier of Goods or provider of the Services as set out in the Equality Legislation and take reasonable endeavours to ensure its Staff do not unlawfully discriminate within the meaning of the Equality Legislation;

26.1.2 in the management of its affairs and the development of its equality and diversity policies, cooperate with the Authority in light of the Authority's obligations to comply with its statutory equality duties whether under the Equality Act 2010 or otherwise. The Supplier shall take such reasonable and proportionate steps as the Authority considers appropriate to promote equality and diversity, including race equality, equality of opportunity for disabled people, gender equality, and equality relating to religion and belief, sexual orientation and age; and

26.1.3 the Supplier shall impose on all its Sub-contractors and suppliers, obligations substantially similar to those imposed on the Supplier by Clause 26 of this Schedule 2 of these Call-off Terms and Conditions.

26.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of Clause 26 of this Schedule 2 of these Call-off Terms and Conditions.

27 Notice

27.1 Subject to clause 22.5 of Schedule 2 of these Call-off Terms and Conditions, 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 Order Form or such other person as one Party may inform the other Party in writing from time to time or to a director of the relevant Party at the head office, main UK office or registered office of such Party.

27.2 A notice shall be treated as having been received:

- 27.2.1 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
- 27.2.2 if sent by first class recorded delivery mail on a normal Business Day, at 9.00 am on the second Business Day subsequent to the day of posting, or, if the notice was not posted on a Business Day, at 9.00 am on the third Business Day subsequent to the day of posting; or
- 27.2.3 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.

28 Assignment, novation and Sub-contracting

- 28.1 The Supplier shall not, except where Clause 28.2 of this Schedule 2 of these Call-off Terms and Conditions applies, assign, Sub-contract, novate, create a trust in, or in any other way dispose of the whole or any part of this Contract without the prior consent in writing of the Authority such consent not to be unreasonably withheld or delayed. If the Supplier Sub-contracts any of its obligations under this Contract, every act or omission of the Sub-contractor shall for the purposes of this Contract be deemed to be the act or omission of the Supplier and the Supplier shall be liable to the Authority as if such act or omission had been committed or omitted by the Supplier itself.
- 28.2 Notwithstanding Clause 28.1 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier may assign to a third party ("**Assignee**") the right to receive payment of any sums due and owing to the Supplier under this Contract for which an invoice has been issued. Any assignment under this Clause 28.2 of this Schedule 2 of these Call-off Terms and Conditions shall be subject to:
 - 28.2.1 the deduction of any sums in respect of which the Authority exercises its right of recovery under Clause 9.9 of this Schedule 2 of these Call-off Terms and Conditions;
 - 28.2.2 all related rights of the Authority in relation to the recovery of sums due but unpaid;
 - 28.2.3 the Authority receiving notification of the assignment and the date upon which the assignment becomes effective together with the Assignee's contact information and bank account details to which the Authority shall make payment;
 - 28.2.4 the provisions of Clause 9 of this Schedule 2 of these Call-off Terms and Conditions continuing to apply in all other respects after the assignment which shall not be amended without the prior written approval of the Authority; and
 - 28.2.5 payment to the Assignee being full and complete satisfaction of the Authority's obligation to pay the relevant sums in accordance with this Contract.
- 28.3 Any authority given by the Authority for the Supplier to Sub -contract any of its obligations under this Contract shall not impose any duty on the Authority to enquire

as to the competency of any authorised Sub-contractor. The Supplier shall ensure that any authorised Sub-contractor has the appropriate capability and capacity to perform the relevant obligations and that the obligations carried out by such Sub-contractor are fully in accordance with this Contract.

- 28.4 Where the Supplier enters into a Sub-contract in respect of any of its obligations under this Contract relating to the manufacture, supply, delivery or installation of or training in relation to the Goods or the provision of the Services, the Supplier shall include provisions in each such Sub-contract, unless otherwise agreed with the Authority in writing, which:
- 28.4.1 contain at least equivalent obligations as set out in this Contract in relation to such manufacture, supply, delivery or installation of or training in relation to the Goods or the performance of the Services to the extent relevant to such Sub-contracting;
 - 28.4.2 contain at least equivalent obligations as set out in this Contract in respect of confidentiality, information security, data protection, Intellectual Property Rights, compliance with Law and Guidance and record keeping;
 - 28.4.3 contain a prohibition on the Sub-contractor Sub-contracting, assigning or novating any of its rights or obligations under such Sub-contract without the prior written approval of the Authority (such approval not to be unreasonably withheld or delayed);
 - 28.4.4 contain a right for the Authority to take an assignment or novation of the Sub-contract (or part of it) upon expiry or earlier termination of this Contract;
 - 28.4.5 requires the Supplier or other party receiving goods or services under the contract to consider and verify invoices under that contract in a timely fashion;
 - 28.4.6 provides that if the Supplier or other party fails to consider and verify an invoice in accordance with Clause 28.4.5 of this Schedule 2 of these Call-off Terms and Conditions, the invoice shall be regarded as valid and undisputed for the purpose of Clause 28.4.7 of this Schedule 2 of these Call-off Terms and Conditions after a reasonable time has passed;
 - 28.4.7 requires the Supplier 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;
 - 28.4.8 permitting the Supplier to terminate, or procure the termination of, the relevant Sub-contract in the event the Sub-contractor fails to comply in the performance of its Sub-contract with legal obligations in the fields of environmental, social or labour Law where the Supplier is required to replace such Sub-contractor in accordance with Clause 15.7.4 of this Schedule 2 of these Call-off Terms and Conditions;
 - 28.4.9 permitting the Supplier to terminate, or to procure the termination of, the relevant Sub-contract where the Supplier is required to replace such Sub-contractor in accordance with Clause 28.5 of this Schedule 2 of these Call-off Terms and Conditions; and

- 28.4.10 requires the Sub-contractor to include a clause to the same effect as this Clause 28.4 of this Schedule 2 of these Call-off Terms and Conditions in any Sub-contract which it awards.
- 28.5 Where the Authority considers that the grounds for exclusion under Regulation 57 of the Public Contracts Regulations 2015 apply to any Sub-contractor, then:
- 28.5.1 if the Authority finds there are compulsory grounds for exclusion, the Supplier shall ensure, or shall procure, that such Sub-contractor is replaced or not appointed; or
- 28.5.2 if the Authority finds there are non-compulsory grounds for exclusion, the Authority may require the Supplier to ensure, or to procure, that such Sub-contractor is replaced or not appointed and the Supplier shall comply with such a requirement.
- 28.6 The Supplier 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. Where the Authority pays the Supplier's valid and undisputed invoices earlier than thirty (30) days from verification in accordance with any applicable government prompt payment targets, the Supplier shall use its reasonable endeavours to pay its relevant Sub-contractors within a comparable timeframe from verifying that an invoice is valid and undisputed.
- 28.7 The Authority shall upon written request have the right to review any Sub-contract entered into by the Supplier in respect of the supply of the Goods and/or the provision of the Services and the Supplier shall provide a certified copy of any Sub -contract within five (5) Business Days of the date of a written request from the Authority. For the avoidance of doubt, the Supplier shall have the right to redact any confidential pricing information in relation to such copies of Sub-contracts.
- 28.8 The Authority may at any time transfer, assign, novate, sub-contract or otherwise dispose of its rights and obligations under this Contract or any part of this Contract and the Supplier warrants that it will carry out all such reasonable further acts required to effect such transfer, assignment, novation, sub-contracting or disposal. If the Authority novates this Contract to any body that is not a Contracting Authority, from the effective date of such novation, the party assuming the position of the Authority shall not further transfer, assign, novate, sub-contract or otherwise dispose of its rights and obligations under this Contract or any part of this Contract without the prior written consent of the Supplier, such consent not to be unreasonably withheld or delayed by the Supplier.

29 Prohibited Acts

- 29.1 The Supplier warrants and represents that:
- 29.1.1 it has not committed any offence under the Bribery Act 2010 or done any of the following ("**Prohibited Acts**"):
- (i) offered, given or agreed to give any officer or employee of the Authority any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this or any other agreement with the Authority or for showing or not showing favour or disfavour to any person in relation to this or any other agreement with the Authority; or

- (i) in connection with this Contract paid or agreed to pay any commission other than a payment, particulars of which (including the terms and conditions of the agreement for its payment) have been disclosed in writing to the Authority; and
- 29.1.2 it has in place adequate procedures to prevent bribery and corruption, as contemplated by section 7 of the Bribery Act 2010.
- 29.2 If the Supplier or its Staff (or anyone acting on its or their behalf) has done or does any of the Prohibited Acts or has committed or commits any offence under the Bribery Act 2010 with or without the knowledge of the Supplier in relation to this or any other agreement with the Authority:
 - 29.2.1 the Authority shall be entitled:
 - (i) to terminate this Contract and recover from the Supplier the amount of any loss resulting from the termination;
 - (ii) to recover from the Supplier the amount or value of any gift, consideration or commission concerned; and
 - (iii) to recover from the Supplier any other loss or expense sustained in consequence of the carrying out of the Prohibited Act or the commission of the offence under the Bribery Act 2010;
 - 29.2.2 any termination under Clause 29.2.1 of this Schedule 2 of these Call-off Terms and Conditions shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to the Authority; and
 - 29.2.3 notwithstanding Clause 22 of this Schedule 2 of these Call-off Terms and Conditions, any Dispute relating to:
 - (i) the interpretation of Clause 29 of this Schedule 2 of these Call-off Terms and Conditions; or
 - (ii) the amount or value of any gift, consideration or commission,
 shall be determined by the Authority, acting reasonably, and the decision shall be final and conclusive.

30 General

- 30.1 Each of the Parties is independent of the other and nothing contained in this Contract shall be construed to imply that there is any relationship between the Parties of partnership or of principal/agent or of employer/employee nor are the Parties hereby engaging in a joint venture and accordingly neither of the Parties shall have any right or authority to act on behalf of the other nor to bind the other by agreement or otherwise, unless expressly permitted by the terms of this Contract.
- 30.2 Failure or delay by either Party to exercise an option or right conferred by this Contract shall not of itself constitute a waiver of such option or right.
- 30.3 The delay or failure by either Party to insist upon the strict performance of any provision, term or condition of this Contract or to exercise any right or remedy

consequent upon such breach shall not constitute a waiver of any such breach or any subsequent breach of such provision, term or condition.

- 30.4 Any provision of this Contract which is held to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions of this Contract and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.
- 30.5 Each Party acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of this Contract and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the other Party for any misrepresentation or undertaking (whether made carelessly or not) or for breach of any warranty unless the representation, undertaking or warranty relied upon is set out in this Contract or unless such representation, undertaking or warranty was made fraudulently.
- 30.6 Each Party shall bear its own expenses in relation to the preparation and execution of this Contract including all costs, legal fees and other expenses so incurred.
- 30.7 The rights and remedies provided in this Contract are independent, cumulative and not exclusive of any rights or remedies provided by general law, any rights or remedies provided elsewhere under this Contract or by any other contract or document. In this Clause 30.7 of this Schedule 2 of these Call-off Terms and Conditions, right includes any power, privilege, remedy, or proprietary or security interest.
- 30.8 Unless otherwise expressly stated in this Contract, a person who is not a party to this Contract shall have no right to enforce any terms of it which confer a benefit on such person except that a Successor and/or a Third Party may directly enforce any indemnities or other rights provided to it under this Contract. No such person shall be entitled to object to or be required to consent to any amendment to the provisions of this Contract.
- 30.9 This Contract, any variation in writing signed by an authorised representative of each Party and any document referred to (explicitly or by implication) in this Contract or any variation to this Contract, contain the entire understanding between the Supplier and the Authority relating to the supply of the Goods and the provision of the Services to the exclusion of all previous agreements, confirmations and understandings and there are no promises, terms, conditions or obligations whether oral or written, express or implied other than those contained or referred to in this Contract. Nothing in this Contract seeks to exclude either Party's liability for Fraud. Any tender conditions and/or disclaimers set out in the Authority's procurement documentation leading to the award of this Contract shall form part of this Contract.
- 30.10 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.
- 30.11 Subject to Clause 22 of this Schedule 2 of these Call-off Terms and Conditions, the Parties irrevocably agree that the courts of England and Wales shall have non-exclusive jurisdiction to settle any Dispute or claim that arises out of or in connection with this Contract or its subject matter.
- 30.12 All written and oral communications and all written material referred to under this Contract shall be in English.

31 Official Secrets Acts and Finance Act

31.1 The Contractor shall comply with, and shall ensure the Contractor Personnel comply with, the provisions of:

31.1.1 the Official Secrets Acts 1911 to 1989; and

31.1.2 section 182 of the Finance Act 1989.

31.2 The Authority may terminate the Contract with immediate effect by giving written notice to the Contractor if the Contractor or any of the Contractor Personnel do not comply with Clause 31.1 of this Schedule 2.

32 Preventing Modern Slavery

32.1 The Contractor:

32.1.1 shall not use, nor allow its sub-contractors to use forced, bonded or involuntary prison labour;

32.1.2 shall not require any Contractor Personnel or the personnel of any sub - contractors to lodge deposits or identity papers with their employer and shall be free to leave their employer after reasonable notice;

32.1.3 warrants and represents that it has not been convicted of any slavery or human trafficking offences anywhere around the world;

32.1.4 warrants that to the best of its knowledge it is not currently under investigation, inquiry or enforcement proceedings in relation to any allegation of slavery or human trafficking offences anywhere around the world;

32.1.5 shall make reasonable enquires to ensure that its officers, employees and sub-contractors have not been convicted of slavery or human trafficking offences anywhere around the world;

32.1.6 shall have and maintain throughout the Term its own policies and procedures to ensure its compliance with the Modern Slavery Act 2015 and include in its contracts with its sub-contractors anti-slavery and human trafficking provisions;

- 32.1.7 shall implement due diligence procedures to ensure that there is no slavery or human trafficking in any part of its supply chain performing obligations under the Contract;
- 32.1.8 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;
- 32.2 If the Contractor notifies the Authority pursuant to Clause 32.4 it 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 the Contract.
- 32.3 If the Contractor is in Default under Clause 32.1 the Authority may by notice:
 - 32.3.1 require the Contractor to remove from performance of the Contract any Sub-Contractor, Contractor Personnel or other persons associated with it whose acts or omissions have caused the Default; or
 - 32.3.2 immediately terminate the Contract.

Whistleblowing

- 32.4 As soon as it is aware of it the Contractor and Contractor Personnel must report to the Authority any actual or suspected breach of:
 - 32.4.1 Law;
 - 32.4.2 Clauses 331 to 32.1 or 32.5; or
 - 32.4.3 Clause 25 or 26
- 32.5 The Contractor must not retaliate against any of the Contractor Personnel who in good faith reports a breach listed in this Clause to the Authority or a Prescribed Person.

Schedule 3

Information and Data Provisions

1 Confidentiality

- 1.1 In respect of any Confidential Information it may receive directly or indirectly from the other Party ("**Discloser**") and subject always to the remainder of Clause 1 of this Schedule 3 of these Call-off Terms and Conditions, each Party ("**Recipient**") undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party without the Discloser's prior written consent provided that:
- 1.1.1 the Recipient shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the Commencement Date;
- 1.1.2 the provisions of Clause 1 of this Schedule 3 of these Call-off Terms and Conditions shall not apply to any Confidential Information:
- (i) which is in or enters the public domain other than by breach of this Contract or other act or omissions of the Recipient;
 - (ii) which is obtained from a third party who is lawfully authorised to disclose such information without any obligation of confidentiality;
 - (iii) which is authorised for disclosure by the prior written consent of the Discloser;
 - (iv) which the Recipient can demonstrate was in its possession without any obligation of confidentiality prior to receipt of the Confidential Information from the Discloser; or
 - (v) which the Recipient is required to disclose purely to the extent to comply with the requirements of any relevant stock exchange.
- 1.2 Nothing in Clause 1 of this Schedule 3 of these Call-off Terms and Conditions shall prevent the Recipient from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by applicable Law, including the Freedom of Information Act 2000 ("**FOIA**"), Codes of Practice on Access to Government Information, on the Discharge of Public Authorities' Functions or on the Management of Records ("**Codes of Practice**") or the Environmental Information Regulations 2004 ("**Environmental Regulations**").
- 1.3 The Authority may disclose the Supplier's Confidential Information:
- 1.3.1 on a confidential basis, to any Contracting Authority (the Parties agree that all Contracting Authorities receiving such Confidential Information shall be entitled to further disclose the Confidential Information to other Contracting Authorities on the basis that the information is confidential and is not to be disclosed to a third party which is not part of any Contracting Authority);

- 1.3.2 on a confidential basis, to any consultant, contractor or other person engaged by the Authority and/or the Contracting Authority receiving such information;
- 1.3.3 to any relevant party for the purpose of the examination and certification of the Authority's accounts;
- 1.3.4 to any relevant party for 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;
- 1.3.5 to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirements; or
- 1.3.6 on a confidential basis to a proposed successor body in connection with any proposed or actual, assignment, novation or other disposal of rights, obligations, liabilities or property in connection with this Contract;

and for the purposes of this Contract, references to disclosure "on a confidential basis" shall mean the Authority making clear the confidential nature of such information and that it must not be further disclosed except in accordance with Law or this Clause 1.3 of this Schedule 3 of these Call-off Terms and Conditions.

- 1.4 The Supplier may only disclose the Authority's Confidential Information, and any other information provided to the Supplier by the Authority in relation to this Contract, to the Supplier's Staff or professional advisors who are directly involved in the performance of or advising on the Supplier's obligations under this Contract. The Supplier shall ensure that such Staff or professional advisors are aware of and shall comply with the obligations in Clause 1 of this Schedule 3 of these Call-off Terms and Conditions as to confidentiality and that all information, including Confidential Information, is held securely, protected against unauthorised use or loss and, at the Authority's written discretion, destroyed securely or returned to the Authority when it is no longer required. The Supplier shall not, and shall ensure that the Staff do not, use any of the Authority's Confidential Information received otherwise than for the purposes of performing the Supplier's obligations in this Contract.
- 1.5 For the avoidance of doubt, save as required by Law or as otherwise set out in this Schedule 3 of these Call-off Terms and Conditions, the Supplier shall not, without the prior written consent of the Authority (such consent not to be unreasonably withheld or delayed), announce that it has entered into this Contract and/or that it has been appointed as a Supplier to the Authority and/or make any other announcements about this Contract.
- 1.6 Clause 1 of this Schedule 3 of these Call-off Terms and Conditions shall remain in force:
 - 1.6.1 without limit in time in respect of Confidential Information which comprises Personal Data or which relates to national security; and
 - 1.6.2 for all other Confidential Information for a period of three (3) years after the expiry or earlier termination of this Contract unless otherwise agreed in writing by the Parties.

2 Data protection

- 2.1 The Parties acknowledge their respective duties under Data Protection Legislation and shall give each other all reasonable assistance as appropriate or necessary to enable each other to comply with those duties. For the avoidance of doubt, the Supplier shall take reasonable steps to ensure it is familiar with the Data Protection Legislation and any obligations it may have under such Data Protection Legislation and shall comply with such obligations.
- 2.2 Where the Supplier is Processing Personal Data under or in connection with this Contract, the Parties shall comply with the Data Protection Protocol.
- 2.3 The Supplier and the Authority shall ensure that Personal Data is safeguarded at all times in accordance with the Law, and this obligation will include (if transferred electronically) only transferring Personal Data (a) if essential, having regard to the purpose for which the transfer is conducted; and (b) that is encrypted in accordance with any international data encryption standards for healthcare, and as otherwise required by those standards applicable to the Authority under any Law and Guidance (this includes, data transferred over wireless or wired networks, held on laptops, CDs, memory sticks and tapes).
- 2.4 Where, as a requirement of this Contract, the Supplier is Processing Personal Data relating to patients and/or service users as part of the Services, the Supplier shall:
- 2.4.1 complete and publish an annual information governance assessment using the NHS information governance toolkit;
 - 2.4.2 achieve a minimum level 2 performance against all requirements in the relevant NHS information governance toolkit;
 - 2.4.3 nominate an information governance lead able to communicate with the Supplier's board of directors or equivalent governance body, who will be responsible for information governance and from whom the Supplier's board of directors or equivalent governance body will receive regular reports on information governance matters including, but not limited to, details of all incidents of data loss and breach of confidence;
 - 2.4.4 report all incidents of data loss and breach of confidence in accordance with Department of Health and/or the NHS England and/or Health and Social Care Information Centre guidelines;
 - 2.4.5 put in place and maintain policies that describe individual personal responsibilities for handling Personal Data and apply those policies vigorously;
 - 2.4.6 put in place and maintain a policy that supports its obligations under the NHS Care Records Guarantee (being the rules which govern information held in the NHS Care Records Service, which is the electronic patient/service user record management service providing authorised healthcare professionals access to a patient's integrated electronic care record);
 - 2.4.7 put in place and maintain agreed protocols for the lawful sharing of Personal Data with other NHS organisations and (as appropriate) with non-NHS

organisations in circumstances in which sharing of that data is required under this Contract;

- 2.4.8 where appropriate, have a system in place and a policy for the recording of any telephone calls in relation to the Services, including the retention and disposal of those recordings;
 - 2.4.9 at all times comply with any information governance requirements and/or processes as may be set out in the Specification and Tender Response Document; and
 - 2.4.10 comply with any new and/or updated requirements, Guidance and/or Policies notified to the Supplier by the Authority from time to time (acting reasonably) relating to the Processing and/or protection of Personal Data.
- 2.5 Where any Personal Data is Processed by any Sub-contractor of the Supplier in connection with this Contract, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in Clause 2 of this Schedule 3 of these Call-off Terms and Conditions, as if such Sub-contractor were the Supplier.
- 2.6 The Supplier shall indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings whatsoever or howsoever arising from the Supplier's unlawful or unauthorised Processing, destruction and/or damage to Personal Data in connection with this Contract.

3 Freedom of Information and Transparency

- 3.1 The Parties acknowledge the duties of Contracting Authorities under the FOIA, Codes of Practice and Environmental Regulations and shall give each other all reasonable assistance as appropriate or necessary to enable compliance with those duties.
- 3.2 The Supplier shall assist and cooperate with the Authority to enable it to comply with its disclosure obligations under the FOIA, Codes of Practice and Environmental Regulations. The Supplier agrees:
- 3.2.1 that this Contract and any recorded information held by the Supplier on the Authority's behalf for the purposes of this Contract are subject to the obligations and commitments of the Authority under the FOIA, Codes of Practice and Environmental Regulations;
 - 3.2.2 that the decision on whether any exemption to the general obligations of public access to information applies to any request for information received under the FOIA, Codes of Practice and Environmental Regulations is a decision solely for the Authority;
 - 3.2.3 that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier itself is subject to the FOIA, Codes of Practice and Environmental Regulations it will liaise with the Authority as to the contents of any response before a response to a request is issued and will promptly (and in any event within two (2) Business Days) provide a copy of the request and any response to the Authority;

- 3.2.4 that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier is not itself subject to the FOIA, Codes of Practice and Environmental Regulations, it will not respond to that request (unless directed to do so by the Authority) and will promptly (and in any event within two (2) Business Days) transfer the request to the Authority;
- 3.2.5 that the Authority, acting in accordance with the Codes of Practice issued and revised from time to time under both section 45 of FOIA, and regulation 16 of the Environmental Regulations, may disclose information concerning the Supplier and this Contract; and
- 3.2.6 to assist the Authority in responding to a request for information, by processing information or environmental information (as the same are defined in FOIA and the Environmental Regulations) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section 46 of FOIA, and providing copies of all information requested by the Authority within five (5) Business Days of that request and without charge.
- 3.3 The Parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations, the content of this Contract is not Confidential Information.
- 3.4 Notwithstanding any other term of this Contract, the Supplier consents to the publication of this Contract in its entirety (including variations), subject only to the redaction of information that is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations.
- 3.5 In preparing a copy of this Contract for publication under Clause 3.4 of this Schedule 3 of these Call-off Terms and Conditions, the Authority may consult with the Supplier to inform decision making regarding any redactions but the final decision in relation to the redaction of information will be at the Authority's absolute discretion.
- 3.6 The Supplier shall assist and cooperate with the Authority to enable the Authority to publish this Contract.
- 3.7 Where any information is held by any Sub-contractor of the Supplier in connection with this Contract, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in Clause 3 of this Schedule 3 of these Call-off Terms and Conditions, as if such Sub-contractor were the Supplier.

4 Information Security

- 4.1 Without limitation to any other information governance requirements set out in this Schedule 3 of these Call-off Terms and Conditions, the Supplier shall:
 - 4.1.1 notify the Authority forthwith of any information security breaches or near misses (including without limitation any potential or actual breaches of confidentiality or actual information security breaches) in line with the Authority's information governance Policies; and
 - 4.1.2 fully cooperate with any audits or investigations relating to information security and any privacy impact assessments undertaken by the Authority

and shall provide full information as may be reasonably requested by the Authority in relation to such audits, investigations and assessments.

- 4.2 Where required in accordance with the Specification and Tender Response Document, the Supplier will ensure that it puts in place and maintains an information security management plan appropriate to this Contract, the type of Services being provided and the obligations placed on the Supplier. The Supplier shall ensure that such plan is consistent with any relevant Policies, Guidance, Good Industry Practice and with any relevant quality standards as may be set out in the Key Provisions and/or the Specification and Tender Response Document.
- 4.3 Where required in accordance with the Specification and Tender Response Document, the Supplier shall obtain and maintain certification under the HM Government Cyber Essentials Scheme at the level set out in the Specification and Tender Response Document.

Schedule 4 of these Call-off Terms and Conditions

Definitions and Interpretations

1 Definitions

- 1.1 In this Contract the following words shall have the following meanings unless the context requires otherwise:

“Actual Services Commencement Date”	means the date the Supplier actually commences delivery of all of the Services;
“Authority”	means the authority named on the Order Form;
“Authority’s Obligations”	means the Authority’s further obligations, if any, referred to in the Specification and Tender Response Document and/or the Order Form;
“Breach Notice”	means a written notice of breach given by one Party to the other, notifying the Party receiving the notice of its breach of this Contract;
“Business Continuity Event”	means any event or issue that could impact on the operations of the Supplier and its ability to supply the Goods and/or provide the Services including an influenza pandemic and any Force Majeure Event;
“Business Continuity Plan”	means the Supplier’s business continuity plan which includes its plans for continuity of the supply of the Goods and the provision of the Services during a Business Continuity Event;
“Business Day”	means any day other than Saturday, Sunday, Christmas Day, Good Friday or a statutory bank holiday in England and Wales;
“Cabinet Office Statement”	the Cabinet Office Statement of Practice – Staff Transfers in the Public Sector 2000 (as revised 2013) as may be amended or replaced;
“Call-off Terms and Conditions”	means these Call-off Terms and Conditions for the Supply of Goods and the Provision of Services;
“Change Control Process”	means the change control process, if any, referred to in any Key Provisions;
“Codes of Practice”	shall have the meaning given to the term in Clause 1.2 of Schedule 3 of these Call-off Terms and Conditions;
“Commencement Date”	means the date of the Order Form;

“Confidential Information”	means information, data and material of any nature, which either Party may receive or obtain in connection with the conclusion and/or operation of the Contract including any procurement process which is: (a) Personal Data including without limitation which relates to any patient or other service user or his or her treatment or clinical or care history; (b) designated as confidential by either party or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored); and/or (c) Policies and such other documents which the Supplier may obtain or have access to through the Authority’s intranet;
“Contract”	means the Order Form, the provisions on the front page and all Schedules of these Call-off Terms and Conditions, the Specification and Tender Response Document and the applicable provisions of the Framework Agreement;
“Contracting Authority”	means any contracting authority as defined in Regulation 3 of the Public Contracts Regulations 2015 (SI 2015/102) (as amended), other than the Authority;
“Contract Manager”	means for the Authority and for the Supplier the individuals specified in the Order Form or as otherwise agreed between the Parties in writing or such other person notified by a Party to the other Party from time to time in accordance with Clause 8.1 of Schedule 2 of these Call-off Terms and Conditions;
“Contract Price”	means the price exclusive of VAT that is payable to the Supplier by the Authority under the Contract for the full and proper performance by the Supplier of its obligations under the Contract calculated in accordance with the provisions of the Framework Agreement and as confirmed in the Order Form;
“Controller”	shall have the same meaning as set out in the GDPR;
“Convictions”	means, other than in relation to minor road traffic offences, any previous or pending prosecutions, convictions, cautions and binding-over orders (including any spent convictions as contemplated by Section 1(1) of the Rehabilitation of Offenders Act 1974 or any replacement or amendment to that Act);
“Data Protection Legislation”	means (i) the Data Protection Act 1998 or, from the date it comes into force, the Data Protection Act 2018 to the extent that it relates to processing of personal data and privacy; (ii) the GDPR, the Law Enforcement Directive (Directive (EU) 2016/680) and any applicable national implementing Law as amended from time to time; and (iii) all applicable Law about the processing of personal data and privacy;

“Data Protection Protocol”	means any document of that name as provided to the Supplier by the Authority (as amended from time to time in accordance with its terms) which shall include, without limitation, any such document appended to the Order Form;
“Defective Goods”	has the meaning given under Clause 3.6 of Schedule 2 of these Call-off Terms and Conditions;
“Dispute(s)”	means any dispute, difference or question of interpretation or construction arising out of or in connection with this Contract, including any dispute, difference or question of interpretation relating to the Goods and/or Services, any matters of contractual construction and interpretation relating to the Contract, or any matter where this Contract directs the Parties to resolve an issue by reference to the Dispute Resolution Procedure;
“Dispute Notice”	means a written notice served by one Party to the other stating that the Party serving the notice believes there is a Dispute;
“Dispute Resolution Procedure”	means the process for resolving Disputes as set out in Clause 22 of Schedule 2 of these Call-off Terms and Conditions;
“DOTAS”	means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and 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 (Application of Part 7 of the Finance Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992;
“Electronic Trading System(s)”	means such electronic data interchange system and/or world wide web application and/or other application with such message standards and protocols as the Authority may specify from time to time;
“Employment Liabilities”	means all claims, demands, actions, proceedings, damages, compensation, tribunal awards, fines, costs (including but not limited to reasonable legal costs), expenses and all other liabilities whatsoever;
“Environmental Regulations”	shall have the meaning given to the term in Clause 1.2 of Schedule 3 of these Call-off Terms and Conditions;
“eProcurement Guidance”	means the NHS eProcurement Strategy available via: http://www.gov.uk/government/collections/nhs-procurement together with any further Guidance issued by the Department of Health in connection with it;

“Equality Legislation”	means any and all legislation, applicable guidance and statutory codes of practice relating to equality, diversity, non-discrimination and human rights as may be in force in England and Wales from time to time including, but not limited to, the Equality Act 2010, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000 and the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034) and the Human Rights Act 1998;
“Fair Deal for Staff Pensions”	means guidance issued by HM Treasury entitled “Fair Deal for staff pensions: staff transfer from central government” issued in October 2013 (as amended, supplemented or replaced);
“FOIA”	shall have the meaning given to the term in Clause 1.2 of Schedule 3 of these Call-off Terms and Conditions;
“Force Majeure Event”	means any event beyond the reasonable control of the Party in question to include, without limitation: (a) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party’s ability to perform its obligations under this Contract; (b) acts of terrorism; (c) flood, storm or other natural disasters; (d) fire; (e) unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning; (f) government requisition or impoundment to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, laws or procedures (including such laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment; (g) compliance with any local law or governmental order, rule, regulation or direction applicable outside of England and Wales that could not have been reasonably foreseen; (h) industrial action which affects the ability of the Supplier to supply the Goods and/or to provide the Services, but which is not confined to the workforce of the Supplier or the workforce of any Sub-contractor of the Supplier; and (i) a failure in the Supplier’s and/or Authority’s supply chain to the extent that such failure is due to any event suffered by a member of such supply chain, which would also

	qualify as a Force Majeure Event in accordance with this definition had it been suffered by one of the Parties; but excluding, for the avoidance of doubt, the withdrawal of the United Kingdom from the European Union and any related circumstances, events, changes or requirements;
“Framework Agreement”	means the Framework Agreement referred to in the Order Form;
“Fraud”	means any offence under any law in respect of fraud in relation to this Contract or defrauding or attempting to defraud or conspiring to defraud the government, parliament or any Contracting Authority;
GDPR	means the General Data Protection Regulation (Regulation (EU) 2016/679);
“General Anti-Abuse Rule”	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”	means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled and experienced supplier and/or service provider engaged in the manufacture and/or supply of goods and/or the provision of services similar to the Goods and Services under the same or similar circumstances as those applicable to this Contract; including in accordance with any codes of practice published by relevant trade associations;
“Goods”	means all goods, materials or items that the Supplier is required to supply to the Authority under this Contract;
“Guidance”	means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Goods and/or Services, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by the Authority and/or have been published and/or notified to the Supplier by the Department of Health, Monitor, NHS England, the Medicines and Healthcare Products Regulatory Agency, the European Medicine Agency, the European Commission, the Care Quality Commission and/or any other regulator or competent body;
“Halifax Abuse Principle”	means the principle explained in the CJEU Case C-255/02 Halifax and others;
“HM Government Cyber Essentials Scheme	means the HM Government Cyber Essentials Scheme as further defined in the documents relating to this scheme published at:

	https://www.gov.uk/government/publications/cyber-essentials-scheme-overview ;
“Implementation Plan”	means the implementation plan, if any, referred to in the Key Provisions;
“Implementation Requirements”	means the Authority’s implementation and mobilisation requirements (if any), as may be set out in the Specification and Tender Response Document and/or otherwise as part of this Contract, which the Supplier must comply with as part of implementing the Services;
“Intellectual Property Rights”	means all patents, copyright, design rights, registered designs, trade marks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trade marks and registered designs;
“Interested Party”	means any organisation which has a legitimate interest in providing services of the same or similar nature to the Services in immediate or proximate succession to the Supplier or any Sub-contractor and who had confirmed such interest in writing to the Authority;
“Key Provisions”	means the key provisions set out in Schedule 1 of these Call - off Terms and Conditions and/or as part of the Order Form;
“KPI”	means the key performance indicators as set out in the Specification and Tender Response Document and/or the Order Form, if any;
“Law”	means any applicable legal requirements including, without limitation,: (a) any applicable statute or proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument as applicable in England and Wales; (b) any applicable European Union obligation, directive, regulation, decision, law or right (including any such obligations, directives, regulations, decisions, laws or rights that are incorporated into the law of England and Wales or given effect in England and Wales by any applicable statute, proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument); (c) any enforceable community right within the meaning of section 2(1) European Communities Act 1972; (d) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; (e) requirements set by any regulatory body as applicable in England and Wales; (f) any relevant code of practice as applicable in England and Wales; and

	(g) any relevant collective agreement and/or international law provisions (to include, without limitation, as referred to in (a) to (f) above);
“Long Stop Date”	means the date, if any, specified in the Specification and Tender Response Document;
“NHS”	means the National Health Service;
“Occasion of Tax Non-Compliance”	means: (a) any tax return of the Supplier 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: (i) a Relevant Tax Authority successfully challenging the Supplier 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; (ii) the failure of an avoidance scheme which the Supplier 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 (b) any tax return of the Supplier 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;
“Order Form”	means the order form for the Goods and/or Services issued by the Authority in accordance with the Framework Agreement and which is added at Schedule 1A of these Call-Off Terms and Conditions;
“Party”	means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier;
Performance Monitoring Tool	means the performance monitoring tool template at Annex A to the Order Form.
“Personal Data”	shall have the same meaning as set out in the GDPR;
“Policies”	means the policies, rules and procedures of the Authority as notified to the Supplier from time to time;
“Premises and Locations”	has the meaning given under Clause 4.1 of Schedule 2 of these Call-off Terms and Conditions;
“Process”	shall have the same meaning as set out in the GDPR. Processing and Processed shall be construed accordingly;

“Processor”	shall have the same meaning as set out in the GDPR;
“Product Information”	means information concerning the Goods as may be reasonably requested by the Authority and supplied by the Supplier to the Authority in accordance with Clause 20 of Schedule 2 of these Call-off Terms and Conditions for inclusion in the Authority’s product catalogue from time to time;
“Rejected Goods”	has the meaning given under Clause 3.2 of Schedule 2 of these Call-off Terms and Conditions;
“Relevant Tax Authority”	means HM Revenue and Customs, or, if applicable, a tax authority in the jurisdiction in which the Supplier is established;
“Remedial Proposal”	has the meaning given under Clause 15.3 of Schedule 2 of these Call-off Terms and Conditions;
“Requirement to Recall”	has the meaning given under 3.9 of Schedule 2 of these Call-off Terms and Conditions;
“Services”	means the services set out in this Contract which for the avoidance of doubt includes the Stockpile Services which are described in the Additional Terms at Schedule 5;
“Services Commencement Date”	means the date delivery of the Services shall commence as specified in the Order Form. If no date is specified in the Order Form, this services commencement date shall be the Commencement Date;
“Services Information”	means information concerning the Services as may be reasonably requested by the Authority and supplied by the Supplier to the Authority in accordance with Clause 20 of Schedule 2 of these Call-off Terms and Conditions for inclusion in the Authority’s services catalogue from time to time;
“Specification and Tender Response Document”	means the Specification and Tender Response Document set out in the Framework Agreement as supplemented by any further information set out and/or referred to in the Order Form and as amended and/or updated in accordance with this Contract;
“Staff”	means all persons employed or engaged by the Supplier to perform its obligations under this Contract including any Sub-contractors and person employed or engaged by such Sub-contractors;
“Sub-contract”	means a contract between two or more suppliers, at any stage of remoteness from the Supplier in a sub-contracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of the whole or any part of this Contract;
“Sub-contractor”	means a party to a Sub-contract other than the Supplier;

“Subsequent Transfer Date”	means the point in time, if any, at which services which are fundamentally the same as the Services (either in whole or in part) are first provided by a Successor or the Authority, as appropriate, giving rise to a relevant transfer under TUPE;
“Subsequent Transferring Employees”	means any employee, agent, consultant and/or contractor who, immediately prior to the Subsequent Transfer Date, is wholly or mainly engaged in the performance of services fundamentally the same as the Services (either in whole or in part) which are to be undertaken by the Successor or Authority, as appropriate;
“Successor”	means any third party who provides services fundamentally the same as the Services (either in whole or in part) in immediate or subsequent succession to the Supplier upon the expiry or earlier termination of this Contract;
“Supplier”	means the supplier named on the Order Form;
“Supplier Code of Conduct”	means the code of that name published by the Government Commercial Function originally dated September 2017, as may be amended, restated, updated, re-issued or re-named from time to time;
“Supplier Personnel”	means any employee, agent, consultant and/or contractor of the Supplier or Sub-contractor who is either partially or fully engaged in the performance of the Services;
“Term”	means the term as referred to in the Key Provisions;
“Termination Notice”	means a written notice of termination given by one Party to the other notifying the Party receiving the notice of the intention of the Party giving the notice to terminate this Contract on a specified date and setting out the grounds for termination;
“Third Party”	means any supplier of services fundamentally the same as the Services (either in whole or in part) immediately before the Transfer Date;
“Third Party Body”	has the meaning given under Clause 8.5 of Schedule 2 of these Call-off Terms and Conditions;
“Transfer Date”	means the Actual Services Commencement Date;
"TUPE"	means the Transfer of Undertakings (Protection of Employment) Regulations 2006 (2006/246) and/or any other regulations or other legislation enacted for the purpose of implementing or transposing the Acquired Rights Directive (77/187/EEC, as amended by Directive 98/50 EC and consolidated in 2001/23/EC) into English law; and
“VAT”	means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax.

- 1.2 References to any Law shall be deemed to include a reference to that Law as amended, extended, consolidated, re-enacted, restated, implemented or transposed from time to time.
- 1.3 References to any legal entity shall include any body that takes over responsibility for the functions of such entity.
- 1.4 References in this Contract to a "Schedule", "Appendix", "Paragraph" or to a "Clause" are to schedules, appendices, paragraphs and clauses of this Contract.
- 1.5 References in this Contract to a day or to the calculation of time frames are references to a calendar day unless expressly specified as a Business Day.
- 1.6 Unless set out in the Contract as a chargeable item and subject to Clause 30.6 of Schedule 2 of these Call-off Terms and Conditions, the Supplier shall bear the cost of complying with its obligations under this Contract.
- 1.7 The headings are for convenience only and shall not affect the interpretation of this Contract.
- 1.8 Words denoting the singular shall include the plural and vice versa.
- 1.9 Where a term of this Contract provides for a list of one or more items following the word "including" or "includes" then such list is not to be interpreted as an exhaustive list. Any such list shall not be treated as excluding any item that might have been included in such list having regard to the context of the contractual term in question. General words are not to be given a restrictive meaning where they are followed by examples intended to be included within the general words.
- 1.10 Where there is a conflict between the Supplier's responses to the requirements set out in the Specification and Tender Response Document and any other part of this Contract, such other part of this Contract shall prevail.
- 1.11 Where a document is required under this Contract, the Parties may agree in writing that this shall be in electronic format only.
- 1.12 Where there is an obligation on the Authority to procure any course of action from any third party, this shall mean that the Authority shall use its reasonable endeavours to procure such course of action from that third party.
- 1.13 Any Breach Notice issued by a Party in connection with this Contract shall not be invalid due to it containing insufficient information. A Party receiving a Breach Notice ("**Receiving Party**") may ask the Party that issued the Breach Notice ("**Issuing Party**") to provide any further information in relation to the subject matter of the Breach Notice that it may reasonably require to enable it to understand the Breach Notice and/or to remedy the breach. The Issuing Party shall not unreasonably withhold or delay the provision of such further information as referred to above as may be requested by the Receiving Party but no such withholding or delay shall invalidate the Breach Notice.
- 1.14 Any terms defined as part of a Schedule or other document forming part of this Contract shall have the meaning as defined in such Schedule or document.

Schedule 5 of these call-off terms and conditions
Additional Terms

Schedule 5

Stockpile Service Terms

This Schedule sets out the terms governing the stockpile arrangements of the Products during the Term (the Stockpile Services).

Definitions used in this Schedule:

Authorised Release	An event commencing when the Authority gives notice to the Supplier under Clause 8 to allow a release of the Stockpiled Products in accordance with an agreed Release Plan or Exit Plan
Delivery Notice	notice in writing in the form set out in Annex 1 of the Schedule confirming delivery to be sent as soon as a Stockpiled Product is placed in to the Stockpile to DHSC Renal Admin Inbox (renaladmin@dhsc.gov.uk) such other person notified to the Supplier by the Authority
Delivery Schedule	the delivery schedule set out in the Order Form
Exit Buyback Price	being 90% of the original purchase price set out in the Order Form
Exit Phase	a period of 3 months, commencing on one or more of the following events: (i) 3 months before the first anniversary of the commencement date; (ii) 3 months before the second anniversary of the commencement date; (iii) 3 months before expiry of this Contract; or (iv) if earlier, from the date of any notice to terminate this Contract or any part of this Contract and continuing for a period of 3 months or as agreed by both parties
Exit Plan	the plan(s), a template of which is set out in Annex 2 of this Schedule, to be sent to DHSC Renal Admin Inbox (renaladmin@dhsc.gov.uk) or such other person notified to the Supplier by the Authority
Exit Plan Report	the report(s) to be completed during the Exit Phase(s) as set out in Annex 2 of this Schedule
Licencing Authority	MHRA
Marketing Authorisation	the relevant approvals granted by the Medicines and Healthcare products Regulatory Agency authorising the Supplier to market and sell the Products

MHRA	Medicines and Healthcare products Regulatory Agency
Minimum Shelf Life	shall be a minimum of twelve (12) months throughout the Term
OMCL	Official Medicines Control Laboratory
Payment Terms	means the terms set out in Annex 5 of this Schedule
Product Price	as set out in the Order Form
Products	the products set out in the Order Form
Registered Shelf Life	the shelf life that the Products are registered as having as part of the Marketing Authorisation process.
Rejected Product	any Units of the Products rejected by the Authority under Clause 10.2 or 10.3
Release Buyback Price	means the original price for which DHSC purchased product from Supplier
Release Plan	a plan for the Authorised Release of the Stockpiled Products prepared under this Contract in the form set out in Annex 3 and sent to DHSC Renal Admin Inbox (renaladmin@dhsc.gov.uk) or such other person notified to the Supplier by the Authority
Released Products	Stockpiled Products that are the subject of an Authorised Release
Release Report	the report to be completed as part of any Release Plan the template for which is set out in Annex 3 of this Schedule
Replacement Products	Products used to replace: (a) Stockpiled Products removed from the Stockpile in accordance with Clause 6; and (b) Rejected Products
Required Volume	has the meaning set out in the Order Form in respect of each of the Products, as varied in accordance with any Exit Plan
Services	the Storage Services, the supply and delivery to the stockpile of the Products in accordance with Clauses 1.3, 34 and 4 stock rotation and any Authorised Release in accordance with this Contract, and any other services provided by the Supplier under this Schedule
SmPC	means the Summary of Product Characteristics
Stock Building Phase	is the period from 1 October to 2 October 2022 during which the Supplier builds the Stockpile to the Required Volume, in accordance with Clause 3 and the Delivery Schedule
Stock Report	to be provided as set out in Annex 4 of this Schedule
Stockpile	where the Stockpiled Products are held within the Storage Facilities

Stockpiled Products	Products held in and stored within the Stockpile, including any Replacement Products supplied under this
Storage Charge	the weekly charge for storage and other services in respect of each pallet of Product as set out in Order Form, fixed for the duration of this Contract
Storage Facilities	the location(s) in England where the Stockpiled Products are to be stored as determined by the Supplier from time to time
Storage Provider	any third party provider of Storage Services appointed by the Supplier in accordance with Call off Terms and as agreed with the Supplier
Storage Services	storage of the Products in accordance with Clause 7
Technical Agreement	means the agreement in Annex 6 of this Schedule to be entered into by the Supplier to ensure compliance with the Authority's Wholesale Distribution Authorisation
Unit	a unit of the Products
Wholesale Distribution Authorisation	has the meaning set out in the Human Medicines Regulations 2012/2016 or any replacement regulation

1. BACKGROUND

- 1.1. The Authority wishes to purchase a range of Continuous Renal Replacement Therapies Consumables and Equipment, as indicated in the Order Form which will then be stored as a Stockpile by the Supplier. The Supplier shall be responsible for rotating the stock so that it has a minimum agreed shelf life of twelve (12) months throughout the Term.
- 1.2. It is intended for the Products to be distributed for patients solely in the UK during a pandemic or other period of increased demand and / or potential shortage in the UK and for this purpose the Stockpiled Products must be stored in the UK. In the event of a shortage in the UK, the Authority can direct the Supplier to buy back all or some of the stock they hold, and release it through the normal UK supply chain.
- 1.3. In the period leading up to expiry of the Contract, the Supplier will be required, through an agreed Exit Plan, to buy back the stock. Title to the stock (prior to any buy back) will remain with the Authority, but the Supplier must store the stock at their own risk and manage it, to include regular reporting and review meetings with the Authority. The stock should also be subject to the Supplier's own internal audits.

2. STOCK PILE SERVICES

- 2.1. The Supplier shall, after the completion of the Stock Building Phase, maintain a Stockpile of the Products in accordance with the terms of this Schedule throughout the Term.
- 2.2. The Term is set out in the Order Form.

3. STOCK BUILDING

- 3.1. During the Stock Building Phase in respect of each Product, the Supplier shall build up the stockpile for each Product in accordance with the Delivery Schedule. Throughout the Stockpiling Period, the Supplier shall supply to the Authority the Product at the Product Price, in accordance with the Delivery Schedule to ensure there is the Required Volume of the Products.
- 3.2. The Supplier shall deliver the Product to the UK based Storage Facilities set out in Clause 4. For the sake of clarity all the Products in the Stockpile shall be stored in the UK.

- 3.3. If the Supplier becomes aware that, for any reason, it will or may not be able to supply the Products in accordance with the Delivery Schedule, it shall promptly give notice in writing to the Authority setting out the reasons for the delay and the anticipated time for delivery. Following receipt of notice under this Clause 3.3, the Authority may review with the Supplier the reasons for the delay and steps which may be taken to mitigate any delay or risk of delay and to secure delivery as promptly as possible and agree to a revised Delivery Schedule. Where despite the revised Delivery Schedule, delivery has not taken place the Authority may at any time thereafter make time for delivery of the essence and terminate this Agreement for breach.
- 3.4. Without prejudice to any other right or remedy of the Authority in respect of any delay, both parties shall use reasonable endeavours to agree a revised Delivery Schedule.
- 3.5. On delivery in good order and condition in full of the Required Volume of a Product as set out in the Delivery Schedule or revised Delivery Schedule (taking into account any Product which has been the subject of an Authorised Release or removal or is to be treated as removed from the Stockpile in accordance with this Agreement), the Supplier shall give to the Authority written confirmation in the form of a Delivery Notice that the Required Volume of such Product has been received and the Stock Building Phase is complete.

4. DELIVERY AND STOCKPILING

- 4.1. The Supplier shall:
- 4.1.1. transport all Units of the Products to the Storage Facilities, unload the Units, inspect the Units, designate the Units as Stockpiled Products and deliver them into the Stockpile as set out under this Agreement;
 - 4.1.2. transport and deliver the Products in such manner necessary to ensure that they are delivered in good and usable condition and with such duty and care expected to meet Good Distribution Practice and Good Industry Practice standards;
 - 4.1.3. without prejudice to Clause 4.1.2, store the Products during transportation and delivery in accordance with strict temperature controls as specified in the relevant SmPC and as required to ensure that the Products remain in good and useable condition; and
 - 4.1.4. where applicable, maintain complete accurate records showing the temperature controls implemented under Clause 4.1.3 above at all times and make such records available to the Authority on request.
- 4.2. The Supplier shall deliver all Units of the Products securely packaged with the following details being shown clearly on the shipping carton or other such outer packaging and shall record the following details and make such records available to the Authority on request:

- 4.2.1. a description of the Products including the Manufacturer's brand name and/or the generic drug name and the holder of the Marketing Authorisation;
- 4.2.2. the quantity of Units in the Packs;
- 4.2.3. special directions for storage and handling (if any);
- 4.2.4. expiry date for the Products in the Packs;
- 4.2.5. batch number;
- 4.2.6. name of the Supplier;
- 4.2.7. name of the Manufacturer or holder of the Marketing Authorisation (if different from the Supplier); and
- 4.2.8. any other information required by the Licensing Authority to be provided.
- 4.3. The Supplier shall be responsible for all transport and all related costs associated with the delivery of the Products.
- 4.4. All third party carriers engaged to deliver the Products shall at no time be agents of the Authority and accordingly the Supplier shall be liable to the Authority for the acts and omissions of all third party carriers engaged to deliver the Products.
- 4.5. The Supplier shall be deemed to have delivered Units of the Products to the Authority when the requirements of clause 4.8 have been completed to the satisfaction of the Authority.
- 4.6. The labelling and marking of all Packs of the Products and all relevant information accompanying them shall be in accordance with their Marketing Authorisation and the relevant SmPC.
- 4.7. The Supplier shall apply Good Distribution Practice and Good Industry Practice at all times. In addition the Supplier shall ensure that the Products are processed, checked and handled with all due care and skill and to the highest standard available in the industry.
- 4.8. Immediately upon each delivery of the Products to the Storage Facilities the Supplier shall:
 - 4.8.1. ensure all the obligations set out in this Clause 4 have been met;
 - 4.8.2. ensure that temperature checks and records, where applicable, are in line with good distribution practice;
 - 4.8.3. check that the quantity, batch numbers, expiry dates and other details of the Products are in accordance with the Delivery Schedule and record the results of such checks;

- 4.8.4. subject the Products to a visual inspection of the Packs and containers without opening or tampering with any Products packaging to ensure that there is no obvious damage and record the results of such inspection;
 - 4.8.5. designate the Products as Stockpiled Products and place them into the Stockpile;
 - 4.8.6. send an electronic Delivery Notice to the Authority stating that the Products are deemed to be acceptable (having made the necessary checks set out in this Clause 4) and have been designated as Stockpiled Products and placed in the Stockpile; and
 - 4.8.7. include in the Delivery Notice the details and quantity of any products which should be deemed to be Rejected Products.
- 4.9. The Supplier shall maintain a record of each delivery of the Products stating the information required under Clause 4.2 that shall at all times be immediately available to the Authority upon request for the duration of this Agreement and a further 6 years following the expiry or termination of this Agreement.

5. MANUFACTURE AND CHAIN OF SUPPLY

- 5.1. The Supplier shall:
 - 5.1.1. ensure it has or it has access to manufacturing capacity for each Product sufficient to comply with its obligations under this Agreement;
 - 5.1.2. ensure that the production facilities used in the manufacture of the Products are in a state and condition necessary to comply with any legal requirements in relation to the Products, and their production and to enable the Supplier to comply with its obligations to supply the Products to the Authority in accordance with this Agreement;
 - 5.1.3. ensure that all Products when manufactured are done so with all due care and skill and are stored in an environment suitable for such goods with the necessary protection and conditions according to Good Manufacturing Practice, Good Industry Practice, the Marketing Authorisation, the product specification, and the relevant SmPC.

6. STOCK ROTATION

- 6.1. The Supplier shall ensure that:
 - 6.1.1. the Required Volume of Stockpiled Products as is required in accordance with the Delivery Schedule is attained during the Stock Building Phase and that the Stockpiled Products in the Stockpile are stored in accordance with these stock rotation provisions throughout the Term subject only to Authorised Releases under a Release Plan or Exit Plan in accordance with this Agreement; and

6.1.2. all Stockpiled Products in the Stockpile shall at all times throughout the term have a Minimum Shelf Life being an unexpired Registered Shelf Life of at least 12 months.

6.2. The Supplier may remove (sell or otherwise dispose of) Stockpiled Products from the Stockpile for the purpose of complying with Clause 6.1, provided that no later than such removal the Supplier has placed in the Stockpile in accordance with this (including but not limited to Clause 4) at least sufficient Units of Replacement Product to replace the removed Stockpiled Products as are necessary to comply with its obligation under Clause 6.1.,.

Such Units of Replacement Product shall be supplied into the Stockpile without charge.

6.3. Save as set out in this Agreement the Supplier shall not remove any Stockpiled Products from the Stockpile, without the Authority's prior written notice.

6.4. The Supplier shall not at any time use the Stockpiled Products to further its position in the market for the relevant Products.

6.5. For the avoidance of doubt the requirements of this Clause 6 shall continue during any Exit Phase.

6.6. If changes are required to a Product as a result of a licensing change (such as a new pack insert or change to the packaging), the Supplier at no additional charge to the Authority, shall rotate the Stockpile to ensure it is compliant with those changes.

7. STORAGE SERVICES

7.1. The Supplier shall store the Stockpiled Products in the Stockpile at the Storage Facilities in accordance with this Agreement and shall invoice the Authority for these services as set out in the Payment Terms.

7.2. The Supplier shall maintain the Storage Facilities in accordance with:

7.2.1. the marketing authorisation for the relevant stockpiled products;

7.2.2. the Wholesale Distribution Authorisation;

7.2.3. any other requirements of the Licensing Authority; and

7.2.4. Good Industry Practice;

7.3. The Supplier shall only store the Stockpiled Products at the Storage Facilities. If the Supplier wishes to relocate the Stockpiled Products for storage at any location other than the Storage Facilities or to move the Stockpiled Products within the Storage Facilities:

7.3.1. the Supplier shall keep the Authority informed of any such movement;

- 7.3.2. the Supplier shall only be entitled to do so with the prior written consent of the Authority; and
- 7.3.3. irrespective of approval being provided by the Authority, any such movement of the Stockpiled Products will be at the full risk of the Supplier.
- 7.4. Where the Supplier shall change the location of the storage facilities at any time or from time to time, the Authority shall not be liable to pay any additional costs (including costs charged by the Licensing Authority to the Authority) attributable to the change in the location and the Supplier shall indemnify the Authority in respect of such additional costs.
- 7.5. The Supplier shall:
 - 7.5.1. store the Stockpiled Products in accordance with strict temperature controls as specified in the relevant SmPC and as required to ensure that the Stockpiled Products remain in good and useable condition;
 - 7.5.2. maintain records showing the temperature controls implemented under Clause 7.5.1 above at all times and make such records available to the Authority on request;
 - 7.5.3. ensure all Stockpiled Products are clearly identifiable as Stockpiled Products belonging to the Authority;
 - 7.5.4. store, handle and carry the Units of the Stockpiled Products separately from any other goods;
 - 7.5.5. allocate sufficient space at the Storage Facilities to store the Stockpiled Products in the Required Volume in accordance with the Delivery Schedule;
 - 7.5.6. ensure that Products are stored in an orderly and well organised manner, and adequate records are maintained such that it is readily possible to identify stock location, have access to and inspect different Stockpiled Products, and each Stockpiled Product by reference to different characteristics such as formulation, shelf life, pack size or other relevant characteristics;
 - 7.5.7. operate and manage the Storage Facilities and storage of the Stockpiled Products in accordance with Good Industry Practice and the Wholesale Distribution Authorisation in relation to the Products;
 - 7.5.8. enter into a Technical Agreement as set out at Annex 6 with the Authority to ensure compliance with the Authority's Wholesale Distribution Authorisation
 - 7.5.9. not remove or tamper with any markings on the Products or the packaging of the Products, other than as expressly stated in writing by the Authority;

- 7.5.10. deploy a comprehensive stock management system in respect of the Stockpiled Products in accordance with the law, regulations, directions, and guidance, and provide any information in relation to stock control of the Stockpiled Products that may be requested by the Authority;
- 7.5.11. provide the Storage Services in accordance with its standard operating procedures and not make any material changes to its standard operating procedures, if such proposed changes do or could impact on the provision of the Storage Services, without the prior written consent of the Authority, such consent not to be unreasonably withheld or delayed;
- 7.5.12. employ sufficient staff to ensure that the Storage Services are provided at all times and in all respects in compliance with this Agreement and to ensure that a sufficient reserve of staff is available to provide the Storage Services during holidays or absences;
- 7.5.13. not alter the size of the container or presentation of the items to be supplied (including pallet configuration) to the extent that it affects the Storage Charges; and
- 7.5.14. provide a quarterly Stock Report.
- 7.6. The Supplier shall advise the Authority forthwith in writing of any damage to or loss of the Stockpiled Products that occurs in the performance of the Storage Services and shall provide evidence in writing of such damage to the Authority where requested by the Authority.
- 7.7. Should the Authority undertake a stock audit in relation to the Stockpiled Products, the Supplier shall comply with all reasonable requests to facilitate such audit and shall put into effect changes as may reasonably be required by the Authority as a result of the audit.
- 7.8. The Supplier shall be solely responsible for the direction, management, reporting and organisation of all that is necessary in order to carry out the Storage Services including:
 - 7.8.1. the provision and supervision of use of all the premises, plant, machinery, equipment and delivery vehicles necessary to carry out the Storage Services;
 - 7.8.2. maintenance of all premises, plant, machinery, equipment and delivery vehicles necessary to carry out the Storage Services; and
 - 7.8.3. any and all relevant insurance policies required by law, arising out of the Supplier's performance of the Agreement, including death or personal injury, loss of or damage to property (including the Products) or any other loss. Such policies shall include cover in respect of any financial loss arising from any advice given or omitted to be given by the Supplier.
 - 7.8.4. security at the Storage Facilities.

- 7.9. Where the Storage Services are provided by a Storage Provider, any obligation on the Supplier under this Agreement shall be taken as a requirement on the Supplier to procure the compliance of the Storage Provider with such obligations to the extent necessary to ensure the relevant obligations are fully met.

8. AUTHORISED RELEASE

- 8.1. The Authority and the Supplier shall promptly notify the other party in writing if either party anticipates that there may be a shortage in the supply of any of the Stockpiled Products in the UK.
- 8.2. The Authority and the Supplier shall review together any such anticipated shortages and the means for minimising such shortages or their impact, and the Supplier, in consultation with the Authority, shall draw up a draft Release Plan relation to releasing Stockpiled Products for addressing such shortages and submit it to the Authority for approval.
- 8.3. If the Authority at its sole discretion considers that any of the Stockpiled Products should be released it shall review the draft Release Plan and provide written notice of approval of the Release Plan to the Supplier. The reviewed and approved Release Plan shall include and advise the Supplier of the volume of Stockpiled Product that will be subject to an Authorised Release under the Release Plan.
- 8.4. The Supplier shall then purchase the volume of Stockpiled Product set out in the Release Plan from the Authority at the Release Buyback Price in accordance with the Release Plan.
- 8.5. During an Authorised Release, the Supplier shall:
- 8.5.1. ensure that the Released Products are supplied no later than 48 hours into the supply chain upon demand in the UK for such Products in accordance with any applicable Release Plan and protocols and any reasonable instructions received from time to time from the Authority;
 - 8.5.2. comply with the Release Plan in respect of the Released Products;
 - 8.5.3. attend any meetings as reasonably requested by the Authority;
 - 8.5.4. provide a Release Report to the Authority following an Authorised Release at the end of each week in which an Authorised Release has been made as required by the Authority setting out:
 - 8.5.4.1. the number of Units of Stockpiled Products removed from the Stockpile during the previous week;
 - 8.5.4.2. the number of Units of Stockpiled Products remaining within the Stockpile;
 - 8.5.4.3. the Release Buyback Price;

- 8.5.4.4. the identities of the customers to whom the Supplier has supplied Released Product during the previous week;
 - 8.5.4.5. the per Unit and total product prices for the Released Products, as per applicable protocols, and
 - 8.5.4.6. any other information reasonably requested by the Authority in relation to the distribution of the Released Products.
- 8.5.5. release product in accordance with a triage process agreed with the Authority;
- 8.5.6. Where customer orders are fulfilled from Released Products from the Stockpile, the Supplier will charge the customer at their pre-agreed rates in accordance with NHS Supply Chain framework pricing or the existing Supplier-Customer contract as applicable.
- 8.6. Following an Authorised Release, the Required Volume will be reduced by the number of Units of Stockpiled Products removed in accordance with such Authorised Release, unless the Parties agree that additional Products should be supplied into the Stockpile.

9. TITLE AND RISK

- 9.1. In addition to the provisions contained in clause 2.7 of Schedule 2 to the Framework Call off Terms and Conditions risk in all Units of the Products shall pass to the Authority when the relevant Units are deemed to have been delivered in accordance with Clause 4.5, save that risk in all Units of the Stockpiled Products in the Stockpile shall remain with the Supplier to the extent that the Supplier:
- 9.2. breaches this Agreement;
- 9.3. is negligent; or
- 9.4. fails to take reasonable steps to forestall the effects of any reasonably foreseeable events that could cause loss or damage to such Products, having regard to the value of such Products.
- 9.5. In addition to the provisions contained in clause 2.8 of Schedule 2 to the Framework Call off Terms and Conditions title to all Units of the Products shall pass to the Authority:
 - 9.5.1. When the relevant Units are deemed to have been delivered in accordance with Clause 4.5 and the Delivery Notice has been accepted by written notice from the Authority; or
 - 9.5.2. At the time of payment for such Stockpiled Products by the Authority in accordance with the Payment Terms;whichever is earlier.
- 9.6. The Supplier acknowledges and agrees that the Authority shall retain full title to the Stockpiled Products and at no time shall the Supplier hold any proprietary or other interest in the Stockpiled Products other than as required to provide an insurable interest to allow the Supplier to put in place all relevant insurance policies needed to comply with Clause 7.8.3
- 9.7. If any Stockpiled Product is removed from the Stockpile by the Supplier in accordance with Clause 6.2, then:
 - 9.7.1. risk in such Units of the Products shall pass to the Supplier upon such removal; and
 - 9.7.2. title to such Units of the Products shall pass to the Supplier upon removal in accordance with Clause 6.2.
- 9.8. If the Supplier removes any Stockpiled Products from the Stockpile during a Release Plan or an Exit Phase then:
 - 9.8.1. risk in such Units of the Products shall pass to the Supplier upon Authorised Release; and

- 9.8.2. title to such Units of the Products shall pass to the Supplier on the date of the appropriate Authorised Release.

10. INSPECTION OF PRODUCTS AND STORAGE FACILITIES

- 10.1. In addition to the provisions contained in clause 3 of Schedule 2 to the Framework Call off Terms and Conditions the Authority or its authorised representative may at any time during normal business hours carry out an inspection of the Storage Facilities and the Stockpiled Products provided that the Authority gives prior written notice to the Supplier of no less than five (5) working days. Such inspection may include but is not limited to:
- 10.1.1. reviewing the Supplier's compliance with this Agreement;
 - 10.1.2. checking any records held by the Supplier under this Agreement;
 - 10.1.3. checking the Stockpiled Products to ensure there is no damage to them;
 - 10.1.4. checking batch numbers and expiry dates in accordance with the delivery documents; and
 - 10.1.5. checking the quantity of Stockpiled Products.
- 10.2. The Authority may reject any Units of the Products:
- 10.2.1. where inspection reveals such Units or their packaging to be damaged and/or to have batch numbers and/or expiry dates which do not correspond to the relevant delivery documents and/or the provisions of this Agreement;
 - 10.2.2. where the Authority is notified in accordance with Clause 4.8.7 that Products should be rejected; and
 - 10.2.3. in respect of which the Supplier fails to provide complete and accurate temperature records which show that the relevant temperatures have been maintained within the correct range.
- 10.3. The Authority may at any time by written notice to the Supplier reject any defective products. Where the Authority discovers more than one Defective Product in any given batch of the Products, the Authority shall be entitled to reject the entire batch provided always that the Authority shall take due account of all relevant guidance received from the Licensing Authority.
- 10.4. Without prejudice to any other right or remedy of the Authority:
- 10.4.1. the Authority may by written notice to the Supplier require the Supplier to replace Rejected Products with Replacement Products that are in compliance with this Agreement free of charge; or

- 10.4.2. the Authority may choose to source some or all of the Products (which for the sake of clarity shall include all services which enable the Authority to supply and store the Product on similar terms as this Agreement) or a substitute product from a third party, and without prejudice to the Authority's other rights or remedies the Supplier shall pay all the Authority's, damages and costs incurred in having to source the Product from a third party, provided however that such compensation shall not exceed the Storage Charges that would have applied for the relevant period during which the Authority has to source the substitute products from a third party, had the Supplier been able to supply the Products in accordance with this Agreement.
- 10.5. Where the Authority requires the Supplier to replace the Rejected Products, the Supplier shall use its best endeavours to minimise the time taken to provide such Replacement Products and in any event shall do so at its own cost and within one week of the date of the rejection or such longer period as the Authority may agree in writing at the Supplier's own cost. Where the Authority notifies the Supplier that it will source Replacement Products elsewhere, the Supplier shall refund to the Authority any sums paid for the Rejected Products within 30 days of the date of such notification.
- 10.6. No act or omission of the Authority including in particular taking delivery, keeping a sample, inspection of or payment for any Units of the Products by the Authority shall constitute acceptance, waiver or approval of the Products or limit the Authority's right subsequently to reject Units of the Products should such Units be defective products.
- 10.7. Rejected Products shall be physically removed by the Supplier from the Stockpile immediately and at the Supplier's expense which shall include all associated costs including but not limited to any cost of storage.
- 10.8. The Authority shall be entitled to charge the Supplier for any losses, costs or damages incurred by the Authority as a result of any Rejected Products in accordance with this Agreement provided that the Authority shall use its reasonable endeavours to mitigate the same. The Supplier shall pay such losses, costs or damages to the Authority within 30 days of the date of the Authority's invoice for the same.

11. REGULATORY REQUIREMENTS

- 11.1. The Supplier shall ensure that it or the Manufacturer or the holder of the Marketing Authorisation maintain a valid Marketing Authorisation in respect of each Product in accordance with the provisions of Directive 2001/83 and where applicable the Human Medicines Regulations 2012/1916 (or any directive or regulation replacing the same).
- 11.2. The Supplier shall promptly and in any event within 7 days inform the Authority in writing if it knows or believes there to be any delay or other problem with the Marketing Authorisation or its renewal.

11.3. If, for any reason a Marketing Authorisation in respect of a Product is:

11.3.1. withdrawn by the Licensing Authority; or

11.3.2. suspended by the Licensing Authority; or

11.4. not renewed by the Licensing Authority;

then the authority shall be entitled to immediately terminate this agreement in respect of the relevant product upon written notice to the supplier.

11.5. Upon any termination under 11.3 the Supplier shall at the discretion of the Authority immediately purchase the Stockpiled Products from the Authority at the Release Buyback Price.

11.6. The Supplier shall comply with the requirements as set out in the Technical Agreement as shown in Annex 6.

12. QUALITY ASSURANCE

12.1. The Supplier shall comply with its quality control monitoring system details of which are included in the Marketing Authorisation. The Supplier shall manufacture or procure the manufacture of the Products in accordance with Good Distribution Practice, Good Manufacturing Practice, Good Industry Practice, any other requirement of the Licensing Authority and the terms of this Agreement.

12.2. To ensure compliance with Clause 12.1 the Supplier shall ensure that the Manufacturer or holder of the Marketing Authorisation shall maintain the Marketing Authorisation and all other licences necessary for the manufacture of the Products during the Term and not make any changes (including any changes which shall or may have an impact on the quality or use of the Products) to the same or to the Specification or the Supplier's quality control monitoring system in relation to the Products without:

12.2.1. notifying the Authority in writing in advance of the intention to implement such change and giving the Authority the opportunity to make representations to the Supplier within twenty one (21) days of receipt by the Authority of notice that the Supplier intends making such change, such notice to include details of the consequences which will follow such change being implemented; and

12.2.2. the Licensing Authority formally approving such change.

13. WARRANTIES

13.1. In addition to the provisions contained in clause 10 of Schedule 2 to the Framework Call off Terms and Conditions the Supplier warrants and undertakes that:

- 13.1.1. the Supplier, and any Sub-contractor that may require the same for the activities subcontracted to it under this Agreement, hold and will hold throughout the Term of this Agreement a Wholesale Distribution Authorisation or equivalent licence to deal in the Products;
- 13.1.2. all Units of the Stockpiled Products will throughout the Term of this Agreement comply fully with the relevant Specification and Marketing Authorisation;
- 13.1.3. all Units of the Products are new and have not been rejected by any other entity prior to their supply of the Stockpiled Products;
- 13.1.4. the Products will be manufactured in accordance with Good Manufacturing Practice;
- 13.1.5. all Units of Stockpiled Products will at all times while in the Stockpile have the Minimum Shelf Life as per this Agreement;
- 13.1.6. the Storage Facilities, other premises, vehicles, facilities and all equipment necessary for the provision of the Services are and will be maintained by the Supplier and any other procured third party so that they are suitable and fit for the purpose of providing the Services;
- 13.1.7. it will comply with all Law applicable to the Products;
- 13.1.8. it has the right and authority to enter into this Agreement;
- 13.1.9. it shall comply with all relevant Law and Guidance and shall use Good Industry Practice to ensure that the requirements as set out in this Agreement is upheld at all times;
- 13.1.10. all statements or representations by the Supplier as to actions or steps the Supplier will do or take during the Term are made honestly and in good faith, and, unless determined otherwise by the Authority in writing, the Supplier will be bound to, and shall do or take such actions or steps; and
- 13.1.11. Any warranties provided under this Agreement are both independent and cumulative and may be enforced independently or collectively at the sole discretion of the enforcing Party.

14. CHANGES IN THE MARKET

- 14.1. The Supplier shall promptly give notice in writing to the Authority setting out details of the relevant circumstances if it becomes aware of:
 - 14.1.1. any changes or potential changes in market requirements for any of the Products;
 - 14.1.2. anything that the Supplier reasonably considers may have an adverse effect on the market value of any of the Products in the UK;
 - 14.1.3. anything that the Supplier reasonably considers may have an adverse impact on the Supplier's or Authority's ability to sell or supply any of the Products to the supply chain in the UK in accordance with this Agreement and any Release Plan or Exit Plan; and
 - 14.1.4. if its market share will change in such a way as to impact its ability to rotate the Stockpiled Products in the Stockpile;
- 14.2. The Supplier shall notify the Authority in writing as soon as reasonably possible if it becomes aware that a patent having effect in the UK in respect of a Product will or may expire, lapse, be withdrawn, be revoked or be declared invalid.
- 14.3. In the event of any circumstances in Clause 14 and 15.4 arising the parties shall agree in writing to any changes.

15. EXIT PLAN(S) AND EXIT PHASE(S)

- 15.1. The Supplier during an Exit Phase shall:
 - 15.1.1. where the Term will continue at the end of that Exit Phase, buy back such Stockpiled Product in excess of the new Required Volume, following the end of that Exit Phase at the Exit Buyback Price before the end of the relevant Exit Phase.
 - 15.1.2. where the Term will end by way of expiry or termination at the end of that Exit Phase, buy back all of the Stockpiled Product at the Exit Buyback Price before the end of the Term.
- 15.2. The Supplier shall during the Stockpiling Phase produce an Exit Plan and provide to the Authority for approval. The Authority and Supplier shall use all reasonable endeavours to agree any updated version of the Exit Plan within fifteen Business Days of receipt by the Authority.

- 15.3. In respect of an Exit Phase at the conclusion of which the Contract will expire or terminate, the Supplier must continue to rotate the Stockpiled Products during the Exit Phase. Any stock that cannot be rotated must be purchased by the Supplier at the Exit Buyback Price, unless otherwise directed by the Authority. The parties shall comply with all their obligations under the agreed Exit Plan(s) during the relevant Exit Phase(s) to ensure that the Authorised Release of the Stockpiled Products as set out in the final Exit Plan are supplied into the supply chain in accordance with the Exit Plan.
- 15.4. The Supplier shall provide to the Authority an Exit Report(s) as set out in the relevant Exit Plan.
- 15.5. Once the Exit Phase begins the agreed Authorised Release of the Stockpiled Products should be on the first working day of each month over a three month period unless otherwise agreed by the Authority.
- 15.6. During each Exit Phase, the Supplier shall:
- 15.6.1. provide to the Authority, at the start of each month, an updated Exit Plan stating that the Stockpiled Products have been taken from the Stockpile and the actual amount of released stock;
 - 15.6.2. use all reasonable endeavours to ensure that the supply of Stockpiled Products into the supply chain does not materially disrupt or otherwise impact the market for such Products in the UK, including the market price for such Products;
 - 15.6.3. comply with any obligations set out in the Exit Plan to meet with and report to the Authority; and
 - 15.6.4. continue to comply with its obligations under this Contract in respect of all remaining Stockpiled Products.
- 15.7. Should the Authority need to action an Authorised Release of a Stockpiled Product whilst an Exit Plan is being implemented any Release Plan shall override the relevant Exit Plan.
- 15.8. Prior to the final 3 months of the Contract, the Authority enact the Exit Plan.

16. REPORTING AND CONTRACT MANAGEMENT

- 16.1. The Supplier shall keep all records in connection with the provision of the Products and Services as required under this Contract, any Release Plan, any Exit Plan, details of financial transactions and payment of all sums under this Contract and as the Authority may otherwise reasonably require for a period of six years after the later of either the expiry or earlier termination of this Contract

- 16.2. The Supplier shall provide the Authority and any person authorised in writing by the Authority with access to and copies of any documents, records, data and such other information related to the Stockpiled Products and the performance of the Services as may be reasonably required by the Authority, including access to all temperature monitoring records applicable to the Services and all records of all checks and inspections of the Products undertaken upon their receipt or collection, as appropriate, and stock records. The Supplier shall provide information and documents for review meetings in a format and medium specified by the Authority.
- 16.3. The Supplier shall comply with the reporting requirements set out in this Contract.
- 16.4. During the Stock Building Phase, the Supplier shall participate in contract review meetings with the Authority at monthly intervals. Such meetings may be conducted by phone or teleconference unless otherwise required by the Authority. The Supplier shall report to the Authority during such meetings about the progress of the Stock Building Phase and shall provide to the Authority all information reasonably requested by the Authority in respect of the Stock Building Phase.
- 16.5. The Supplier shall participate in contract review meetings with the Authority at least once every month and at such other times as reasonably requested by the Authority from time to time. Such meetings may be conducted by phone or teleconference unless otherwise required by the Authority. The Supplier shall report to the Authority during such meetings about the Supplier's compliance with its obligations under this Contract (including under Clause 6) and shall provide to the Authority all information reasonably requested by the Authority in respect of its provision of the Goods and Services.
- 16.6. Review meetings shall include the Supplier's performance under this Contract, production plans, Release Plan and Exit Plan.
- 16.7. If any issue or problem arises or the Supplier reasonably believes an issue or problem may arise in relation to the Products and/or the performance of the Services, the Supplier shall notify the Authority in writing forthwith.

- 16.8. The Supplier shall notify the Authority of the identity of the manager who is in charge of the provision of the Services to the Authority. The Authority may make representations to the Supplier concerning the performance of the manager from time to time. The Supplier shall have due regard for all such representations. If the Authority so requires, the Supplier will cease to use any given manager in connection with the Services and provide a replacement acceptable to the Authority within one month of the date of request to do so. The manager shall have full authority to act on behalf of the Supplier during the Term. The Authority shall be entitled to treat any act of the manager in connection with this Contract as being expressly authorised by the Supplier and the Authority shall not be required to determine whether any express authority has in fact been given. Unless given prior approval by the Authority the Supplier shall make the manager available for the entire period needed to fulfil his part in the provision of the Services, whilst he is employed or engaged by the Supplier.
- 16.9. The Supplier shall be responsible for the accuracy of all documentation and other information supplied to the Authority by the Supplier in connection with the performance of its obligations under this Contract and shall pay the Authority any extra costs occasioned by any discrepancies, errors or omissions in it.
- 16.10. The Supplier shall reply promptly to all reasonable enquiries and complaints by the Authority relating to the use, effective administration, quality, performance and durability of the Products.

17. ACCESS PROVISIONS

- 17.1. At any time during the term of this Contract the Authority shall be allowed access to the Stockpile with 24 hours' notice for any purpose whatsoever (including the collection, removal and rapid distribution of the Stockpiled Products and/or supply of the Stockpiled Products into the supply chain in the UK). The Supplier shall thereafter provide to the Authority and any person authorised by the Authority:
- 17.1.1. reasonable access to the Stockpile to allow the Authority to access and/or remove any Stockpiled Products efficiently from the Stockpile;
 - 17.1.2. access to the Storage Facilities, vehicles and any other premises or facilities where the Stockpiled Products are stored and/or the Storage Services are carried out;
 - 17.1.3. access to any personnel and information necessary to enable the Authority to exercise its rights under this Clause 17 (including the records held under Clause 3 identifying the Stockpiled Products);
 - 17.1.4. delivery of the Stockpiled Product to the Storage Facilities loading bay in a deliverable state packaged for transportation and load the Products onto a vehicle provided by a third party for transportation by the Authority;

- 17.2. any cooperation and assistance reasonably requested by the Authority in relation to the Authority exercising its rights under this Clause 17.

provided that, where the Authority removes any Stockpiled Product from the Stockpile it will forthwith provide a report to the Supplier providing relevant details of the removed product, and any delivery or removal under this Clause other than as part of an Authorised Release shall not be deemed to be an Authorised Release and further provided that the Authority will comply with Licensing Authority Good Distribution Practice when accessing the Storage Facilities.

18. BUYBACK

- 18.1. For each Authorised Release the Supplier shall purchase the Stockpiled Products at the Release Buyback Price which shall be the price at which the Authority purchased the Products from the Supplier.
- 18.2. Where the Supplier is to purchase the Stockpiled Products from the Authority during an Exit Phase pursuant to clause 15, the Supplier shall purchase the Stockpiled Products at the Exit Buyback Price.

Annex 1 – Delivery Notice Template



Delivery Notice.xlsx

Annex 2 - Exit Plan and Exit Plan Report



Exit Plan.xlsx



Exit Plan Report.xlsx

Annex 3 - Release Plan and Release Report



Release Plan.xlsx



Release Report.xlsx

Annex 4 – Stock Report



Stock Report.xlsx

Annex 5 – Payment Terms

- 1.1. In consideration of the provision of the Products, storage and rotation of the Stockpiled Products in accordance with this Contract the Authority shall pay the Supplier in accordance with the Contract.

Stock Building

- 1.2. Prior to the Stock Building Phase the Authority will provide the Supplier with a purchase order. At the end of each month during the Stock Building Phase, the Supplier shall send to the Authority an invoice, quoting the Authority's purchase order, in respect of all Units of Products delivered to the Stockpile during the relevant month as set out in the Delivery Schedule calculated by reference to the Product Price of such Products.
- 1.3. The Authority shall pay to the Supplier the Product Price for the Products delivered during the Stock Building Phase within 30 calendar days of receipt of a valid invoice and a Delivery Notice in respect of the Products delivered. In respect of any Rejected Products, no payment shall be due whatsoever.
- 1.4. The Product Price is inclusive of any and all royalties, licence fees, packaging, and storage by the Supplier prior to delivery to the Stockpile and the cost of delivery to the Storage Facilities, or similar expenses in connection with the Products.

Storage charges

- 1.5. The Supplier shall send the Authority an invoice for Storage Charges incurred as set out below:

Month invoice to be sent	Month's payment due
December	October – December
March	January – March
June	April – June
September	July – September

- 1.6. The invoice will detail the Storage Charge as set out in the Order Form, and the generic Product name and Volume of Product that has been stored.
- 1.7. For the avoidance of doubt, the Storage Charge shall not be affected by a reduction following an Authorised Release of the Stockpile.

Authorised Release

- 1.8. The Supplier shall pay the relevant Release Buyback Price as set out under this Contract at Clause 8 in respect of an Authorised Release of such Stockpiled Products within 30 calendar days of receipt of each invoice.
- 1.8.1. An invoice shall be issued by the Authority to the Supplier within 30 days following each release of Stockpiled Products agreed by the parties from the Stockpile pursuant to an Authorised Release.

General

- 1.9. All prices set out in this Contract are stated exclusive of any applicable VAT.
- 1.10. The Supplier shall pay all invoices issued by the Authority within 30 calendar days.
- 1.11. Where the Supplier submits an invoice to the Authority (in accordance with this Clause 1, the Authority will consider and verify that invoice in a timely fashion.
- 1.12. The Authority shall pay the Supplier any sums due under such an invoice no later than a period of 30 days from the date on which the Authority has determined that the invoice is valid and undisputed.
- 1.13. Where the Authority fails to comply with clause 1.11 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 1.12 after a reasonable time has passed.
- 1.14. Where the Supplier enters into a Sub-contract, the Supplier shall include in that Sub-contract:
- 1.14.1. Provisions having the same effect as clauses 1.11 to 1.13 of this Annex; and
- 1.14.2. A provision requiring the counterparty to that Sub-contract to include in any Sub-contract which it awards provisions having the same effect as clauses 1.11 to 1.13 of this Annex.

Annex 6 – Technical Agreement

[N.B. The Technical Agreement will be updated for the issue of the final contract]

THIS **TECHNICAL AGREEMENT** is made the

BETWEEN: -

SECRETARY OF STATE FOR HEALTH Wellington House, 133-155 Waterloo Road,
London SE1 8UG (the **Licence Holder**); and

B. Braun Avitum (UK) Ltd. having their registered storage site as
(the **Service Provider**)

RECITALS: -

(A) By an agreement with a commencement date of 1 October 2022 (**the Agreement**) the Service Provider and the Secretary of State for Health (the **Authority**) have agreed upon the terms and conditions upon which certain services (as defined therein) shall be provided by the Service Provider to the Authority.

(B) One of the services to be provided by the Service Provider to the Authority under the Agreement is the storage of certain products which must be stored pursuant to the European Commission Directive 2001/83/EC (as amended) relating to “work contracted out” (**Medicinal Storage Directive**).

(C) The Medicines and Healthcare products Regulatory Agency (**MHRA**) issues licences to organizations and bodies who wish to store products pursuant to the Medicinal Storage Directive.

(D) The Licence Holder is an authorized licence holder of a wholesale dealers licence issued by the MHRA number 1511/0001 (**MHRA Licence**) and the Licence Holder holds the licence on behalf of the Department of Health.

(E) The Licence Holder has agreed to enter into this agreement with the Service Provider at the request of the Authority in order to ensure that the Service Provider can satisfy some of its obligations under the Agreement.

(F) This agreement is made pursuant to the Medicinal Storage Directive and sets out the terms and conditions on which the Service Provider will provide storage and order fulfilment and distribution services relating to the products listed in Appendix I **Pharmaceutical Products**.

PROVISIONS: -

1. WHOLESALE DEALER'S LICENCE

1.1 The Licence Holder shall:

- (a) nominate the Service Provider's storage premises on its MHRA Licence or on its application for such licence;
- (b) provide to the Service Provider a copy of the MHRA Licence and any variations made to the MHRA Licence from time to time; and
- (c) maintain the procurement/administration arrangements detailed in the MHRA Licence.

2. QUALITY SYSTEM

- 2.1 The Service Provider will implement and operate a quality system based on and complying with the requirements of EU Legislation Directive 2001/83/EC Title VII Wholesale Distribution Articles 76-85 - working to EU GDP Guidelines (94/C 63/03) (**GDP Guidelines**).

3. STORAGE CONDITIONS

3.1 The Service Provider shall store all **Pharmaceutical Products in compliance with:**

- (a) the GDP Guidelines;
- (b) the requirements of the relevant summary of product characteristics; and
- (c) the storage conditions specified by the manufacturer of the Pharmaceutical Products.

4. SECURITY

- 4.1 The Service Provider shall store all of the **Pharmaceutical Products** under secure conditions and in compliance with the security requirements set out in the Agreement.

5. RECALL PROCEDURE

- 5.1 The Service Provider shall maintain a Standard Operating Procedure that shall be applied to recall defective **Pharmaceutical Products** from the market.
- 5.2 The Service Provider will use all reasonable endeavours to assist the Licence Holder to conduct a recall whether in relation to **Pharmaceutical Products** held by the Service Provider or to **Pharmaceutical Products** already distributed to third parties. The Service Provider will follow the instructions of the Licence Holder as regards retrieval, storage, status labelling and destruction of any recalled products.

6. PERSONNEL

- 6.1 The Licence Holder shall notify the Service Provider of the name of the Responsible Person (**RP**) named on its MHRA Licence and any variation thereto and this person will be responsible for ensuring that the requirements of the Marketing Authorisation are complied with at the Service Provider's site(s) in association with the Service Provider's management.
- 6.2 The Service Provider shall ensure that:
- (a) its personnel involved in the warehousing of the **Pharmaceutical Products** have appropriate skills and experience for the proper storage and handling of medicinal products;
 - (b) its personnel are appropriately trained and have the skills necessary to handle such goods;
 - (c) training records are maintained as defined in Directive 2001/83/EC; and
 - (d) its training records are available for inspection by the Licence Holder or by the RP on reasonable request.

7. ACCESS TO DOCUMENTATION

- 7.1 The Licence Holder and the Service Provider will ensure that relevant documentation is made available on the request of competent authorities.

8. STANDARD OPERATING PROCEDURES

- 8.1 The Service Provider shall implement and comply with written procedures either provided by the Licence Holder or compiled by the Service Provider in relation to the following activities: -
- Receipt and checking of deliveries;
 - Storage;
 - Cleaning and maintenance of the premises (including pest control);
 - Recording of storage conditions (temperature);
 - Recording of temperatures during the delivery process;
 - Security on site and in transit;
 - Withdrawal from saleable stock;
 - Records (including orders, invoices, dispatch notes, returns, recalls); and
 - MHRA Goods distribution using first expiry: first out product system (FEFO).
- 8.2 No Standard Operating Procedure shall be varied or waived in such a way that may impact on Product(s) or Service(s) provided without the express consent of both the Authority and the RP.

9. RECORDS

- 9.1 The Licence Holder and the Service Provider shall record each of its respective

activities under this Agreement in accordance with Good Distribution Practice.

10. PREMISES AND EQUIPMENT

- 10.1 The Service Provider will ensure its premises and equipment are adequate to maintain proper conservation of medicinal products and that monitoring devices are calibrated.

11. RECEIPT OF GOODS

- 11.1 The Service Provider will use its best endeavours to ensure that:
- (a) consignments received correspond with the delivery details advised by the Authority (or the authorized representatives of the Authority) under the Agreement; and
 - (b) **Pharmaceutical Products** subject to specific storage conditions are immediately identified and stored in accordance with:
 - (i) the Service Provider's Standard Operating Procedure;
 - (ii) the summary of the product characteristics; and
 - (iii) relevant law.

12. STORAGE CONDITIONS

- 12.1 The Service Provider shall:
- (a) monitor and record storage temperatures in the main warehouse areas and in cold storage areas;
 - (b) review records;
 - (c) advise the Licence Holder and Authority (and the authorised representatives of the Authority), in writing, of occasions where temperatures deviate from the specified ranges for the **Pharmaceutical Products**.
- 12.2. The parties acknowledge that the Authority (or the authorised representatives of the Authority) will issue instructions to the Service Provider under the Agreement on the action to be taken following any reported temperature deviation as described in clause 12.1.

13. QUARANTINE

- 13.1 The Service Provider will maintain one or more segregated areas for damaged stock; rejects; returned goods; recalls and so on. Any **Pharmaceutical Products** waiting on instructions from the Authority (or the authorised representatives of the Authority) shall be held in a quarantine hold status and shall not be released by the Service Provider until it has received instructions from the Authority (or the authorised representatives of the Authority) under the Agreement.
- 13.2 Copies of the authorised signatures will be held on file by the Service Provider's responsible person.

13.3 The Service Provider shall:

- (a) store all inbound **Pharmaceutical Products** in quarantine hold until an email is sent to the Service Provider inbound department with the signature of the Authority (or the authorised representatives of the Authority) releasing the **Pharmaceutical Products**;
- (b) check the instruction against the list held by it and if agreed the **Pharmaceutical Products** will be released; and
- (c) if the Authority's (or the authorised representatives of the Authority's) authorised signature does not match that held on file by the Service Provider, the Service Provider shall not release the relevant **Pharmaceutical Products** from the quarantine hold and shall notify the Authority accordingly.

13.4 The Service Provider shall keep copies of all communications authorising the release of the **Pharmaceutical Products** from quarantine hold for audit purposes.

14. RETURNS

14.1 The Service Provider shall keep non-defective **Pharmaceutical Products** that have been returned appropriately labelled in a Returns area segregated from defective (Rejected) **Pharmaceutical Products**.

14.2 The Service Provider shall comply with the relevant Standard Operating Procedure in relation to returned **Pharmaceutical Products**.

15. SELF INSPECTION

15.1 The Service Provider will carry out self-inspections of the quality system at appropriate intervals and record the results.

16. AUDITING

16.1 The Licence Holder (or an authorised representative of the Licence Holder) may audit the premises of the Service Provider from time to time, by prior arrangement, to ensure that the storage conditions specified in the Marketing Authorisation(s) for the **Pharmaceutical Products** are being complied with and maintained and that there is compliance with the terms of the MHRA Licence.

17. SUB-CONTRACTING

17.1 The Service Provider shall not subcontract any activity contemplated by this Agreement that relates in any way to the storage, distribution or control of the **Pharmaceutical Products** without prior written approval of the Authority.

17.2 Details of approved sub-contractors for all transport and packaging services required under the Agreement shall be available upon request.

18. PERSONNEL CHANGES

- 18.1 The Licence Holder and the Service Provider will notify each other immediately, in writing, of any changes in key personnel, especially Responsible Persons as named on the MHRA Licence (Appendix II).

19. HEALTH AND SAFETY

- 19.1 Any **Pharmaceutical Products** that are subject to the requirements of the Control of Substances Hazardous to Health Regulations 1994 will be supported by appropriate hazard data sheets.

20. OTHER ACTIVITIES AND CONFIDENTIALITY

- 20.1 The Service Provider agrees to abstain from any activity, which may adversely affect the quality of the product(s) stored. All information furnished by the Licence Holder to the Service Provider must be held in strict confidence and may not be disclosed to any other party without the express written consent of the Licence Holder except at the time of a MHRA or other official inspection or request.

21. COMMUNICATIONS

- 21.1 The primary contact for the Licence Holder regarding this Agreement is:

[Insert details]

- 21.2 The primary contact point for the Service Provider regarding this Agreement is:

[Insert supplier address]

22. AMENDMENTS ETC.

- 22.1 No amendments may be made to this Agreement unless by an instrument in writing signed by a duly authorized officer of each of the parties.

23. TIMELY COMMUNICATIONS ETC.

- 23.1 All communications between the parties will be made in a correct and timely manner to ensure the commercial efficiency of both parties.

24. GOVERNING LAW

- 24.1 This Agreement shall be governed and construed in accordance with the laws of England.

25. REFERENCE TO LAW ETC.

- 25.1 Any reference in this Agreement to “law”, “regulation”, “rule”, “statute”, “guidance”, “directive” and the like is deemed to include a reference to re-enactment, amendment etc. of such laws, regulations, rules, statutes,

guidance, directives and relates specifically to any law, regulation, rule, statute, guidance, directive and analogous expression that shall be in full force and effect during the term of this Agreement. The Licence Holder and the Service Provider agree to furnish each other, in writing, with any information that comes to their notice or attention relating to the laws, regulations, rules, statutes, guidance and directives and the like relevant to this Agreement.

26. INDEPENDENT PARTIES

- 26.1 Each of the parties hereto is an independent contractor. Neither party is a joint venture with the other and in no way shall the employees or consultants of one party be deemed employees or consultants of the other party.

27. CLAUSE HEADINGS

- 27.1 Clause headings are inserted for convenience only and shall not affect the construction or the interpretation of this Agreement.

28. DELIVERY OF OTHER DOCUMENTS ETC.

- 28.1 Each party agrees to deliver to the other all such documents, instruments and information as may be required by the other party to perform and comply with its obligations under this Agreement.

Signed for and on behalf of

Name:

Position:

Date:

Signed

Signed for and on behalf of the Licence Holder

Name:

Position:

Date:

Signed

APPENDIX I TO TECHNICAL AGREEMENT

Pharmaceutical Products

Category	Product code	Description
[TO BE INSERTED]	[TO BE INSERTED]	[TO BE INSERTED]

APPENDIX II TO TECHNICAL AGREEMENT

PERSONNEL

Licence Holder

Signatories

[Insert DHSC Signatories]

Responsible Person

[Insert DHSC Responsible Person]

Service Provider

B. Braun Avitum (UK) Ltd.
Brookdale Road
Thornccliffe Park
Sheffield
S35 2PW

Signatories

Responsible Person

Redacted Under FOIA Section 40, Personal Information

Schedule 6 of these call off terms and conditions
Operational requirements of suppliers

Schedule not used and deliberately left blank

Schedule 7 of these call off terms and conditions
Supplier Code of Conduct

Schedule not used and deliberately left blank

