

Call-Off Schedule 20 (Call-Off Specification)

This Schedule sets out the characteristics of the Deliverables that the Supplier will be required to make to the Buyer (also referred to as DHSC in this Schedule) under this Call-Off Contract.

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1. BACKGROUND TO REQUIREMENT

- 1.1 As part of the Mass Testing programme, several channels have been created to deliver Covid-19 test-kits within the UK.
- 1.2 DHSC now requires Bulk Storage capacity to support the Mass Testing programme.
- 1.3 DHSC requires a Supplier to provide the following services:
- Inbound receipt of palletised deliveries;
 - Storage and warehousing management;
 - Temperature monitored warehousing;
 - Palletised stock removal preparation from pick to staging;
 - Handling queries and complaints; and
 - Provision of operational MI relating to stock control order status.
- 1.4 An overall need of DHSC in setting up this Agreement is to ensure that DHSC can manage its requirements and outputs in a way that:
- i. Increases DHSC organisation's efficiency.
 - ii. Promotes the use of 'best practice' in the operation.
 - iii. Drives maximum savings.
 - iv. Reduces DHSC's impact on the environment.
- 1.5 DHSC is keen to work with the Supplier who will deliver large savings to the public sector by offering the most cost-effective solutions to DHSC's requirements. It is seeking the most technically competent Suppliers who can enable an effective and balanced service, whilst driving innovation and continuous improvement over the lifetime of the Agreement.
- 1.6 A key driver behind the Agreement is the optimization of the supply chain and reduction of costs associated with the supply of services and associated solutions. The challenge for the Supplier is to ensure the competitiveness of its services not only in comparison with other providers but with other technologies and services available.

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- 1.7 The Supplier shall provide all the requirements in respect of the Agreement. The Agreement does permit the Supplier to subcontract with a named third party, subject to DHSC's consent, in order to be able to provide all aspects of the requirement. However, the use of third-party suppliers should not impact the quality of the service provided, including communication channels that are critical to the effectiveness of this service.
- 1.8 The Supplier shall ensure full visibility of the supply chain, as a minimum these should be:
- 1.8.1 Use of Sub-Contractors.
- 1.8.2 Attribution of cost.
- 1.9 Critical to the success of the Agreement are:
- 1.9.1 Joint and partnered strategies between DHSC and the Supplier to maximise efficiency and deliver cost saving initiatives.
- 1.9.2 Appropriate services that achieve efficiencies.
- 1.9.3 Compliance with standards and requirements.
- 1.9.4 Excellent Management Information that delivers the requested data in line with DHSC IT requirements.
- 1.9.5 Outstanding service, determined by what DHSC's needs, not by what the Supplier has to sell.
- 1.9.6 Relationships that identify and focus on the priorities that delivers excellence in public service and value by storage and fulfilment to the required DHSC's standards but with due consideration for costs.
- 1.9.7 Proactive strategies that analyse and report potential areas for increased efficiency and sustainability.
- 1.9.8 Strategies that facilitate business transformation in order to produce a positive impact on all elements of the supply chain.
- 1.10 All forecast volumes are current best estimates and provided purely for information purposes only.

2. SCOPE OF REQUIREMENTS

Headline requirements:

- DHSC requires the capability to receive and store up to 35,000 pallets. DHSC will provide a 3-month rolling forecast of pallet space requirements for planning purposes.

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- The Supplier must have a Warehouse and Inventory Management System (WMS) to control first expired first out (FEFO) and batch control of Test Kits.
- For inbound shipments the Supplier will be responsible for receipting and storage.
- For outbound shipments the Supplier is responsible for the picking, packing, address labelling palletised Test Kits where requested.
- The Supplier must be able to report on the end to end chain of custody reporting and MI (Realtime / Near Realtime).
- The Supplier will participate in a Supplier relations programme which jointly enables the weekly, monthly and quarterly review of Safety, Quality, Service, Cost and forthcoming Plans.

3. WAREHOUSING REQUIREMENTS

3.1 Inbound

- 3.1.1 The Supplier must have the ability to provide Goods Receipt to IMS/WMS.
- 3.1.2 The Supplier must have the capability to receive inbound pallets from Contract Commencement.
- 3.1.3 The Supplier must ensure each of the received pallets is affixed with a physical form of identification (i.e. labels, barcode).
- 3.1.4 The Supplier must ensure physical pallet removal off the marshalling bay into allocated pallet locations.
- 3.1.5 The Supplier must Receipt and Put-away pallets so that the pallets are available for picking.
- 3.1.6 The Supplier must have the ability to perform visual inspections for paperwork, damages and broken tamper seals. Visual check that paperwork matches quantity physically delivered and that the consignment is not damaged in anyway. Visual inspection also includes confirmation that the inside of the vehicle is clean and dry. Any deviations must be reported within 24 hours to DHSC.
- 3.1.7 The Supplier must have the ability to refuse delivery or quarantine goods failing visual inspection.
- 3.1.8 DHSC reserves the right to perform basic product spot checks either directly or through a 3rd party supplier (providing suitable notice to and training of the supplier).

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3.2 Inbound Volumes

3.2.1 DHSC requires available storage capacity from the Supplier to store up to [REDACTED] at any one time.

3.2.2 For the Heywood Facility, the Supplier will be able to accept stock at a rate of [REDACTED] per day, 7 days a week up to a maximum of [REDACTED] pallets.

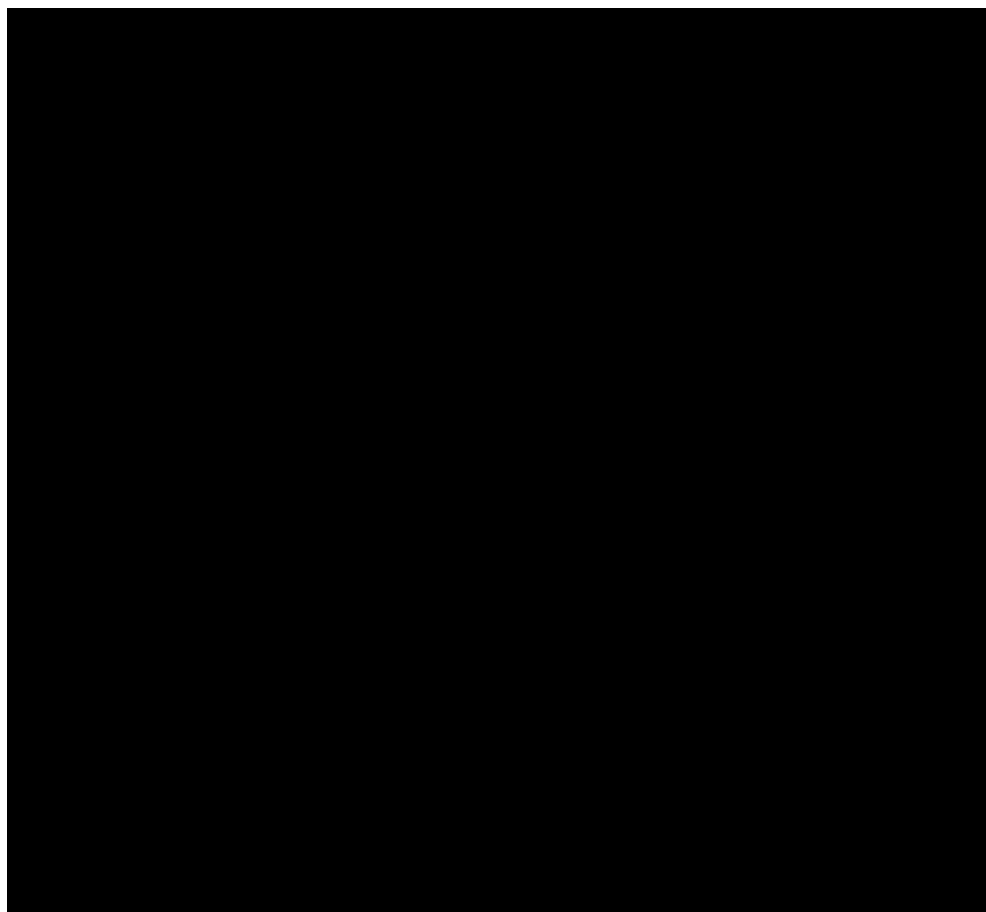
3.2.3 The inbound delivery slots are:

Time	Number of vehicles scheduled
06:00 to 07:00	[REDACTED]
07:00 to 08:00	
08:00 to 09:00	
09:00 to 10:00	
10:00 to 11:00	
12:00 to 13:00	
13:00 to 14:00	
14:00 to 15:00	
15:00 to 16:00	

3.2.4 A second facility: White Hart Triangle Facility, 20 White Hart Avenue, Thamesmead, SE28 0GU shall be available to store another 14,000 pallets in line with the table below:

Weeks	Calendar Dates	Maximum inbound pallets (7 day week)	Comments
Time		Number of vehicles scheduled	

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- 3.2.5 Deliveries shall be scheduled in consolidated loads where possible, however the Supplier should provision for multiple inbound deliveries.

3.3 **Storage**

- 3.3.1 All received Goods are to be stored in racked pallets.
- 3.3.2 The Supplier shall ensure sufficient capacity to meet loading / offloading schedules to ensure compliance with shipment frequency and to avoid demurrage and detention of vehicles (and extended put away times).
- 3.3.3 The Supplier must have the ability to manage resource schedules to ensure sufficient resources are available, including balancing staffing levels at peak periods.
- 3.3.4 Incoming products will be palletised to different heights (standard pallet height is between 1.2m and 1.6m). The Supplier shall accommodate this standard height as a minimum. The ability to reconfigure racking, or skim pallets to improve storage utilisation will also be advantageous.

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- 3.3.5 Unless further advised, pallets will not be block stacked nor be stacked on each other.
- 3.3.6 The Supplier must have the ability to select and manage optimum warehouse operating hours to meet SLAs including peak periods - the optimum warehouse hours should include cost effectiveness.
- 3.3.7 The Supplier shall ensure sufficient capacity to meet loading/offloading schedules to ensure compliance with shipment frequency and to avoid demurrage and detention of vehicles (and extended put away times).

3.4 Storage Volumes

- 3.4.1 DHSC requires up to [REDACTED] pallet storage capacity.
- 3.4.2 Storage space may be split across a maximum of two locations.
- 3.4.3 The Supplier shall amend storage capacity in line with a request by DHSC, within a mutually agreeable time frame.

3.5 Storage - Inventory Management

- 3.5.1 DHSC has commissioned an Inventory Management System to track stock centrally across all its facilities. The Supplier shall share data with DHSC's Inventory Management system.
- 3.5.2 If any other IMS/ WMS system is utilised by the Supplier, the system must have the capability to interface directly with DHSC's Inventory management system & middleware (Oracle Integration Cloud) using pre-specified interfaces. The following functionality is required:
 - i. Provide/consume all data that affects stock, stock status, batches, shipments, orders, SKU's, BOM management information and reports, as requested by DHSC.
 - ii. The IMS/ WMS must be used and updated in real-time.
 - iii. Internal transfers between stock locations in the warehouse to be recorded (preferably with RF device or similar).
 - iv. Stock records will show the associated batch details for every SKU in every location.
- 3.5.3 The Supplier shall implement stock control process for control of stock either recalled, expired or obsolete.

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- 3.5.4 Inventory accuracy will be maintained through a documented process, allowing for perpetual inspection (or similar) and reconciliation process for understanding all discrepancies
- 3.5.5 The Supplier shall demonstrate full product / lot tracing capability.
- 3.5.6 The Supplier shall provide 100% of batch information. Chain of custody must be recorded and shared with DHSC.
- 3.5.7 The Supplier shall track expiry dates to ensure FEFO process is followed.
- 3.5.8 Where required by DHSC, pick and pack of pallets should be done at batch level.
- 3.5.9 The Supplier must liaise and interact with other providers in the supply chain for coordinating and managing the end to end supply chain as directed by DHSC.
- 3.5.10 The Suppliers shall report on the end to end chain of custody reporting and Management Information (Real-time/Near Real-time).
- 3.5.11 The Suppliers must participate in a Supplier relations programme which jointly enables the monthly review of Safety, Quality, Service, Cost, Volume and forthcoming Plans.

3.6 Storage - Operational Management

- 3.6.1 The Supplier must protect product integrity at all times, including
 - i. Maintaining Storage locations to hygiene and pest control standards
 - ii. Keeping Stock in compliance with storage conditions
 - iii. Keeping Stock secure (physical location).

3.7 Storage - Non-compliant goods handling

- 3.7.1 The Supplier must ensure that an appropriate Quality Control inbound inspection takes place. This covers the following activities;
 - i. Receiving materials (quantity and external check for damage against PO, ASN and / or delivery documentation).
 - ii. Documenting Key information upon receipt
 - iii. QC inspection and recording of data
- 3.7.2 The Supplier shall demonstrate and operate a process to identify non-compliant goods at the Storage Facility.

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- 3.7.3 The Supplier shall segregate non-compliant goods from other quality approved ones electronically (using WMS) and physically to ensure Products are blocked from further entering the downstream supply chain process.
- 3.7.4 No Pallets of mixed batch numbers should be accepted or stored in the warehouses.
- 3.7.5 The Supplier must communicate to DHSC the discovery of non-compliant goods and seek further guidance. The agreed corrective action may include the actions listed below between DHSC and Supplier:
- i. Return to Supplier
 - ii. Supplier collection of returns
 - iii. Goods write-off process and credit note / replacement
 - iv. Arrange with Suppliers for on-site resolution for non-compliant goods
 - v. If goods need to be destroyed, a destruction certificate must be made available by the DC

3.8 Temperature Monitoring

- 3.8.1 The Suppliers must ensure the storage facility is temperature monitored at all times (range of 2 - 30 °C).

4. FULFILMENT REQUIREMENTS

4.1 Overview

- 4.1.1 Fulfilment comprises of the following activities:
- 4.1.1.1 Receive a transfer order from DHSC
 - 4.1.1.2 Agree the pickup delivery window
 - 4.1.1.3 Pick, pack and label and move to staging the order.
Allow the carrier to load the order

4.2 Volumes and Outbound Stock

- 4.2.1 It is expected that demand for transfer of stock, out of the warehouse will be on an as required basis as this will be a sunset storage facility. Therefore, there are no projected volumes available.

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- 4.2.2 Requests for transfer should be actioned to ensure that the outbound supplier can pick up the pallets per the required date/time.

5. GENERAL REQUIREMENTS

5.1 Booking and Receipt

- 5.1.1 The Supplier must ensure pallets are receipted and stored within 24 hours.
- 5.1.2 The Supplier shall provide Goods Receipt including relevant item data to the Inventory Management System/Warehouse Management System and provide booking references and item data within 24hrs.
- 5.1.3 The Supplier must ensure each of the received pallets is affixed with a physical form of identification (i.e. labels, barcode).
- 5.1.4 The Supplier must ensure physical pallet removal off the marshalling bay into allocated pallet locations.
- 5.1.5 The Supplier must perform visual inspections for paperwork, damages and broken tamper seals.
- 5.1.6 The Supplier shall refuse delivery or quarantine components failing visual inspection.
- 5.1.7 The Supplier must ensure that incorrect inbound orders are quarantined and not un-palletised.
- 5.1.8 The Supplier must ensure that it has sufficient capacity in all Bulk Storage Warehouses to accept deliveries to the agreed maximum delivery requirements, during agreed delivery windows with appropriate traffic flow measures to ensure safe working procedures.
- 5.1.9 The Supplier must agree specific delivery windows with Bulk suppliers to ensure deliveries are made during operational hours but not impacting site operations.
- 5.1.10 DHSC reserves the right to perform basic product storage spot checks either directly or through a 3rd party supplier (providing suitable notice).
- 5.1.11 The Supplier shall accommodate a minimum of 2 DHSC or 3rd party supplier staff on-site at any site, 24 hours of the day for the purposes

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of inspection, quality assurance and operational support activities.
The Supplier will provide all necessary desk space.

5.2 Traceability

5.2.1 The Supplier must ensure full traceability throughout the full end to end process by adhering to the following:

5.2.1.1 All in-coming bulk components have an assigned batch number (where applicable). These must be recorded within the WMS/IMS as part of the goods-in process.

5.2.1.2 Any change in item status is recorded systemically and physical segregation performed as necessary.

5.3 Contingency Planning

5.3.1 The Supplier shall provide DHSC with a Risk Assessment of warehouse processes which has been completed.

5.3.2 The Supplier must have a Business Continuity Plan (BCP) in place to address risks identified through a prioritised risk assessment.

5.3.3 The Supplier shall regularly assess, test and update the BCP and share with DHSC.

6. SECURITY REQUIREMENTS

6.1 The Supplier must have in place a proportionate and considered protective security plan that effectively protects Bulk Storage and Fulfilment.

6.2 The Supplier must provide evidence and assurance of its processes and standards that apply to the storage of goods, the transportation of goods and the storage of information.

6.3 Security Standards

6.3.1 Where applicable, the Supplier must adhere to appropriate statutory and legal requirements.

6.3.2 The Supplier must adhere to the ISO standards. The specific standards required are to be confirmed and contingent on the outcome of a risk assessment.

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- 6.4 The Supplier must conduct a comprehensive security risk assessment, which:
- 6.4.1 Identifies a senior risk owner;
 - 6.4.2 Accounts for physical, personnel, cyber and information security risks;
 - 6.4.3 Outlines threats that would hinder business continuity;
 - 6.4.4 Outlines a risk mitigation plan for the identified risks; and
 - 6.4.5 Is a mutually agreed and shared document between the Supplier, DHSC and the Department's expert security advice.
- 6.5 A significant security breach or change in structure must prompt the re-evaluation of risk assessments and mitigation plans.
- 6.6 The Supplier must continually share information relating to the security and integrity of the DHSC supply chain, including:
- 6.6.1 The names of any sub-contracted parties used by the Supplier to deliver this contract;
 - 6.6.2 Internal security Standard Operating Procedures (SOP) that are mutually agreeable and satisfy expert security advice;
 - 6.6.3 Contingency plans, detailing response processes in the event of a security incident;
 - 6.6.4 Organisational and environmental changes that could affect the security of DHSC assets and the following of SR's;
 - 6.6.5 Vulnerabilities, incidents and risks that were not foreseeable at the risk assessment stage.
- 6.7 The Supplier must ensure for the appropriate security of all personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.
- 6.8 The Supplier must ensure that all visitors are escorted when on site and denied the opportunity for indirect access to DHSC assets. Additionally, all Supplier staff must be reminded of the need to guard against compromising DHSC assets.
- 6.9 **Security reporting**
- 6.9.1 The Supplier must report security incidents in a timely manner as set out by DHSC guidelines for reporting such incidents.
 - 6.9.2 The Supplier must report risks and vulnerabilities as they arise and prior to contract agreement.

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- 6.9.3 The Supplier must report any internal changes that could impact the security of DHSC assets and the following of SR's.
- 6.9.4 The Supplier must alert DHSC if a security KPI is unlikely to be met and any contingency plans.

6.10 Security breaches and corrective action

- 6.10.1 The Supplier must ensure that any breach in security is thoroughly investigated and corrective action for any vulnerabilities identified are taken in a timely manner.
 - 6.10.2 The Supplier shall accept that any breaches in key security performance indicators will trigger a review and/or corrective action by an independent party.
- 6.11 The Supplier must ensure the appropriate level of vetting for staff on and who have access to DHSC assets and sites.
 - 6.12 The Supplier must actively engage with government security agencies on an ongoing basis, ensuring the continual development and integrity of the supply chain
 - 6.13 The Supplier must accept the right of DHSC, or an independent party on behalf of the Department, to audit the entirety of the supply chains processes and security standards that relates to DHSC's assets, at a time convenient to the Department.
 - 6.14 The Supplier must also accept the right of DHSC to inspect or request information under the RFI process, as applicable to the security of the contract, its provisions and the compliance of the Supplier with the overall requirements.
 - 6.15 In the event a third-party provider must be used, security standards and practices must adhere to the same Security Requirements.
 - 6.16 Where requested information is commercially sensitive to the Supplier, DHSC can offer a Non-Disclosure Agreement.

7. REGULATORY REQUIREMENTS

- 7.1 The Supplier must meet all regulatory requirements (e.g. MHRA) and quality guidelines defined by the DHSC and have the necessary certifications in place. MHRA regulatory requirements include but are not limited to the below
 - 7.1.1 MHRA guidelines require that in the case of a faulty/damaged/dangerous product, the end user of the product can be contacted in a timely manner.

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- 7.2 The Supplier must be compliant to Good Distribution Practices standards and work to ISO 9001: 2015 specifications, including the 2013 MHRA guidelines.
- 7.3 The Supplier must be working towards the requirement of ISO 13485.
- 7.4 The Supplier must allow for quality and regulatory audits by external companies given 48 hrs notice as a minimum.

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8. NOT USED

9. MANAGEMENT INFORMATION/REPORTING

9.1 The Supplier must ensure that all MI provided in respect of the requirements under this section are in an appropriate readable format, summarised in line with DHSC reporting requirements as advised from time to time.

9.1 The Supplier must have the ability to prevent the booking of Goods Received with expiry dates with less than the minimum life duration as defined by DHSC.

9.2 General Reporting

9.2.1 The Supplier must generate a report of stock expiry dates daily.

9.2.2 The Supplier must generate a report of blocked stock daily.

9.2.3 The Supplier must generate a report of quarantined stock daily.

9.2.4 The Supplier must generate a report of space utilisation daily.

9.2.5 The Supplier must generate a report of inventory levels daily.

9.2.6 The Supplier must generate a report of Quality Issues found daily.

9.2.7 Reporting of stock levels to the DHSC to ensure visibility daily.

9.2.8 The Supplier must report on the number of outbound shipments daily.

9.3 Bulk Storage Reporting

9.3.1 The Supplier must provide reporting of OTIF for in-bound shipments - actual received vs ASN.

9.3.2 The Supplier must report on in-bound shipments received without an ASN.

9.3.3 The Supplier must report ASN compliance for in-bound shipments.

9.3.4 The Supplier must report the volume of non-arrivals, by component vendor.

9.3.5 The Supplier must report the Volume of non-scheduled arrivals, by component vendor.

9.3.6 The Supplier must report the Volume of late/early inbound by component vendors.

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9.3.7 The Supplier must report the Volume of Damaged stock vs Suppliers.

10. CONTINUOUS IMPROVEMENT

- 10.1 The Supplier will continually improve the way in which the required Services are to be delivered throughout the Contract duration.
- 10.2 The Supplier must work with DHSC quality teams on all matters of continuous improvement.
- 10.3 Changes to the way in which the Services are to be delivered must be brought to the DHSC's attention and agreed prior to any changes being implemented.

11. SUSTAINABILITY

This paragraph outlines the Buyer's requirements in relation to the environmental and sustainability requirements of the Agreement:

- 11.1 The government is committed to environmental improvement through integrating environmental protection and sustainable development into its decision-making processes in respect of both the execution of its core functions and responsibilities and the management of day-to-day operations.
- 11.2 DHSC requires that the Supplier considers the relevance of sustainability at all lifecycle stages of the Services provided under this Agreement. This includes not only consideration of commercial needs and minimisation of negative impacts but also the maximisation of positive impacts on society and the environment. The Supplier shall seek to reduce the sustainability impacts in all lifecycle stages of the Agreement.
- 11.3 The Supplier shall work with DHSC to identify opportunities to introduce innovation, reduce cost and waste and ensure sustainable development is at the heart of its operations. This shall include but is not limited to product rationalisation and standardisation; leverage opportunities within the Supplier's supply chain and reviewing order placement methods, frequency and quantity.
- 11.4 The Supplier shall provide information on new or improved environmentally preferable products when they become commercially available and, promote their use under the Agreement.
- 11.5 The Supplier shall demonstrate its measured progress on climate change adaptation, mitigation and sustainable development including performance against carbon reduction management plans.

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- 11.6 The Supplier shall complete annual Corporate Social Responsibility (CSR) assessments upon request from DHSC.
- 11.7 The Supplier shall monitor and manage emissions from its transport operations and shall update DHSC on the findings, results and progress achieved.
- 11.8 The Supplier shall fully comply with the following government standards for the duration of the Agreement:
www.gov.uk/government/policies/sustainable-development.

12. QUALITY STANDARDS

- 12.1 The Supplier must provide details demonstrating that it has a Comprehensive Quality Assurance Policy in place.
- 12.2 The Supplier must have a Quality Management System in place including but not limited to a Quality plan, Internal Audit Schedule, Document control process CAPA process and Quality Management Meeting.
- 12.3 DHSC requires that in the case of a faulty/damaged/dangerous product that the end user of the product can be contacted in a timely manner; Supplier systems and records must enable this traceability.
- 12.4 The Supplier must ensure that an appropriate Quality Control inbound inspection takes place. This covers the following activities;
 - 12.4.1 Receiving test-kits.
 - 12.4.2 Documenting Key information upon receipt.
 - 12.4.3 QC inspection and recording of data.
- 12.5 Non-compliant goods handling.
 - 12.5.1 Non-compliant components/test-kits clearly identified at the Bulk Component Storage Warehouse.
 - 12.5.2 Non-compliant goods to be segregated from other quality approved ones electronically (using IMS/WMS) and physically to ensure components/test-kits are blocked from further entering the downstream supply chain process.
 - 12.5.3 Communication to DHSC of non-compliant goods and seek further guidance.

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- 12.5.4 Communication and implementation of agreed corrective action between DHSC and the Supplier. The agreed corrective action may include the actions listed below between DHSC and the Supplier:
 - 12.5.4.1 Return to Vendor.
 - 12.5.4.2 Vendor collection of returns.
 - 12.5.4.3 Goods write-off process and credit note/replacement.
 - 12.5.4.4 Arrange with the Supplier for on-site resolution for non-compliant goods.
 - 12.5.4.5 Arrange for products to be destroyed in accordance with DHSC guidelines. If goods need to be destroyed, a destruction certificate must be made available to the DHSC.
- 12.6 The Supplier must ensure its Quality Management Systems provide adequate management and control of the following activities:
 - 12.6.1 Maintaining traceability of test-kits.
 - 12.6.2 Completing document data requirements in line with GDP (Good Document Practice).
 - 12.6.3 Appropriate storage of finished test-kits prior to quality release.
 - 12.6.4 Create shipping notes for goods out including all the agreed data.
- 12.7 The Supplier must establish Standard operating procedures (SOP) to clearly describe how key activities are carried out.
- 12.8 The Supplier's SOP must describe the different operations which may affect the performance of the medical devices; Training - Documentation control - Approval of suppliers and customers - Order processing and deliveries - Waste management - Audits - Change control - Management review - Quality risk management - Management of Field Safety Corrective Actions/recalls - Non-conformance management - Corrective and preventive actions.
- 12.9 The Quality Management System must include the Supplier SOP and work instructions that fulfil the quality requirements of DHSC, including the following elements:
 - 12.9.1 Quality Manual.
 - 12.9.2 Quality Policy.
 - 12.9.3 Record Control.
 - 12.9.4 CAPA process (Correction Action Preventive Action).

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- 12.9.5 Document Change Control within the Quality Management System to ensure that all documents are controlled, issued at the correct revision and each employee is trained to the correct version.
- 12.10 The Supplier must operate an internal audit programme framework to manage and control all elements of the Quality Management System, and will agree to an external audit program, conducted by DHSC, that drives adherence and continuous improvements.
- 12.11 The Supplier must ensure traceability with good record keeping.
- 12.12 All external audits to an agreed schedule and providing the Supplier with reasonable advance notice.

13. RECORDS

- 13.1 The Supplier shall keep adequate records, including records of customers and suppliers to and from whom test-kits have been distributed.
- 13.2 Records should include but are not limited to, medical device name and/or code, batch numbers, expiry dates, quantities and delivery or receipt date.
- 13.3 The Supplier must have a change control procedure and associated forms should be implemented and appropriately documented.
- 13.4 The purpose of the procedure should be to ensure that all changes to the operation are fully evaluated in terms of impact on the medical device's performance and traceability.

14. VALIDATION OF PROCESSES

- 14.1 The Supplier shall have validation processes in place where the resulting output cannot be or is not verified by subsequent monitoring or measurement. Validation shall demonstrate the ability of these processes to achieve planned results consistently.
- 14.2 The Supplier shall include key critical steps for validation such as; Goods-in, Storage, Order processing.

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15. TRAINING

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

16. PEST CONTROL

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

17. STAFF AND CUSTOMER SERVICE

- 17.1 The Supplier shall provide a sufficient level of resource throughout the duration of the Agreement in order to consistently deliver a quality service.
- 17.2 The Supplier's staff assigned to the Agreement shall have the relevant qualifications and experience to deliver the Contract to the required standard.
- 17.3 The Supplier shall ensure that staff understand DHSC's vision and objectives and will provide excellent customer service to the DHSC throughout the duration of the Agreement.

18. PAYMENT AND INVOICING

- 18.1 The Supplier shall submit an invoice monthly in arrears as per Attachment 5 – Call-off Order Form (Contract) for the Provision of Services.

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18.2 Payment can only be made following satisfactory delivery of pre-agreed certified products and deliverables.

18.3 Before payment can be considered, each invoice must include a detailed elemental breakdown of work completed and the associated costs.

19. CONTRACT MANAGEMENT

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

Meeting type	Frequency	Purpose
Operational	Daily/Weekly	Review and monitor the operational performance of the Services.
Contract/Performance	Monthly	Review and monitor the commercial aspects of the Services, including: <ul style="list-style-type: none">-SLA's/KPI's,- Service Delivery- Financials- Risk- Innovation/Improvement
Quality	Daily	Review and monitor all quality issues, Quality Alerts; NCR's, CAPA's/SCAR's.
Continuous Improvement	TBA	TBA

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

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

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

19.4.1 SLA's/KPI's;

19.4.2 Service delivery;

19.4.3 Financials;

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19.4.4 Risk; and

19.4.5 Customer service.

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

19.6 The first Monthly Reporting Pack shall be submitted within one month of contract commencement.

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