



Ministry of Defence

UK STRATEGIC COMMAND DEFENCE MEDICAL SERVICES

CONTRACT NUMBER : 703897450

FOR

THE PROVISION OF ELECTRONIC QUALITY MANAGEMENT SYSTEM (eQMS)

Between the Secretary of State for Defence of
the United Kingdom of Great Britain and
Northern Island

Team Name: **Defence Medical Services**

Address: **DMS Whittington, Lichfield, WS14
9PY**

Email Address: **lynn.wallace110@mod.gov.uk**

Tel: No: **[Redacted]**

And

Contractor Name: **Genial ComplianceSystem
Ltd**

Address: **Unit 52, CoWorkz Business Centre,
Minerva Avenue, Chester, CH1 4QL**

Email Address: **[Redacted]**

Tel No:

TABLE OF CONTENTS

Terms & Conditions.....	2
Schedule 1 – DEFFORM 32.....	15
Schedule 2 – Pricing	23
Schedule 3 – Statement Relating to Good Standing	25
Schedule 4 – Statement of Requirement	28
Annex A – Key Performance Indicators	33
Defform 111- Addresses and Other Information	34

1 Definitions - In the Contract:

The Authority means the Secretary of State for Defence of the United Kingdom of Great Britain and Northern Ireland, (referred to in this document as "the Authority"), acting as part of the Crown;

Business Day means 09:00 to 17:00 Monday to Friday, excluding public and statutory holidays;

Contract means the agreement concluded between the Authority and the Contractor, including all terms and conditions, associated purchase order, specifications, plans, drawings, schedules and other documentation, expressly made part of the agreement in accordance with Clause 2.c;

Contractor means the person, firm or company specified as such in the purchase order. Where the Contractor is an individual or a partnership, the expression shall include the personal representatives of the individual or of the partners, as the case may be;

Contractor Commercially Sensitive Information means the information listed as such in the purchase order, which is information notified by the Contractor to the Authority, which is acknowledged by the Authority as being commercially sensitive;

Contractor Deliverables means the goods and / or services including packaging (and supplied in accordance with any QA requirements if specified) which the Contractor is required to provide under the Contract in accordance with the schedule to the purchase order;

Effective Date of Contract means the date stated on the purchase order or, if there is no such date stated, the date upon which both Parties have signed the purchase order;

Firm Price means a price excluding Value Added Tax (VAT) which is not subject to variation;

Government Furnished Assets (GFA) is a generic term for any MOD asset such as equipment, information or resources issued or made available to the Contractor in connection with the Contract by or on behalf of the Authority;

Hazardous Contractor Deliverable means a Contractor Deliverable or a component of a Contractor Deliverable that is itself a hazardous material or substance or that may in the course of its use, maintenance, disposal, or in the event of an accident, release one or more hazardous materials or substances and each material or substance that may be so released;

Issued Property means any item of Government Furnished Assets (GFA), including any materiel issued or otherwise furnished to the Contractor in connection with the Contract by or on behalf of the Authority;

Legislation means in relation to the United Kingdom any Act of Parliament, any subordinate legislation within the meaning of section 21 of the Interpretation Act 1978, any exercise of Royal Prerogative or any enforceable community right within the meaning of Section 2 of the European Communities Act 1972.

Notices means all notices, orders, or other forms of communication required to be given in writing under or in connection with the Contract;

Parties means the Contractor and the Authority, and Party shall be construed accordingly;

Transparency Information means the content of this Contract in its entirety, including from time to time agreed changes to the Contract, and details of any payments made by the Authority to the

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Contractor under the Contract.

2 General

- a. The Contractor shall comply with all applicable Legislation, whether specifically referenced in this Contract or not.
- b. Any variation to the Contract shall have no effect unless expressly agreed in writing and signed by both Parties.
- c. If there is any inconsistency between these terms and conditions and the purchase order or the documents expressly referred to therein, the conflict shall be resolved according to the following descending order of priority:
 - (1) the terms and conditions;
 - (2) the purchase order; and
 - (3) the documents expressly referred to in the purchase order.
- d. Neither Party shall be entitled to assign the Contract (or any part thereof) without the prior written consent of the other Party.
- e. Failure or delay by either Party in enforcing or partially enforcing any provision of the Contract shall not be construed as a waiver of its rights or remedies. No waiver in respect of any right or remedy shall operate as a waiver in respect of any other right or remedy.
- f. The Parties to the Contract do not intend that any term of the Contract shall be enforceable by virtue of the Contracts (Rights of Third Parties) Act 1999 by any person that is not a Party to it.
- g. The Contract and any non-contractual obligations arising out of or in connection with it shall be governed by and construed in accordance with English Law, and subject to Clause 15 and without prejudice to the dispute resolution procedure set out therein, the Parties submit to the exclusive jurisdiction of the English courts. Other jurisdictions may apply solely for the purpose of giving effect to this Clause 2.g and for enforcement of any judgement, order or award given under English jurisdiction.

3 Application of Conditions

- a. The purchase order, these terms and conditions and the specification govern the Contract to the entire exclusion of all other terms and conditions. No other terms or conditions are implied.
- b. The Contract constitutes the entire agreement and understanding and supersedes any previous agreement between the Parties relating to the subject matter of the Contract.

4 Disclosure of Information

Disclosure of information under the Contract shall be managed in accordance with DEFCON 531 (SC1).

5 Transparency

- a. Subject to Clause 5.b, but notwithstanding Clause 4, the Contractor understands that the Authority may publish the Transparency Information to the general public. The Contractor shall assist and cooperate with the Authority to enable the Authority to publish the Transparency

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Information.

b. Before publishing the Transparency Information to the general public in accordance with Clause 5.a, the Authority shall redact any information that would be exempt from disclosure if it was the subject of a request for information under the Freedom of Information Act 2000 or the Environmental Information Regulations 2004, including the Contractor Commercially Sensitive Information.

c. The Authority may consult with the Contractor before redacting any information from the Transparency Information in accordance with Clause 5.b. The Contractor acknowledges and accepts that its representations on redactions during consultation may not be determinative and that the decision whether to redact information is a matter in which the Authority shall exercise its own discretion, subject always to the provisions of the Freedom of Information Act 2000 or the Environmental Information Regulations 2004.

d. For the avoidance of doubt, nothing in this Clause 5 shall affect the Contractor's rights at law.

6 Notices

a. A Notice served under the Contract shall be:

- (1) in writing in the English Language;
- (2) authenticated by signature or such other method as may be agreed between the Parties;
- (3) sent for the attention of the other Party's representative, and to the address set out in the purchase order;
- (4) marked with the number of the Contract; and
- (5) delivered by hand, prepaid post (or airmail), facsimile transmission or, if agreed in the purchase order, by electronic mail.

b. Notices shall be deemed to have been received:

- (1) if delivered by hand, on the day of delivery if it is the recipient's Business Day and otherwise on the first Business Day of the recipient immediately following the day of delivery;
- (2) if sent by prepaid post, on the fourth Business Day (or the tenth Business Day in the case of airmail) after the day of posting;
- (3) if sent by facsimile or electronic means:
 - (a) if transmitted between 09:00 and 17:00 hours on a Business Day (recipient's time) on completion of receipt by the sender of verification of the transmission from the receiving instrument; or
 - (b) if transmitted at any other time, at 09:00 on the first Business Day (recipient's time) following the completion of receipt by the sender of verification of transmission from the receiving instrument.

7 Intellectual Property

a. The Contractor shall as its sole liability keep the Authority fully indemnified against an infringement or alleged infringement of any intellectual property rights or a claim for Crown use of a UK patent or registered design caused by the use, manufacture or supply of the Contractor Deliverables.

b. The Authority shall promptly notify the Contractor of any infringement claim made against it

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relating to any Contractor Deliverable and, subject to any statutory obligation requiring the Authority to respond, shall permit the Contractor to have the right, at its sole discretion to assume, defend, settle or otherwise dispose of such claim. The Authority shall give the Contractor such assistance as it may reasonably require to dispose of the claim and will not make any statement which might be prejudicial to the settlement or defence of the claim

8 Supply of Contractor Deliverables and Quality Assurance

- a. This Contract comes into effect on the Effective Date of Contract.
- b. The Contractor shall supply the Contractor Deliverables to the Authority at the Firm Price stated in the Schedule to the purchase order.
- c. The Contractor shall ensure that the Contractor Deliverables:
 - (1) correspond with the specification;
 - (2) are of satisfactory quality (within the meaning of the Sale of Goods Act 1979, as amended) except that fitness for purpose shall be limited to the goods being fit for the particular purpose held out expressly by or made known expressly to the Contractor and in this respect the Authority relies on the Contractor's skill and judgement; and
 - (3) comply with any applicable Quality Assurance Requirements specified in the purchase order.
- d. The Contractor shall apply for and obtain any licences required to import any material required for the performance of the Contract in the UK. The Authority shall provide to the Contractor reasonable assistance with regard to any relevant defence or security matter arising in the application for any such licence.

9 Supply of Data for Hazardous Contractor Deliverables

- a. The Contractor shall establish if the Contractor Deliverables are, or contain, Dangerous Goods as defined in the Regulations set out in this Clause 9. Any that do shall be packaged for UK or worldwide shipment by all modes of transport in accordance with the following unless otherwise specified in the Schedule to the purchase order:
 - (1) the Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO), IATA Dangerous Goods Regulations;
 - (2) the International Maritime Dangerous Goods (IMDG) Code;
 - (3) the Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID); and
 - (4) the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR).
- b. Certification markings, incorporating the UN logo, the package code and other prescribed information indicating that the package corresponds to the successfully designed type shall be marked on the packaging in accordance with the relevant regulation.
- c. As soon as possible and in any event within the period specified in the purchase order (or if no such period is specified no later than one month prior to the delivery date), the Contractor shall provide to the Authority's representatives in the manner and format prescribed in the purchase order:

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- (1) confirmation as to whether or not to the best of its knowledge any of the Contractor Deliverables are Hazardous Contractor Deliverables; and
 - (2) for each Hazardous Contractor Deliverable, a Safety Data Sheet containing the data set out at Clause 9.d, which shall be updated by the Contractor during the period of the Contract if it becomes aware of any new relevant data.
- d. Safety Data Sheets if required under Clause 9.c shall be provided in accordance with the extant UK REACH Regulation and any additional information required by the Health and Safety at Work etc. Act 1974 and shall contain:
- (1) information required by the Classification, Labelling and Packaging (GB CLP) Regulation or any replacement thereof; and
 - (2) where the Hazardous Contractor Deliverable is, contains or embodies a radioactive substance as defined in the extant Ionising Radiation Regulations, details of the activity, substance and form (including any isotope); and
 - (3) where the Hazardous Contractor Deliverable has magnetic properties, details of the magnetic flux density at a defined distance, for the condition in which it is packed.
- e. The Contractor shall retain its own copies of the Safety Data Sheets provided to the Authority in accordance with Clause 9.d for 4 years after the end of the Contract and shall make them available to the Authority's representatives on request.
- f. Nothing in this Clause 9 reduces or limits any statutory or legal obligation of the Authority or the Contractor.
- g. Where delivery is made to the Defence Fulfilment Centre (DFC) and / or other Team Leidos location / building, the Contractor must comply with the Logistic Commodities and Services Transformation (LCST) Supplier Manual.

10 Delivery / Collection

- a. The purchase order shall specify whether the Contractor Deliverables are to be delivered to the consignee by the Contractor or collected from the consignor by the Authority.
- b. Title and risk in the Contractor Deliverables shall pass from the Contractor to the Authority on delivery or on collection in accordance with Clause 10.a.
- c. The Authority shall be deemed to have accepted the Contractor Deliverables within a reasonable time after title and risk has passed to the Authority unless it has rejected the Contractor Deliverables within the same period.

11 Marking of Contractor Deliverables

- a. Each Contractor Deliverable shall be marked in accordance with the requirements specified in the purchase order. or if no such requirement is specified, the Contractor shall mark each Contractor Deliverable clearly and indelibly in accordance with the requirements of the relevant DEF-STAN 05-132 as specified in the contract or specification. In the absence of such requirements, the Contractor Deliverables shall be marked with the MOD stock reference, NATO Stock Number (NSN) or alternative reference number shown in the Contract.
- b. Any marking method used shall not have a detrimental effect on the strength, serviceability or

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corrosion resistance of the

Contractor Deliverables.

c. The marking shall include any serial numbers allocated to the Contractor Deliverable.

d. Where because of its size or nature it is not possible to mark a Contractor Deliverable with the required particulars, the required information should be included on the package or carton in which the Contractor Deliverable is packed, in accordance with condition 12 (Packaging and Labelling (excluding Contractor Deliverables containing Ammunition or Explosives)).

12 Packaging and Labelling of Contractor Deliverables (Excluding Contractor Deliverables Containing Ammunition or Explosives)

The Contractor shall pack or have packed the Contractor Deliverables in accordance with any requirements specified in the purchase order and Def Stan 81-041 (Part 1 and Part 6).

13 Progress Monitoring, Meetings and Reports

The Contractor shall attend progress meetings and deliver reports at the frequency or times (if any) specified in the purchase order and shall ensure that its Contractor's representatives are suitably qualified to attend such meetings. Any additional meetings reasonably required shall be at no cost to the Authority.

14 Payment

a. Payment for Contractor Deliverables will be made by electronic transfer and prior to submitting any claims for payment under clause 14b the Contractor will be required to register their details (Supplier on-boarding) on the Contracting, Purchasing and Finance (CP&F) electronic procurement tool.

b. Where the Contractor submits an invoice to the Authority in accordance with clause 14a, the Authority will consider and verify that invoice in a timely fashion.

c. The Authority shall pay the Contractor 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.

d. Where the Authority fails to comply with clause 14b and there is undue delay in considering and verifying the invoice, the invoice shall be regarded as valid and undisputed for the purpose of clause 14c after a reasonable time has passed.

e. The approval for payment of a valid and undisputed invoice by the Authority shall not be construed as acceptance by the Authority of the performance of the Contractor's obligations nor as a waiver of its rights and remedies under this Contract.

f. Without prejudice to any other right or remedy, the Authority reserves the right to set off any amount owing at any time from the Contractor to the Authority against any amount payable by the Authority to the Contractor under the Contract or under any other contract with the Authority, or with any other Government Department.

15 Dispute Resolution

a. The Parties will attempt in good faith to resolve any dispute or claim arising out of or relating to the Contract through negotiations between the respective representatives of the Parties having

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authority to settle the matter, which attempts may include the use of any alternative dispute resolution procedure on which the Parties may agree.

b. In the event that the dispute or claim is not resolved pursuant to Clause 15.a the dispute shall be referred to arbitration and shall be governed by the Arbitration Act 1996. For the purposes of the arbitration, the arbitrator shall have the power to make provisional awards pursuant to Section 39 of the Arbitration Act 1996.

c. For the avoidance of doubt it is agreed between the Parties that the arbitration process and anything said, done or produced in or in relation to the arbitration process (including any awards) shall be confidential as between the Parties, except as may be lawfully required in judicial proceedings relating to the arbitration or otherwise. No report relating to anything said, done or produced in or in relation to the arbitration process may be made beyond the tribunal, the Parties, their legal representatives and any person necessary to the conduct of the proceedings, without the concurrence of all the Parties to the arbitration.

16 Termination for Corrupt Gifts

The Authority may terminate the Contract with immediate effect, without compensation, by giving written notice to the Contractor at any time after any of the following events:

a. where the Authority becomes aware that the Contractor, its employees, agents or any sub-contractor (or anyone acting on its behalf or any of its or their employees):

- (1) has offered, promised or given to any Crown servant any gift or financial or other advantage of any kind as an inducement or reward;
- (2) commits or has committed any prohibited act or any offence under the Bribery Act 2010 with or without the knowledge or authority of the Contractor in relation to this Contract or any other contract with the Crown;
- (3) has entered into this or any other contract with the Crown in connection with which commission has been paid or has been agreed to be paid by it or on its behalf, or to its knowledge, unless before the contract is made particulars of any such commission and of the terms and conditions of any such agreement for the payment thereof have been disclosed in writing to the Authority.

b. In exercising its rights or remedies to terminate the Contract under Clause 16.a. the Authority shall:

- (1) act in a reasonable and proportionate manner having regard to such matters as the gravity of, and the identity of the person committing the prohibited act;
- (2) give due consideration, where appropriate, to action other than termination of the Contract, including (without being limited to):
 - (a) requiring the Contractor to procure the termination of a subcontract where the prohibited act is that of a Subcontractor or anyone acting on its or their behalf;
 - (b) requiring the Contractor to procure the dismissal of an employee (whether its own or that of a Subcontractor or anyone acting on its behalf) where the prohibited act is that of such employee.

c. Where the Contract has been terminated under Clause 16.a. the Authority shall be entitled to purchase substitute Contractor Deliverables from elsewhere and recover from the Contractor any costs and expenses incurred by the Authority in obtaining the Contractor Deliverables in

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substitution from another

supplier.

17 Material Breach

In addition to any other rights and remedies, the Authority shall have the right to terminate the Contract (in whole or in part) with immediate effect by giving written notice to the Contractor where the Contractor is in material breach of its obligations under the Contract. Where the Authority has terminated the Contract under Clause 17 the Authority shall have the right to claim such damages as may have been sustained as a result of the Contractor's material breach of the Contract.

18 Insolvency

The Authority shall have the right to terminate the contract if the Contractor is declared bankrupt or goes into liquidation or administration. This is without prejudice to any other rights or remedies under this Contract.

19 Limitation of Contractor's Liability

- a. Subject to Clause 19.b the Contractor's liability to the Authority in connection with this Contract shall be limited to £5m (five million pounds).
- b. Nothing in this Contract shall operate to limit or exclude the Contractor's liability:
 - (1) for:
 - a. any liquidated damages (to the extent expressly provided for under this Contract);
 - b. any amount(s) which the Authority is entitled to claim, retain or withhold in relation to the Contractor's failure to perform or under-perform its obligations under this Contract, including service credits or other deductions (to the extent expressly provided for under this Contract);
 - c. any interest payable in relation to the late payment of any sum due and payable by the Contractor to the Authority under this Contract;
 - d. any amount payable by the Contractor to the Authority in relation to TUPE or pensions to the extent expressly provided for under this Contract;
 - (2) under Condition 7 of the Contract (Intellectual Property), and DEFCONs 91 or 638 (SC1) where specified in the contract;
 - (3) for death or personal injury caused by the Contractor's negligence or the negligence of any of its personnel, agents, consultants or sub-contractors;
 - (4) for fraud, fraudulent misrepresentation, wilful misconduct or negligence;
 - (5) in relation to the termination of this Contract on the basis of abandonment by the Contractor;
 - (6) for breach of the terms implied by Section 2 of the Supply of Goods and Services Act 1982; or
 - (7) for any other liability which cannot be limited or excluded under general (including statute and common) law.
- c. The rights of the Authority under this Contract are in addition to, and not exclusive of, any rights or remedies provided by general (including statute and common) law.

20 The project specific DEFCONs and DEFCON SC variants that apply to this Contract are:

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DEFCON 502 (SC1) (Edn. 12/16) - Specifications Changes

DEFCON 503 (SC1) (Edn. 07/21) - Formal Amendments To Contract

DEFCON 531 (SC1) (Edn. 09/21) - Disclosure of Information

DEFCON 532B (Edn. 04/20) -Protection Of Personal Data (Where Personal Data is being processed on behalf of the Authority)

DEFCON 534 (Edn. 06/21) - Subcontracting and Prompt Payment

DEFCON 537 (Edn. 12/21) - Rights of Third Parties

DEFCON 538 (Edn. 06/02) - Severability

DEFCON 566 (Edn. 12/18) - Change of Control of Contractor

DEFCON 658 (SC1) (Edn. 09/21) – Cyber - The Authority has determined the level of risk at **Very Low (Reference: RAR-6U33THAA)** as defined in DEF Stan 05-138.

DEFCON 687A (SC1A) (Edn. 06/21) - Provision of a Shared Data Environment Service

21 The special conditions that apply to this Contract are:

The contract start date is 01st July 2022 and ends on 30th June 2025. There are 2 option years to extend the contract further at the Authority's sole discretion.

21.1 Contract Risk Management

21.1.1 Both Parties shall pro-actively manage risks attributed to them under the terms of this Contract.

21.1.2 The Contractor shall develop, operate, maintain and amend, as agreed with the Authority, processes for:

21.2.1 the identification and management of risks;

21.2.2 the identification and management of issues; and

21.2.3 monitoring and controlling project plans.

21.3 The Contractor allows the Authority to inspect at any time within working hours the accounts and records which the Contractor is required to keep.

21.4 The Contractor will maintain a risk register of the risks relating to the Contract which the Authority and the Contractor have identified.

21.2 AUTHORISATION BY THE CROWN FOR USE OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS

21.2.1 Notwithstanding any other provisions of the Contract and for the avoidance of doubt, award of the Contract by the Authority and placement of any contract task under it does not constitute an authorisation by the Crown under Sections 55 and 56 of the Patents Act

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1977 or Section 12 of the Registered Designs Act 1949. The Contractor acknowledges that any such authorisation by the Authority under its statutory powers must be expressly provided in writing, with reference to the acts authorised and the specific intellectual property involved.

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Personal Data Particulars

This Form forms part of the Contract and must be completed and attached to each Contract containing DEFCON 532B.

Data Controller	<p>The Data Controller is the Secretary of State for Defence (the Authority).</p> <p>The Personal Data will be provided by: [Redacted]</p>
Data Processor	<p>The Data Processor is the Contractor.</p> <p>The Personal Data will be processed at: [Redacted] [insert location(s), address and contact details]</p>
Data Subjects	<p>The Personal Data to be processed under the Contract concern the following Data Subjects or categories of Data Subjects: [please specify]</p> <p>The eQMS is to be configured to allow for management of Blood transfusion and pathology services, this is web based standalone system which will contain MoD data.</p>
Categories of Data	<p>The Personal Data to be processed under the Contract concern the following categories of data: [please specify]</p> <p>As this is a web based system electronic Quality Management System (eQMS), which will be implemented at CD Path to ensure compliance with National Guidelines relating to assured blood management, therefore no personal data held or stored by Contractor.</p>
Special Categories of data (if appropriate)	<p>The Personal Data to be processed under the Contract concern the following Special Categories of data: [please specify]</p> <p>If any other personal data which may identify as a special category of data as per Paragraph 1 of Article 9 of the EU General Data Protection Regulation (GDPR), should not be recorded unless required as per Paragraph 2 of Article 9.</p>
Subject matter of the processing	<p>The processing activities to be performed under the contract are as follows: [please specify]</p>

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	The management of Pathology Processes, audits, change control documentation will be recorded by the eQMS and then accessed by authorised users via an encrypted cloud serviced by a secure server operated by the contractor
Nature and the purposes of the Processing	<p>The Personal Data to be processed under the Contract will be processed as follows: [please specify]</p> <p>The names of authorised users (Defence Pathology personnel) will be maintained securely within the eQMS.</p>
Technical and organisational measures	<p>The following technical and organisational measures to safeguard the Personal Data are required for the performance of this Contract: [please specify]</p> <p>Authority Technical Measures:</p> <p>The Authority has established organisational measures to ensure that all data is secure and measures are in place that guarantees protection level appropriate to the risk concerning confidentiality, integrity, availability and resilience of the systems. A full cyber assessment has been completed to identify the level of risk concerned within this contract.</p> <p>Contractor Technical and Organisational Measures:</p> <p>[Redacted]</p>
Instructions for disposal of Personal Data	<p>The disposal instructions for the Personal Data to be processed under the Contract are as follows (where Disposal Instructions are available at the commencement of Contract): [please specify]</p> <p>The data should be held for the length of the contract and all data returned to the MoD and destroyed by the Contractor as soon as the contract has ceased.</p>
Date from which Personal Data is to be processed	<p>Where the date from which the Personal Data will be processed is different from the Contract commencement date this should be specified here:</p> <p>N/A</p>

The capitalised terms used in this form shall have the same meanings as in the General Data Protection Regulations.

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PURCHASE ORDER

Contract No: 703897450

Dated: 8th June 2022

Contractor	Quality Assurance Requirement (Clause 8)
<p>Name: Genial Compliance Systems Ltd</p> <p>Registered Address:</p> <p>Unit 62, CoWorkz Business Centre, Minerva Avenue, Chester, CH1 4QL</p>	<p>_____</p>

Consignor (if different from Contractor's registered address)	Transport Instructions (Clause 10)
Name:	Select method of transport of Deliverables
Address:	<p>To be Delivered by the Contractor [Special Instructions]</p> <p>To be Collected by the Authority [Special Instructions]</p> <p>Each consignment of the Deliverables shall be accompanied by a delivery note.</p>

Progress Meetings (Clause 13)	Progress Reports (Clause 13)
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<p>The Contractor shall be required to attend the following meetings:</p> <p>Subject: Progress Meeting</p> <p>Frequency: Bi-annually</p> <p>Location: TBC</p>	<p>The Contractor is required to submit the following Reports:</p> <p>Subject:</p> <p>Frequency:</p> <p>Method of Delivery:</p> <p>Delivery Address:</p>
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Payment (Clause 14)

Payment is to be enabled by CP&F.

Forms and Documentation	Supply of Hazardous Deliverables (Clause 9)
<p>Forms can be obtained from the following websites:</p> <p>https://www.aof.mod.uk/aofcontent/tactical/toolkit (Registration is required).</p> <p>https://www.gov.uk/government/organisations/mini-stry-of-defence/about/procurement#invoice-processing</p> <p>https://www.dstan.mod.uk/ (Registration is required).</p> <p>The MOD Forms and Documentation referred to in the Conditions are available free of charge from:</p> <p>Ministry of Defence, Forms and Pubs Commodity Management PO Box 2, Building C16, C Site Lower Arncott Bicester, OX25 1LP (Tel. 01869 256197 Fax: 01869 256824)</p>	<p>A completed DEFFORM 68 and, if applicable, Safety Data Sheet(s) are to be provided by email with attachment(s) in Adobe PDF or MS WORD format to:</p> <p>a. The Commercial Officer detailed in the Purchase Order, and</p> <p>b. DSA-DLSR-MovTpt-DGHSIS@mod.uk</p> <p>by the following date:</p> <p>or if only hardcopy is available to the addresses below:</p> <p>Hazardous Stores Information System (HSIS) Defence Safety Authority (DSA) Movement Transport Safety Regulator (MTSR) Hazel Building Level 1, #H019 MOD Abbey Wood (North) Bristol BS34 8QW</p>

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<p>Applications via email: DESLCSLS-OpsFormsandPubs@mod.uk</p> <p>If you require this document in a different format (i.e. in a larger font) please contact the Authority's Representative (Commercial Officer), detailed below.</p>	
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Contractor Commercially Sensitive Information (Clause 5). Not to be published.
Description of Contractor's Commercially Sensitive Information:
Cross reference to location of sensitive information:
Explanation of Sensitivity:
Details of potential harm resulting from disclosure:
Period of Confidence (if Applicable):
Contact Details for Transparency / Freedom of Information matters: Name: Position: Address: Telephone Number: E-mail Address:

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Offer and Acceptance	
<p>A) Offer</p> <p>Contract 703897450 constitutes an offer by the Authority for the supplier to supply the Deliverables. This is open for acceptance by the supplier until 27th June 2022.</p> <p>Signed by:</p> <p>Name (Block Capitals):</p> <p>Position: Commercial Officer</p> <p>For and on behalf of the Authority</p> <p>Authorised Signatory:</p> <p>Date: 17 June 2022</p>	<p>B) Acceptance of Offer of Contract</p> <p>I acknowledge receipt of the Authority's contract letter reference 703897450-EQMS.</p> <p>I confirm that I accept the Offer it contains and by signing below I agree to be bound by the attached Contract terms and conditions..</p> <p>Signed by:</p> <p>Name (Block Capitals):</p> <p>Position:</p> <p>For and on behalf of</p> <p>Authorised Signatory:</p> <p>Date¹:</p>

¹ The date of unqualified acceptance by signature is the effective date of the contract

SCHEDULE OF REQUIREMENTS FOR THE SUPPLY OF AN ELECTRONIC QUALITY MANAGEMENT SYSTEM

Serial No	Requirement	Total Qty	Cost Year 4 Option Year 1 01/07/2025 – 30/06/2026	Cost Year 5 Option Year 2 01/07/2026 – 30/06/2027	Total
	[Redacted]				

Years	Cost
Years 1 - 3	£17,965.00
	[Redacted]
	[Redacted]

Statement of Good Standing

The Statement Relating To Good Standing

Contract Title: Provision of an Electronic Quality Management System(eQMS) for Defence Pathology

Contract Number: 703897450

1. We confirm, to the best of our knowledge and belief, that **Genial Compliance Systems Ltd** including its directors or any other person who has powers of representation, decision or control or is a member of the administrative, management or supervisory body of Genial Compliance has not been convicted of any of the following offences within the past 5 years:
- a. conspiracy within the meaning of section 1 or 1A of the Criminal Law Act 1977 or article 9 or 9A of the Criminal Attempts and Conspiracy (Northern Ireland) Order 1983 where that conspiracy relates to participation in a criminal organisation as defined in Article 2 of Council Framework Decision 2008/841/JHA;
 - b. corruption within the meaning of section 1(2) of the Public Bodies Corrupt Practices Act 1889 or section 1 of the Prevention of Corruption Act 1906;
 - c. common law offence of bribery;
 - d. bribery within the meaning of section 1,2 or 6 of the Bribery Act 2010; or section 113 of the Representation of the People Act 1983;
 - e. any offence listed:
 - (1) in section 41 of the Counter Terrorism Act 2008; or
 - (2) in Schedule 2 to that Act where the court has determined that there is a terrorist connection;
 - f. any offence under sections 44 to 46 of the Serious Crime Act 2007 which relates to an offence covered by (f) above;
 - g. money laundering within the meaning of section 340(11) and 415 of the Proceeds of Crime Act 2002;
 - h. an offence in connection with the proceeds of criminal conduct within the meaning of section 93A, 93B, or 93C of the Criminal Justice Act 1988 or article 45, 46 or 47 of the Proceeds of Crime (Northern Ireland) Order 1996;
 - i. an offence under section 4 of the Asylum and Immigration (Treatment of Claimants etc) Act 2004;
 - j. an offence under section 59A of the Sexual Offences Act 2003;
 - k. an offence under section 71 of the Coroners and Justice Act 2009;

OFFICIAL-SENSITIVE COMMERCIAL

l. an offence in connection with the proceeds of drug trafficking within the meaning of section 49, 50 or 51 of the Drug Trafficking Act 1994; or

m. an offence under section 2 or 4 of the Modern Slavery Act 2015;

n. any other offence within the meaning of Article 57(1)(a), (b), (d), (e), or (f) of Public Contracts Directive –

(1) as defined by the law of any jurisdiction outside England and Wales and Northern Ireland: or

(2) created in the law of England and Wales or Northern Ireland after the day on which these Regulations were made;

p. any breach of its obligations relating to the payment of taxes or social security contributions where the breach has been established by a judicial or administrative decision having final and binding effect in accordance with the legal provisions of the country in which it is established or with those of any jurisdictions of the United Kingdom.

2. Genial Compliance Systems Ltd further confirms to the best of our knowledge and belief that within the last 3 years it:

a. has fulfilled its obligations relating to the payment of taxes and social security contributions of the country in which it is established or with those of any jurisdictions of the United Kingdom;

b. is not bankrupt or is not the subject of insolvency or winding-up proceedings, where its assets are being administered by a liquidator or by the court, where it is in an agreement with creditors, where its business activities are suspended or it is in any analogous situation arising from a similar procedure under the laws and regulations of any State;

c. has not committed an act of grave professional misconduct, which renders its integrity questionable;

d. has not entered into agreements with other suppliers aimed at distorting competition;

e. Is not subject to a conflict of interest within the meaning of regulation 24;

f. has not been involved in the preparation of this procurement procedure which would result in distortion of competition which could not be remedied by other, less intrusive, measures other than exclusion from this procedure;

g. has not had a contract terminated, damages or other comparable sanctions taken as a result of significant or persistent deficiencies in the performance of a substantive requirement under a prior public contract, a prior contract, or a prior concession contract as defined by the Concession Contracts Regulations 2016;

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h. is not guilty of serious misrepresentation in providing any information required by this statement.

i. has not unduly influenced the decision-making process of the Authority or obtained confidential information that may confer upon it undue advantages in the procurement procedure;

j. in relation to procedures for the award of a public services contract, is licensed in the relevant State in which he is established or is a member of an organisation in that relevant State where the law of that relevant State prohibits the provision of the services to be provided under the contract by a person who is not so licensed or who is not such a member;

k. has fulfilled its obligations in the fields of environmental, social and labour law established by national law, collective agreements or by the international environmental, social and labour law provisions listed in the Public Contracts Directive as amended from time to time (as listed in PPN 8/16 Annex C).

I confirm that to the best of my knowledge my declaration is correct. I understand that the contracting authority will use the information in the selection process to assess my organisation's suitability to be invited to participate further in this procurement, and I am signing on behalf of my organisation. I understand that the Authority may reject my submission if there is a failure to provide a declaration or if I provide false or misleading information.

Organisation's name

Signed
(By Director of the Organisation or equivalent)

Name

Position

Date

Schedule 4

**STATEMENT OF REQUIREMENT FOR THE PROVISION OF AN ELECTRONIC QUALITY
MANAGEMENT SYSTEM FOR DEFENCE PATHOLOGY**

BACKGROUND

1. Defence Pathology provides for a deployable Pathology Service to Defence. Biomedical Scientists (BMS) are trained to provide a complex, multidisciplinary service using a diverse range of diagnostic equipment across all echelons of care. The Centre of Defence Pathology (CD Path) reinforces the deployed BMS with Operational and technical support by managing all documentation and procedures applicable to Defence Pathology under the direction of Defence Consultant Advisor (DCA) Pathology and Defence Specialist Advisor (DSA) Pathology. Blood components are provided by CD Path which operates as the MoD's Registered Blood Establishment. The delivery of these functions must comply with UK Guidelines to assure the safety of blood components and valid diagnostic pathology capability². The Authority has a requirement for an effective Quality Management System (QMS) to ensure compliance.

INTRODUCTION

2. This Statement of Requirement (SoR) details the Authority's requirement for an electronic Quality Management System (eQMS), which will be implemented at CD Path to ensure compliance with National Guidelines relating to assured blood management³. It will allow for significantly improved quality management of the deployable pathology capability and ensure that BMS have access to authorised and current versions of procedures.

REQUIREMENT

3. The eQMS is to be configured to allow for management of Blood transfusion and pathology services. It is to be implemented by the Quality Manager (RP Blood) at CD Path. CD path personnel will operate the eQMS under their direction. Deployed BMS must be able to access the system as required via a secure cloud through the internet from anywhere in the world. The system is to be standalone, it is not required to interact with the MoD systems.

4. The eQMS shall operate through web access to the secure server by application of licences giving appropriate levels of operability:

- a. A minimum of 5 password protected licences allowing full editorial access for CD Path Quality personnel or other BMS as directed by the Quality manager.
- b. A minimum of 10 password protected licences allowing for concurrent 'read only' access by deployed BMS.
- c. A facility to cancel accounts and create new accounts must also be provided by the Contractor within 2 working days of the request being made.

5. The eQMS must have the capability to allow for management of the following quality functions:

- a. **Document Control.** To ensure the ability to amend Pathology Procedures, protocols and forms such that authorised versions are circulated, and obsolete versions are archived. Change management and version control is an essential requirement of the standards which should be applied to Blood and Pathology practice.

² ISO 9001:2015 and 15189:2012 Respectively

³ The Blood Safety and Quality Regulations 2005

- b. **Audit capability.** Audit management is a core concept of effective Quality management. An audit schedule and record of audits must be managed via the eQMS. Any amendments to practice and procedure which derive from audit must be traceable.
- c. **Quality Improvement.** Records of Quality Improvements must be managed by the system and should cross reference audit, procedures, processes and related aspects which feature as part of the eQMS.
- d. It must have an online training function to allow newly appointed personnel to gain appropriate knowledge of the eQMS functions.
- e. Provide an English speaking online technical support to ensure 24/7 provision of services. Resolution requests must occur within a maximum of 48 hours.
- f. It must be configured to comply with national guidelines pertaining to safe blood transfusion practice (BSQR 8th edn.), whilst maintaining appropriate functionality such that it complies with the guidelines established by best practice for pathology services (ISO 15189).
- g. The eQMS system will allow for monitoring of non-conformities and adverse events.
- h. The eQMS should be configured to allow for monitoring of metrics applicable to quality management.
- i. The eQMS must be easily scale-able to allow for provision of additional licences as required to support a surge in activity.
- j. The system must be compatible with Microsoft Office packages and have the capability to allow for downloading of files to removable media as required. It must therefore be operable via Google Chrome and Internet Explorer.
- k. The system must be capable of managing up to 1,000 separate documents of up to 500mb each concurrently.
- l. Execution of scheduled maintenance is to be notified to the Authority a month in advance and where feasible is to be carried out between the hours of 0000 and 0500.
- m. Emergency maintenance is to be notified as soon as discovered and again when completed.

BUSINESS CONTINUITY

- 6. The Contractor must have and maintain a robust business continuity plan (with remedies) that can be implemented to manage/limit the impact of disruptions which would affect their ability to continue with normal service delivery. The business continuity plan shall, as a minimum, cover the following areas:
 - a. A secure system back-up which allows for continuous access to the software by end users in case of server or hardware failure.
 - b. Maintaining one backup of the Authority data at the Contractor's designated hosting centre, for an orderly and timely recovery so such data in the event that the Services

may be interrupted. The Contractor shall maintain a backup of Authority data that can be recovered within 24 hours at any point in time.

CONTRACTOR'S RESPONSIBILITIES

7. The Contractor will:
 - a. Provide a year-round secure web-based system accessible via the eGS accounts to the internet.
 - b. Inform the authority least 7 calendar days before implementation of any upgrades which may impact upon service provision.
 - c. On completion and/or termination of the contract the Contractor is to provide the data held in the system to the Authority in a format that can be transferred without corruption or loss of integrity within 24 hours.

QUALITY STANDARDS

8. The Contractor is to be a minimum of ISO27001 (Information Security Management Systems) compliant.

AUTHORITY'S RESPONSIBILITIES

9. The Authority will:
 - a. Notify the Contractor of any amendments to the technical requirement which fit within the scope of the arrangement.
 - b. Review the requirement bi-annually to ensure compliance with the requirement.
 - c. Audit performance of the system to ensure document version control.
 - d. Audit the system to ensure conformance with applicable quality standards.

CONFIDENTIALITY

10. The Contractor shall be responsible for the storage and safekeeping of electronic versions of CD Path documentation in accord with appropriate guidelines. It is not envisaged that patient identifiable data or other records relating to individual Service Persons are to be managed via the eQMS.

11. In the course of their responsibilities, the Contractor and/or their employees should not be privy to any personal information. The Contractor shall ensure that all personnel employed in connection with this contract adhere to the Data Protection Act 2018 and General Data Protection Regulations (2018).

PERFORMANCE/QUALITY INDICATORS

12. Key Performance Indicators (KPIs) are listed at Annex A.

CONTRACT MONITORING

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13. A Contract Review Meeting will be held on a quarterly basis between the Contractor and the Authority. The location of these meetings will be agreed by both parties; where appropriate/available, video conferencing may be utilised for these purposes. The meetings will be chaired by the Authority's representative (usually the DO) and will run to an agreed standing agenda that will include the following items:

- a. DO update/matters (Authority).
- b. Activity and Performance Review (Contractor).

14. Meetings will be "minuted" and digital recording may be utilised to assist in production of minutes; the Contractor will be asked to support the Authority in this task. The Contractor will provide all relevant information at least 2 weeks in advance of the contract review meeting to allow for onward distribution to relevant parties. Any further information that adds value and clarity to the delivery of the Service can be included at the discretion of the Contractor.

COMPLAINTS

15. The Contractor shall operate an unambiguous written procedure for handling complaints from the Authority about the service provided under this contract.

16. All complaints made by the Authority to the Contractor shall be acknowledged in writing within 3 working days by the Contractor.

17. The Contractor shall keep a full written record of the nature of each complaint and details of the action taken as a result of the complaint.

18. The Contractor shall use all reasonable endeavours to ensure that all complaints are resolved within 15 working days of the complaint being notified to the Contractor, unless the nature of the complaint requires additional investigation or action by a Professional and Regulatory Body (the RCGP), or other government organisations in which case the Contractor shall use all reasonable endeavours to ensure that the complaint is resolved as soon as possible thereafter.

19. The details of how the complaint has been resolved is to be notified to the Authority in writing within 7 working days thereafter and the Contractor will, on request from the Authority at any time, provide the Authority with an update as to the progress of the resolution of the complaint.

FINANCE REPORTING

20. Data is agreed between the Authority and the Contractor and this will form the foundation of an invoice. The only persons that can approve the invoice for payment will be the DO. These persons will be available during normal working hours 0800 – 1700 hours Mon – Fri.

21. The Authority does not approve any form of pre-payment; all invoices are to be submitted for services agreed as completed. The Contractor shall specify on the invoice:

- a. CD Path eQMS D1889A
- b. VAT
- c. Total

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CYBER SECURITY

22. The Authority has a duty to protect itself from Cyber threats and now we extend this to Suppliers we engage with. As an extension of the Government's Cyber Essentials Scheme the Authority, working together with Industry and other Government Departments, have developed a more robust Cyber Security Model, under the umbrella of the Defence Cyber Protection Partnership (DCPP). All prime contractors must have the cyber security controls specified in DEF Stan 05-138 (Cyber Security for Defence Suppliers), as appropriate to the cyber risk level specified in the contract.

23. The Authority has determined the level of risk as **Very Low** (Reference: **[Redacted]**) as defined in DEF Stan 05-138. To do business with the MOD you must have the cyber security controls required as shown above.

Annex:

A. Key Performance Indicators

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Annex A

KEY PERFORMANCE INDICATORS

PERFORMANCE INDICATOR	PARAGRAPH NO	ACTION	OUTCOME	MEASURE BY WHOM	REVIEWED
Uninterrupted Access to the eQMS system.	7b	Pre-agreed system upgrades advised to CD Path	100% within 7 calendar days before implementation	Contractor	Reviewed at Bi-Annual review meetings
	5l	Overall uptime of server including downtime for system upgrades Any downtimes to be no greater than 24 hours in length. Where scheduled, maintenance is required this is undertaken between the hours of 0000 and 0500h	99% total uptime throughout contract, 100% of any downtime less than 24 hours in length	Contractor	Manual recording of downtimes by Authority and reviewed at Bi-Annual review meetings
User Support	5e	Timely response and resolution to technical support enquiries	100% within 48 hrs	Contractor	Ad-Hoc Sample checks to be made by Authority and reviewed at Bi-Annual review meetings

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DEFFORM 111

Appendix - Addresses and Other Information

1. Commercial Officer

Name: Lynn Wallace

Address: DMS Whittington, Lichfield. WS14 9PY

Email: lynn.wallace110@mod.gov.uk ☎☎

2. Project Manager, Equipment Support Manager or PT Leader (from whom technical information is available)

Name: [Redacted]

Address Centre of Defence Pathology | Royal Centre for Defence Medicine (Operational) | Joint Hospital Group | ICT Building, Birmingham Research Park, Vincent drive, BIRMINGHAM. B15 2SQ

Email: [Redacted]☎☎ [Redacted]

3. Packaging Design Authority Organisation & point of contact:

N/A

(Where no address is shown please contact the Project Team in Box 2)

☎☎ N/A

4. (a) Supply / Support Management Branch or Order Manager:

Branch/Name: N/A

☎☎ N/A

(b) U.I.N. N/A

5. Drawings/Specifications are available from N/A

6. Intentionally Blank

7. Quality Assurance Representative: Dana Willis

Commercial staff are reminded that all Quality Assurance requirements should be listed under the General Contract Conditions.

AQAPS and **DEF STANs** are available from UK Defence Standardization, for access to the documents and details of the helpdesk visit <http://dstan.gateway.isg-r.r.mil.uk/index.html> [intranet] or <https://www.dstan.mod.uk/> [extranet, registration needed].

8. Public Accounting Authority

1. Returns under DEFCON 694 (or SC equivalent) should be sent to DBS Finance ADMT – Assets In

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Industry 1, Level 4 Piccadilly Gate, Store Street, Manchester, M1 2WD

☎☎ 44 (0) 161 233 5397

2. For all other enquiries contact DES Fin FA-AMET Policy, Level 4 Piccadilly Gate, Store Street, Manchester, M1 2WD

☎☎ 44 (0) 161 233 5394

9. Consignment Instructions The items are to be consigned as follows: N/A

10. Transport. The appropriate Ministry of Defence Transport Offices are:

A. DSCOM, DE&S, DSCOM, MoD Abbey Wood, Cedar 3c, Mail Point 3351, BRISTOL BS34 8JH

Air Freight Centre

IMPORTS ☎☎ 030 679 81113 / 81114 Fax 0117 913 8943

EXPORTS ☎☎ 030 679 81113 / 81114 Fax 0117 913 8943

Surface Freight Centre

IMPORTS ☎☎ 030 679 81129 / 81133 / 81138 Fax 0117 913 8946

EXPORTS ☎☎ 030 679 81129 / 81133 / 81138 Fax 0117 913 8946

B.JSCS

JSCS Helpdesk No. 01869 256052 (select option 2, then option 3)

JSCS Fax No. 01869 256837

Users requiring an account to use the MOD Freight Collection Service should contact UKStratCom-DefSp-RAMP@mod.gov.uk in the first instance.

11. The Invoice Paying Authority

Ministry of Defence, DBS Finance, Walker House, Exchange Flags Liverpool, L2 3YL

☎☎ 0151-242-2000 Fax: 0151-242-2809

Website is: <https://www.gov.uk/government/organisations/ministry-of-defence/about/procurement#invoice-processing>

12. Forms and Documentation are available through *:

Ministry of Defence, Forms and Pubs Commodity Management PO Box 2, Building C16, C Site, Lower Arncott, Bicester, OX25 1LP (Tel. 01869 256197 Fax: 01869 256824)

Applications via fax or email: Leidos-FormsPublications@teamleidos.mod.uk

*** NOTE**

1. Many **DEFCONs** and **DEFFORMs** can be obtained from the MOD Internet Site: <https://www.aof.mod.uk/aofcontent/tactical/toolkit/index.htm>

2. If the required forms or documentation are not available on the MOD Internet site requests should be submitted through the Commercial Officer named in Section 1.

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