



Chemical Biological Radiological Nuclear (CBRN) Delivery Team

Contract No: CBRN/00276

For: Provision of an Auto-Injector Partner

Between Secretary of State for Defence of the United Kingdom of Great Britain and Northern Ireland	And
Team Name and Address: Chemical Biological Radiological Nuclear (CBRN) Delivery Team Yew 3A, #1342 MOD Abbey Wood Bristol BS34 8JH	Contractor Name and Address: Chemprotect.SK s.r.o. Stanicna 1119/8 Turcianske Teplice Slovakia 03901
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Standardised Contracting Terms**GENERAL CONDITIONS****1. General**

- a. The defined terms in the Contract shall be as set out in Schedule 1.
- b. The Contractor shall comply with all applicable Legislation, whether specifically referenced in this Contract or not.
- c. The Contractor warrants and represents, that:
 - (1) it has the full capacity and authority to enter into, and to exercise its rights and perform its obligations under, the Contract;
 - (2) from the Effective Date of Contract and for so long as the Contract remains in force it shall give the Authority Notice of any litigation, arbitration (unless expressly prohibited from doing so in accordance with the terms of the arbitration), administrative or adjudication or mediation proceedings before any court, tribunal, arbitrator, administrator or adjudicator or mediator or relevant authority against itself or a Subcontractor which would adversely affect the Contractor's ability to perform its obligations under the Contract;
 - (3) as at the Effective Date of Contract no proceedings or other steps have been taken and not discharged (nor, to the best of the knowledge of the Contractor, threatened) for its winding-up or dissolution or for the appointment of a receiver, administrative receiver, administrator, liquidator, trustee or similar officer in relation to any of its assets or revenues;
 - (4) for so long as the Contract remains in force it shall give the Authority Notice of any proceedings or other steps that have been taken but not discharged (nor to the best of the knowledge of the Contractor, threatened) for its winding-up or dissolution or for the appointment of a receiver, administrator, liquidator, trustee or similar officer in relation to any of its assets or revenues.
- d. Unless the context otherwise requires:
 - (1) The singular includes the plural and vice versa, and the masculine includes the feminine and vice versa.
 - (2) The words "include", "includes", "including" and "included" are to be construed as if they were immediately followed by the words "without limitation", except where explicitly stated otherwise.
 - (3) The expression "person" means any individual, firm, body corporate, unincorporated association or partnership, government, state or agency of a state or joint venture.
 - (4) References to any statute, enactment, order, regulation, or other similar instrument shall be construed as a reference to the statute, enactment, order, regulation, or instrument as amended, supplemented, replaced or consolidated by any subsequent statute, enactment, order, regulation, or instrument.
 - (5) The heading to any Contract provision shall not affect the interpretation of that provision.
 - (6) Any decision, act or thing which the Authority is required or authorised to take or do under the Contract may be taken or done only by the person (or their nominated deputy) authorised in Schedule 3 (Contract Data Sheet) to take or do that decision, act, or thing on behalf of the Authority.
 - (7) Unless excluded within the Conditions of the Contract or required by law, references to submission of documents in writing shall include electronic submission.

2. Duration of Contract

This Contract comes into effect on the Effective Date of Contract and will expire automatically on the date identified in Schedule 3 (Contract Data Sheet) unless it is otherwise terminated in accordance with the provisions of the Contract, or otherwise lawfully terminated.

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This Contract constitutes the entire agreement between the Parties relating to the subject matter of the Contract. The Contract supersedes, and neither Party has relied upon, any prior negotiations, representations and undertakings, whether written or oral, except that this condition shall not exclude liability in respect of any fraudulent misrepresentation.

4. Governing Law

- a. Subject to clause 4.d, the Contract shall be considered as a contract made in England and subject to English Law.
- b. Subject to clause 4.d and 40 (Dispute Resolution) and without prejudice to the dispute resolution process set out therein, each Party submits and agrees to the exclusive jurisdiction of the Courts of England to resolve, and the laws of England to govern, any actions proceedings, controversy or claim of whatever nature arising out of or relating to the Contract or breach thereof.
- c. Subject to clause 4.d any dispute arising out of or in connection with the Contract shall be determined within the English jurisdiction and to the exclusion of all other jurisdictions save that other jurisdictions may apply solely for the purpose of giving effect to this condition 4 and for the enforcement of any judgment, order or award given under English jurisdiction.
- d. If the Parties agree pursuant to the Contract that Scots Law should apply then the following amendments shall apply to the Contract:

(59) Clause 4.a, 4.b and 4.c shall be amended to read:

“a. The Contract shall be considered as a contract made in Scotland and subject to Scots Law.

b. Subject to condition 40 (Dispute Resolution) and without prejudice to the dispute resolution process set out therein, each Party submits and agrees to the exclusive jurisdiction of the Courts of Scotland to resolve, and the laws of Scotland to govern, any actions, proceedings, controversy or claim of whatever nature arising out of or relating to the Contract or breach thereof.

c. Any dispute arising out of or in connection with the Contract shall be determined within the Scottish jurisdiction and to the exclusion of all other jurisdictions save that other jurisdictions may apply solely for the purpose of giving effect to this condition 4 and for the enforcement of any judgment, order or award given under Scottish jurisdiction.” Clause 40.b shall be amended to read:

“In the event that the dispute or claim is not resolved pursuant to clause 40.a the dispute shall be referred to arbitration. Unless otherwise agreed in writing by the Parties, the arbitration and this clause 40.b shall be governed by the Arbitration (Scotland) Act 2010. The seat of the arbitration shall be Scotland. For the avoidance of doubt, for the purpose of arbitration the tribunal shall have the power to make provisional awards pursuant to Rule 53 of the Scottish Arbitration Rules, as set out in Schedule 1 to the Arbitration (Scotland) Act 2010.”

- e. Each Party warrants to each other that entry into the Contract does not, and the performance of the Contract will not, in any way violate or conflict with any provision of law, statute, rule, regulation, judgement, writ, injunction, decree or order applicable to it. Each Party also warrants that the Contract does not conflict with or result in a breach or termination of any provision of, or constitute a default under, any mortgage, contract or other liability, charge or encumbrance upon any of its properties or other assets.
- f. Each Party agrees with each other Party that the provisions of this condition 4 shall survive any termination of the Contract for any reason whatsoever and shall remain fully enforceable as between the Parties notwithstanding such a termination.

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- g. Where the Contractor's place of business is not in England or Wales (or Scotland where the Parties agree pursuant to this Contract that Scots Law should apply), the Contractor irrevocably appoints the solicitors or other persons in England and Wales (or Scotland where the Parties agree pursuant to the Contract that Scots Law should apply) detailed in Schedule 3 (Contract Data Sheet) as its agents to accept on its behalf service of all process and other documents of whatever description to be served on the Contractor in connection with any litigation or arbitration within the English jurisdiction (or Scottish jurisdiction where the Parties agree pursuant to this Contract that Scots Law should apply) arising out of or relating to the Contract or any issue connected therewith.

5. Precedence

- a. If there is any inconsistency between the different provisions of the Contract the inconsistency shall be resolved according to the following descending order of precedence:
 - (1) Conditions 1 – 44 (and 45 – 47, if included in this Contract) of the Conditions of the Contract shall be given equal precedence with Schedule 1 (Definitions of Contract) and Schedule 3 (Contract Data Sheet);
 - (2) Schedule 2 (Schedule of Requirements) and Schedule 8 (Acceptance Procedure);
 - (3) the remaining Schedules; and
 - (4) any other documents expressly referred to in the Contract.
- b. If either Party becomes aware of any inconsistency within or between the documents referred to in clause 5.a such Party shall notify the other Party forthwith and the Parties will seek to resolve that inconsistency on the basis of the order of precedence set out in clause 5.a. Where the Parties fail to reach agreement, and if either Party considers the inconsistency to be material to its rights and obligations under the Contract, then the matter will be referred to the dispute resolution procedure in accordance with condition 40 (Dispute Resolution).

6. Amendments to Contract

- a. Except as provided in condition 31 all amendments to this Contract shall be serially numbered, in writing, issued only by the Authority's Representative (Commercial), and agreed by both Parties.
- b. Where the Authority or the Contractor wishes to introduce a change which is not minor or which is likely to involve a change to the Contract Price, the provisions of Schedule 4 (Contract Change Control Procedure) shall apply. The Contractor shall not carry out any work until any necessary change to the Contract Price has been agreed and a written amendment in accordance with clause 6.a above has been issued.

7. Variations to Specification

- a. The Authority's Representative may, by Notice (following consultation with the Contractor as necessary), alter the Specification as from a date agreed by both Parties and to the extent specified by the Authority, provided that any such variations shall be limited to the extent that they do not alter the fit, form, function or characteristics of the Contractor Deliverables to be supplied under the Contract. The Contractor shall ensure that the Contractor Deliverables take account of any such variations. Such variations shall not require formal amendment of the Contract in accordance with the process set out in condition 6 (Amendments to Contract) and shall be implemented upon receipt, or at the date specified in the Authority's Notice, unless otherwise specified.
- b. Any variations that cause a change to:
 - (1) fit, form, function or characteristics of the Contractor Deliverables;

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- (2) the cost;
- (3) Delivery Dates;
- (4) the period required for the production or completion; or
- (5) other work caused by the alteration, shall be the subject to condition 6 (Amendments to Contract). Each amendment under condition 6 shall be classed as a formal change.

8. Authority Representatives

- a. Any reference to the Authority in respect of:
 - (1) the giving of consent;
 - (2) the delivering of any Notices; or
 - (3) the doing of any other thing that may reasonably be undertaken by an individual acting on behalf of the Authority, shall be deemed to be references to the Authority's Representatives in accordance with this condition 8.
- b. The Authority's Representatives detailed in Schedule 3 (Contract Data Sheet) (or their nominated deputy) shall have full authority to act on behalf of the Authority for all purposes of the Contract. Unless notified in writing before such act or instruction, the Contractor shall be entitled to treat any act of the Authority's Representatives which is authorised by the Contract as being expressly authorised by the Authority and the Contractor shall not be required to determine whether authority has in fact been given.
- c. In the event of any change to the identity of the Authority's Representatives, the Authority shall provide written confirmation to the Contractor, and shall update Schedule 3 (Contract Data Sheet) in accordance with condition 6 (Amendments to Contract).

9. Severability

- 59. If any provision of the Contract is held to be invalid, illegal or unenforceable to any extent then:
 - (1) such provision shall (to the extent that it is invalid, illegal or unenforceable) be given no effect and shall be deemed not to be included in the Contract but without invalidating any of the remaining provisions of the Contract; and
 - (2) the Parties shall use all reasonable endeavours to replace the invalid, illegal or unenforceable provision by a valid, legal and enforceable substitute provision the effect of which is as close as possible to the intended effect of the invalid, illegal or unenforceable provision.

10. Waiver

- a. No act or omission of either Party shall by itself amount to a waiver of any right or remedy unless expressly stated by that Party in writing. In particular, no reasonable delay in exercising any right or remedy shall by itself constitute a waiver of that right or remedy.
- b. No waiver in respect of any right or remedy shall operate as a waiver in respect of any other right or remedy.

11. Assignment of Contract

Neither Party shall be entitled to assign the Contract (or any part thereof) without the prior written consent of the other Party.

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Notwithstanding anything to the contrary elsewhere in the Contract, no right is granted to any person who is not a Party to the Contract to enforce any term of the Contract in its own right and the Parties to the Contract declare that they have no intention to grant any such right.

13. Transparency

- a. Subject to clause 13.b but notwithstanding condition 14 (Disclosure of Information), 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 Information.
- b. Before publishing the Transparency Information to the general public in accordance with clause 13.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, and any Information which has been acknowledged by the Authority at Schedule 5 – Contractor's Commercially Sensitive Information.
- c. The Authority may consult with the Contractor before redacting any Information from the Transparency Information in accordance with clause 13.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 condition 13 shall affect the Contractor's rights at law.

14. Disclosure of Information

- a. Subject to clauses 14.d, 14.e, 14.h and condition 13 each Party:
 - (1) shall treat in confidence all Information it receives from the other;
 - (2) shall not disclose any of that Information to any third party without the prior written consent of the other Party, which consent shall not unreasonably be withheld, except that the Contractor may disclose Information in confidence, without prior consent, to such persons and to such extent as may be necessary for the performance of the Contract;
 - (3) shall not use any of that Information otherwise than for the purpose of the Contract; and
 - (4) shall not copy any of that Information except to the extent necessary for the purpose of exercising its rights of use and disclosure under the Contract.
- b. The Contractor shall take all reasonable precautions necessary to ensure that all Information disclosed to the Contractor by or on behalf of the Authority under or in connection with the Contract:
 - (1) is disclosed to its employees and Subcontractors, only to the extent necessary for the performance of the Contract; and
 - (2) is treated in confidence by them and not disclosed except with the prior written consent of the Authority or used otherwise than for the purpose of performing work or having work performed for the Authority under the Contract or any subcontract.
- c. The Contractor shall ensure that its employees are aware of the Contractor's arrangements for discharging the obligations at clauses 14.a and 14.b before receiving Information and shall take such steps as may be reasonably practical to enforce such arrangements.
- d. Clauses 14.a and 14.b shall not apply to any Information to the extent that either Party:

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- (1) exercises rights of use or disclosure granted otherwise than in consequence of, or under, the Contract;
- (2) has the right to use or disclose the Information in accordance with other Conditions of the Contract; or
- (3) can show:
 - (a) that the Information was or has become published or publicly available for use otherwise than in breach of any provision of the Contract or any other agreement between the Parties;
 - (b) that the Information was already known to it (without restrictions on disclosure or use) prior to receiving the Information under or in connection with the Contract;
 - (c) that the Information was received without restriction on further disclosure from a third party which lawfully acquired the Information without any restriction on disclosure; or
 - (d) from its records that the same Information was derived independently of that received under or in connection with the Contract;

provided that the relationship to any other Information is not revealed.

- e. Neither Party shall be in breach of this condition where it can show that any disclosure of Information was made solely and to the extent necessary to comply with a statutory, judicial or parliamentary obligation. Where such a disclosure is made, the Party making the disclosure shall ensure that the recipient of the Information is made aware of and asked to respect its confidentiality. Such disclosure shall in no way diminish the obligations of the Parties under this condition.
- f. The Authority may disclose the Information:
 - (1) on a confidential basis to any Central Government Body for any proper purpose of the Authority or of the relevant Central Government Body, which shall include: disclosure to the Cabinet Office and/or HM Treasury for the purpose of ensuring effective cross Government procurement processes, including value for money and related purposes;
 - (2) to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirement;
 - (3) to the extent that the Authority (acting reasonably) deems disclosure necessary or appropriate in the course of carrying out its public functions;
 - (4) on a confidential basis to a professional adviser, consultant or other person engaged by any of the entities defined in Schedule 1 (including benchmarking organisations) for any purpose relating to or connected with this Contract;
 - (5) on a confidential basis for the purpose of the exercise of its rights under the Contract; or
 - (6) on a confidential basis to a proposed body in connection with any assignment, novation or disposal of any of its rights, obligations or liabilities under the Contract;

and for the purposes of the foregoing, references to disclosure on a confidential basis shall mean disclosure subject to a confidentiality agreement or arrangement containing terms no less stringent than those placed on the Authority under this condition.
- g. Before sharing any Information in accordance with clause 14.f, the Authority may redact the Information. Any decision to redact Information made by the Authority shall be final.
- h. The Authority shall not be in breach of the Contract where disclosure of Information is made solely and to the extent necessary to comply with the Freedom of Information Act 2000 (the "Act") or the Environmental Information Regulations 2004 (the "Regulations"). To the extent permitted by the time for compliance under the Act or the Regulations, the Authority shall consult the Contractor where the Authority is considering the disclosure of Information under the Act or the Regulations and, in any event, shall provide prior notification to the Contractor of any decision to disclose the Information. The Contractor acknowledges and accepts that its representations on disclosure during consultation may not be determinative and that the decision whether to disclose Information in order to comply with the Act or the Regulations is a matter in which the Authority shall exercise its own discretion, subject always to the provisions of the Act or the Regulations.

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- i. Nothing in this condition shall affect the Parties' obligations of confidentiality where Information is disclosed orally in confidence.

15. Publicity and Communications with the Media

The Contractor shall not and shall ensure that any employee or Subcontractor shall not communicate with representatives of the press, television, radio or other media on any matter concerning the Contract unless the Authority has given its prior written consent.

16. Change of Control of Contractor

- a. The Contractor shall notify the Representative of the Authority at the address given in clause 16.b, as soon as practicable, in writing of any intended, planned or actual change in control of the Contractor. The Contractor shall not be required to submit any notice which is unlawful or is in breach of either any pre-existing non-disclosure agreement or any regulations governing the conduct of the Contractor in the UK or other jurisdictions where the Contractor may be subject to legal sanction arising from issuing such a notice.
- b. Each notice of change of control shall be taken to apply to all contracts with the Authority. Notices shall be submitted to: Mergers & Acquisitions Section

Strategic Supplier Management Team
Spruce 3b # 1301
MOD Abbey Wood,
Bristol, BS34 8JH

The Representative of the Authority shall consider the notice of change of control and advise the Contractor in writing of any concerns the Authority may have. Such concerns may include but are not limited to potential threats to national security, the ability of the Authority to comply with its statutory obligations or matters covered by the declarations made by the Contractor prior to Contract Award.

- c. The Authority may terminate the Contract by giving written notice to the Contractor within six months of the Authority being notified in accordance with clause 16.a. The Authority shall act reasonably in exercising its right of termination under this condition.
- d. If the Authority exercises its right to terminate in accordance with clause 16.c the Contractor shall be entitled to request the Authority to consider making a payment representing any commitments, liabilities or expenditure incurred by the Contractor in connection with the Contract up to the point of termination. Such commitments, liabilities or expenditure shall be reasonably and properly chargeable by the Contractor, and shall otherwise represent an unavoidable loss by the Contractor by reason of the termination of the Contract. Any payment under this clause 16.d must be fully supported by documentary evidence. The decision whether to make such a payment shall be at the Authority's sole discretion.
- e. Notification by the Contractor of any intended, planned or actual change of control shall not prejudice the existing rights of the Authority or the Contractor under the Contract nor create or imply any rights of either the Contractor or the Authority additional to the Authority's rights set out in this condition.

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The Contractor shall in all its operations to perform the Contract, adopt a sound proactive environmental approach that identifies, considers, and where possible, mitigates the environmental impacts of its supply chain. The Contractor shall provide evidence of so doing to the Authority on demand.

18. Contractor's Records

- a. The Contractor and its sub-contractors shall maintain all records specified in and connected with the Contract (expressly or otherwise) and make them available to the Authority when requested on reasonable notice.
- b. The Contractor and its sub-contractors shall also permit access to relevant records that relate to the contractual obligations to supply goods or services under the Contract, held by or controlled by them and reasonably required by the Comptroller and Auditor General, their staff and any appointed representative of the National Audit Office, and provide such explanations and information as reasonably necessary for the following purposes:
 - (1) to enable the National Audit Office to carry out the Authority's statutory audits and to examine and/or certify the Authority's annual and interim report and accounts; and
 - (2) to enable the National Audit Office to carry out an examination pursuant to Part II of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority has used its resources.
- c. With regard to the records made available to the Authority under clause 1 of this Condition, and subject to the provisions of SC2 conditions of contract clause 14, the Contractor shall permit records to be examined and if necessary copied, by the Authority, or Representative of the Authority, as the Authority may require.
- d. Unless the Contract specifies otherwise the records referred to in this Condition shall be retained for a period of at least 6 years from:
 - (1) the end of the Contract term;
 - (2) termination of the Contract; or
 - (3) the final payment whichever occurs latest.

19. 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 Schedule 3 (Contract Data Sheet);
 - (4) marked with the number of the Contract; and
 - (5) delivered by hand, prepaid post (or airmail), facsimile transmission or, if agreed in Schedule 3 (Contract Data Sheet), 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 a Business Day in the place of receipt, and otherwise on the first Business Day in the place of receipt 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

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- (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.

20. Progress Monitoring, Meetings and Reports

- a. The Contractor shall attend progress meetings at the frequency or times (if any) specified in Schedule 3 (Contract Data Sheet) and shall ensure that its Contractor's Representatives are suitably qualified to attend such meetings.
- b. The Contractor shall submit progress reports to the Authority's Representatives at the times and in the format (if any) specified in Schedule 3 (Contract Data Sheet). The reports shall detail as a minimum:
 - (1) performance/Delivery of the Contractor Deliverables;
 - (2) risks and opportunities;
 - (3) any other information specified in Schedule 3 (Contract Data Sheet); and
 - (4) any other information reasonably requested by the Authority.

SUPPLY OF CONTRACTOR DELIVERABLES**21. Supply of Contractor Deliverables and Quality Assurance**

- a. The Contractor shall provide the Contractor Deliverables to the Authority, in accordance with the Schedule of Requirements and the Specification, and shall allocate sufficient resource to the provision of the Contractor Deliverables to enable it to comply with this obligation.
- b. The Contractor shall:
 - (1) comply with any applicable quality assurance requirements specified in Schedule 3 (Contract Data Sheet) in providing the Contractor Deliverables; and
 - (2) discharge its obligations under the Contract with all due skill, care, diligence and operating practice by appropriately experienced, qualified and trained personnel.
- c. The provisions of clause 21.b. shall survive any performance, acceptance or payment pursuant to the Contract and shall extend to any remedial services provided by the Contractor.
- d. The Contractor shall:
 - (1) observe, and ensure that the Contractor's Team observe, all health and safety rules and regulations and any other security requirements that apply at any of the Authority's premises;
 - (2) notify the Authority as soon as it becomes aware of any health and safety hazards or issues which arise in relation to the Contractor Deliverables; and
 - (3) before the date on which the Contractor Deliverables are to start, obtain, and at all times maintain, all necessary licences and consents in relation to the Contractor Deliverables.

22. Marking of Contractor Deliverables

- a. Each Contractor Deliverable shall be marked in accordance with the requirements specified in Schedule 3 (Contract Data Sheet), 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 specified in Schedule 2 (Schedule of Requirements).

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- b. Any marking method used shall not have a detrimental effect on the strength, serviceability or 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 23 (Packaging and Labelling (excluding Contractor Deliverables containing Munitions)).

23. Packaging and Labelling (excluding Contractor Deliverables containing Munitions)

- a. Packaging responsibilities are as follows:
 - (1) The Contractor shall be responsible for providing Packaging which fully complies with the requirements of the Contract.
 - (2) The Authority shall indicate in the Contract the standard or level of Packaging required for each Contractor Deliverable, including the PPQ. If a standard or level of Packaging (including the PPQ) is not indicated in the Contract, the Contractor shall request such instructions from the Authority before proceeding further.
 - (3) The Contractor shall ensure all relevant information necessary for the effective performance of the Contract is made available to all subcontractors.
 - (4) Where the Contractor or any of their subcontractors have concerns relating to the appropriateness of the Packaging design and or MPL prior to manufacture or supply of the Contractor Deliverables they shall use DEFFORM 129B to feedback these concerns to the Contractor or Authority, as appropriate.
- b. The Contractor shall supply Commercial Packaging meeting the standards and requirements of Def Stan 81-041 (Part 1). In addition the following requirements apply:
 - (1) The Contractor shall provide Packaging which:
 - (a) will ensure that each Contractor Deliverable may be transported and delivered to the consignee named in the Contract in an undamaged and serviceable condition; and
 - (b) is labelled to enable the contents to be identified without need to breach the package; and
 - (c) is compliant with statutory requirements and this Condition.
 - (2) The Packaging used by the Contractor to supply identical or similar Contractor Deliverables to commercial customers or to the general public (i.e. point of sale packaging) will be acceptable, provided that it complies with the following criteria:
 - (a) reference in the Contract to a PPQ means the quantity of a Contractor Deliverable to be contained in an individual package, which has been selected as being the most suitable for issue(s) to the ultimate user;
 - (b) Robust Contractor Deliverables, which by their nature require minimal or no packaging for commercial deliveries, shall be regarded as "PPQ packages" and shall be marked in accordance with Clauses 23.i to 23.l. References to "PPQ packages" in subsequent text shall be taken to include Robust Contractor Deliverables; and
 - (c) for ease of handling, transportation and delivery, packages which contain identical Contractor Deliverables may be bulked and overpacked, in accordance with clauses 23.i to 23.k.
- c. The Contractor shall ascertain whether the Contractor Deliverables being supplied are, or contain, Dangerous Goods, and shall supply the Dangerous Goods in accordance with:
 - (1) The Health and Safety At Work Act 1974 (as amended);
 - (2) The Classification Hazard Information and Packaging for Supply Regulations (CHIP4) 2009 (as amended);

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- (3) The REACH Regulations 2007 (as amended); and
 - (4) The Classification, Labelling and Packaging Regulations (CLP) 2009 (as amended).
- d. The Contractor shall package the Dangerous Goods as limited quantities, excepted quantities or similar derogations, for UK or worldwide shipment by all modes of transport in accordance with the regulations relating to the Dangerous Goods and:
- (1) The Safety Of Lives At Sea Regulations (SOLAS) 1974 (as amended); and
 - (2) The Air Navigation Order.
- e. As soon as possible, and in any event no later than one month before delivery is due, the Contractor shall provide a Safety Data Sheet in respect of each Dangerous Good in accordance with the REACH Regulations 2007 (as amended) and the Health and Safety At Work Act 1974 (as amended) and in accordance with condition 24 (Supply of Hazardous Materials or Substances in Contractor Deliverables).
- f. The Contractor shall comply with the requirements for the design of MLP which include clauses 23.f and 23.g as follows:
- (1) Where there is a requirement to design UK or NATO MLP, the work shall be undertaken by an MPAS registered organisation, or one that although non-registered is able to demonstrate to the Authority that its quality systems and military package design expertise are of an equivalent standard.
 - (a) The MPAS certification (for individual designers) and registration (for organisations) scheme details are available from: DES SEOC SCP-SptEng-Pkg

MOD Abbey Wood
Bristol, BS34 8JH
Tel. +44(0)30679-35353
DESSEOCSCP-SptEng-PKg@mod.uk
 - (b) The MPAS Documentation is also available on the Dstan website.
 - (2) MLP shall be designed to comply with the relevant requirements of Def Stan 81-041, and be capable of meeting the appropriate test requirements of Def Stan 81-041 (Part 3). Packaging designs shall be prepared on a SPIS, in accordance with Def Stan 81-041 (Part 4).
 - (3) The Contractor shall ensure a search of the SPIS index (the 'SPIN') is carried out to establish the SPIS status of each requirement (using DEFFORM 129a 'Application for Packaging Designs or their Status').
 - (4) New designs shall not be made where there is an existing usable SPIS, or one that may be easily modified.
 - (5) Where there is a usable SFS, it shall be used in place of a SPIS design unless otherwise stated by the Contract. When an SFS is used or replaces a SPIS design, the Contractor shall upload this information on to SPIN in Adobe PDF.
 - (6) All SPIS, new or modified (and associated documentation), shall, on completion, be uploaded by the Contractor on to SPIN. The format shall be Adobe PDF.
 - (7) Where it is necessary to use an existing SPIS design, the Contractor shall ensure the Packaging manufacturer is a registered organisation in accordance with clause 23.f(1) above, or if un-registered, is compliant with MPAS ANNEX A Supplement (Code) M. The Contractor shall ensure, as far as possible, that the SPIS is up to date.
 - (8) The documents supplied under clause 23.f(6) shall be considered as a contract data requirement and be subject to the terms of DEFCON 15 and DEFCON 21.
- g. Unless otherwise stated in the Contract, one of the following procedures for the production of new or modified SPIS designs shall be applied:
- (1) If the Contractor or their subcontractor is the PDA they shall:
 - (a) On receipt of instructions received from the Authority's representative nominated in Box 2 of DEFFORM 111 at Annex A to Schedule 3 (Contract Data Sheet), prepare the required package design in accordance with clause 23.f.

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- (b) Where the Contractor or their subcontractor is registered they shall, on completion of any design work, provide the Authority with the following documents electronically:
 - i. a list of all SPIS which have been prepared or revised against the Contract; and
 - ii. a copy of all new / revised SPIS, complete with all continuation sheets and associated drawings, where applicable, to be uploaded onto SPIN.
 - (c) Where the PDA is not a registered organisation, then they shall obtain approval for their design from a registered organisation before proceeding, then follow clause 23.g(1)(b).
 - (2) Where the Contractor or their subcontractor is not the PDA and is un-registered, they shall not produce, modify, or update SPIS designs. They shall obtain current SPIS design(s) from the Authority or a registered organisation before proceeding with manufacture of Packaging. To allow designs to be provided in ample time, they should apply for SPIS designs as soon as practicable.
 - (3) Where the Contractor or their subcontractor is un-registered and has been given authority to produce, modify, and update SPIS designs by the Contract, he shall obtain approval for their design from a registered organisation using DEFFORM 129a before proceeding, then follow clause 23.g(1)(b).
 - (4) Where the Contractor or their subcontractor is not a PDA but is registered, he shall follow clauses 23.g(1)(a) and 23.g(1)(b).
- h. If special jigs, tooling etc., are required for the production of MLP, the Contractor shall obtain written approval from the Commercial Officer before providing them. Any approval given will be subject to the terms of DEFCON 23 (SC2) or equivalent condition, as appropriate.
- i. In addition to any marking required by international or national legislation or regulations, the following package labelling and marking requirements apply:
- (1) If the Contract specifies UK or NATO MPL, labelling and marking of the packages shall be in accordance with Def Stan 81-041 (Part 6) and this Condition as follows:
 - (a) Labels giving the mass of the package, in kilograms, shall be placed such that they may be clearly seen when the items are stacked during storage.
 - (b) Each consignment package shall be marked with details as follows:
 - i. name and address of consignor; ii. Name and address of consignee (as stated in the Contract or order); iii. Destination where it differs from the consignee's address, normally either:
 - (i). delivery destination / address; or
 - (ii). transit destination, where delivery address is a point for aggregation / disaggregation and / or onward shipment elsewhere, e.g. railway station, where that mode of transport is used;
 - iv. the unique order identifiers and the CP&F Delivery Label / Form which shall be prepared in accordance with DEFFORM 129J.
 - (i). If aggregated packages are used, their consignment marking and identification requirements are stated at clause 23.I.
 - (2) If the Contract specifies Commercial Packaging, an external surface of each PPQ package and each consignment package, if it contains identical PPQ packages, shall be marked, using details of the Contractor Deliverables as shown in the Contract schedule, to state the following:
 - (a) description of the Contractor Deliverable;
 - (b) the full thirteen digit NATO Stock Number (NSN);
 - (c) the PPQ;
 - (d) maker's part / catalogue, serial and / or batch number, as appropriate;
 - (e) the Contract and order number when applicable;
 - (f) the words "Trade Package" in bold lettering, marked in BLUE in respect of trade packages, and BLACK in respect of export trade packages;
 - (g) shelf life of item where applicable;

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- (h) for rubber items or items containing rubber, the quarter and year of vulcanisation or manufacture of the rubber product or component (marked in accordance with Def Stan 81-041);
 - (i) any statutory hazard markings and any handling markings, including the mass of any package which exceeds 3kg gross; and
 - (j) any additional markings specified in the Contract.
- j. Bar code marking shall be applied to the external surface of each consignment package and to each PPQ package contained therein. The default symbology shall be as specified in Def Stan 81-041 (Part 6). As a minimum the following information shall be marked on packages:
 - (1) the full 13-digit NSN;
 - (2) denomination of quantity (D of Q);
 - (3) actual quantity (quantity in package);
 - (4) manufacturer's serial number and / or batch number, if one has been allocated; and (5) the CP&F-generated unique order identifier.
- k. Requirements for positioning bar codes in relation to related text, as well as positioning on package etc., are defined in Def Stan 81-041 (Part 6). If size of the bar code does not allow a label to be directly attached, then a tag may be used. Any difficulties over size or positioning of barcode markings shall initially be referred to the organisation nominated in Box 3 of DEFFORM 111 at Annex A to Schedule 3 (Contract Data Sheet).
- l. The requirements for the consignment of aggregated packages are as follows:
 - (1) With the exception of packages containing Dangerous Goods, over-packing for delivery to the consignee shown in the Contract may be used by the consignor to aggregate a number of packages to different Packaging levels, provided that the package contains Contractor Deliverables of only one NSN or class group. Over-packing shall be in the cheapest commercial form consistent with ease of handling and protection of over-packed items.
 - (2) Two adjacent sides of the outer container shall be clearly marked to show the following:
 - (a) class group number;
 - (b) name and address of consignor;
 - (c) name and address of consignee (as stated on the Contract or Order); (d) destination if it differs from the consignee's address, normally either:
 - i. delivery destination / address; or
 - ii. transit destination, if the delivery address is a point of aggregation / disaggregation and / or onward shipment e.g. railway station, where that mode of transport is used;
 - (e) the CP&F-generated shipping label; and
 - (f) any statutory hazard markings and any handling markings.
- m. Authorisation of the Contractor to undertake Packaging design, or to use a packaging design, that was not part of the original requirement under the Contract, shall be considered as an alteration to the specification in accordance with condition 7 (Variations to Specification).
- n. The Contractor shall ensure that timber and wood-containing products supplied under the Contract comply with the provisions of condition 25 (Timber and Wood-Derived Products) and Annex I and Annex II of the International Standards for Phytosanitary Measures, "Guidelines for Regulating Wood Packaging Material in International Trade", Publication No 15 (ISPM 15).
- o. All Packaging shall meet the requirements of the Packaging (Essential Requirements) Regulations 2003 (as amended) where applicable.

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- p. In any design work the Contractor shall comply with the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (as amended) or equivalent legislation. Evidence of compliance shall be a contractor record in accordance with condition 18 (Contractor's Records).
- q. This Condition is concerned with the supply of Packaging suitable to protect and ease handling, transport and storage of specified items. Where there is a failure of suitable Packaging (a design failure), or Packaging fails and this is attributed to the Packaging supplier, then the supplier shall be liable for the cost of replacing the Packaging.
- r. Liability for other losses resulting from Packaging failure or resulting from damage to Packaging, (such as damage to the packaged item etc.), shall be specified elsewhere in the Contract.
- s. General requirements for service Packaging, including details of UK and NATO MLP and Commercial Packaging descriptions, are contained in Def Stan 81-041 (Part 1) "Packaging of Defence Materiel". Def Stans, NATO Standardisation Agreements (STANAGs), and further information are available from the Dstan internet site at: <https://www.dstan.mod.uk/>.
- t. Unless specifically stated otherwise in the invitation to tender or the Contract, reference to any standard including Def Stans or STANAGs in any invitation to tender or Contract document means the edition and all amendments extant at the date of such tender or Contract.
- u. In the event of conflict between the Contract and Def Stan 81-041, the Contract shall take precedence.

24. Supply of Hazardous Materials or Substances in Contractor Deliverables

- a. The Contractor shall provide to the Authority:
 - (1) for each hazardous material or substance supplied, a Safety Data Sheet (SDS) in accordance with the extant Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP) and / or the Classification, Labelling and Packaging (CLP) Regulation 1272/2008 (whichever is applicable), and
 - (2) for each Contractor Deliverable containing hazardous materials or substances, safety information as required by the Health and Safety at Work, etc Act 1974, at the time of supply.

Nothing in this Condition shall reduce or limit any statutory duty or legal obligation of the Authority or the Contractor.

- b. If the Contractor Deliverable contains hazardous materials or substances, or is a substance falling within the scope of the REACH Regulation (EC) No 1907/2006:
 - (1) the Contractor shall provide to the Authority an SDS for the substance in accordance with the Regulation. If the Contractor becomes aware of new information which may affect the risk management measures or new information on the hazard, the Contractor shall update the SDS and forward it to the Authority and to the address listed in clause 24.h below, and
 - (2) the Authority, if it becomes aware of new information regarding the hazardous properties of the substance, or any other information that might call into question the appropriateness of the risk management measures identified in the SDS supplied, shall report this information in writing to the Contractor.
- c. If the Contractor is required, under, or in connection with the contract, to supply Contractor Deliverables or components of Contractor Deliverables that, in the course of their use,

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maintenance, disposal, or in the event of an accident, may release hazardous materials or substances, they shall provide to the Authority a list of those hazardous materials or substances, and for each hazardous material or substance listed, provide an SDS.

- d. The Contractor shall provide to the Authority a completed Schedule 6 (Hazardous Contractor Deliverables, Materials or Substances Supplied under the Contract: Data Requirements) in accordance with Schedule 3 (Contract Data Sheet).
- e. If the Contractor Deliverables, materials or substances are ordnance, munitions or explosives, in addition to the requirements of CHIP and / or the CLP Regulation 1272/2008 (whichever is applicable) and REACH the Contractor shall comply with hazard reporting requirements of DEF STAN 07-085 Design Requirements for Weapons and Associated Systems.
- f. If the Contractor Deliverables, materials or substances are or contain or embody a radioactive substance as defined in the Ionising Radiation Regulations SI 1999/3232, the Contractor shall additionally provide details of:
 - (1) activity;
 - (2) the substance and form (including any isotope);
- g. If the Contractor Deliverables, materials or substances have magnetic properties, the Contractor shall additionally provide details of the magnetic flux density at a defined distance, for the condition in which it is packed.
- h. Any SDS to be provided in accordance with this Condition, including any related information to be supplied in compliance with the Contractor's statutory duties under Clause 24.a, any information arising from the provisions of Clauses 24.e, 24.f and 24.g and the completed Schedule 6, shall be sent directly to the Authority's Representative (Commercial) as soon as practicable, and no later than one (1) month prior to the Contract delivery date, unless otherwise stated in Schedule 3 (Contract Data Sheet). In addition, so that the safety information can reach users without delay, a copy shall be sent preferably as an email with attachment(s) in Adobe PDF or MS WORD format, or, if only hardcopy is available, to the addresses below:
 - (1) Hard copies to be sent to: 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
 - (2) Emails to be sent to:
DSA-DLSR-MovTpt-DGHSIS@mod.uk
- i. Failure by the Contractor to comply with the requirements of this Condition shall be grounds for rejecting the affected Contractor Deliverables. Any withholding of information concerning hazardous Contractor Deliverables, materials or substances shall be regarded as a material breach of Contract under Condition 43 (Material Breach) for which the Authority reserves the right to require the Contractor to rectify the breach immediately at no additional cost to the Authority or to terminate the Contract in accordance with Condition 43.

25. Timber and Wood-Derived Products

- a. All Timber and Wood-Derived Products supplied by the Contractor under the Contract:
 - (1) shall comply with the Contract Specification; and
 - (2) must originate either:

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- (a) from a Legal and Sustainable source; or
 - (b) from a FLEGT-licensed or equivalent source.
- b. In addition to the requirements of clause 25.a, all Timber and Wood-Derived Products supplied by the Contractor under the Contract shall originate from a forest source where management of the forest has full regard for:
 - (1) identification, documentation and respect of legal, customary and traditional tenure and use rights related to the forest;
 - (2) mechanisms for resolving grievances and disputes including those relating to tenure and use rights, to forest management practices and to work conditions; and
 - (3) safeguarding the basic labour rights and health and safety of forest workers.
- c. If requested by the Authority, the Contractor shall provide to the Authority Evidence that the Timber and Wood-Derived Products supplied to the Authority under the Contract comply with the requirements of clause 25.a or 25.b or both.
- d. The Authority reserves the right at any time during the execution of the Contract and for a period of five (5) years from final Delivery under the Contract to require the Contractor to produce the Evidence required for the Authority's inspection within fourteen (14) days of the Authority's request.
- e. If the Contractor has already provided the Authority with the Evidence required under clause 25.c, the Contractor may satisfy these requirements by giving details of the previous notification and confirming the Evidence remains valid and satisfies the provisions of clauses 25.a or 25.b or both.
- f. The Contractor shall maintain records of all Timber and Wood-Derived Products delivered to and accepted by the Authority, in accordance with condition 18 (Contractor's Records).
- g. Notwithstanding clause 25.c, if exceptional circumstances render it strictly impractical for the Contractor to record Evidence of proof of timber origin for previously used Recycled Timber, the Contractor shall support the use of this Recycled Timber with:
 - (1) a record tracing the Recycled Timber to its previous end use as a standalone object or as part of a structure; and
 - (2) an explanation of the circumstances that rendered it impractical to record Evidence of proof of timber origin.
- h. The Authority may disclose the Information:
 - (1) The Authority reserves the right to decide, except where in the Authority's opinion the timber supplied is incidental to the requirement and from a low risk source, whether the Evidence submitted to it demonstrates compliance with clause 25.a or 25.b, or both. In the event that the Authority is not satisfied, the Contractor shall commission and meet the costs of an Independent Verification and resulting report that will:
 - (2) verify the forest source of the timber or wood; and
 - (3) assess whether the source meets the relevant criteria of clause 25.b.
- i. The statistical reporting requirement at clause 25.j applies to all Timber and Wood-Derived Products delivered under the Contract. The Authority reserves the right to amend the requirement for statistical reporting, in the event that the UK Government changes the requirement for reporting compliance with the Government Timber Procurement Policy. Amendments to the statistical reporting requirement will be made in accordance with condition 6 (Amendments to Contract).
- j. The Contractor shall provide to the Authority, a completed Schedule 7 (Timber and Wood-Derived Products Supplied under the Contract: Data Requirements), the data or Information the Authority requires in respect of Timber and Wood-Derived Products delivered to the Authority under the

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Contract, or in respect of each Order in the case of a Framework Agreement, or at such other frequency as stated in the Contract. The Contractor shall send all completed Schedule 7s (Timber and Wood-Derived Products Supplied under the Contract: Data Requirements), including Nil Returns where appropriate, to the Authority's Representative (Commercial).

- k. The Schedule 7 (Timber and Wood-Derived Products Supplied under the Contract: Data Requirements) may be amended by the Authority from time to time, in accordance with condition 6 (Amendments to Contract).
- l. The Contractor shall obtain any wood, other than processed wood, used in Packaging from:
 - (1) companies that have a full registered status under the Forestry Commission and Timber Packaging and Pallet Confederation's UK Wood Packaging Material Marking Programme (more detailed information can be accessed at www.forestry.gov.uk) and all such wood shall be treated for the elimination of raw wood pests and marked in accordance with that Programme; or
 - (2) sources supplying wood treated and marked so as to conform to Annex I and Annex II of the International Standard for Phytosanitary Measures, "Guidelines for Regulating Wood Packaging Material in International Trade", Publication No 15 published by the Food and Agricultural Organisation of the United Nations (ISPM15) (more detailed information can be accessed at www.fao.org).

26. Certificate of Conformity

- a. Where required in Schedule 3 (Contract Data Sheet) the Contractor shall provide a Certificate of Conformity (CofC) in accordance with Schedule 2 (Schedule of Requirements) and any applicable Quality Plan. One copy of the CofC shall be sent to the Authority's Representative (Commercial) upon Delivery, and one copy shall be provided to the Consignee upon Delivery.
- b. The Contractor shall consider the CofC to be a record in accordance with condition 18 (Contractor's Records).
- c. The Information provided on the CofC shall include:
 - (1) Contractor's name and address;
 - (2) Contractor unique CofC number;
 - (3) Contract number and where applicable Contract amendment number;
 - (4) details of any approved concessions;
 - (5) acquirer name and organisation;
 - (6) Delivery address;
 - (7) Contract Item Number from Schedule 2 (Schedule of Requirements);
 - (8) Description of Contractor Deliverable, including, part number, specification and configuration status;
 - (9) identification marks, batch and serial numbers in accordance with the Specification;
 - (10) quantities;
 - (11) a signed and dated statement by the Contractor that the Contractor Deliverables comply with the requirements of the Contract and approved concessions. Exceptions or additions to the above are to be documented.
- d. Where Schedule 2 (Schedule of Requirements) and any applicable Quality Plan require demonstration of traceability and design provenance through the supply chain the Contractor shall include in any relevant subcontract the requirement for the Information called for at clause 26.c. The Contractor shall ensure that this Information is available to the Authority through the supply chain upon request in accordance with condition 18 (Contractor Records).

27. Access to Contractor's Premises

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- a. The Contractor shall provide to the Authority's Representatives following reasonable Notice, relevant accommodation/facilities, at no direct cost to the Authority, and all reasonable access to its premises for the purpose of monitoring the Contractor's progress and quality standards in performing the Contract.
- b. As far as reasonably practical, the Contractor shall ensure that the provisions of clause 1 are included in their subcontracts with those suppliers identified in the Contract. The Authority, through the Contractor, shall arrange access to such subcontractors.

28. Delivery / Collection

- a. Schedule 3 (Contract Data Sheet) 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. Where the Contractor Deliverables are to be Delivered by the Contractor (or a third party acting on behalf of the Contractor), the Contractor shall, unless otherwise stated in writing:
 - (1) contact the Authority's Representative as detailed in Schedule 3 (Contract Data Sheet) in advance of the Delivery Date in order to agree administrative arrangements for Delivery and provide any Information pertinent to Delivery requested;
 - (2) comply with any special instructions for arranging Delivery in Schedule 3 (Contract Data Sheet);
 - (3) ensure that each consignment of the Contractor Deliverables is accompanied by, (as specified in Schedule 3 (Contract Data Sheet)), a DEFFORM 129J in accordance with the instructions;
 - (4) be responsible for all costs of Delivery; and
 - (5) Deliver the Contractor Deliverables to the Consignee at the address stated in Schedule 2 (Schedule of Requirements) by the Delivery Date between the hours agreed by the Parties.
- c. Where the Contractor Deliverables are to be Collected by the Authority (or a third party acting on behalf of the Authority), the Contractor shall, unless otherwise stated in writing:
 - (1) comply with any special instructions for arranging Collection in Schedule 3 (Contract Data Sheet);
 - (2) ensure that each consignment of the Contractor Deliverables is accompanied by, (as specified in Schedule 3 (Contract Data Sheet)), a DEFFORM 129J in accordance with the instructions;
 - (3) ensure that the Contractor Deliverables are available for Collection by the Authority from the Consignor (as specified in Schedule 3 (Contract Data Sheet)) by the Delivery Date between the hours agreed by the Parties; and
 - (4) in the case of Overseas consignments, ensure that the Contractor Deliverables are accompanied by the necessary transit documentation. All Customs clearance shall be the responsibility of the Authority's Representative (Transport).
- d. Title and risk in the Contractor Deliverables shall only pass from the Contractor to the Authority:
 - (1) on the Delivery of the Contractor Deliverables by the Contractor to the Consignee in accordance with clause 28.b; or
 - (2) on the Collection of the Contractor Deliverables from the Consignor by the Authority once they have been made available for Collection by the Contractor in accordance with clause 28.c.

29. Acceptance

- 59. Acceptance of the Contractor Deliverables shall occur in accordance with any acceptance procedure specified in Schedule 8 (Acceptance Procedure). If no acceptance procedure is so specified acceptance shall occur when either:

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- (1) the Authority does any act in relation to the Contractor Deliverable which is inconsistent with the Contractor's ownership; or
- (2) the time limit in which to reject the Contractor Deliverables defined in clause 30.b has elapsed.

30. Rejection

- a. If any of the Contractor Deliverables Delivered to the Authority do not conform to the Specification or any other terms of this Contract, then (without limiting any other right or remedy that the Authority may have) the Authority may reject the Contractor Deliverables (in whole or in part). The Authority shall return these Contractor Deliverables to the Contractor at the Contractor's risk and cost.
- b. Rejection of any of the Contractor Deliverables under clause 30.a shall take place by the time limit for rejection specified in Schedule 3 (Contract Data Sheet), or if no such period is specified within thirty (30) Business Days.

31. Diversion Orders

- a. The Authority shall notify the Contractor at the earliest practicable opportunity if it becomes aware that a Contractor Deliverable is likely to be subject to a Diversion Order.
- b. The Authority may issue a Diversion Order for the urgent delivery of the Contractor Deliverables identified in it. These Contractor Deliverables are to be delivered by the Contractor using the quickest means available as agreed by the Authority.
- c. The Authority reserves the right to cancel the Diversion Order.
- d. If the terms of the Diversion Order are unclear, the Contractor shall immediately contact the Representative of the Authority who issued it for clarification and/or further instruction.
- e. If the Diversion Order increases the quantity of Contractor Deliverables beyond the scope of the Contract, it is to be returned immediately to the Authority's Commercial Officer with an appropriate explanation.
- f. The Contractor shall be entitled to reasonable additional delivery and packaging costs incurred in complying with the Diversion Order or cancellation. Claims are to be submitted by the Contractor to the Authority's Commercial Officer together with applicable receipts and agreed as an amendment to the Contract in accordance with condition 6 (Amendments to Contract). The Contractor shall comply with the requirements of the Diversion Order upon receipt of the Diversion Order.

32. Self-to-Self Delivery

Where it is stated in Schedule 3 (Contract Data Sheet) that any Contractor Deliverable is to be Delivered by the Contractor to its own premises, or to those of a Subcontractor ('self-to-self delivery'), the risk in such a Contractor Deliverable shall remain vested in the Contractor until such time as it is handed over to the Authority.

LICENCES AND INTELLECTUAL PROPERTY**33. Import and Export Licences**

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- a. If, in the performance of the Contract, the Contractor needs to import into the UK or export out of the UK anything not supplied by or on behalf of the Authority and for which a UK import or export licence is required, the responsibility for applying for the licence shall rest with the Contractor. The Authority shall provide the Contractor with sufficient information, certification, documentation and other reasonable assistance in obtaining any necessary UK import or export licence.
- b. When an export licence or import licence or authorisation either singularly or in combination is required from a foreign government for the performance of the Contract, the Contractor shall as soon as reasonably practicable consult with the Authority on the licence requirements. Where the Contractor is the applicant for the licence or authorisation the Contractor shall:
 - (1) ensure that when end use or end user restrictions, or both, apply to all or part of any Contractor Deliverable (which for the purposes of this Condition shall also include information, technical data and software), the Contractor, unless otherwise agreed with the Authority, shall identify in the application:
 - (a) the end user as: Her Britannic Majesty's Government of the United Kingdom of Great Britain and Northern Ireland (hereinafter "HM Government"); and
 - (b) the end use as: For the Purposes of HM Government; and
 - (2) include in the submission for the licence or authorisation a statement that "information on the status of processing this application may be shared with the Ministry of Defence of the United Kingdom".
- c. If the Contractor or any subcontractor in the performance of the Contract needs to export materiel not previously supplied by or on behalf of the Authority for which an export licence or import licence or authorisation from a foreign government is required, the responsibility for instituting expeditious action to apply for and obtain the licence shall rest with the Contractor or that subcontractor. For the purposes of this Condition materiel shall mean information, technical data and items, including Contractor Deliverables, components of Contractor Deliverables and software.
- d. Where the Contract performance requires the export of materiel for which a foreign export licence or import licence or authorisation is required, the Contractor shall include the dependencies for the export licence or import licence or authorisation application, grant and maintenance in the Contract risk register and in the risk management plan for the Contract, with appropriate review points. Where there is no requirement under the Contract for a risk management plan the Contractor shall submit this information to the Authority's representative.
- e. During the term of the Contract and for a period of up to 2 years from completion of the Contract, the Authority may make a written request to the Contractor to seek a variation to the conditions to a foreign export licence or import licence or authorisation to enable the Authority to re-export or re-transfer a licensed or authorised item or licensed or authorised information from the UK to a non-licensed or unauthorised third party. If the Authority makes such a request it will consult with the Contractor before making a determination of whether the Authority or the Contractor is best placed in all the circumstance to make the request. Where, subsequent to such consultation the Authority notifies the Contractor that the Contractor is best placed to make such request:
 - (1) the Contractor shall, or procure that the Contractor's subcontractor shall, expeditiously consider whether or not there is any reason why it should object to making the request and, where it has no objection, file an application to seek a variation of the applicable export licence or import licence or authorisation in accordance with the procedures of the licensing authority. Where the contractor has an objection, the Parties shall meet within five (5) working days to resolve the issue and should they fail the matter shall be escalated to an appropriate level within both Parties' organisations, to include their respective export licensing subject matter experts; and
 - (2) the Authority shall provide sufficient information, certification, documentation and other reasonable assistance as may be necessary to support the application for the requested variation.

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- f. Where the Authority determines that it is best placed to make such request the Contractor shall provide sufficient information, certification, documentation and other reasonable assistance as may be necessary to support the Authority to make the application for the requested variation.
- g. Where the Authority invokes clause 33.e or 33.f the Authority will pay the Contractor a fair and reasonable charge for this service based on the cost of providing it.
- h. Where the Contractor subcontracts work under the Contract, which is likely to be subject to foreign export control, import control or both the Contractor shall use reasonable endeavours to incorporate in each subcontract equivalent obligations to those set out in this Condition. Where it is not possible to include equivalent terms to those set out in this Condition, the Contractor shall report that fact and the circumstances to the Authority.
- i. Without prejudice to HM Government's position on the validity of any claim by a foreign government to extra-territoriality, the Authority shall provide the Contractor with sufficient information, certification, documentation and other reasonable assistance to facilitate the granting of export licences or import licences or authorisations by a foreign Government in respect of the performance of the Contract.
- j. The Authority shall provide such assistance as the Contractor may reasonably require in obtaining any UK export licences necessary for the performance of the Contract.
- k. The Contractor shall use reasonable endeavours to identify whether any Contractor Deliverable is subject to:
 - (1) a non-UK export licence, authorisation or exemption; or
 - (2) any other related transfer or export control, that imposes or will impose end use, end user or re-transfer or re-export restrictions, or restrictions on disclosure to individuals based upon their nationality. This does not include the Intellectual Property-specific restrictions of the type referred to in condition 34 (Third Party Intellectual Property – Rights and Restrictions).
- l. If at any time during the term of the Contract the Contractor becomes aware that all or any part of the Contractor Deliverables are subject to Clause 33.k(1) or 33.k(2), it shall notify the Authority of this as soon as reasonably practicable by providing details in the DEFFORM 528 or other mutually agreed alternative format. Such notification shall be no later than thirty (30) days of knowledge of any affected Contractor Deliverable and in any event such notification shall be not less than thirty (30) days prior to delivery of the Contractor Deliverables.
- m. If the information to be provided under Clause 33.l has been provided previously to the Authority by the Contractor under the Contract, the Contractor may satisfy these requirements by giving details of the previous notification and confirming they remain valid and satisfy the provisions of Clause 33.l.
- n. During the term of the Contract, the Contractor shall notify the Authority as soon as reasonably practicable of any changes in the information notified previously under clauses 33.l or 33.m of which it becomes or is aware that would affect the Authority's ability to use, disclose, re-transfer or re-export an item or part of it as is referred to in those Clauses by issuing an updated DEFFORM 528 to the Authority.
- o. For a period of up to 2 years from completion of the Contract and in response to a specific request by the Authority, the Contractor shall notify the Authority as soon as reasonably practicable of any changes in the information notified previously under Clause 33.l or 33.m of which it becomes aware that would affect the Authority's ability to use, disclose, re-transfer or reexport an item or part of it as is referred to in those Clauses by issuing an updated DEFFORM 528 to the Authority.
- p. Where following receipt of materiel from a subcontractor or any of its other suppliers restrictions are notified to the Contractor by that subcontractor, supplier or other third party or are identified

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by the Contractor, the Contractor shall immediately inform the Authority by issuing an updated DEFFORM 528. Within ten (10) days of such notification, the Contractor shall propose to the Authority actions to mitigate the impact of such restrictions. Such proposals may include, where appropriate, mutually supported attempts to obtain removal or modification to the restrictions or to obtain appropriate authorisations from the relevant foreign government. The Authority shall notify the contractor within ten (10) days of receipt of a proposal whether it is acceptable and where appropriate the Contract shall be modified in accordance with its terms to implement the proposal.

- q. If the restrictions prevent the Contractor from performing its obligations under the Contract and have not been removed, modified or otherwise satisfactorily managed within a reasonable time, the Authority may at its absolute discretion elect to amend the contract in accordance with condition 6 or 7 or as otherwise may be provided by the Contract, or to terminate the Contract. Except as set out in clause 33.r, in the event of termination in these circumstances termination shall be on fair and reasonable terms having regard to all the circumstances including payments already made and that would otherwise be due under the Contract, costs incurred by the Contractor and benefits received by the Authority. The Parties, acting in good faith, will use all reasonable endeavours to agree such fair and reasonable terms failing which either Party may refer the matter to dispute resolution in accordance with the provisions in the Contract.
- r. In the event that the restrictions notified to the Authority pursuant to Clause 33.l were known or ought reasonably have been known by the Contractor (but were not disclosed) at contract award or if restrictions notified to the Authority pursuant to clauses 33.n or 33.p were known or ought reasonably to have been known by the Contractor at the date of submission of the most recent DEFFORM 528 submitted to the Authority in accordance with Clause 33.l, termination under Clause 33.q will be in accordance with condition 43 (Material Breach) and the provisions of clause 33.v will not apply.
- s. In the event that the Authority becomes aware that the DEFFORM 528 disclosure was incomplete or inaccurate or in the event additional such material is identified then the Authority shall provide, as soon as reasonably practicable a new or revised DEFFORM 528. In the event that the Authority becomes aware that a prior disclosure included in DEFFORM 528 submitted to the Contractor was incomplete or inaccurate less than thirty (30) days prior to the delivery to the Contractor of any material to which the updated or new disclosure relates, the Parties will meet as soon as reasonably practicable to discuss how to mitigate the impact of the incomplete or inaccurate disclosure.
- t. Where:
 - (1) restrictions are advised by the Authority to the Contractor in a DEFFORM 528 provided pursuant to Clauses 33.s or 33.t or both; or
 - (2) any of the information provided by the Authority in any DEFFORM 528 proves to be incorrect or inaccurate; the Authority and the Contractor shall act promptly to mitigate the impact of such restrictions or incorrect or inaccurate information. Such mitigation shall include, where appropriate, mutually supported attempts to obtain removal or modification to the restrictions or to obtain appropriate authorisations from the relevant foreign government. If the restrictions or incorrect or inaccurate information adversely affect the ability of the Contractor to perform its obligations under the Contract, the matter shall be handled under the terms of condition 6 (Amendments to Contract) or condition 7 (Variations to Specification) or as may otherwise be provided by the Contract as appropriate and if no alternative solution satisfies the essential terms of the Contract and the restrictions have not been removed, modified or otherwise satisfactorily managed within a reasonable time the Authority may terminate the Contract. Termination under these circumstances will be under the terms of condition 42 (Termination for Convenience) and as referenced in the Contract.
- u. Pending agreement of any amendment of the Contract as set out in clause 33.q or 33.u, provided the Contractor takes such steps as are reasonable to mitigate the impact, the Contractor shall

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be relieved from its obligations to perform those elements of the Contract directly affected by the restrictions or provision of incorrect or incomplete information.

34. Third Party Intellectual Property – Rights and Restrictions

- a. The Contractor and, where applicable any Subcontractor, shall promptly notify the Authority as soon as they become aware of:
 - (1) any invention or design the subject of patent or registered Design Rights (or application thereof) owned by a third party which appears to be relevant to the performance of the Contract or to use by the Authority of anything required to be done or delivered under the Contract;
 - (2) any restriction as to disclosure or use, or obligation to make payments in respect of any other intellectual property (including technical Information) required for the purposes of the Contract or subsequent use by the Authority of anything delivered under the Contract and, where appropriate, the notification shall include such Information as is required by Section 2 of the Defence Contracts Act 1958;
 - (3) any allegation of infringement of intellectual property rights made against the Contractor and which pertains to the performance of the Contract or subsequent use by the Authority of anything required to be done or delivered under the Contract.

Clause 34.a does not apply in respect of Contractor Deliverables normally available from the Contractor as a Commercial Off The Shelf (COTS) item or service.

- b. If the Information required under clause 34.a has been notified previously, the Contractor may meet its obligations by giving details of the previous notification.
- c. For COTS Contractor Deliverables patents and registered designs in the UK, in respect of any question arising (by way of an allegation made to the Authority or Contractor, or otherwise) that the manufacture or provision under the Contract of Contractor Deliverables normally available from the Contractor as a COTS item or service is an infringement of a UK patent or registered design not owned or controlled by the Contractor or the Authority, the Contractor shall, subject to the agreement of the third party owning such patent or registered design, be given exclusive conduct of any and all negotiations for the settlement of any claim or the conduct of any litigation arising out of such question. The Contractor shall indemnify the Authority, its officers, agents and employees against any liability and cost arising from such allegation. This condition shall not apply if:
 - (1) the Authority has made or makes an admission of any sort relevant to such question;
 - (2) the Authority has entered or enters into any discussions on such question with any third party without the prior written agreement of the Contractor;
 - (3) the Authority has entered or enters into negotiations in respect of any relevant claim for compensation in respect of Crown Use under Section 55 of the Patents Act 1977 or Section 12 of the Registered Designs Act 1977;
 - (4) legal proceedings have been commenced against the Authority or the Contractor in respect of Crown Use, but only to the extent of such Crown Use that has been properly authorised.
- d. The indemnity in clause 34.c does not extend to use by the Authority of anything supplied under the Contract where that use was not reasonably foreseeable at the time of the Contract.
- e. In the event that the Authority has entered into negotiation in respect of a claim for compensation, or legal proceedings in respect of the Crown Use have commenced, the Authority shall forthwith authorise the Contractor for the purposes of performing the Contract (but not otherwise) to utilise a relevant invention or design in accordance with Sections 55 and 56 of the Patents Act 1977 or Section 12 of the Registered Designs Act 1949 and to use any model, document or information relating to any such invention or design which may be required for that purpose.
- f. For all other Contractor Deliverables patents and registered designs in the UK, if a relevant invention or design has been notified to the Authority by the Contractor prior to the Effective Date

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of Contract, then unless it has been otherwise agreed, under the provisions of Sections 55 and 56 of the Patents Act 1977 or Section 12 of the Registered Designs Act 1949, the Contractor is hereby authorised to utilise that invention or design, notwithstanding the fact that it is the subject of a UK Patent or UK Registered Design, for the purpose of performing the Contract.

- g. If, under clause 34.a, a relevant invention or design is notified to the Authority by the Contractor after the Effective Date of Contract, then:
 - (1) if the owner (or its exclusive licensee) takes or threatens in writing to take any relevant action against the Contractor, the Authority shall issue to the Contractor a written authorisation in accordance with the provisions of Sections 55 and 56 of the Patents Act 1977 or Section 12 of the Registered Designs Act 1949, and
 - (2) in any event, unless the Contractor and the Authority can agree an alternative course of action, the Authority shall not unreasonably delay the issue of a written authorisation in accordance with the provisions of Sections 55 and 56 of the Patents Act 1977 or Section 12 of the Registered Designs Act 1949.
- h. The Authority shall assume all liability and shall indemnify the Contractor, its officers, agents and employees against liability, including the Contractor's costs, as a result of infringement by the Contractor or their suppliers of any patent, utility model, registered design or like protection outside the United Kingdom in the performance of the Contract when such infringement arises from or is incurred by reason of the Contractor following any specification, statement of work or instruction in the Contract or using, keeping or disposing of any item given by the Authority for the purpose of the Contract in accordance with the Contract.
- i. The Contractor shall assume all liability and shall indemnify the Authority, its officers, agents and employees against liability, including the Authority's costs, as a result of infringement by the Contractor or their suppliers of any patent, utility model, registered design or like protection outside the UK in the performance of the Contract when such infringement arises from or is incurred otherwise than by reason of the Contractor following any specification, statement of work or instruction in the Contract or using, keeping or disposing of any item given by the Authority for the purpose of the Contract in accordance with the Contract.
- j. The Contractor shall not be entitled to any reimbursement of any royalty, licence fee or similar expense incurred in respect of anything to be done under the Contract, where:
 - (1) a relevant discharge has been given under Section 2 of the Defence Contracts Act 1958, or relevant authorisation in accordance with Sections 55 or 57 of the Patents Act 1977, Section 12 of the Registered Designs Act 1949 or Section 240 of the Copyright, Designs and Patents Act 1988 in respect of any intellectual property; or
 - (2) any obligation to make payments for intellectual property has not been promptly notified to the Authority under clause 34.a.
- k. Where authorisation is given by the Authority under clause 34.e, 34.f or 34.g, to the extent permitted by Section 57 of the Patents Act 1977, Section 12 of the Registered Designs Act 1949 or Section 240 of the Copyright, Designs and Patents Act 1988, the Contractor shall also be:
 - (1) released from payment whether by way of royalties, licence fees or similar expenses in respect of the Contractor's use of the relevant invention or design, or the use of any relevant model, document or information for the purpose of performing the Contract; and
 - (2) authorised to use any model, document or information relating to any such invention or design which may be required for that purpose.
- l. The Contractor shall assume all liability and indemnify the Authority and its officers, agents and employees against liability, including costs as a result of:
 - (1) infringement or alleged infringement by the Contractor or their suppliers of any copyright, database right, Design Right or the like protection in any part of the world in respect of any item to be supplied under the Contract or otherwise in the performance of the Contract;
 - (2) misuse of any confidential information, trade secret or the like by the Contractor in performing the Contract;

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- (3) provision to the Authority of any Information or material which the Contractor does not have the right to provide for the purpose of the Contract.
- m. The Authority shall assume all liability and indemnify the Contractor, its officers, agents and employees against liability, including costs as a result of:
 - (1) infringement or alleged infringement by the Contractor or their suppliers of any copyright, database right, Design Right or the like protection in any part of the world in respect of any item provided by the Authority for the purpose of the Contract but only to the extent that the item is used for the purpose of the Contract;
 - (2) alleged misuse of any confidential Information, trade secret or the like by the Contractor as a result of use of Information provided by the Authority for the purposes of the Contract, but only to the extent that Contractor's use of that Information is for the purposes intended when it was disclosed by the Authority.
- n. The general authorisation and indemnity is:
 - (1) clauses 34.a – 34.m represents the total liability of each Party to the other under the Contract in respect of any infringement or alleged infringement of patent or other Intellectual Property Right (IPR) owned by a third party;
 - (2) neither Party shall be liable, one to the other, for any consequential loss or damage arising as a result, directly or indirectly, of a claim for infringement or alleged infringement of any patent or other IPR owned by a third party;
 - (3) a Party against whom a claim is made or action brought, shall promptly notify the other Party in writing if such claim or action appears to relate to an infringement which is the subject of an indemnity or authorisation given under this Condition by such other Party. The notification shall include particulars of the demands, damages and liabilities claimed or made of which the notifying Party has notice;
 - (4) the party benefiting from the indemnity or authorisation shall allow the other Party, at its own expense, to conduct any negotiations for the settlement of the same, and any litigation that may arise therefrom and shall provide such information as the other Party may reasonably require;
 - (5) following a notification under clause 34.n(3), the Party notified shall advise the other Party in writing within thirty (30) Business Days whether or not it is assuming conduct of the negotiations or litigation. In that case the Party against whom a claim is made or action brought shall not make any statement which might be prejudicial to the settlement or defence of such a claim without the written consent of the other Party;
 - (6) the Party conducting negotiations for the settlement of a claim or any related litigation shall, if requested, keep the other Party fully informed of the conduct and progress of such negotiations.
- o. If at any time a claim or allegation of infringement arises in respect of copyright, database right, Design Right or breach of confidence as a result of the provision of any Contractor Deliverable by the Contractor to the Authority, the Contractor may at its own expense replace the item with an item of equivalent functionality and performance so as to avoid infringement or breach. The Parties will co-operate with one another to mitigate any claim or damage which may arise from use of third party IPR.
- p. Nothing in condition 34 shall be taken as an authorisation or promise of an authorisation under Section 240 of the Copyright, Designs and Patents Act 1988.

PRICING AND PAYMENT**35. Contract Price**

- a. The Contractor shall provide the Contractor Deliverables to the Authority at the Contract Price. The Contract Price shall be a Firm Price unless otherwise stated in Schedule 3 (Contract Data Sheet).

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- b. Subject to condition 35.a the Contract Price shall be inclusive of any UK custom and excise or other duty payable. The Contractor shall not make any claim for drawback of UK import duty on any part of the Contract Deliverables supplied which may be for shipment outside of the UK.

36. Payment and Recovery of Sums Due

- a. Payment for Contractor Deliverables will be made by electronic transfer and prior to submitting any claims for payment under clause 36b 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 36a, 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 36b 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 36c 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.

37. Value Added Tax

- a. The Contract Price excludes any UK output Value Added Tax (VAT) and any similar EU (or nonEU) taxes chargeable on the supply of Contractor Deliverables by the Contractor to the Authority.
- b. If the Contractor is required by UK VAT law to be registered for UK VAT (or has registered voluntarily) in respect of his business activities at the time of any supply, and the circumstances of any supply are such that the Contractor is liable to pay the tax due to HM Revenue and Customs (HMRC), the Authority shall pay to the Contractor in addition to the Contract Price (or any other sum due to the Contractor) a sum equal to the output VAT chargeable on the tax value of the supply of Contractor Deliverables, and all other payments under the Contract according to the law at the relevant tax point.
- c. The Contractor is responsible for the determination of VAT liability. The Contractor shall consult its Client Relationship Manager or the HMRC Enquiries Desk (and not the Authority's Representative (Commercial)) in cases of doubt. The Contractor shall notify the Authority's Representative (Commercial) of the Authority's VAT liability under the Contract, and any changes to it, within twenty (20) Business Days of becoming aware the liability is other than at the standard rate of VAT. In the event of any doubt about the applicability of the tax in such cases, the Authority may require the Contractor to obtain, and pass to the Authority, a formal ruling from HMRC. The Contractor shall comply promptly with any such requirement. Where the Contractor obtains a ruling from HMRC, it shall supply a copy to the Authority within three (3) Business Days of receiving that ruling unless it proposes to challenge the ruling. Where the Contractor challenges

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the ruling it shall supply to the Authority a copy of any final decisions issued by HMRC on completion of the challenge within three (3) Business Days of receiving the decision.

- d. Where supply of Contractor Deliverables comes within the scope of UK VAT, but the Contractor is not required by UK VAT law to be registered for UK VAT (and has not registered voluntarily), the Authority shall be responsible for assessing and paying over directly to HMRC any UK output VAT due in respect of the Contractor Deliverables. The Contractor shall be responsible for ensuring it takes into account any changes in VAT law regarding registration.
- e. Where Contractor Deliverables are deemed to be supplied to the Authority outside the UK, the Contractor may be required by the laws of the country where the supply takes place to register there for EU (or non-EU) turnover or similar tax. In that event, the Authority shall pay to the Contractor in addition to the Contract Price (and any other sum due to the Contractor under the Contract) a sum equal to the tax the Contractor is liable to pay to the tax authorities of the country in question in relation to the Contractor Deliverables within thirty (30) calendar days of a written request for payment of any such sum by the Contractor.
- f. In relation to the Contractor Deliverables supplied under the Contract the Authority shall not be required to pay any sum in respect of the Contractor's input VAT (or similar EU or non-EU or both input taxes). However, these input taxes will be allowed where it is established that, despite the Contractor having taken all reasonable steps to recover them, it has not been possible to do so. Where there is any doubt that the Contractor has complied with this requirement the matter shall be resolved in accordance with condition 40 (Dispute Resolution).
- g. Should HMRC decide that the Contractor has incorrectly determined the VAT liability, in accordance with clause 37.b above, the Authority will pay the VAT assessed by HMRC. In the event that HMRC so determines, the Contractor shall pay any interest charged on any assessment or penalties or both directly to HMRC. Such interest or penalties or both shall not be recoverable from the Authority under this Contract or any other contract. The Contractor shall supply the Authority with a copy of all correspondence between HMRC and the Contractor's advisors regarding the VAT assessment within three (3) Business Days of a written request from the Authority for such correspondence.

38. Debt Factoring

- a. Subject to the Contractor obtaining the prior written consent of the Authority in accordance with condition 11 (Assignment of Contract), the Contractor may assign to a third Party ("the Assignee") the right to receive payment of the Contract Price or any part thereof due to the Contractor under the Contract (including interest which the Authority incurred through late payment under the Late Payment of Commercial Debts (Interest) Act 1998 ("the Act")). Any assignment of the right to receive payment of the Contract Price (or any part thereof) under this condition 38 shall be subject to:
 - (1) reduction of any sums in respect of which the Authority exercises its right of recovery under clause 36.f
 - (2) all related rights of the Authority under the Contract in relation to the recovery of sums due but unpaid; and
 - (3) the Authority receiving notification under both clauses 38.b and 38.c(2).
- b. In the event that the Contractor obtains from the Authority the consent to assign the right to receive the Contract Price (or any part thereof) under clause 38.a, the Contractor shall notify the Authority in writing of the assignment and the date upon which the assignment becomes effective.
- c. The Contractor shall ensure that the Assignee:
 - (1) is made aware of the Authority's continuing rights under clauses 38.a(1) and 38.a(2); and
 - (2) notifies the Authority of the Assignee's contact Information and bank account details to which the Authority shall make payment, subject to any reduction made by the Authority in accordance with clauses 38.a(1) and 38.a(2).

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- d. The provisions of condition 36 (Payment and Recovery of Sums Due) shall continue to apply in all other respects after the assignment and shall not be amended without the prior approval of the Authority.

39. Subcontracting and Prompt Payment

- a. Subcontracting any part of the Contract shall not relieve the Contractor of any of the Contractor's obligations, duties or liabilities under the Contract.
- b. Where the Contractor enters into a Subcontract he shall cause a term to be included in such

Subcontract:

- (1) providing that where the Subcontractor submits an invoice to the Contractor, the Contractor will consider and verify that invoice in a timely fashion;
- (2) providing that the Contractor shall pay the Subcontractor any sums due under such an invoice no later than a period of thirty (30) days from the date on which the Contractor has determined that the invoice is valid and undisputed;
- (3) providing that where the Contractor fails to comply with clause 39.b(1) above, and there is an undue delay in considering and verifying the invoice, that the invoice shall be regarded as valid and undisputed for the purposes of clause 39.b(2) after a reasonable time has passed; and
- (4) requiring the counterparty to that Subcontract to include in any Subcontract which it awards, provisions having the same effect as clauses 39.b(1) to 39.b(4).

TERMINATION**40. 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 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 40.a the dispute shall be referred to arbitration. Unless otherwise agreed in writing by the Parties, the arbitration and this clause 40.b 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, anything said, done or produced in or in relation to the arbitration process (including any awards) shall be confidential between the Parties, except as may be lawfully required in judicial proceedings relating to the arbitration or otherwise.

41. Termination for Insolvency or Corrupt Gifts**Insolvency:**

- a. The Authority may terminate the Contract, without paying compensation to the Contractor, by giving written Notice of such termination to the Contractor at any time after any of the following events:

Where the Contractor is an individual or a firm:

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- (1) the application by the individual or, in the case of a firm constituted under English law, any partner of the firm to the court for an interim order pursuant to Section 253 of the Insolvency Act 1986; or
- (2) the court making an interim order pursuant to Section 252 of the Insolvency Act 1986; or
- (3) the individual, the firm or, in the case of a firm constituted under English law, any partner of the firm making a composition or a scheme of arrangement with his or its creditors; or
- (4) the presentation of a petition for bankruptcy order against the individual or, in the case of a firm constituted under English law, any partner of the firm unless it is withdrawn within three (3) Business Days from the date on which the Contractor is notified of the presentation; or
- (5) the court making a bankruptcy order in respect of the individual or, in the case of a firm constituted under English law, any partner of the firm; or
- (6) where the Contractor is either unable to pay his debts as they fall due or has no reasonable prospect of being able to pay debts which are not immediately payable. The Authority shall regard the Contractor as being unable to pay his debts if:
 - (a) he has failed to comply with or to set aside a Statutory demand under Section 268 of the Insolvency Act 1986 within twenty-one (21) days of service of the Statutory Demand on him; or
 - (b) execution or other process to enforce a debt due under a judgement or order of the court has been returned unsatisfied in whole or in part.
- (7) the presentation of a petition for sequestration in relation to the Contractor's estates unless it is withdrawn within three (3) Business Days from the date on which the Contractor is notified of the presentation; or
- (8) the court making an award of sequestration in relation to the Contractor's estates.

Where the Contractor is a company registered in England:

- (9) the presentation of a petition for the appointment of an administrator; unless it is withdrawn within three (3) Business Days from the date on which the Contractor is notified of the presentation; or
- (10) the court making an administration order in relation to the company; or
- (11) the presentation of a petition for the winding-up of the company unless it is withdrawn within three (3) Business Days from the date on which the Contractor is notified of the presentation; or
- (12) the company passing a resolution that the company shall be wound-up; or
- (13) the court making an order that the company shall be wound-up; or
- (14) the appointment of a Receiver or manager or administrative Receiver.

Where the Contractor is a company registered other than in England, events occur or are carried out which, within the jurisdiction to which it is subject, are similar in nature or effect to those specified in clauses 41.a(9) to 41.a(14) inclusive above.

- b. Such termination shall be without prejudice to and shall not affect any right of action or remedy which shall have accrued or shall accrue thereafter to the Authority and the Contractor.

Corrupt Gifts:

- c. The Contractor shall not do, and warrants that in entering the Contract it has not done any of the following (hereafter referred to as 'prohibited acts'):
- (1) offer, promise or give to any Crown servant any gift or financial or other advantage of any kind as an inducement or reward;
 - (a) for doing or not doing (or for having done or not having done) any act in relation to the obtaining or execution of this or any other contract with the Crown; or
 - (b) for showing or not showing favour or disfavour to any person in relation to this or any other Contract with the Crown.
 - (2) enter 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,

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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.

- d. If the Contractor, its employees, agents or any subcontractor (or anyone acting on its behalf or any of its or their employees) does any of the prohibited acts or commits 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, the Authority shall be entitled:
 - (1) to terminate the Contract and recover from the Contractor the amount of any loss resulting from the termination;
 - (2) to recover from the Contractor the amount or value of any such gift, consideration or commission; and
 - (3) to recover from the Contractor any other loss sustained in consequence of any breach of this condition, where the Contract has not been terminated.
- e. In exercising its rights or remedies under this condition, 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 performing, the prohibited act;
 - (2) give all 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.
- f. Recovery action taken against any person in Her Majesty's service shall be without prejudice to any recovery action taken against the Contractor pursuant to this Condition.

42. Termination for Convenience

- a. The Authority shall have the right to terminate the Contract in whole or in part at any time by giving the Contractor at least twenty (20) business days written notice (or such other period as may be stated in Schedule 3 (Contract Data Sheet)). Upon expiry of the notice period the Contract, or relevant part thereof, shall terminate without prejudice to the rights of the parties already accrued up to the date of termination. Where only part of the Contract is being terminated, the Authority and the Contractor shall owe each other no further obligations in respect of the part of the Contract being terminated, but will continue to fulfil their respective obligations on all other parts of the Contract not being terminated.
- b. Following the above notification the Authority shall be entitled to exercise any of the following rights in relation to the Contract (or part being terminated) to direct the Contractor to:
 - (1) not start work on any element of the Contractor Deliverables not yet started;
 - (2) complete in accordance with the Contract the provision of any element of the Contractor Deliverables;
 - (3) as soon as may be reasonably practicable take such steps to ensure that the production rate of the Contractor Deliverables is reduced as quickly as possible;
 - (4) terminate on the best possible terms any subcontracts in support of the Contractor Deliverables that have not been completed, taking into account any direction given under clauses 42.b(2) and 42.b(3) of this condition.
- c. Where this condition applies (and subject always to the Contractor's compliance with any direction given by the Authority under clause 42.b):
 - (1) The Authority shall take over from the Contractor at a fair and reasonable price all unused and undamaged materiel and any Contractor Deliverables in the course of manufacture that are:
 - (a) in the possession of the Contractor at the date of termination; and

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- (b) provided by or supplied to the Contractor for the performance of the Contract, except such materiel and Contractor Deliverables in the course of manufacture as the Contractor shall, with the agreement of the Authority, choose to retain;
 - (2) the Contractor shall deliver to the Authority within an agreed period, or in absence of such agreement within a period as the Authority may specify, a list of:
 - (c) all such unused and undamaged materiel; and
 - (d) Contractor Deliverables in the course of manufacture, that are liable to be taken over by, or previously belonging to the Authority, and shall deliver such materiel and Contractor Deliverables in accordance with the directions of the Authority;
 - (3) in respect of Services, the Authority shall pay the Contractor fair and reasonable prices for each Service performed, or partially performed, in accordance with the Contract.
- d. The Authority shall (subject to clause 42.e below and to the Contractor's compliance with any direction given by the Authority in clause 42.b above) indemnify the Contractor against any commitments, liabilities or expenditure which would otherwise represent an unavoidable loss by the Contractor by reason of the termination of the Contract, subject to:
- (1) the Contractor taking all reasonable steps to mitigate such loss; and
 - (2) the Contractor submitting a fully itemised and costed list of such loss, with supporting evidence, reasonably and actually incurred by the Contractor as a result of the termination of the Contract or relevant part.
- e. The Authority's total liability under the provisions of this Condition shall be limited to the total price of the Contractor Deliverables payable under the contract (or relevant part), including any sums paid, due or becoming due to the Contractor at the date of termination.
- f. The Contractor shall include in any subcontract over £250,000 which it may enter into for the purpose of the Contract, the right to terminate the subcontract under the terms of clauses 42.a to 42.e except that:
- (1) the name of the Contractor shall be substituted for the Authority except in clause 42.c(1);
 - (2) the notice period for termination shall be as specified in the subcontract, or if no period is specified twenty (20) business days; and
 - (3) the Contractor's right to terminate the subcontract shall not be exercised unless the main Contract, or relevant part, has been terminated by the Authority in accordance with the provisions of this condition 42.
- g. Claims for payment under this condition shall be submitted in accordance with the Authority's direction.

43. Material Breach

- a. 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.
- b. Where the Authority has terminated the Contract under clause 43.a 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, including but not limited to any costs and expenses incurred by the Authority in:
 - (1) carrying out any work that may be required to make the Contractor Deliverables comply with the Contract; or
 - (2) obtaining the Contractor Deliverable in substitution from another supplier.

44. Consequences of Termination

The termination of the Contract, however arising, shall be without prejudice to the rights and duties of either Party accrued prior to termination. The Conditions that expressly or by implication have effect after termination shall continue to be enforceable even after termination.

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45. Project specific DEFCONs and DEFCON SC variants that apply to this contract

DEFCON 23 (SC2) (Edn. 11/17) – Special Jigs, Tooling and Test Equipment

DEFCON 514A (Edn 03/16) – Failure of Performance under Research and Development Contracts

DEFCON 524A (Edn 02/20) – Counterfeit Materiel

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

DEFCON 601 (SC) (Edn. 03/15) – Redundant Material

The Clause will apply to the extent that the redundant materiel derives from the property owned by the Authority and issued to the Contractor. This includes scrap, redundant material arising from repair contracts, and items subject to the provisions of DEFCON 23 (SC2) (Edn. 11/17) – Special Jigs, Tooling and Test Equipment where title in the items has passed to the Authority.

DEFCON 605 (SC2) (Edn. 11/17) – Financial Reports

DEFCON 611 (SC2) (Edn. 02/16) – Issued Property

DEFCON 612 (Edn 10/98) – Loss of or Damage to the Articles

DEFCON 624 SC2 (Edn 11/17) – Use of Asbestos

DEFCON 645 (Edn 07/99) – Export Potential

DEFCON 647 SC2 (Edn 11/17)– Financial Management Information

DEFCON 649 SC2 (Edn 11/17) – Vesting

DEFCON 653 (Edn12/14) – Pricing on Ascertained Costs

DEFCON 658 SC2 (Edn 11/17) – Cyber

Further to DEFCON 658 the Cyber Risk Profile of the Contract is Very Low, as defined in Def Stan 05-138.

DEFCON 660 (Edn 12/15) – Official-Sensitive Security Requirements.

A requirement Security Aspects Letter is detailed at Annex D to the Contract together with additional Official and Official Sensitive Security Conditions for UK Contracts at Annex I to the Contract.

DEFCON 670 SC2 (Edn 11/17) – Tax Compliance

DEFCON 694 (SC2) (Edn. 08/18) – Accounting for Property of The Authority

Intellectual Property Rights

DEFCON 014 (Edn. 11/05) – Inventions and Designs Crown Rights and Ownership of Patents and Registered Designs

DEFCON 015 (Edn. 02/98) – Design Rights and Rights to Use Design Information. See DEFORM 315's at Annex J)

DEFCON 021 (Edn. 10/04) – Retention of Records

DEFCON 090 (Edn. 11/06) – Copyright

DEFCON 126 (Edn. 11/06) – International Collaboration Clause

SPECIAL CONDITIONS THAT APPLY TO THIS CONTRACT**46. Contractor Performance measurement and incentivisation**

- a. The Contractor's performance under the Contract shall be monitored by the Authority on delivery of the deliverables stated in the Statement of Work at Annex A and assessed against a series of Key Performance Indicators (KPIs) and Performance Indicators (Pis) as set out in Annex C to this Contract.
- b. The Authority reserves the right to amend Annex C during the lifetime of this Contract to ensure the KPIs are relevant and appropriate to the support being provided. In the event the Authority wishes to raise an amendment to Annex C it will provide the Contractor with a draft Annex C amendment at least 10 working days before a quarterly review meeting. The parties shall consider the amendment and agree a form of the amendment in the quarterly review meeting. The Authority shall confirm the agreed position through this issue of a Contract Amendment that changes the Annex C.
- c. The Contractor's performance under the Contract shall be monitored by means of a performance dashboard that shall be presented to the Authority monthly by the Contractor and subjected to a formal review by both parties at each quarterly review meeting. The Contractor shall be assessed by the Authority as either having met or not met its performance targets.
- d. The KPIs identified at Annex C to the Contract are Specific, Measurable, Achievable, Realistic and Time-bound (SMART) objectives, against which performance can be assessed.
- e. The Contractor shall be responsible for raising the performance dashboard and detailing performance against the KPIs. The performance dashboard shall be submitted to the Authority's Project Manager (as specified in Schedule 3 (Contract Data Sheet)) or their nominated representative and the Authority's Commercial Officer (as specified in Schedule 3 (Contract Data Sheet)) or their nominated representative, five working days prior to each quarterly review meeting. Scores assessed by reference to the KPIs at Annex C to this Contract shall be allocated wholly by the Authority.
- f. In the event the Contractor is required to implement a remedy to rectify a KPI that is not green the Contractor must work in a manner that is appropriate and relevant to the remedy being implemented in line or in advance of the agreed timeframe for remedy.

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- g. The Authority reserves the right to terminate the Contract with immediate effect for Material Breach in accordance with Clause 47 if the Contractor continually fails to remedy a scored 'Red' KPI or if the Contractor scores 'Red' on more than 40% of the KPIs for which the assessment is undertaken.

47. Notification of Default

- a. If before completion of any of the milestones stated in the Schedule of Requirements, the Contractor:
 - i. Without reasonable cause wholly or substantially suspends the carrying of the services required under this contract;
 - ii. Fails to proceed regularly and diligently with the performance of his obligations under this contract;
 - iii. Without consent of the Authority, sub-contracts or assigns the whole or any part of the Contract;
 - iv. Fails to comply with the statutory licencing requirements and processes required under the Statement of Work;
 - v. Refuses or neglects to comply with any notice or instruction issued by the Authority in accordance with this contract,
 - vi. Fails to correct any errors, omissions or defaults identified in deliverables or supporting information provided to the Authority, or
 - vii. Commits any other serious breach of his obligations under the Contract,

The Authority may issue to the Contractor a notice specifying the default or defaults.

- b. If the Contractor fails to rectify the default specified within the notice within 14 days from the receipt of that notice, then the default may be regarded as a material breach of contract. The Authority will be entitled to terminate the Contract under clause 43.

48. Security of Supply

- a. To ensure security of supply for the Authority's requirements the Contractor shall, in relation to the Articles, produce and maintain a technical data pack including therein sufficient information in sufficient detail to enable a competent third party to produce and maintain the Articles at the most recent standard that is used by the Authority. The technical data pack shall also be deemed to include, but not limited to; method statements, protocols and the latest version of any batch manufacturing records.
- b. The Contractor shall be entitled to fair and reasonable payment for the production and maintenance of the technical data pack and such payment shall take into account the existing rights of the Authority with regard to the Articles; the technical data pack shall at all times be the property of the Authority and the Contractor shall ensure that it is clearly marked as such.

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- c. The technical data pack shall be held by the Contractor and may be accessed by the Authority in the following circumstances:
 - i. from time to time in order to verify the existence of the technical data pack and that its contents meet the Authority's requirements, as stated in the Statement of Work (Annex A to the Contract).
 - ii. in the event that the Contractor is unwilling or unable to supply the Articles to the Authority on fair and reasonable terms.
 - iii. where the Authority has terminated the Contract under clause 42 (Termination for Convenience) or clause 43 (Material Breach).
- d. In the event that the Authority does access the technical data pack as provided in clause 48(c)(ii) or 48(c)(iii), it shall have the free right to use the information therein for the purposes of procuring the Articles from an alternative source and also for the purposes of having the Articles maintained, updated or modified by an alternative contractor.
- e. Where the Contractor is unwilling or unable to supply the Articles on fair and reasonable terms, he shall, to the extent he is able, at the Authority's request, provide the Authority or any replacement contractor engaged by the Authority with the technical assistance necessary to enable a third party competent in the technical disciplines involved to produce and maintain the Articles.
- f. Without prejudice to any other obligations of the Contractor under the Contract, in the event that the Contractor does not possess sufficient rights in the Articles, to comply with the terms of this clause, he will obtain an undertaking from the owner of those rights to enter into a direct agreement with the Authority on the same terms as this condition.
- g. For the avoidance of doubt, nothing in this clause shall alter either the ownership of the intellectual property embodied in the Articles, or any rights subsisting therein, save to the extent that additional usage rights are provided to the Authority pursuant to clause 48(d) in those circumstances defined in clause 48(c)(ii) or 48(c)(iii).
- h. The Contractor shall supply the Authority with the technical data pack within 3 months of the contract end date.
- i. The provisions of this clause shall not diminish any obligations which the Contractor otherwise has under the Contract.

49. Management and Sub-Contractor Management

- a. The Contractor shall assume full responsibility for any sub-contractor that they employ for the manufacture, testing, storage or distribution of the Articles (including but not limited to; components, documentation and packaging of the Articles). The Authority must be notified in writing of any changes to the Contractor's sub-contractors before use.
- b. The Contractor shall complete a regular programme of audits of the sub-contractors used in the manufacture, packaging or testing of the Articles. Any major or critical non-conformances found will be notified to the Authority immediately.

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- c. The Contractor shall ensure its sub-contractors comply with cGMP.
- d. The Contractor shall maintain a current supply chain risk assessment for the duration of the Contract for the Articles.

50. Quality Assurance

- a. The Contractor (or agreed sub-contractor) shall hold and maintain all necessary manufacturing and other licenses or equivalents issued by the requisite regulatory agencies to carry out current Good Manufacturing Practice (cGMP) manufacture of medicinal products.
- b. It is a condition of this Contract that cGMP audits are performed by the Authority on the Contractor's or sub-contractor(s)' facilities required in the manufacture of the Articles, and that such audits produce a successful outcome. A successful outcome shall be defined in three stages:
 - i. From the audit conducted by the Authority, zero critical findings and no more than four major findings to be identified.
 - ii. If any findings are identified, the Contractor shall submit to the Authority a mitigation plan within one month. This mitigation plan must be agreed with the Authority.
 - iii. If a mitigation plan is required, the Contractor shall provide evidence to the Authority confirming the agreed actions have been completed. This evidence shall be provided within six months from the date the mitigation plan has been agreed.
- c. If the conditions detailed in clause 49(b) are not met, the Authority has, at its sole discretion, the right to terminate the Contract with immediate effect in accordance with Condition 43 (Material Breach). Alternatively, the Authority has the right to extend the period for which the Contractor can achieve compliance in accordance with clause 49(b) and permit a further audit.

51. Regulatory

- a. All activities will be conducted by the Contractor and its subcontractors in a manner consistent with the objective of gaining a Marketing Authorisation (MA) for the final medicinal product in the UK. To this end:
 - i. The Contractor will maintain a certificate of cGMP compliance.
 - ii. The Articles shall be in accordance with the requirements of EC Directive 91/356/EEC as amended and the principles and guidelines for Good Manufacturing Practice shall be followed.
 - iii. In performing its obligations under or pursuant to this Contract the Contractor and his sub-contractors shall ensure that it obtains and maintains at its own expense, all necessary permits, licences, authorisations and any other permissions (whether statutory or otherwise) required to carry out the activities of the Contractor hereunder.
 - iv. All stages of the manufacturing and distribution process will be conducted to the relevant GxP (Good Practice) standards.
 - v. The Articles shall be packaged in compliance with cGMP / Good Distribution Practice (GDP) guidelines and consistent with data generated in laboratory studies.
 - vi. Storage and transportation of the Articles shall be carried out in accordance with the requirements of GDP and the Guidelines of GDP on Medicinal Products for Human Use (94/C/63/03) or as subsequently amended.

52. Retention of Quality Control / Inspection Records

- a. The Contractor shall retain the Quality Control / Inspection Records for the period specified by the Authority and shall make them accessible to the Authority on request. At the end of the retention period the Contractor shall seek from the Authority instructions regarding the disposal / continued retention of the Quality Control / Inspection Records. The records shall not be disposed of without prior written authority having first been obtained from the Authority's Commercial Officer.

53. Manufacturing Variances

- a. In discharging its obligations under the Contract, the Contractor shall at all times seek to deliver as a minimum the total quantity of Articles required by the Contract. The Contractor shall therefore use all best endeavours to deliver the total quantity required by the Contract.
- b. Where it is reasonable and feasible the Contractor shall agree to make good as part of the next order any underage that may occur beyond its control. Where any underage occurs within its control (e.g. negligence) the Contractor shall agree to immediately make good the underage at its own expense. This condition does not prejudice the rights, obligations or remedies afforded to each Party under the Contract.
- c. The Contractor shall at all times inform the Authority of any losses that occur within the manufacturing, packaging or delivery processes for each order or campaign placed by the Authority prior to the delivery of the finished Articles. In each case the Contractor shall provide a clear indication of the reason for the loss together with full and accurate details of the actual loss incurred.
- d. The Contractor shall be responsible for certifying the quality of all components that make up the complete Articles before commencement of manufacture.

54. Stability Studies

- a. Should any discrepancy be identified by any of the stability studies then the discrepancy shall be immediately notified to the Authority.

55. Authorisation by the Crown for Use of Third Party Intellectual Property Rights

- b. 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 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.

Redacted version for publishing – April 2021**56. COVID19**

- a. The Parties recognise that the performance of this Contract/Contract Amendment may be adversely affected by the COVID-19 pandemic.
- b. If, despite the relevant Party taking reasonable steps to mitigate the adverse impact of such pandemic upon its performance of its obligations provided in this Contract/Contract Amendment, such performance is adversely affected, this must be fully evidenced in writing within 30 calendar days. For the avoidance of doubt, in the case of the Contractor this includes its sub-contractors.
- c. The Parties shall then work together in good faith to consider how (if at all) any such adverse impact on the performance of the Contract is recognised in the Contract, using existing provisions where possible.
- d. Any request for relief will be considered on a case by case basis in accordance with the above provisions. This provision shall apply until there is a widely available vaccine for COVID-19 in the United Kingdom.
- e. Nothing in this provision shall in itself create a precedent or save to the extent that any relief is granted under its provisions, operate to waive or reduce either Party's obligations under or in connection with this Contract/Contract Amendment. To this extent the Authority reserves its right to terminate for non-performance following review.
- f. This Clause and the Contractor's rights provided in this Clause constitute the Contractor's sole rights in relation to COVID-19 and in connection with this Contract and shall operate to the exclusion of any and all other rights and remedies it may otherwise have in connection with the same.

57. Pricing the Contract Requirements

- a. This clause 57 covers the pricing and payment of all sums agreed under Contract Items 1.0 of the Schedule of Requirement at Schedule 2 of this Contract (the 'Contract Requirements').
- b. Any variation to the Contract Requirements stated under Schedule 2 may be priced as an adjustment to the Target Cost stated under the Schedule of Requirements, or, may be agreed as a Firm Price which will be priced and paid separately to the agreed Target Cost.
- c. The total amount to be paid by the Authority to the Contractor under the Contract shall not, without any agreement in writing of the Authority's Representative as detailed at Box 1 of the DEFFORM 111 (Annex A to Schedule 3), exceed the Maximum Price as shown on the Schedule of Requirements at Schedule 2 of the Contract.
- d. The price for the works as shown in the Contract Requirements at Schedule 2 will be based on an agreed Target Cost. The Target Cost for the performance of work under the Contract Requirements shall be £[REDACTED] with a Target Fee of £[REDACTED], giving a Target Price of £[REDACTED] exclusive of VAT. The contract price shall be subject to an overall Maximum Price of £5,986,045.00, exclusive of VAT.
- e. Target Fee means a fixed percentage of the Target Cost. For the purpose of this contract the Target Fee is [REDACTED] %.
- f. The Target Cost shall be calculated using the Schedule of Requirements at Schedule 2 of the Contract and in accordance with Target Cost provisions of the Target Cost Incentive Fee Arrangement at Annex N of the Contract.

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- g. The total amount paid by the Authority to the Contractor will be the Contractor's Actual Cost plus the agreed Target Fee. Payment will be made by the Authority in accordance with the provisions of the Target Cost Incentive Fee Arrangement at Annex N of the Contract.
- h. If the Contractor exceeds the Target Cost stated in clause 57(e) or when it becomes reasonably known that the Contractor will exceed the Target Cost stated in clause 57(e), the Contractor shall immediately notify the Authority's Project Manager as detailed at Annex A to Schedule 3 of the Contract, and provide a forecast of the Contractor's total Actual Cost to complete the works under the contract.
- i. If at any time the Contractor considers that the contract cannot be completed for the Maximum Target Price, the Contractor must immediately inform the Authority's Project Manager as detailed at Annex A to Schedule 3 of the Contract and at the same time provide an explanation of the circumstances causing the overspend. The Authority shall be under no obligation to amend the Maximum Target Price.
- j. Once the Contract Requirements under Schedule 2 have been completed, the Contractor will issue a final cost statement to the Authority. When submitting the request for final settlement in respect of this Contract, the Contractor shall forward to the Commercial Manager as detailed at Box 1 of the DEFFORM 111 (Annex A to Schedule 3) a certified cost statement of the total Actual Cost of the work to completion using DEFFORM 812 (At Annex I to the Contract).
- k. The agreed Target Cost and Maximum Target Price will be jointly reviewed by the Contractor and the Authority every 36 months, starting from the date of Contract Award. Should any variance to the Target Cost be agreed between the Authority and the Contractor, this variance will be subject to the change control procedure under this contract.

58. Option Pricing

- a. The Contractor hereby grants to the Authority the following irrevocable options to undertake the activities detailed under Contract Option No 2.0 (2.1 to 2.3) and Contract Option No 3.0 (3.1 to 3.2) of the Schedule of Requirements at Schedule 2 of this Contract. The commencement of these options are as follows:
 - I. Contract Option No 2.1 – 01 January 2022
 - II. Contract Option No 2.2 – 01 January 2023
 - III. Contract Option No.2.3 – 01 January 2024
 - IV. Contract Option No. 3.1 – dates to be confirmed.
 - V. Contract Option No. 3.2 – dates to be confirmed.
- b. These Options shall be exercised and subject to the terms and conditions set out in this Contract. The Options will be exercised six months prior to the commencement of the Option Period. The Authority reserves the right to amend the commencement date of any option and the date by which the option is required to be exercised.
- c. All Options priced under Contract Option No 2.0 and Contract Option No.3 will be a 'Maximum Price'. A Maximum Price is an indicative price that is 'not-to-be-exceeded'.
- d. All Maximum Prices will be reviewed jointly by the Authority and Contractor prior to the exercise of any Option. The Contractor will have the opportunity to provide a Firm Price for the specified Option, which will supersede the Maximum Price. Any Firm price agreed will not be subject to variation.
- e. The Options stated under Contract Option No.3 are based on prices for the purchase of specified quantities of Tier 1 and Tier 3 Auto-injectors. These are prices for the Auto-injector Device only. Should there be a requirement for any Tier 1 and Tier 3 Auto-injector devices, then the Authority shall also review whether there is any requirement for the Contractor to also purchase or develop

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the API and request a price for filling the device. The additional requirements will be assessed as a 'Future Requirement' in accordance with clause 59.

- f. The Authority shall not be obliged to exercise any of the options stated under this contract.

59. Future Auto-Injector Requirements

- a. A 'Future Requirement' is any amendment, variation or option that is not included in the Schedule of Requirements at Schedule 2 of this contract.
- b. The Authority reserves the right to award any Future Requirement to an alternative contractor should the Contractor provide a price that does not represent value for money or cannot be completed in accordance with the timescales required.
- c. Any Future Requirements will be priced in accordance with Annex O to this Contract (Future Auto-Injector Requirements).

60. Commercial Exploitation

- a. This Contract shall require the Contractor to sign a 'Commercial Exploitation Levy' (CEL) as detailed on Annex K to this Contract. A supporting Profit-Sharing Agreement and Abatement Agreement are enclosed at Annexes L and M to this contract, these supporting agreements may be agreed in addition and after contract award.
- b. The following DEFCONs include an obligation on the Contractor to notify the MOD of all transactions, actual or prospective, which will attract CEL:
 - i. DEFCON 15 – Design Rights;
 - ii. DEFCON 23 – Special Jigs, Tooling and Test Equipment; and
 - iii. DEFCON 91 – Intellectual Property Rights in Software

61. Contract Data Requirement (DEFFORM 315)

- a. A Contract Data Requirement (DEFFORM 315) is enclosed, at Annex J to the contract, in accordance with the Statement of Work at Annex A to the Contract. The Authority intends to agree specific Intellectual Property Right ('IPR') requirements for each and any Future Requirement.

DEFINITIONS OF CONTRACT

Articles	means the Contractor Deliverables (goods and/or the services), including Packaging (and Certificate(s) of Conformity and supplied in accordance with any QA requirements if specified) which the Contractor is required to provide under the Contract in accordance with Schedule 2 (Schedule of Requirements), but excluding incidentals outside Schedule 2 (Schedule of Requirements) such as progress reports. (This definition only applies when DEFCONs are added to these Conditions);
Authority	means the Secretary of State for Defence acting on behalf of the Crown;
Authority's Representative(s)	shall be those person(s) defined in Schedule 3 (Contract Data Sheet) who will act as the Authority's Representative(s) in connection with the Contract. Where the term "Authority's Representative(s)" in the Conditions is immediately followed by a functional description in brackets, the appropriate Authority's Representative(s) shall be the designated person(s) for the purposes of condition 8;
Business Day	means 09:00 to 17:00 Monday to Friday, excluding public and statutory holidays;
Central Government Body	<p>a body listed in one of the following sub-categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics:</p> <ul style="list-style-type: none">a. Government Department;b. Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal);c. Non-Ministerial Department; ord. Executive Agency;
Collect	means pick up the Contractor Deliverables from the Consignor. This shall include loading, and any other specific arrangements, agreed in accordance with clause 28.c and Collected and Collection shall be construed accordingly;
Commercial Packaging	means commercial Packaging for military use as described in Def Stan 81-041 (Part 1)
Conditions	means the terms and conditions set out in this document;
Consignee	means that part of the Authority identified in Schedule 3 (Contract Data Sheet) to whom the Contractor Deliverables are to be Delivered or on whose behalf they are to be Collected at the address specified in Schedule 3 (Contract Data Sheet) or such other part of the Authority as may be instructed by the Authority by means of a Diversion Order;

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Consignor	means the name and address specified in Schedule 3 (Contract Data Sheet) from whom the Contractor Deliverables will be dispatched or Collected;
Contract	means the Contract including its Schedules and any amendments agreed by the Parties in accordance with condition 6 (Amendments to Contract);
Contract Price	means the amount set out in Schedule 2 (Schedule of Requirements) to be paid (inclusive of Packaging and exclusive of any applicable VAT) by the Authority to the Contractor, for the full and proper performance by the Contractor of its obligations under the Contract.
Contractor	means the person who, by the Contract, undertakes to supply the Contractor Deliverables, for the Authority as is provided by the Contract. 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, and the expression shall also include any person to whom the benefit of the Contract may be assigned by the Contractor with the consent of the Authority;
Contractor Commercially Sensitive Information	means the Information listed in the completed Schedule 5 (Contractor's Commercially Sensitive Information Form), 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 the services, including Packaging (and Certificate(s) of Conformity and supplied in accordance with any QA requirements if specified) which the Contractor is required to provide under the Contract;
Control	<p>means the power of a person to secure that the affairs of the Contractor are conducted in accordance with the wishes of that person:</p> <p>a. by means of the holding of shares, or the possession of voting powers in, or in relation to, the Contractor; or</p> <p>b. by virtue of any powers conferred by the constitutional or corporate documents, or any other document, regulating the Contractor;</p> <p>and a change of Control occurs if a person who Controls the Contractor ceases to do so or if another person acquires Control of the Contractor;</p>
CPET	means the UK Government's Central Point of Expertise on Timber, which provides a free telephone helpline and website to support implementation of the UK Government timber procurement policy;
Crown Use	in relation to a patent means the doing of anything by virtue of Sections 55 to 57 of the Patents Act 1977 which otherwise would be an

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infringement of the patent and in relation to a Registered Design has the meaning given in paragraph 2A(6) of the First Schedule to the Registered Designs Act 1949;

Dangerous Goods	<p>means those substances, preparations and articles that are capable of posing a risk to health, safety, property or the environment which are prohibited by regulation, or classified and authorised only under the conditions prescribed by the:</p> <ul style="list-style-type: none">a. Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG) (as amended 2011);b. European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR);c. Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID);d. International Maritime Dangerous Goods (IMDG) Code;e. International Civil Aviation Organisation (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air;f. International Air Transport Association (IATA) Dangerous Goods Regulations.
DBS Finance	<p>means Defence Business Services Finance, at the address stated in Schedule 3 (Contract Data Sheet);</p>
DEFFORM	<p>means the MOD DEFFORM series which can be found at https://www.aof.mod.uk;</p>
DEF STAN	<p>means Defence Standards which can be accessed at https://www.dstan.mod.uk;</p>
Deliver	<p>means hand over the Contractor Deliverables to the Consignee. This shall include unloading, and any other specific arrangements, agreed in accordance with condition 28 and Delivered and Delivery shall be construed accordingly;</p>
Delivery Date	<p>means the date as specified in Schedule 2 (Schedule of Requirements) on which the Contractor Deliverables or the relevant portion of them are to be Delivered or made available for Collection;</p>
Denomination of Quantity (D of Q)	<p>means the quantity or measure by which an item of material is managed;</p>
Design Right(s)	<p>has the meaning ascribed to it by Section 213 of the Copyright, Designs and Patents Act 1988;</p>
Diversion Order	<p>means the Authority's written instruction (typically given by MOD Form 199) for urgent Delivery of specified quantities of Contractor</p>

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Deliverables to a Consignee other than the Consignee stated in Schedule 3 (Contract Data Sheet);

Effective Date of Contract	means the date specified on the Authority's acceptance letter;
Evidence	means either: a. an invoice or delivery note from the timber supplier or Subcontractor to the Contractor specifying that the product supplied to the Authority is FSC or PEFC certified; or b. other robust Evidence of sustainability or FLEGT licensed origin, as advised by CPET;
Firm Price	means a price (excluding VAT) which is not subject to variation;
FLEGT	means the Forest Law Enforcement, Governance and Trade initiative by the European Union to use the power of timber-consuming countries to reduce the extent of illegal logging;
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;
Independent Verification	means that an evaluation is undertaken and reported by an individual or body whose organisation, systems and procedures conform to "ISO Guide 65:1996 (EN 45011:1998) General requirements for bodies operating product certification systems or equivalent", and who is accredited to audit against forest management standards by a body whose organisation, systems and procedures conform to "ISO 17011: 2004 General Requirements for Providing Assessment and Accreditation of Conformity Assessment Bodies or equivalent";
Information	means any Information in any written or other tangible form disclosed to one Party by or on behalf of the other Party under or in connection with the Contract;
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;
Legal and Sustainable	means production and process methods, also referred to as timber production standards, as defined by the document titled "UK Government Timber Production Policy: Definition of legal and

SCHEDULE 1 – To Contract CBRN/0276

sustainable for timber procurement". The edition current on the day the Contract documents are issued by the Authority shall apply;

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;
Military Level Packaging (MLP)	means Packaging that provides enhanced protection in accordance with Def Stan 81-041 (Part 1), beyond that which Commercial Packaging normally provides for the military supply chain;
Military Packager Approval Scheme (MPAS)	is a MOD sponsored scheme to certify military Packaging designers and register organisations, as capable of producing acceptable Services Packaging Instruction Sheet (SPIS) designs in accordance with Defence Standard (Def Stan) 81-041 (Part 4);
Military Packaging Level (MPL)	shall have the meaning described in Def Stan 81-041 (Part 1);
MPAS Registered Organisation	is a packaging organisation having one or more MPAS Certificated Designers capable of Military Level designs. A company capable of both Military Level and commercial Packaging designs including MOD labelling requirements;
MPAS Certificated Designer	shall mean an experienced Packaging designer trained and certified to MPAS requirements;
NATO	means the North Atlantic Treaty Organisation which is an inter-governmental military alliance based on the North Atlantic Treaty which was signed on 4 April 1949;
Notices	shall mean all Notices, orders, or other forms of communication required to be given in writing under or in connection with the Contract;
Overseas	shall mean non-UK or foreign;
Packaging	Verb. The operations involved in the preparation of materiel for; transportation, handling, storage and Delivery to the user; Noun. The materials and components used for the preparation of the Contractor Deliverables for transportation and storage in accordance with the Contract;
Packaging Design Authority (PDA)	shall mean the organisation that is responsible for the original design of the Packaging except where transferred by agreement. The PDA shall be identified in the Contract, see Annex A to Schedule 3 (Appendix – Addresses and Other Information), Box 3;

SCHEDULE 1 – To Contract CBRN/0276

Parties	means the Contractor and the Authority, and Party shall be construed accordingly;
Primary Packaging Quantity (PPQ)	means the quantity of an item of material to be contained in an individual package, which has been selected as being the most suitable for issue(s) to the ultimate user, as described in Def Stan 81-041 (Part 1);
Recycled Timber	<p>means recovered wood that prior to being supplied to the Authority had an end use as a standalone object or as part of a structure. Recycled Timber covers:</p> <ul style="list-style-type: none">a. pre-consumer reclaimed wood and wood fibre and industrial by-products;b. post-consumer reclaimed wood and wood fibre, and driftwood;c. reclaimed timber abandoned or confiscated at least ten years previously; <p>it excludes sawmill co-products;</p>
Safety Data Sheet	has the meaning as defined in the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulations 2007 (as amended);
Schedule of Requirements	means Schedule 2 (Schedule of Requirements), which identifies, either directly or by reference, Contractor Deliverables to be provided, the quantities and dates involved and the price or pricing terms in relation to each Contractor Deliverable;
Short-Rotation Coppice	means a specific management regime whereby the poles of trees are cut everyone to two years and which is aimed at producing biomass for energy. It is exempt from the UK Government timber procurement policy. For avoidance of doubt, Short-Rotation Coppice is not conventional coppice, which is subject to the timber policy;
Specification	means the description of the Contractor Deliverables, including any specifications, drawings, samples and / or patterns, referred to in Schedule 2 (Schedule of Requirements);
STANAG 4329	means the publication NATO Standard Bar Code Symbology's which can be sourced at https://www.dstan.mod.uk/faqs.html ;
Subcontractor	means any subcontractor engaged by the Contractor or by any other subcontractor of the Contractor at any level of subcontracting to provide Contractor Deliverables wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of this Contract and 'Subcontract' shall be interpreted accordingly;

SCHEDULE 1 – To Contract CBRN/0276

Timber and Wood-Derived Products	means timber (including Recycled Timber and Virgin Timber but excluding Short-Rotation Coppice) and any products that contain wood or wood fibre derived from those timbers. Such products range from solid wood to those where the manufacturing processes obscure the wood element;
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 Contractor under the Contract;
Virgin Timber	means Timber and Wood-Derived Products that do not include Recycled Timber.

DEFFORM 110		
Name and Address of Contractor: ChemProtect.SK s.r.o. Staničná 1119/8 039 01 Turčianské Teplice Slovakia	<u>MINISTRY OF DEFENCE</u> SCHEDULE OF REQUIREMENTS	Contract No: CBRN/00276

THE CONTRACT REQUIREMENTS

CONTRACT ITEM No.	STATEMENT OF WORK REF. (ANNEX A)	DESCRIPTION	DATE		Notes to Supplier	Unit Price (£ Sterling)	Total ITEM PRICE (£ Sterling) (Ex VAT)
			From	To			
			1.0 SCHEDULE OF REQUIREMENTS				
1.1	SOW Line Item 1	DRUG FORMULATION AND DEVICE	Delivery dates are as per the Statement of Work (annex A) and as agreed at contract award under the baseline contract delivery schedule.		£ £ £ £ £ £ £	£	
1.2	SOW Line Item 2	STABILITY			£ £	£	
1.3	SOW Line Item 3	DEMONSTRATION AND ASSESSMENTS			£ £ £ £	£	

SCHEDULE 2 – To Contract CBRN/0276

					£ ■	
1.4	SOW Line Item 4	SPECIFICATION DOCUMENTATION			£ ■	£ ■
1.5	SOW Line Item 5	MANUFACTURE			£ ■ £ ■	£ ■
1.6	SOW Line Item 6	TRAINING DEVICE AND MANUALS			£ ■	£ ■
1.7	SOW Line Item 7	PROTOCOLS			£ ■ £ ■	£ ■
1.8	SOW Line Item 8	PROJECT MANAGEMENT D22 – Project Plan and Schedules D23 – Monthly Reports and Progress D24 – Annual Development Reports D25 – Annual Quality Summary Reports		Monthly Report requirement will cease upon production of Auto- Injector	£ ■ £ ■ £ ■ £ ■	£ ■
1.9	SOW Line Item 9	CE CERTIFICATION			£ ■	£ ■
1.10	SOW Line Item 10	CTO DOCUMENTATION REVIEW			£ ■	£ ■
1.11	SOW 11.1a	Earned Value Management			£ ■	£ ■
				TARGET COST TOTAL		£ ■
				FEE		£ ■
				TARGET PRICE		£ 5,622,520.00

OPTIONS

CONTRACT Option No.	STATEMENT OF WORK REF. (ANNEX A)	DESCRIPTION								
				DATE		Notes Supplier	to	Unit Price (£ Sterling)	Quantity	Total ITEM PRICE (£ Sterling) (Ex VAT)
				From	To					
2.1	SOW Line Item 11.3c	Final Product Procurement - Initial Supply final product – 2022.	Project Management	Tbc	Tbc		█	█	£ █ [MAXIMUM PRICE]	
			Purchase of Auto- Injector Device Price	Tbc	Tbc		£ █	█	£ █ [MAXIMUM PRICE]	
			█	Tbc	Tbc		£ █	█	£ █ [MAXIMUM PRICE]	
TOTAL SUPPLY PRICE (2021 – 2022)								█	£ █	
2.2	SOW Line Item 11.4d	Final Product Procurement - Supply final product – 2023.	Project Management	Tbc	Tbc		£ █	█	£ █ [MAXIMUM PRICE]	
			Purchase of Auto- Injector Device Price	Tbc	Tbc		£ █	█	£ █ [MAXIMUM PRICE]	
			█	Tbc	Tbc		£ █	█	£ █ [MAXIMUM PRICE]	
TOTAL SUPPLY PRICE (2022 – 2023)								█	£ █	
2.3	SOW Line Item 11.5e	Final Product Procurement - Initial	Project Management	Tbc	Tbc		£ █	█	£ █ [MAXIMUM PRICE]	

SCHEDULE 2 – To Contract CBRN/0276

		Supply final product – 2024.	Purchase of Auto-Injector Device Price	Tbc	Tbc		£ [REDACTED]	[REDACTED]	£ [REDACTED] [MAXIMUM PRICE]
			[REDACTED]	Tbc	Tbc		£ [REDACTED]	[REDACTED]	£ [REDACTED] [MAXIMUM PRICE]
TOTAL SUPPLY PRICE (2023 – 2024)								[REDACTED]	£ [REDACTED]
3.1	SOW Line Item 11.2b	Future Works TIER 1 – Supply Product	Project Management	Tbc	Tbc		£ [REDACTED]	[REDACTED]	£ [REDACTED] [MAXIMUM PRICE]
			Purchase of Auto-Injector Device Price	Tbc	Tbc		£ [REDACTED]	[REDACTED]	£ [REDACTED] [MAXIMUM PRICE]
TOTAL SUPPLY PRICE FOR A TIER 1 AUTO-INJECTOR								[REDACTED]	£ [REDACTED]
3.2	SOW Line Item 11.2b	Future Works TIER 3 – Supply Product	Project Management	Tbc	Tbc		£ [REDACTED]	[REDACTED]	£ [REDACTED] [MAXIMUM PRICE]
			Purchase of Auto-Injector Device Price –	Tbc	Tbc		£ [REDACTED]	[REDACTED]	£ [REDACTED] [MAXIMUM PRICE]
TOTAL SUPPLY PRICE FOR A TIER 3 AUTO-INJECTOR								[REDACTED]	£ [REDACTED]

**Appendix 1 to Schedule of Requirements (Schedule 2) – To Contract CBRN/0276
Target Cost Breakdown**

CONTRACT ITEM No.	STATEMENT OF WORK REF. (ANNEX A)	DESCRIPTION	LABOUR	TRAVEL / SUBSISTENCE / ACCOMODATION	Sub- Contract Cost	Materials Cost	Total Target Cost
1	SOW Line Item 1	DRUG FORMULATION AND DEVICE					
2	SOW Line Item 2	STABILITY					
3	SOW Line Item 3	DEMONSTRATION AND ASSESSMENTS					
4	SOW Line Item 4	SPECIFICATION DOCUMENTATION					
5	SOW Line Item 5	MANUFACTURE					
6	SOW Line Item 6	TRAINING DEVICE AND MANUALS					
7	SOW Line Item 7	PROTOCOLS					

Appendix 1 to Schedule of Requirements (Schedule 2) – To Contract CBRN/0276
Target Cost Breakdown

8	SOW Line Item 8	PROJECT MANAGEMENT	████	████	████	████	████
		D22 – Project Plan and Schedules	████	████	████	████	
		D23 – Monthly Reports and Progress	████	████	████	████	
		D24 – Annual Development Reports	████	████	████	████	
		D25 – Annual Quality Summary Reports	████	████	████	████	
9	SOW Line Item 9	CE CERTIFICATION	████	████	████	████	████
		████████████████████	████	████	████	████	
10	SOW Line Item 10	CTO DOCUMENTATION REVIEW	████	████	████	████	████
		████████████████████	████	████	████	████	
11	SOW 11.1a	Earned Value Management	████	████	████	████	████
		Earned Value Management	████	████	████	████	
Target Total Cost							████

Schedule of Labour Rates

The following Labour Rates will be used in accordance with the Target Cost Fee arrangement as follows:

- To price the Target Cost in the Schedule of Requirements; and
- To recover payment for labour via the Contractor's invoice of Actual Cost.

These rates are Firm and will not be subject to variance, unless, the Authority agrees to vary these rates as part of the pricing review that will be undertaken by the Authority and the Contractor every 36 months from commencement of this contract.

A. LABOUR RATES (Hourly Rate):

Grade of Staff	HOURLY RATE £'s (Ex VAT)
Executive Manager	████
Senior Project Manager	████
Project Manager – Pharmacy specialist	████
Project Manager – Pharmacy specialist	████
Production Manager	████
Senior Account Project Manager	████
Account Project Manager	████
Backoffice Manager	████
Pharmacy, Toxicology Consultant	████
Military, Pharmacy and Toxicology Consultant Assoc	████

The Daily rates in the table above shall be all-inclusive with the sole exception of those detailed below:

B. Travel and Subsistence

1. The Contractor may include prices for travel, accommodation and subsistence in Appendix 1 to the Schedule of Requirements – the Target Cost Breakdown, for any travel, accommodation and subsistence which is required solely in connection with the Contractor's performance of this Contract.
2. The Contractor may claim for an over-night stay, evening meal and / or day-visit subsistence, should the Contractor be required to conduct work in accordance with the contract away from his premises.
3. The reimbursement of hotel and travel expenses will be admissible as Actual Cost under the Target Cost fee arrangement at Annex N.
4. Any claim for hotel stays that are over £[REDACTED] per night (including an evening meal) will not be an admissible claim or recovered as 'Actual Cost' unless prior approval is sought and agreed by the Authority.
5. The Contractor may submit expense claims as part of their invoice in accordance with the following:
 - a. Car journeys using the Contractor's own vehicle will be paid using the following rate for mileage £ [REDACTED]. The Contractor shall produce a signed certificate detailing the number of miles travelled and confirming that the claim relates solely to travel in connection with the performance of the contract. Claims relating to vehicle insurance are inadmissible.
 - b. Travel expenses other than the Contractor's own vehicle mileage rate stated above will be reimbursed upon receipt of evidence of actual expenditure (such as rail, air fares and taxi).
6. Rail and Air fares will be recoverable by the Contractor if the fare is purchased based on standard-class travel. Any fares purchase based on first-class travel will not be permissible as 'Actual Cost' under this contract.

Schedule 3 – Contract Data Sheet for Contract No: CBRN/00265

<p>General Conditions</p>
<p>Condition 2 – Duration of Contract:</p> <p>The contract duration shall be 24 February 2021 to 24 February 2036</p> <p>Options:</p> <p>The Authority has stipulated Option prices for future supply and batches of various auto-injector devices under the Schedule of Requirements (Contract Option No. 2.0 and 3.0)</p> <p>The Authority has no obligation to exercise any of the Options stipulated in this Contract.</p>
<p>Condition 4 – Governing Law:</p> <p>Contract to be governed and construed in accordance with:</p> <p>English Law <input checked="" type="checkbox"/></p> <p>Scots Law <input type="checkbox"/> clause 4.d shall apply <i>(one must be chosen)</i></p> <p>Solicitors or other persons based in England and Wales (or Scotland if Scots Law applies) irrevocably appointed for Contractors without a place of business in England (or Scotland, if Scots Law applies) in accordance with clause 4.g (if applicable) are as follows:</p>
<p>Condition 8 – Authority’s Representatives:</p> <p>The Authority’s Representatives for the Contract are as follows:</p> <p>Commercial: ██████ (as per DEFFORM 111)</p> <p>Project Manager: ██████ (as per DEFFORM 111)</p>

<p>Condition 19 – Notices:</p> <p>Notices served under the Contract shall be sent to the following address:</p> <p>Authority: CBRN Commercial Team, #1342, NH1 Yew3a, MOD Abbey Wood, Bristol, BS34 8JH (as per <i>DEFFORM 111</i>)</p> <p>Contractor: TBC</p> <p>Notices can be sent by electronic mail? <input checked="" type="checkbox"/> (tick as appropriate)</p>
<p>Condition 20.a – Progress Meetings:</p> <p>The Contractor will hold a Kick-Off Meeting within 4 weeks of contract award and attend Monthly Review Meetings in accordance with the Statement of Work (Annex A to the Contract). Meetings will be primarily completed via telephone conference.</p> <p>The Monthly Review Meetings shall be convened at a date agreed by the Authority's Project Manager (as detailed on the DEFFORM 111). All Contractor costs for attending the meeting, including all travel and subsistence costs, are included within the existing Contract prices.</p>
<p>Condition 20.b – Progress Reports:</p> <p>The Contractor is required to submit Annual and Monthly Project Reports in accordance with the Statement of Work.</p> <p>Reports shall be Delivered to the following address:</p> <p>Name: [REDACTED] CBRN Project Manager Advanced Development Programme</p> <p>Address: CBRN Commercial Team, #1342, NH1 Yew3a, MOD Abbey Wood, Bristol, BS34 8JH</p> <p>Email: [REDACTED] @mod.gov.uk</p>
<p>Supply of Contractor Deliverables</p>

<p>Condition 21 – Quality Assurance:</p> <p>Is a Deliverable Quality Plan required for this Contract? In accordance with the Statement of Work (Annex A to the Contract) and Clause 50 (Quality Assurance) above.</p> <p>Other Quality Assurance Requirements: In accordance with the Statement of Work (Annex A to the Contract) and Clause 50 (Quality Assurance) above.</p>
<p>Condition 22 – Marking of Contractor Deliverables:</p> <p>Special Marking requirements: In accordance with the Statement of Work (Annex A to the Contract).</p>
<p>Condition 24 - Supply of Data for Hazardous Contractor Deliverables, Materials and Substances:</p> <p>A completed Schedule 6 (Hazardous Contractor Deliverables, Materials or Substance Statement), and if applicable, Safety Data Sheet(s) are to be provided by e-mail with attachments in Adobe PDF or MS WORD format to:</p> <p>a) The Authority's Representative (Commercial)</p> <p>b) Defence Safety Authority – DSA-DLSR-MovTpt-DGHSIS@mod.uk</p> <p>to be Delivered no later than one (1) month prior to the Delivery Date for the Contract Deliverable or by the following date: TBC</p>
<p>Condition 25 – Timber and Wood-Derived Products:</p> <p>A completed Schedule 7 (Timber and Wood-Derived Products Supplied under the Contract: Data Requirements) is to be provided by e-mail with attachments in Adobe PDF or MS WORD format to the Authority's Representative (Commercial) to be Delivered by the following date: TBC</p>
<p>Condition 26 – Certificate of Conformity:</p> <p>Is a Certificate of Conformity required for this Contract? N/A</p> <p>Applicable to Line Items:</p> <p>If required, does the Contractor Deliverables require traceability throughout the supply chain? Yes</p> <p>Applicable to Line Items:</p>

<p>Condition 28.b – Delivery by the Contractor:</p> <p>Delivery will be undertaken in accordance with the Statement of Work at Annex A</p> <p>Each consignment is to be accompanied by a DEFFORM 129J.</p>
<p>Condition 28.c - Collection by the Authority:</p> <p>N/A, delivery will be undertaken in accordance with the Statement of Work at Annex A</p> <p>Special Delivery Instructions:</p> <p>To be agreed on Contract Award.</p> <p>Each consignment is to be accompanied by a DEFFORM 129J.</p>
<p>Condition 30 – Rejection:</p> <p>The default time limit for rejection of the Contractor Deliverables is thirty (30) business days unless otherwise specified here:</p> <p>The time limit for rejection shall be 30 business days.</p>
<p>Condition 32 – Self-to-Self Delivery:</p> <p>Delivery will be undertaken in accordance with the Statement of Work at Annex A</p> <p>If required, Delivery address applicable:</p> <p>As required.</p>
<p>Pricing and Payment</p>
<p>Condition 35 – Contract Price:</p> <ol style="list-style-type: none"> <i>All payments will be made via CP&F in accordance with the Payment Plan at Annex C of the Contract.</i> <i>The Price stated under the Schedule of Requirements at Schedule 2 of this Contract will be Target Cost. Any variance to the requirements stated in the Schedule of Requirements at Schedule 2, may result in an adjustment to the Target Cost.</i> <i>Option Pricing – the unit rates for auto-injector devices under Annex P of this Contract are Firm Rates. These rates may be used to price future works and options.</i> <i>All Future Works and Options will be priced in accordance with clause 58 and Annex O of this Contract.</i> <i>The Authority reserves the right to request that any future works, options or variations be priced on a Target Cost basis or as a Firm / Fixed Price.</i>

Termination
<p>Condition 42 – Termination for Convenience:</p> <p>The Notice period for terminating the Contract shall be twenty (20) Business days.</p>
Other Addresses (<i>forms and publications addresses and official use information</i>)
See Annex A to Schedule 3 (DEFFORM 111)
Other Information
<p>The following documents submitted within the Tender submission are deemed to form part of this contract:</p> <ul style="list-style-type: none"> • Annex A (Offer) to CBRN/00276 ITN DEFFORM 47 • Chemprotect's technical proposal (including Gant Chart) as submitted via Chemprotect's tender submission. • Any additional information or variants in relation to Chemprotect's technical proposal as agreed between both parties during the tender clarification and negotiation process. All tender clarifications were logged via '<i>CBRN 00276 AIP Tender Submission Clarification Register - Chemprotect 2020 11 12</i>' and meeting minutes: '<i>CBRN 00276 MOM - AIP Chemprotect - 2020 11 25</i>'.

Appendix - Addresses and Other Information

1. Commercial Officer

Name: [REDACTED]

Address: MOD Abbey Wood, #1342, Yew 3A, Bristol, BS34 8JH

Email: [REDACTED]

☎ TBC

8. Public Accounting Authority

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

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

Name: [REDACTED]

Address: MOD Abbey Wood, Yew 3A, Bristol, BS34 8JH

Email: [REDACTED] ☎ TBC

9. Consignment Instructions

The items are to be consigned as follows:

3. Packaging Design Authority

Organisation & point of contact: See Box 2 Above.

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

☎

4. (a) Supply / Support Management Branch or Order Manager: Branch/Name: See Box 2 above. ☎ (b) U.I.N.**5. Drawings/Specifications are available from**

See Box 2 above.

6. Intentionally Blank**7. Quality Assurance Representative:**

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.uwh.diif.r.mil.uk/> [intranet] or <https://www.dstan.mod.uk/> [extranet, registration needed].

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

www.freightcollection.com**11. The Invoice Paying Authority**

Ministry of Defence ☎ 0151-242-2000

DBS Finance, Walker House, Exchange Flags. Fax: 0151-242-2809, Liverpool, L2 3YL **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 Arncliffe 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.

Schedule 4 – Contract Change Control Procedure (in accordance with Condition 6b)

1. Authority Changes

Subject always to Condition 6 (Amendments to Contract), the Authority shall be entitled, acting reasonably, to require changes to the Contractor Deliverables (a "Change") in accordance with this Schedule 4.

2. Notice of Change

- a. If the Authority requires a Change, it shall serve a Notice (an "Authority Notice of Change") on the Contractor.
- b. The Authority Notice of Change shall set out the change required to the Contractor Deliverables in sufficient detail to enable the Contractor to provide a written proposal (a "Contractor Change Proposal") in accordance with clause 3 below.

3. Contractor Change Proposal

- a. As soon as practicable, and in any event within fifteen (15) Business Days (or such other period as the Parties may agree) after having received the Authority Notice of Change, the Contractor shall deliver to the Authority a Contractor Change Proposal.
- b. The Contractor Change Proposal shall include:
 1. the effect of the Change on the Contractor's obligations under the Contract;
 2. a detailed breakdown of any costs which result from the Change;
 3. the programme for implementing the Change;
 4. any amendment required to this Contract as a result of the Change, including, where appropriate, to the Contract Price; and
 5. such other information as the Authority may reasonably require.
- c. The price for any Change shall be based on the prices (including all rates) already agreed for the Contract and shall include, without double recovery, only such charges that are fairly and properly attributable to the Change.

4. Contractor Change Proposal – Process and Implementation

- a. As soon as practicable after the Authority receives a Contractor Change Proposal, the Authority shall:
 1. evaluate the Contractor Change Proposal;
 2. where necessary, discuss with the Contractor any issues arising and following such discussions the Authority may modify the Authority Notice of Change and the Contractor shall as soon as practicable, and in any event not more than ten (10) Business Days (or such other period as the Parties may agree) after receipt of such modification, submit an amended Contractor Change Proposal.
- b. As soon as practicable after the Authority has evaluated the Contractor Change Proposal (amended as necessary) the Authority shall:
 1. indicate its acceptance of the Change Proposal by issuing an amendment to the Contract in accordance with Condition 6 (Amendments to Contract); or
 2. serve a Notice on the Contractor rejecting the Contractor Change Proposal and withdrawing (where issued) the Authority Notice of Change.
- c. If the Authority rejects the Change Proposal it shall not be obliged to give its reasons for such rejection.
- d. The Authority shall not be liable to the Contractor for any additional work undertaken or expense incurred unless a Contractor Change Proposal has been accepted in accordance with Condition 4b.(1) above.

6. Contractor changes

If the Contractor wishes to propose a Change, it shall serve a Contractor Change Proposal on the Authority, which shall include all of the information required by Condition 3b above, and the process at Condition 4 above shall apply.

Schedule 5 - Contractor's Commercial Sensitive Information
(i.a.w. condition 13) for Contract No: CBRN/00276

Contract No: CBRN/00276
Description of Contractor's Commercially Sensitive Information: <i>Prices of products</i>
Cross Reference(s) to location of sensitive information: <i>Schedule 2 and Annex P</i>
Explanation of Sensitivity: <i>Prices of our products are not public knowledge and this help us to keep our strategic advantage.</i>
Details of potential harm resulting from disclosure: Should this information be revealed to competition they could set their prices to counter our proposition of any future tenders anywhere.
Period of Confidence (if applicable): 15 years
Contact Details for Transparency / Freedom of Information matters: Name: [REDACTED] Position: Project manager Address: [REDACTED] Telephone Number: [REDACTED] Email Address: [REDACTED] @chemprotect.sk

Schedule 6 - Hazardous Contractor Deliverables, Materials or Substances Statement by the Contractor

Contract No: CBRN/00276


Contract Title: TBC

Contractor: ChemProtect.SK s.r.o., Stanicna 1119/8, 039 01 Turcianske Teplice, SK

Date of Contract: TBC

* To the best of our knowledge there are no hazardous Contractor Deliverables, materials or substances to be supplied. ☒

* To the best of our knowledge the hazards associated with materials or substances to be supplied under the Contract are identified in the Safety Data Sheets (Qty:) attached in accordance with condition 24. ☐

Contractor's Signature: 

Name: 

Job Title: Executive 

Date: 30.9. 2020

* check box (☑) as appropriate

To be completed by the Authority

Domestic Management Code (DMC): N/A

NATO Stock Number: N/A

Contact Name: N/A

Contact Address: N/A

Copy to be forwarded to:

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

Schedule 7 - Timber and Wood-Derived Products Supplied under the Contract: Data Requirements for Contract No: CBRN/00276

There is no Timber or wood used in production of ChemProtect.SK s.r.o. autoinjector

SCHEDULE 8 – To Contract CBRN/0276

Schedule 8 - Acceptance Procedure (i.a.w. condition 29) for Contract No: CBRN/00276

The Contract acceptance procedure is in accordance with the Statement of Work at Annex A to the Contract.

Requirements, Deliverables and Acceptance Criteria

Statement of Work Specification for Contract No: CBRN/00276

#	WORK PACKAGE	STATEMENT OF WORK/ GUIDANCE	CONTRACT DELIVERABLE(S)	DELIVERY DATE	ACCEPTANCE CRITERIA
Line Item 1 – DRUG FORMULATION AND DEVICE					
1.1	API FORMULATION AND DEVICE				
1.1a	Demonstration of wet storage capability in an existing auto-injector.			1.2.2021	Acceptance will be based on evidence supplied as detailed in the guidance column to be provided by email in PDF and Microsoft Word format and approved to the Authority's project manager.
1.2b	Device Suitability			1.8.2021	Acceptance will be based on performance of the auto-injector devices as detailed in the guidance column to be provided by email in PDF and Microsoft Word format and approved to the Authority's project manager.

#	WORK PACKAGE	STATEMENT OF WORK/ GUIDANCE	CONTRACT DELIVERABLE(S)	DELIVERY DATE	ACCEPTANCE CRITERIA
1.3c	Protocols for, and results of, forced degradation studies.			16.3.2022	The decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager within four weeks of receipt.
1.4d				16.3.2022	The decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager within four weeks of receipt.

#	WORK PACKAGE	STATEMENT OF WORK/ GUIDANCE	CONTRACT DELIVERABLE(S)	DELIVERY DATE	ACCEPTANCE CRITERIA
1.5a	Documentation of the processes and validated test methods			6/2021	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager within four weeks of receipt product.
1.6b				7/2021	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager within four weeks of receipt.

#	WORK PACKAGE	STATEMENT OF WORK/ GUIDANCE	CONTRACT DELIVERABLE(S)	DELIVERY DATE	ACCEPTANCE CRITERIA
1.7a	Conversion of API Reporting			7/2021	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager within four weeks of receipt.
Line Item 2 - Stability					
2.1a	Demonstration of stability of active auto-injectors.			16.3.2022	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager within four weeks of receipt.
2.2b	Interim and final study reports			16.3.2022	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.
Line item 3 - Demonstration and Assessments					

#	WORK PACKAGE	STATEMENT OF WORK/ GUIDANCE	CONTRACT DELIVERABLE(S)	DELIVERY DATE	ACCEPTANCE CRITERIA
3.1a	Demonstration of wet storage capability in an auto-injector			1.2.2021	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager within four weeks of receipt.
3.2b	Assessments of the physicochemical properties			16.3.2022	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.
3.3c	Technical performance of device			4/2022	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.
3.4d				With each delivery, so first after 18.7.2022	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.

#	WORK PACKAGE	STATEMENT OF WORK/ GUIDANCE	CONTRACT DELIVERABLE(S)	DELIVERY DATE	ACCEPTANCE CRITERIA
3.5e	Demonstration of robustness (stress testing)			6/2022	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.
3.6f				With each delivery, so first after 18.7.2022	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.
Line Item 4 – Specification Documentation					
4.1a	Specification documentation			On-going	Acceptance of the Specification will be communicated by the Authority's representative Project Manager.
Line Item 5 - Manufacture					

#	WORK PACKAGE	STATEMENT OF WORK/ GUIDANCE	CONTRACT DELIVERABLE(S)	DELIVERY DATE	ACCEPTANCE CRITERIA
5.1a	Manufacture process			11/2021	A decision on the acceptance of the appraisal will be communicated by the Authority's representative Project Manager
5.2b	Consistency Lots			Made with each manufactured batch, so first after 18.7. 2022	A decision on the acceptance of the appraisal will be communicated by the Authority's representative Project Manager
6.1a	Training and Training devices			After 1.5.2021	A decision on the acceptance of the appraisal will be communicated by the Authority's representative Project Manager
Line Item 7 - Protocols					
7.1a	Protocols			16.3.2022	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager within four weeks of receipt.

#	WORK PACKAGE	STATEMENT OF WORK/ GUIDANCE	CONTRACT DELIVERABLE(S)	DELIVERY DATE	ACCEPTANCE CRITERIA
7.2b				16.3.2022	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager with six weeks of receipt.
Line Item 8 – Project Management					
8.1a	Project Plans	Requirement 22: Detailed project plan and schedule defining activities to deliver the contract requirements, available within two months of contract signature.	Deliverable 22: Project plan and schedule within two months of contract signature. The project plan shall be available as an electronic file in Microsoft Project and should indicate each of the deliverables as milestones. Additional milestones may be proposed by the Contractor.	Within 4 weeks following contract placement	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager within four weeks of receipt.
8.2b	Monthly Reporting	Requirement 23: Monthly reports to document project progress.	Deliverable 23: Monthly reports detailing progress towards the objectives and deliverables of the contract. Acceptance of the Monthly Reports will be based on acknowledgement that reports have been received and have sufficient detail / are of appropriate quality – see Paragraph 17 for guidance on the quality expected of Reports.	Monthly from contract award	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager within four weeks of receipt.

#	WORK PACKAGE	STATEMENT OF WORK/ GUIDANCE	CONTRACT DELIVERABLE(S)	DELIVERY DATE	ACCEPTANCE CRITERIA
8.3c		Requirement 24 a-g: Annual development reports of project status and that detail activities conducted in the previous year are required from the end of the first year of the contract up to and including the seventh and final year of the contract.	Deliverable 24 a-g: Annual reports detailing (i) progress towards the objectives and deliverables of the contract in sufficient detail to enable the Authority or its agent to make a comprehensive assessment of the activities undertaken as part of the project, (ii) the results / outcomes of those activities, and (iii) in year highlights, lowlights and lessons learnt are to be described. Acceptance of the Annual Report will be communicated after review by the Authority.	Annually from contract award	A decision on acceptance will be communicated by the Authority's representative Project Manager within four weeks of receipt.
8.4d	Annual Quality Summary reports	Requirement 25 a-f: Provision of manufacturing and stability data to support submissions to Competent Authorities.	Deliverable 25 a-f: Annual Quality Summary reports detailing: <ul style="list-style-type: none"> a. A review of product specifications; <div style="background-color: black; height: 1.2em; width: 100%; margin: 5px 0;"></div> b. A review of all batches that failed to meet established specification(s); c. A review of all critical deviations or non-conformances and related investigations; d. A review of any changes carried out to the processes or analytical methods; 	to be confirmed post-contract award	A decision on the acceptance of the each of the reports / deliverable will be communicated by the Authority's representative Project Manager within four weeks of receipt

#	WORK PACKAGE	STATEMENT OF WORK/ GUIDANCE	CONTRACT DELIVERABLE(S)	DELIVERY DATE	ACCEPTANCE CRITERIA
			<ul style="list-style-type: none"> e. A review of results of the stability monitoring program; f. A review of all quality-related returns, complaints and recalls; and g. A review of adequacy of corrective actions. <p>1. The Annual Quality Summary reports will be a separate document to the Annual Report and are required from the end of the second year of the contract up to and including the seventh and final year of the contract.</p>		
Line Item 9 - CE Certification					
9.1a	CE Certification	Requirement 26: Certification of the auto-injector to CE standard, meeting the requirements of the Medical Device Regulation 2017/745, as amended, and manufactured to ISO13485:2016 (or current version)	Deliverable 26: Certification of the auto-injector i.e. the cartridge (as necessary) and auto-injector device to the CE standard. Activities to support CE certification are the responsibility of the Contractor. Acceptance of the deliverable shall be based on receipt of evidence for the CE Certification of the auto-injector by the Authority.	During 2025	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager within four weeks of receipt.
Line Item 10 – CTD Documentation Review					

#	WORK PACKAGE	STATEMENT OF WORK/ GUIDANCE	CONTRACT DELIVERABLE(S)	DELIVERY DATE	ACCEPTANCE CRITERIA
10.1a	CTD Documents and data review	Requirement 27: Documentation and data review to populate a Common Technical Document prior to Marketing Authorisation Application, including a Paediatric Investigation Plan waiver.		During 2028	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager within six weeks of documentation receipt
Line Item 11 – OPTIONS					
11.1a	EVM	Earn Value Management reporting	Tenderer to propose how this will be provided.	With monthly report	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.
11.2b	Future Tiered Products	Future AI will be added later based on the tiers 1-4 and additional sow per device. SOW covering additional requirement exceeding the Tier base device will be agreed with the tenderer for each new device requirement.	TBC	TBC	TBC
11.3c	Final Product Procurement	Initial Supply final product – 2021-22		After 18.7.2022	A decision on the acceptance of the deliverable will be communicated by the

#	WORK PACKAGE	STATEMENT OF WORK/ GUIDANCE	CONTRACT DELIVERABLE(S)	DELIVERY DATE	ACCEPTANCE CRITERIA
					Authority's representative Project Manager.
11.4d	Final Product Procurement	Supply final product – 2022-23		After 15.5.2023	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.
11.5e	Final Product Procurement	Supply final product - 2023		After 15.11.2023	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.
11.6f	Final Product Procurement	Supply final product - 2024		After 15.11.2024	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.
	Final Product Procurement	Supply final product - 2025		After 17.11.2025	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.

#	WORK PACKAGE	STATEMENT OF WORK/ GUIDANCE	CONTRACT DELIVERABLE(S)	DELIVERY DATE	ACCEPTANCE CRITERIA
	Final Product Procurement	Supply final product - 2026		After 17.11.2026	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.
	Final Product Procurement	Supply final product - 2027		After 20.5.2027	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.
	Final Product Procurement	Supply final product - 2028		After 17.11.2028	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.
	Final Product Procurement	Supply final product - 2029		After 19.11.2029	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.
	Final Product Procurement	Supply final product - 2030		After 19.11.2030	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.

#	WORK PACKAGE	STATEMENT OF WORK/ GUIDANCE	CONTRACT DELIVERABLE(S)	DELIVERY DATE	ACCEPTANCE CRITERIA
	Final Product Procurement	Supply final product - 2031		After 19.11.2031	A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager.
Line Item 12 – Surge Requirement					
12.1a					

Technical Specification

APPENDIX 1 REDACTED IN FULL - MILITARY SENSITIVE TECHNICAL INFORMATION

SUPPORTING AND ADDITIONAL INFORMATION

APPENDIX 2 REDACTED IN FULL - MILITARY SENSITIVE TECHNICAL INFORMATION

Payment Plan

- 1) The Contractor shall submit an invoice to the Authority on the last working day of each month.
- 2) The invoice shall include any necessary reports and documents that record the activities that have been undertaken within that period. The invoice shall also include any other additional information required in accordance with the Target Cost provisions under Annex N of this contract.
- 3) If there is no activity or incurred cost within a given month, then no invoice shall be submitted.
- 4) The Authority shall pay the Contractor in accordance with the Payment terms under clause 36.
- 5) This payment plan is a forecast or 'estimate' of sums that will be come due at each monthly interval in accordance with the Schedule of Requirements and the Target Cost Provisions. As such, this payment plan is not an agreement of any firm sums that will become due to the Contractor each month.

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Annex C – Key Performance Indicators

KPI 1	
Description	<u>API Formulation and device</u>
Type	Key Performance Indicator.
Linked to: Demonstration of wet storage in an existing auto-injector' (SOW Line Item No.1)	<p>PI 1.1 – The contractor shall supply evidence of API formulation within *months of contract award (<i>Linked to D1 on SOR</i>)</p> <p><i>*exact timing to be agreed.</i></p> <p>PI 1.2 – The contractor shall supply reports detailing the development and performance of the auto-injectors. (<i>Linked to D2 on SOR</i>)</p>
Data source	Contractor
Data Owner (Output)	CBRN DT, Project Manager.
Monitoring frequency	Continuous
Reporting frequency	Ad Hoc

Performance Criteria	
Green	The Contractor shall be scored Green where it delivers the evidence of API formulation and supplies the reports detailing the development and performance of the auto-injectors in accordance with the schedule identified in the contract.
Amber	The Contractor shall be scored Amber where it delivers the evidence of API formulation more than 2 weeks over the timescale and/or the reports detailing the development and performance of the auto-injectors more than 2 weeks over the agreed contract schedule.
Red	The Contractor shall be scored Red where it fails deliver the evidence of API formulation and/or the reports detailing the development and performance of the auto-injectors more than 4 weeks over the agreed contract schedule.

Impact/Consequence	<p>In the event of the Contractor being scored Amber for delayed delivery of evidence of API formulation and/or reports detailing the development and performance of the auto-injectors the Authority reserves the right to request a recovery plan within 48 hours.</p> <p>In the event the Contractor scores 'Red' for delayed delivery of evidence of API formulation and/or reports detailing the development and performance of the auto-injectors the</p>
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	Authority reserves the right to make all costs associated with rectifying the delay disallowable costs under the contract.
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KPI 2

Description	<u>Demonstration of stability of active auto-injectors.</u>
Type	Key Performance Indicator.
Linked to: 'Demonstration of Stability' (SOW Line Item No.2)	Demonstration of stability of active auto-injectors, and of the active pharmaceutical ingredients stored within the active auto-injector. These stability studies should be auto-injectors that are manufactured as part of a GMP compliant batch and should be designed to support product expiration dates of auto-injectors that are manufactured for clinical studies should they be required. (Linked to D8 on SOR)
Data source	Contractor
Data Owner (Output)	CBRN DT, Project Manager.
Monitoring frequency	Continuous
Reporting frequency	Ad Hoc

Performance Criteria	
Green	The Contractor shall be scored Green where it demonstrates stability of active auto-injectors in accordance with the contract schedule.
Amber	The Contractor shall be scored Amber where it fails to demonstrate stability of active auto-injectors in accordance with the contract schedule but in a timely manner.
Red	The Contractor shall be scored Red where it fails to demonstrate stability of active auto-injectors and/or fails to deliver within 4 weeks of the scheduled contract delivery date.

Impact/Consequence	<p>In the event of the Contractor being scored Amber the Authority reserves the right to request a recovery plan that clearly demonstrate stability of active auto-injectors and provides a timescale for presenting this that is acceptable to the Authority.</p> <p>In the event the Contractor scores 'Red' because the demonstration of stability of the active auto-injectors has not been delivered in accordance with the agreed programme the Authority shall have the right to seek a recovery plan that will present it in a timescale acceptable to the Authority. Any costs associated with the recovery plan shall be classed as Disallowed Costs.</p>
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	In the event the Contractor scores 'Red' because the stability of the active auto-injectors has failed the Authority shall have the right (but not the obligation) to either terminate the contract in accordance with clause 46 (g) or seek an emergency recovery plan to rectify the inconsistencies at no additional cost to the Authority.
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KPIs 3-6 to apply in the event that option periods are exercised

KPI 3	
Description	<u>Technical performance of device</u>
Type	Key Performance Indicator
Linked to: 'Technical performance of device' (SOW Line Item No.3)	Demonstration of technical and performance (including safety) characteristics of the auto-injector to activate. (Linked to D12 on SOR)
Data source	Contractor
Data Owner (Output)	CBRN DT, Project Manager.
Monitoring frequency	Continuous
Reporting frequency	Ad Hoc

Performance Criteria	
Green	The Contractor shall be scored Green where it demonstrates technical and performance characteristics of the auto-injector to activate in accordance with the contract schedule
Amber	The Contractor shall be scored Amber where it fails to demonstrate technical and performance characteristics of the auto-injector to activate but delivers in a timely manner.
Red	The Contractor shall be scored Red where it fails to demonstrate technical and performance characteristics of the auto-injector to activate and/or fails to deliver in a timely manner.

Impact/Consequence	In the event of the Contractor being scored Amber the Authority reserves the right to request a recovery plan that clearly demonstrates the Contractor understands why they failed to demonstrate technical and performance characteristics of the auto-injector to activate and provides a timescale for presenting this that is acceptable to the Authority.
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	<p>In the event the Contractor scores 'Red' because the technical and performance characteristics have failed to activate the auto-injector in accordance with the agreed programme the Authority shall have the right to seek a recovery plan that will present it in a timescale acceptable to the Authority. Any costs associated with the recovery plan shall be classed as Disallowed Costs.</p> <p>In the event the Contractor scores 'Red' because the technical and performance characteristics have failed to activate the auto-injector the Authority shall have the right (but not the obligation) to either terminate the contract in accordance with clause 46(g) or seek an emergency recovery plan to rectify the inconsistencies at no additional cost to the Authority.</p>
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KPI 4

Description	<u>Demonstration of robustness (stress testing)</u>
Type	Key Performance Indicator
Linked to: 'Demonstration of robustness (stress testing)' (SOW Line Item No.3)	Demonstration of robustness (stress testing) of the tertiary packaging of the assembled auto-injector in its proposed tertiary packaging, and suitability of the packaging for military use. (Linked to SOR D14)
Data source	Contractor
Data Owner (Output)	CBRN DT, Project Manager.
Monitoring frequency	Continuous
Reporting frequency	Ad Hoc

Performance Criteria	
Green	The Contractor shall be scored Green where it demonstrates robustness of the tertiary packaging of the assembled auto-injector in a timely manner.
Amber	The Contractor shall be scored Amber where it fails to demonstrate robustness of the tertiary packaging of the assembled auto-injector but delivers in a timely manner.
Red	The Contractor shall be scored Red where it fails to demonstrate robustness of the tertiary packaging of the assembled auto-injector and/or fails to deliver in a timely manner.

Impact/Consequence	<p>In the event of the Contractor being scored Amber the Authority reserves the right to request a recovery plan that clearly demonstrates the Contractor understands why they failed to demonstrate robustness of the tertiary packaging of the assembled auto-injector and provides a timescale for presenting this that is acceptable to the Authority.</p> <p>In the event the Contractor scores 'Red' because the robustness demonstration has not been delivered in accordance with the agreed programme the Authority shall have the right to seek a recovery plan that will present it in a timescale acceptable to the Authority. Any costs associated with the recovery plan shall be classed as Disallowed Costs.</p> <p>In the event the Contractor scores 'Red' because the robustness demonstration has failed the Authority shall have the right (but not the obligation) to either terminate the contract in accordance with clause 46(g) or seek an emergency recovery plan to rectify the inconsistencies at no additional cost to the Authority.</p>
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KPI 5

Description	<u>CE Certification of device</u>
Type	Key Performance Indicator.
Linked to: 'Support to Marketing Authorisation' (SOW Line Item No. 9)	Certification of the auto-injector to CE standard, meeting the requirements of the Medical Device Regulation 2017/745, as amended, and manufactured to ISO13485:2016 (or current version) (<i>Linked to SOR D26</i>)
Data source	Contractor
Data Owner (Output)	CBRN DT, Project Manager.
Monitoring frequency	Continuous
Reporting frequency	Quarterly

Performance Criteria	
Green	The Contractor shall be scored Green when required deliverables in support of the MA application are provided in a timely manner and in accordance with the identified requirements.
Amber	The Contractor shall be scored Amber where it delivers the required deliverables in support of the MA application in a timely manner but not in accordance with the identified requirements.
Red	The Contractor shall be scored Red where it fails deliver the deliverables in support of the MA application in a timely manner and/or provides an MA application not in accordance with the identified requirements.

Impact/Consequence	<p>In the event of the Contractor being scored Amber the Authority reserves the right to request a recovery plan that clearly demonstrates the Contractor understands why the MA application is not acceptable and provides a timescale for presenting this that is acceptable to the Authority.</p> <p>In the event the Contractor scores 'Red' because the MA application has not been delivered in accordance with the agreed programme the Authority shall have the right to seek a recovery plan that will present it in a timescale acceptable to the Authority. Any costs associated with the recovery plan shall be classed as Disallowed Costs.</p> <p>In the event the Contractor scores 'Red' because the MA application is not in accordance with the MA application identified requirements the Authority shall have the right (but not the obligation) to either terminate the contract in accordance with clause 46(g) or seek an emergency recovery plan to rectify the inconsistencies at no additional cost to the Authority.</p>
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KPI 6

Description	<u>Manufacture Validation</u>
Type	Key Performance Indicator.
Linked to: 'Consistency Lots' (SOW Line Item No. 5)	Demonstration of the consistency of manufacturing of the active auto-injector device through process validation activities according to ICH Q8 R2 Part 1. (Linked to SOR D18)
Data source	Contractor
Data Owner (Output)	CBRN DT, Project Manager.
Monitoring frequency	Continuous
Reporting frequency	Ad Hoc

Performance Criteria	
Green	The Contractor shall be scored Green where it continually delivers consistency in the manufacturing of the active auto-injector device through process validation activities.
Amber	The Contractor shall be scored Amber where it fails to deliver consistency in the manufacturing of the auto-injector device at least once as demonstrated through process validation activities.
Red	The Contractor shall be scored Red where it fails deliver consistency in the manufacturing of the auto-injector

	device at least twice as demonstrated through process validation activities.
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Impact/Consequence	<p>In the event of the Contractor being scored Amber for this KPI the Authority reserves the right to request a recovery plan identifying how the contractor plans to recover the KPI to green.</p> <p>If the Contractors scores 'Red' for this KPI, it shall constitute a material breach by the contractor and the Authority shall have the right, (but not the obligation) to either terminate the contract in accordance with clause 46(g) or seek an emergency recovery plan to rectify the inconsistencies at no additional cost to the Authority.</p> <p>Breach shall result in written notification being sent to the Contractor with the Authority's intended course of action. The Contractor shall respond to this notification within 2 Business Days.</p>
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KPI 7

Description	<u>Project Management</u>
Type	Key Performance Indicator.
Linked to: 'Project Plans' (SOW Line Item No. 8)	<p>a) Submission of an acceptable detailed project plan and schedule defining activities to deliver the contract requirements, available within two months of contract signature. <i>(Linked to SOR D22)</i></p> <p>b) Timely submission of acceptable monthly reports to document project progress. <i>(Linked to SOR D23)</i></p>
Data source	Contractor
Data Owner (Output)	CBRN DT, Project Manager.
Monitoring frequency	Continuous
Reporting frequency	Monthly

Performance Criteria	
Green	The Contractor shall be scored Green if the detailed project plan and schedule and the monthly reports are submitted timely in to an acceptable standard.
Amber	The Contractor shall be scored Amber where it delivers the detailed project plan and schedule more than 2 weeks over the timescale and/or the monthly report more than 5 days over the timescale on more than three occasions

<p style="text-align: center;">Red</p>	<p>The Contractor shall be scored Red where it fails deliver the detailed project plan and schedule more than four weeks over the timescale and/or the monthly report more than 10 days over the timescale on more than six occasions</p>
<p>Impact/Consequence</p>	<p>In the event of the Contractor being scored Amber for delayed delivery of the project plan and schedule the Authority reserves the right to request a recovery plan within 3 days.</p> <p>In the event the Contractor is scored Amber for the delayed delivery of the Monthly Report the Authority reserves the right to request a plan from the Contractor that will stop delayed delivery.</p> <p>In the event the Contractor scores 'Red' for delayed delivery of the project plan and schedule the Authority reserves the right to make all costs associated with rectifying the delay disallowable costs under the contract.</p> <p>In the event the Contractor scores 'Red' for repeated delayed delivery of the Monthly Report the Authority reserves the right to make all costs associated with rectifying the reasons for the delay disallowable costs under the contract.</p>



Ministry
of Defence



DES CBRN-PM45
Defence Equipment and Support
Yew 3a #1342
MOD Abbey Wood
BRISTOL BS34 8JH

Tel: [REDACTED]
Email: [REDACTED]@mod.gov.uk

For the Attention of:
The Company's Security Officer

Your Reference:

Our Reference: 20200721SALAIP

Date: 21st July 2020

Dear Sir/Madam,

CBRN DT Medical Countermeasures Auto-Injector Partner (AIP)


1. On behalf of the Secretary of State for Defence, I hereby give you notice that any sketch, model, article, note or document, or information connected with or arising out of the above-mentioned Invitation to Tender, is subject to the provisions of the Official Secrets Acts 1911-1989. Your attention is particularly drawn to the following specific aspects which must be fully safeguarded:

ASPECTS	CLASSIFICATION
Commercial Aspects of the Contract	Official
Prime Contractor	Official
Sub-contractor/s	Official
Qualified Person	
Qualified Person Services	Official
Technical	
Protocols, Technical Agreement and Procedure reviews, Technical Advice	Official
Batch Release	
Batch release of Products	Official
Quality Assurance	
Supplier Audit, Batch recalls, Product complaints, GMP Compliance review, Corrective and Preventative Action plans, First Aid Kit Assembly.	Official
MHRA Inspection	
MHRA Inspection Attendance, Provision of GMP advice and resolution of issues identified at inspection	Official
Training	
Provision of training	Official

Project Meetings	Official
-------------------------	----------




2. Will you please confirm that:
 - a. This definition of the classified aspects of the above Invitation to Tender has been brought to the attention of the person directly responsible for the security of this tender.
 - b. The definition is fully understood.
 - c. Measures can, and will, be taken to safeguard the protected aspects.
3. If you have any difficulty either in interpreting this definition of the protected aspects or in safeguarding them, will you please let me know immediately.
4. Any access to classified information on MoD premises that may be needed will be subject to MoD security regulations under the direction of the MoD Project Officer.

Regards,

 Medical Countermeasures Senior Project Manager

DEFFORM 129J – The Use of The Electronic Business Delivery Form
Shipping Form Design

Use the following design and complete the fields in accordance with Annex A:

DEFFORM 129J		Edn 09/17
From: 777 ANGEL ROAD St PAULS EDENVILLE HE6 40N		Unique Identifier:  823456-8234/823458234/82349245
Via:	To:	
Demand / Task Reference:  *BC278787*		
Description:		
RDD:	SPC:	UN Haz Code:
Date Shipped:	Batch Number:	Piece Number:
Weight:	Dimensions:	
NSN:  *5120996260953*		
IMC/DMC:	D of Q:	Qty in Package: Total this Delivery:

NB Four fields have been completed for illustration purposes only.

ANNEX A TO DEFFORM 129J

Shipping Form Attributes

The following table details the shipping form fields.

Field	Field Name	Field Description		Field Size	Data Type	Format	Mandatory for:
A	From	Details of the supplier providing the Goods or Service.		256	alphanumeric		Goods & Services
B	Unique Identifier (UOI, URRI or EUPI)	Unique Order Identifier (UOI) Produced by the Contracting, Purchasing and Finance (CP&F) electronic procurement tool for non inventory Purchase Orders	The identifier that CP&F uses to uniquely identify a specific shipment within a Purchase Order Line. These fields are joined together in the UOI. This field should be provided in both Bar Code Symbology 39 and human readable text.	30	Alphanumeric and Bar Code Symbology 39	The PO Number, PO Line Number and PO Shipment Number are separated by the forward slash character '/' If the PO Number is for a Blanket Purchase Agreement (BPA) then the format of the Number is: BPA Number and BPA Release Number delimited by the hyphen character '-'. Example of a UOI for a BPA: 123456-1234/12345/1234 If the PO Number is for a Standard PO and Contract Purchase Agreement (CPA) then the format of the Number is: Numeric Example of a UOI for a Standard PO or CPA: 23456/12345/1234	Goods & Services
		Unique Receipt Reference Identifier (URRI) Produced	An alpha/numeric sequence that links the item received to original Purchase Order/Dues-	6	This attribute is provided in both Bar Code	5 or 6 alphanumeric in the following formats:	Goods and Services

Field	Field Name	Field Description		Field Size	Data Type	Format	Mandatory for:
		by CP&F for Inventory Orders	In. For each full or part item delivery the Trading Partner will add an alpha suffix to the Unique Receipt Reference Number.		39 and human readable text format.	For deliveries to Sea: Sxxxxxa e.g. S1234AA For deliveries to Land: Lxxxxxa e.g. L1234BA For deliveries to Air: xxxxxA e.g. 12345A	
		Electronic Business Capability Unique Package Identifier (EUPI)	An alphanumeric sequence generated by the supplier.	12	alphanumeric		Goods
C	Via	Intermediate Address responsible for forwarding the package to the final destination. The address to which the supplier should send the delivery if filled in.		256	alphanumeric		Goods and Services
D	To	The Final Address to which the package shall be delivered or, in the case of a service, the address of the receipting authority. Unit name Delivery Address 1 Delivery Address 2 Delivery Address 3 Delivery Address 4 Delivery Address 5 Delivery Address Post Code Country		256	alphanumeric		Goods and Services

Field	Field Name	Field Description		Field Size	Data Type	Format	Mandatory for:
E	Demand / Task Reference	Orders from CP&F (Where the Unique Identifier is either the UOI or URRI)	Contract Number identifying the MoD contract placed on a supplier responsible for the supply of specific goods <i>And if an inventory order</i>	12	alphanumeric		Goods and Services
		Inventory Orders from CP&F (where the Unique Identifier is the URRI)	Order Number identifying Purchase Order / warrant Order / Requisition placed against an Enabling Contract for the delivery of goods against that Contract. This attribute is provided in both Bar Code 39 and human readable test format.	20	alphanumeric & Barcode 39		Goods
		Non CP&F electronic Orders (Where the Unique Identifier is the EUPI)	Demand Date + Serial Number + Line number + UIN	8+5+6+6	alphanumeric		DDMMYYYY + 12345678 + 12345 + 123456 + 123456
F	Description	Description of the item or service as defined in the contract.		240	alphanumeric		Goods and Services
G	RDD	Required Delivery Date (RDD) that the package is required at the demander's point of delivery.		8	numeric	DD/MM/YYYY	Goods
H	SPC	The Standard Priority Code denoting at what speed the package should be handled within MoD Supply Chain.		2	numeric		Goods
J	UN Haz Code	UN Hazard Class. Denotes the potential hazard of the items within the package		2	alphanumeric		Goods

Field	Field Name	Field Description	Field Size	Data Type	Format	Mandatory for:
		References: DEFCON 68 and DEFCON 129				
K	Date Shipped	Date package dispatched from the supplier or service provided.	8	Numeric	DD/MM/YYYY	Goods and Services
L	Batch Number	Batch Production Number indicated on the goods if required				Goods
M	Piece Number	The specific number of the package as a constituent of a number of packages delivered to complete one order. i.e. 1 of 1, 2 of 2 or 4 of 10	6	alphanumeric		Goods
N	Weight	The gross weight of the package in metric format.	8	numeric		Goods
P	Dimensions	The size of the package in L x B x H in metric format	15	alphanumeric		Goods
Q	NSN	The NATO Stock number. The NATO supply Classification code (NSC), Nation Code (NC) and Item Identity Number (IIN) that denotes the unique identification of a line item within the inventory system. This 13 character attribute (NSC 4, NC2, IIN 7) is provided in both Barcode 39 and human readable test format.	13	numeric & Barcode 39		Goods
R	IMC/DMC	The Inventory Management Code (IMC) / Domestic management Code (DMC) code given to a range of like or linked items managed by MoD Inventory manager	6	alphanumeric		Goods
S	DofQ	Denomination of Quantity of the items in the package	2	alphanumeric		Goods

Field	Field Name	Field Description	Field Size	Data Type	Format	Mandatory for:
T	Qty in Package	The total quantity of the item contained within the package	7	numeric		Goods
T	Total This Delivery	The total quantity of the item being delivered for a specific order shipment	9	numeric		Goods

DEFFORM 177 – Design Rights and Patents (Sub-Contractors) Agreement

**DEFFORM 177
(Edn 3/80)**

Ministry of Defence

Design Rights and Patents (Sub-Contractor's Agreement)

Notes for Guidance

1. This note has been devised as an aid to the completion of DEFFORM 177.
2. This top sheet is to be detached before inclusion of the Agreement in a Contract or before submission to a sub-contractor.
3. In a draft for typing it will normally only be necessary to give instructions as follows: (although, if the Typing Pool is not one which is dedicated to Contracts work under the "Glasgow System" it will be necessary to attach a copy of DEFFORM 177).

Use a DEFFORM 177 and insert:

- a.* the date of the Agreement;
 - b.* the sub-contractor's full name;
 - c.* the sub-contractor's registered address;
 - d. paragraph 1 - the full name of the main Contractor;
 - e. paragraph 1 - the Contract number of the main contract;
 - f. paragraph 1 - the description of the equipment being designed and developed under the main contract as shown on the Schedule of the Contract;
 - g.* First Schedule - List of items appropriate to the sub-contract in question (the sub-contractor may insert these himself if necessary);
 - h. Second Schedule - List of the relevant Intellectual Property Rights conditions applicable to the Contract (i.e. DEFCONs 14, 15, 15A, 90, 91 and 126 etc.).
4. It will also be necessary to amend the references to "design and development" should the subject Contract be a Feasibility Study, Project Definition etc.
 5. Similarly, as DEFFORM 177 is a drafting form, no references to the DEFFORM should appear in the Contract. This will require:
 - a. the deletion of the legend "DEFFORM 177 (Edn /)";
 - b. that any references required in the Contract should refer to "the Agreement in the form set out in Annex to the Contract".

6. Two copies of the DEFFORM should be signed by a responsible officer on behalf of the sub-contractor and both of these should be returned for signature by the MOD representative. One copy is for the sub-contractor to retain, and the other is for retention by the Contracts Branch.

*N.B. This information will not necessarily be available at the drafting stage.

Ministry of Defence

Design Rights and Patents
(Sub-Contractor's Agreement)

THIS AGREEMENT is made the day of 19

BETWEEN

whose registered office is at

(hereinafter called "the Sub-Contractor") of the one part and THE SECRETARY OF STATE FOR DEFENCE (hereinafter called "the Secretary of State") of the other part

WHEREAS:-

1. The Secretary of State has placed with
(hereinafter called "the main contractor") a contract bearing the reference number
(hereinafter called "the main contract") for the design and
development of the
effect of which is that the costs of such design and development (including the cost referable to any
sub-contracts hereinafter referred to) will be substantially borne by the Secretary of State.
2. The main contractor contemplates that the design development and supply of certain components
needed for performance of the main contract will be undertaken by various third parties in
pursuance of sub-contracts made between them and the main contractor.
3. With a view to securing to the Secretary of State rights as regards inventions designs and other
related matters in respect of any sub-contract the main contract provides that the main contractor
shall not enter into any sub-contract for any component aforesaid without obtaining the prior
approval of the Secretary of State.
4. The main contractor has now informed the Secretary of State that for the purpose of performing the
main contract he wishes to place with the Sub-Contractor a sub-contract for the design and
development of the items described in the First Schedule (hereinafter called "the sub-contracted
items") and has requested the Secretary of State's approval of the sub-contract accordingly.
5. The Secretary of State has signified his willingness to approve the sub-contract on condition that in
consideration of his giving approval the Sub-Contractor enters into a direct Agreement with the
Secretary of State concerning the matters hereinafter appearing and the Sub-Contractor has
signified his willingness to enter into such an agreement.

NOW THIS AGREEMENT made in consideration of the premises and of the rights and liabilities hereunder mutually granted and undertaken WITNESSETH AND IT IS HEREBY AGREED AND DECLARED as follows:-

1. The Sub-Contractor and the Secretary of State hereby agree to be bound to each other by the provisions of the Conditions as set out in the Second Schedule hereto.

DEFFORM 177 (Edn 3/80)

2. No extension alteration or variation in the terms of the sub-contract between the main contractor and the sub-contractor and no other agreement between the main contractor and the sub-contractor relating to the work to be done under the sub-contract or any modification now or hereafter made thereto shall prejudice the operation of this Agreement which shall in all respects apply to the sub-contract as so extended altered varied supplemented or modified as if such extension alteration variation supplementation or modification had been originally provided for in the sub-contract and the expression "the sub-contract items" shall have effect accordingly.

IN WITNESS whereof the parties hereto have set their hands the day and years first before written

Signed on behalf of
the Sub-Contractor

(in capacity of)

Signed on behalf of
The Secretary of
State for Defence

THE FIRST SCHEDULE

The Sub-Contract Items are:-

THE SECOND SCHEDULE

The Clauses which apply to this Agreement are:-

To be
inserted as
appropriate

except that:

- (i) Where "the Contractor" is stated "the Sub-Contractor" shall be substituted.
- (ii) Where "the Authority" is stated "the Secretary of State" shall be substituted.
- (iii) Where "Contract" is stated "sub-contract" shall be substituted.
- (iv) Where "sub-contractor" is stated "further sub-contractor" shall be substituted.
- (v) Where "sub-contract" is stated "further sub-contract" shall be substituted.

DEFFORM 528 – Import and Export Controls

Not Used.

OFFICIAL and OFFICIAL- SENSITIVE Security Condition for UK Contracts

Definitions

30. The term “*Authority*” for the purposes of the Annex means a Ministry of Defence (MOD) official acting on behalf of the Secretary of State for Defence. Security Grading
30. All aspects associated with this Contract are classified OFFICIAL. Some aspects are more sensitive and are classified as OFFICIAL-SENSITIVE. The Security Aspects Letter, issued by the Authority defines the OFFICIAL- SENSITIVE information that is furnished to the Contractor, or which is to be developed by it, under this Contract. The Contractor shall mark all OFFICIAL-SENSITIVE documents which it originates or copies during the Contract clearly with the OFFICIAL-SENSITIVE classification. However, the Contractor is not required to mark information/material related to the contract which is only OFFICIAL.

Official Secrets Acts

30. The Contractor’s attention is drawn to the provisions of the Official Secrets Acts 1911-1989 in general, and to the provisions of Section 2 of the Official Secrets Act 1911 (as amended by the Act of 1989) in particular. The Contractor shall take all reasonable steps to make sure that all individuals employed on any work in connection with the Contract (including sub-contractors) have notice that these statutory provisions, or any others provided by the Authority, apply to them and shall continue so to apply after the completion or earlier termination of the Contract. Protection of OFFICIAL and OFFICIAL- SENSITIVE Information
30. The Contractor shall protect OFFICIAL and OFFICIAL-SENSITIVE information provided to it or generated by it in accordance with the requirements detailed in this Security Condition and any other conditions that may be specified by the Authority. The Contractor shall take all reasonable steps to prevent the loss or compromise of the information or from deliberate or opportunist attack.
30. The contractor shall apply Industry Security Notice (ISN) 2017/01 requirements to every industry owned IT and communication system used to store, process or generate MOD information including those systems containing OFFICIAL and/or OFFICIAL-SENSITIVE information. ISN 2017/01 details Defence Assurance and Risk Tool (DART) registration, IT security accreditation processes, risk assessment and risk management requirements. The ISN is available at:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/594320/DART_ISN
30. OFFICIAL and OFFICIAL-SENSITIVE information shall be protected in a manner to avoid unauthorised access. The Contractor shall take all reasonable steps to prevent the loss, compromise or inappropriate access of the information or from deliberate or opportunist attack.
30. All OFFICIAL and OFFICIAL-SENSITIVE material including documents, media and other material shall be physically secured to prevent unauthorised access. When not in use OFFICIAL and OFFICIAL- SENSITIVE documents/material shall be handled with care. As a minimum, when not in use, OFFICIAL-SENSITIVE material shall be stored under lock and key and in a lockable room, cabinets, drawers or safe and the keys/combinations are themselves to be subject to a level of physical security and control.
30. Disclosure of OFFICIAL and OFFICIAL-SENSITIVE information shall be strictly in accordance with the “*need to know*” principle. Except with the written consent of the Authority, the Contractor shall not disclose any of the classified aspects of the Contract detailed in the Security Aspects Letter other than to a person directly employed by the Contractor or sub-Contractor, or Service Provider.

9. Any samples, patterns, specifications, plans, drawings or any other documents issued by or on behalf of the Authority for the purposes of the Contract remain the property of the Authority and shall be returned on completion of the Contract or, if directed by the Authority, destroyed in accordance with paragraph 32.

Access

10. Access to OFFICIAL and OFFICIAL-SENSITIVE information shall be confined to those individuals who have a “*need-to-know*”, have been made aware of the requirement to protect the information and whose access is essential for the purpose of his or her duties.

11. The Contractor shall ensure that all individuals having access to OFFICIAL- SENSITIVE information have undergone basic recruitment checks. Contractors shall apply the requirements of HMG Baseline Personnel Security Standard (BPSS) for all individuals having access to OFFICIAL-SENSITIVE information. Further details and the full requirements of the BPSS can be found at the Gov.UK website at:

<https://www.gov.uk/government/publications/government-baseline-personnel-security-standard>.

Hard Copy Distribution

12. OFFICIAL and OFFICIAL-SENSITIVE documents shall be distributed, both within and outside company premises in such a way as to make sure that no unauthorised person has access. It may be sent by ordinary post or Commercial Couriers in a single envelope. The words OFFICIAL or OFFICIAL-SENSITIVE shall not appear on the envelope. The envelope should bear a stamp or details that clearly indicates the full address of the office from which it was sent.

13. Advice on the distribution of OFFICIAL-SENSITIVE documents abroad or any other general advice including the distribution of OFFICIAL-SENSITIVE hardware shall be sought from the Authority. Electronic Communication, Telephony and Facsimile Services

14. OFFICIAL information may be emailed unencrypted over the internet. OFFICIAL-SENSITIVE information shall normally only be transmitted over the internet encrypted using either a CESG Commercial Product Assurance (CPA) cryptographic product or a MOD approved cryptographic technique such as Transmission Layer Security (TLS). In the case of TLS both the sender and recipient organisations must have TLS enabled. Details of the required TLS implementation are available at:

<https://www.ncsc.gov.uk/guidance/tls-external-facing-services>

Details of the CPA scheme are available at:

<https://www.ncsc.gov.uk/scheme/commercial-product-assurance-cpa>

Exceptionally, in urgent cases, OFFICIAL-SENSITIVE information may be emailed unencrypted over the internet where there is a strong business need to do so and only with the prior approval of the Authority.

15. OFFICIAL-SENSITIVE information shall only be sent when it is known that the recipient has been made aware of and can comply with the requirements of these Security Conditions and subject to any explicit limitations that the authority shall require. Such limitations, including any regarding publication, further circulation or other handling instructions shall be clearly identified in the email sent with the material.

16. OFFICIAL information may be discussed on fixed and mobile telephones with persons located both within the UK and overseas. OFFICIAL-SENSITIVE information may be discussed on fixed and mobile types of telephone within the UK, but not within earshot of unauthorised persons.

17. OFFICIAL information may be faxed to recipients located both within the UK and overseas, however OFFICIAL-SENSITIVE information may be faxed only to UK recipients. Use of Information Systems

18. The detailed functions that must be provided by an IT system to satisfy the minimum requirements cannot all be described here; it is for the implementers to identify possible means of attack and ensure proportionate security mitigations are applied to prevent a successful attack.

19. The contractor shall ensure 10 Steps to Cyber Security is applied in a proportionate manner for each IT and communications system storing, processing or generating MOD UK OFFICIAL or information. 10 Steps to Cyber Security is available at:

<https://www.ncsc.gov.uk/guidance/10-steps-cyber-security>

The contractor shall ensure competent personnel apply 10 Steps to Cyber Security.

20. As a general rule, any communication path between an unauthorised user and the data can be used to carry out an attack on the system or be used to compromise or ex-filtrate data.

21. Within the framework of the 10 Steps to Cyber Security, the following describes the minimum security requirements for processing and accessing OFFICIAL-SENSITIVE information on IT systems.

30. Access Physical access to all hardware elements of the IT system is to be strictly controlled. The principle of “*least privilege*” will be applied to System Administrators. Users of the IT System - Administrators should not conduct ‘*standard*’ User functions using their privileged accounts.

b. Identification and Authentication (ID&A). All systems shall have the following functionality:

(1) Up-to-date lists of authorised users.

(2) Positive identification of all users at the start of each processing session.

30. Passwords. Passwords are part of most ID&A, Security Measures. Passwords shall be ‘strong’ using an appropriate method to achieve this, for example including numeric and “*special*” characters (if permitted by the system) as well as alphabetic characters.

30. Internal Access Control. All systems shall have internal Access Controls to prevent unauthorised users from accessing or modifying the data.

30. Data Transmission. Unless the Authority authorises otherwise, OFFICIAL-SENSITIVE information shall be transmitted or accessed electronically (e.g. point to point computer links) via a public network like the Internet, using a CPA product or equivalent as described in paragraph 13 above.

30. Security Accounting and Audit. Security relevant events fall into two categories, namely legitimate events and violations.

(1). The following events shall always be recorded:

(a) All log on attempts whether successful or failed,

(b) Log off (including time out where applicable),

(c) The creation, deletion or alteration of access rights and privileges,

(d) The creation, deletion or alteration of passwords,

(2) For each of the events listed above, the following information is to be recorded:

(a) Type of event,

(b) User ID,

(c) Date & Time,

30. Device ID, The accounting records shall have a facility to provide the System Manager with a hard copy of all or selected activity. There shall also be a facility for the records to be printed in an easily readable form. All security records are to be inaccessible to users without a need to know. If the operating system is unable to provide this then the equipment shall be protected by physical means when not in use i.e. locked away or the hard drive removed and locked away.

30. Integrity & Availability. The following supporting measures shall be implemented:

- (1). Provide general protection against normally foreseeable accidents/mishaps and known recurrent problems (e.g. virus power supply variations),
- (2). Defined Business Contingency Plan,
- (3). Data backup with local storage,
- (4). Anti-Virus Software (Implementation, with updates, of an acceptable industry standard Anti-virus software),
- (5). Operating systems, applications and firmware should be supported,
- (6). Patching of Operating Systems and Applications used shall be in line with the manufacturers recommended schedule. If patches cannot be applied an understanding of the resulting risk will be documented,

30. Logon Banners Wherever possible, a *“Logon Banner”* shall be provided to summarise the requirements for access to a system which may be needed to institute legal action in case of any breach occurring. A suggested format for the text (depending on national legal requirements) could be: *“Unauthorised access to this computer system may constitute a criminal offence”*

30. Unattended Terminals. Users are to be automatically logged off the system if their terminals have been inactive for some predetermined period of time, or systems must activate a password protected screen saver after 15 minutes of inactivity, to prevent an attacker making use of an unattended terminal.

30. Internet Connections. Computer systems shall not be connected direct to the Internet or ‘untrusted’ systems unless protected by a firewall (a software based personal firewall is the minimum but risk assessment and management must be used to identify whether this is sufficient). L. Disposal Before IT storage media (e.g. disks) are disposed of, an erasure product shall be used to overwrite the data. This is a more thorough process than deletion of files, which does not remove the data.

Laptops

22. Laptops holding any MOD supplied or contractor generated OFFICIAL-SENSITIVE information are to be encrypted using a CPA product or equivalent as described in paragraph 14 above.

23. Unencrypted laptops not on a secure site¹ are to be recalled and only used or stored in an appropriately secure location until further notice or until 1 Secure Sites are defined as either Government premises or a secured office on the contractor premises approved full encryption is installed. Where the encryption policy cannot be met, a Risk Balance Case that fully explains why the policy cannot be complied with and the mitigation plan, which should explain any limitations on the use of the system, is to be submitted to the Authority for consideration. Unencrypted laptops and drives containing personal data are not to be taken outside of secure sites. For the avoidance of doubt the term *“drives”* includes all removable, recordable media (e.g. memory sticks, compact flash, recordable optical media e.g. CDs and DVDs), floppy discs and external hard drives.

24. Any token, touch memory device or password(s) associated with the encryption package is to be kept separate from the machine whenever the machine is not in use, left unattended or in transit.

25. Portable CIS devices are not to be left unattended in any public location. They are not to be left unattended in any motor vehicles either in view or in the boot or luggage compartment at any time.

When the vehicle is being driven the CIS is to be secured out of sight in the glove compartment, boot or luggage compartment as appropriate to deter opportunist theft. Loss and Incident Reporting

26. The contractor shall immediately report any loss or otherwise compromise of any OFFICIAL or OFFICIAL-SENSITIVE information to the Authority.

27. Accordingly, in accordance with Industry Security Notice 2014/02 as may be subsequently updated at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/293480/ISN2014_02_Incident_Reporting.pdf

any security incident involving any MOD owned, processed, or Contractor generated OFFICIAL or OFFICIAL-SENSITIVE information defined in the contract Security Aspects Letter shall be immediately reported to the MOD Defence Industry Warning, Advice and Reporting Point (WARP), within the Joint Security Co-ordination Centre (JsyCC). This will assist the JsyCC in formulating a formal information security reporting process and the management of any associated risks, impact analysis and upward reporting to the MOD's Chief Information Officer (CIO) and, as appropriate, the company concerned. The MOD WARP will also advise the contractor what further action is required to be undertaken.

JsyCC WARP Contact Details

Email: For those with access to the RLI: CIO-DSAS-JSyCCOperations

Email: For those without access to the RLI: CIO-DSAS-JSyCCOperations@mod.gov.uk

Telephone: Working Hours: 0306 770 2187

Out of Hours/Duty Officer Phone: 07768 558863

Fax: 01480 446328

Mail: Joint Security Co-ordination Centre (JsyCC), X007 Bazalgette Pavilion, RAF Wyton, Huntingdon, Cambs, PE28 2EA.

28. The Contractor may Sub-contract any elements of this Contract to Sub-contractors within the United Kingdom notifying the Authority. When sub-contracting to a Sub-contractor located in the UK the Contractor shall ensure that these Security Conditions shall be incorporated within the Sub-contract document. The prior approval of the Authority shall be obtained should the Contractor wish to Sub-contract any OFFICIAL SENSITIVE elements of the Contract to a Sub-contractor located in another country. The first page of Appendix 5 (MOD Form 1686 (F1686)) of the Security Policy Framework Contractual Process chapter is to be used for seeking such approval. The MOD Form 1686 can be found at Appendix 5 at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/367494/Contractual_Process_-_Appendix_5_form.doc.

If the Sub-contract is approved, the Contractor shall incorporate these security conditions within the Sub-contract document. Publicity Material

29. Contractors wishing to release any publicity material or display hardware that arises from this contract shall seek the prior approval of the Authority. Publicity material includes open publication in the contractor's publicity literature or website or through the media; displays at exhibitions in any country; lectures or symposia; scientific or technical papers, or any other occasion where members of the general public may have access to the information even if organised or sponsored by the MOD, Services or any other government department.

Private Venture

30. Any defence related Private Venture derived from the activities of this Contract are to be formally assessed by the Authority for determination of its appropriate classification. Contractors are to submit a definitive product specification for PV Security Grading in accordance with the requirement detailed at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/414857/20150310_PV_Ex_Guidance_Document.pdf

CONTRACT COSTS STATEMENT DECLARATION - Non-Qualifying Contract

Contractor

Relevant Pricing Unit

Contract No

1. In this Contract Costs Statement the terms 'we', 'our' and 'us' means the contractor named above, certifying this Costs Statement.
2. We certify that the costs incurred on the above Contract as at [enter date] amount to [enter £ amount, Ex VAT], as shown in the attached Costs Statement. (See Appendix A for an example layout and Appendix B for guidance notes on completion.)
3. The costs exclude any profit element agreed in the Contract to be applied to the allowable costs of the Contract.
4. The period for which costs are included in the attached Costs Statement is from [enter date] to [enter date].
5. Either *
 - a. This is provided by us as a Final Contract Costs Statement. The date of the final delivery of the work was [enter date].
 or *
 - b. This is provided by us as an Interim Contract Costs Statement which does not cover the total costs we expect to incur on the above Contract. The planned date of the final delivery of the work is [enter date].
6. Either *
 - a. The date of final payment by the Authority in respect of the above Contract was [enter date].
 or *
 - b. The final payment by the Authority in respect of the above Contract has not yet been made.
7. Either *
 - a. Where a Questionnaire on Method of Allocation of Costs (QMAC) has been agreed with the Authority, the costs shown against each year have been computed in accordance with the relevant QMAC(s).
 or *
 - b. No QMAC appropriate to the period of work has been agreed with the Authority.

Subcontractor information

8. The costs include the costs to us of all subcontracts or bought-out supplies, including those placed with another entity within the same group. Where the value of these transactions exceed £100k the details are included below:

Name of subcontractor / supplier	Same group? (Yes/No)	Amount £
----------------------------------	----------------------	----------

9. Either *

a. No direct costs based on estimates are included.

or *

b. Direct costs based on estimates are included as follows:

Brief Details

Value £

10. Either *

a. The costs do not include any items of a special or unusual nature (for example, costs of a capital nature).

or *

b. The costs include the following items of a special or unusual nature:

Particulars

Amount £

* Delete as appropriate

11. Rates and additives and their status have been included as detailed in the attached Costs Statement.

12. Allowance has been made for all credits due to the Authority under the Contract and no charge is included for items procured or manufactured against, and charged to, another Contract.

13. Special jigs tools and test equipment included in the costs were acquired for the special purpose of the Contract and properly authorised in accordance with the conditions of the Contract. No grant from HM Government funds has been made or claimed in respect of those items.

14. To the best of our knowledge and belief these costs have been reasonably and properly incurred (or are estimated to be incurred) in accordance with the Contract. The costs are in agreement with our books, accounts, records and other documents.

Signed:

Date:

Finance Director (or other signatory authorised by the Authority)

Appendix A**CONTRACT COSTS STATEMENT – (Actual Costs incurred)**

(The contractor may adapt this Contract Costs Statement template as appropriate, subject to the approval of the Authority's investigating accountant and consistency with the signed declaration to which this statement is attached)

	Year 1	Year 2	Total
Direct Labour Hours¹			
Rate Group A			
Rate Group B			
etc			
Recovery Rates			
Direct labour cost rates (£/hr)			
Rate Group A			
Rate Group B			
etc			
Overhead rates (as appropriate for costing system)			
Material			
Subcontract			
Labour			

	Year 1	Year 2	Total
Direct Costs			
Material			
Subcontract			
Labour			
Estimates to complete (final year(s) only) ²			

¹Where more than one recovery rate is used (e.g. Manufacturing, Design, Assembly) then figures for each recovery rate should be included in the table above.

² Estimates to complete should only be included in a Final Contract Costs Statement. In the case of Interim Contract Costs Statements, costs should not include the value of commitments entered into for which expenditure has not been incurred.

Overhead rates (as appropriate for costing system)			
Material			
Subcontract			
Labour			
Estimates to complete (final year(s) only)			
Sub-Total			
G&A on total costs (excluding estimates to complete)			
G&A on total estimates to complete			
TOTAL COSTS			

Status of Rates and Additives

	Year 1	Year 2
Based on (delete as applicable)	Actual or Estimate	Actual or Estimate
Status with MOD (delete as applicable)	Agreed or Not Agreed	Agreed or Not Agreed

Appendix B

Notes for completion of a Contract Costs Statement

1. A template for the Contract Costs Statement is at Appendix A. The contractor may adapt the template Contract Costs Statement as appropriate, subject to the approval of the Authority's investigating accountant and consistency with the signed declaration to which the statement is attached. The following essential features should be incorporated:
 - a. Costs should be summarised separately against each of the contractor's financial years and separately under each function (for example, design, manufacture, tooling) with each element of cost (for example, materials, subcontracts, direct labour and overheads) shown against each function.
 - b. The total cost need not be analysed into items (for example, work packages) of the Contract unless by agreement with the Authority and in these circumstances only where practicable and as the Authority may reasonably require.
 - c. Where there are differential overhead rates, they should be quoted and the direct labour (or other base figures according to the agreed method of overhead recovery) together with the related overheads should be shown for each separate function or department so that, in conjunction with the reference made to overhead rates in the certificate of costs, the calculation of the overheads may readily be followed. Where departmental labour and overheads are expressed as hourly rates they should be detailed in the Contract Costs Statement.
 - d. Where agreement has been reached with the Authority's Commercial Officer and the Cost Assurance and Analysis Service for the use of a standard costing system in the calculation of the Contract costs then the contractor should adapt the Contract Costs Statement as appropriate.
2. If a special method of recovery of the cost of special jigs tools and test equipment has been agreed and authorised for application to the Contract, the basis of recovery should be stated.
3. In the case of Interim Contract Costs Statements, the amount shown should not include the value of commitments entered into for which expenditure has not been incurred.
4. In the case of Final Contract Costs Statements, estimates to completion may be included provided the values are identified and any supporting assumptions are stated.

Supplier Contractual Deliverables

materials or substances are ordnance, munitions or explosives	hazard reporting requirements of DEF STAN 07-085 Design Requirements for Weapons and Associated Systems.		
Obligation Condition 25.c - Source of Timber and Wood	If requested Evidence that the Timber and Wood-Derived Products supplied to the Authority comply with the requirements of clause 25.a or 25.b or both.		Supplier Organization
Obligation Condition 26.a - Certificate of Conformity	Provide a Certificate of Conformity and any applicable Quality Plan		Supplier Organization
Obligation Condition 36.c - Payment	no later than 30 days from receipt of valid undisputed invoice		Supplier Organization
Obligation Condition 37.c - Notification of applicable VAT	Notification of VAT liability or changes to it		Supplier Organization
Obligation Condition 42.c.(2) - Post notification of Termination	List of Unused and undamaged materiel; contractor deliverables in the course of manufacture.		Supplier Organization

Ministry of Defence

CONTRACT DATA REQUIREMENT

1. <u>ITT/Contract Number</u> CBRN/00276	2. <u>CDR Number</u> 01	3. <u>Data Category</u> Manufacture	4. <u>Contract Delivery Date</u> TBC
5. <u>Equipment/Equipment Subsystem Description</u> [REDACTED]		6. <u>General Description of Data Deliverable</u> Drug Formulation and Final Product Device	
7. <u>Purpose for which data is required</u> To allow a technical transfer of manufacturing data to enable an alternative contractor to undertake or continue manufacturing to ensure security of future supply.		8. <u>Intellectual Property Rights</u> a. <u>Applicable DEFCONs</u> DEFCON 15 (Edn 02/98) - Design Rights and Rights to use Design Information DEFCON 21 (Edn 10/04) - (Edn 10/04) - Retention of Records b. <u>Special IP Conditions</u> Clause 48 of Contract CBRN/00276 – Security of Supply.	
9. <u>Update/Further Submission Requirements</u> To be agreed upon contract award.			
10. <u>Medium of Delivery</u> Electronic via E-mail or Defence Share.		11. <u>Number of Copies</u> Paper copies may be applicable, number of copies to be agreed.	

Guidance Notes for the Completion of DEFFORM 315

DEFFORM 315 is a template for a Contract Data Requirement (CDR), and should be used in all contracts requiring a CDR. The relevant information should be entered, by the MoD, in accordance with the following guidelines. These notes should be read in conjunction with Guidelines for Industry (GFI) No 10.

- Block 1. Enter ITT or contract number as appropriate.
- Block 2. Enter a CDR reference number. All CDRs under a Contract should be numbered individually and sequentially, *e.g.* 1,2,3....
- Block 3. Enter the category of data for which the CDR is being prepared, *e.g.*:
- Maintenance/Repair/Reconditioning
 - Manufacture
 - Operation
- Other categories may be used, for example: simulator information or interface information. However, see GFI No 10 Part B, paragraph 7).
- Block 4. Enter the date by which the data item is to be delivered.
- Block 5. Identify the equipment, process or material to which the data item relates.
- Block 6. Enter a general description of the data item and:
- (1) In the case of manufacturing data packs (or process/material data packs) reference the applicable Data Item Description, *e.g.* UK DID MDP (Edn 2/98).
 - (2) In the case of operating manuals, Repair and Maintenance manuals or other standard Repair and Maintenance documentation identify the applicable standard (see GFI No 10 Part B, paragraph 21).
 - (3) In the case of other categories of information, identify the adaptation if any (see GFI No 10, Part B, paragraph 7).
- Block 7. Specify the purpose for which the data item is required, such as
- 1st/2nd level maintenance of the equipment by or for the Services;
 - competitive tendering for manufacture and supply of equipment;
 - operation of the equipment by or for the Services.
- Care should be taken when specifying the purpose for which the information is being supplied as this may affect the liability of the contractor if the information is used for purposes other than those stated.
- Block 8a. Specify which of the new IP DEFCONs (15, 16 and 21 (Edn 2/98)) is applicable to the information. Usually it will be necessary to specify DEFCON 21 and one of either DEFCON 15 or DEFCON 16 as appropriate.
- Block 8b. Where a special condition is being applied to the information in place of one or more of the new IP DEFCONs (15, 16, and 21 (Edn 2/98)), the special condition should be referenced (see GFI No 10, Part B, paragraph 5).

- Block 9. Enter the requirements for delivering updates or re-submissions of the data item, including the frequency of re-submissions.
- Block 10. Specify the medium of delivery, *e.g.* paper, computer disc, CD-ROM.
- Block 11. In the case of paper deliveries, specify the number of copies required.

Ministry of Defence - Commercial Exploitation of Defence Equipment Developed at Government Expense

CEL Agreement No. []

Delivery Team Details: DE&S, Chemical, Biological, Radiological and Nuclear - Medical Countermeasures

Interpretation etc.

1. In this Agreement the following shall have the effect with respect to interpretation:
 - a. 'the Contract(s)' mean(s) Contract No(s) 00276 between the Ministry and the Contractor relating to / for provision of an Auto-injector Partner;
 - b. 'Contract Article' means any article which uses the design produced under the Contract(s) and includes any sub-assemblies, components or spares thereof;
 - c. 'Government-funded tooling' means jigs and tools, etc. provided or paid for by the Ministry and required for the production of a Contract Article;
 - d. the 'Contractor' includes any subsidiary or associated company of the Contractor;
 - e. 'leviable transaction' means a sale or any other transaction giving rise to levy under this Agreement;
 - f. the 'Contractor's selling price' means, subject to the proviso hereto, the price for which the Contractor invoices its customer but excluding the cost of such of the following elements as are applicable and can be identified to the satisfaction of the Ministry:
 - (1) Freight costs and insurance.
 - (2) Cost of packing not developed at UK Government expense.
 - (3) The cost of ECGD servicing and other sales finance charges including interest on customer credit.
 - (4) The cost of any MOD inspection.
 - (5) Installation and commissioning costs where installation and commissioning form no part of the work under the development contract(s).
 - (6) Agents' fees and commission.
 - (7) The price paid by the Contractor for an article or articles supplied to them by a third party for incorporation in the Contract Article, but only if such third party has a separate commercial exploitation agreement with the Ministry relating to such article or articles and has been informed by the Contractor that such article or articles are being used for a leviable transaction.
 - (8) Value Added Tax where applicable.

Provided that any element of profit which the contractor has included in the above items (1) - (8) shall not be so included.

- g. 'Profit' other than for the purposes of the proviso to sub-clause f. of this Clause means the difference between the Contractor's selling price and the allowable costs prescribed by the Ministry for the purpose of the sale in question, provided such difference is a positive sum.

Sales and Licences

2. Should the Contractor sell any Contract Article, other than for any purpose set out in Clauses 5 and 6 hereof, the Contractor shall pay to the Ministry:

- a. a levy for the use of the design to be calculated at ■ per cent of the Contractor's selling price [except that the percentage rate of levy may be revised at the end of the development contract if the Contractor or the Ministry can demonstrate that the design relied more, or less, on private venture research and development than was assumed in agreeing the levy rate].
 - b. a levy of ■ per cent of the Contractor's selling price for the use of Government-funded tooling except that the rate of ■ per cent shall be reduced appropriately where a substantial part of jigs and tools etc. used in connection with a sale or other transaction has not been provided or paid for by the Ministry; except that, unless otherwise agreed by the Ministry, levy on individual sales above £■ in value (for which purpose contemporaneous sales of the same equipment to the same customer will count as one sale) will be payable on an appropriate profit-sharing basis to be agreed between the Contractor and the Ministry before the contract of sale is entered into. The threshold of £■ may be increased from time to time by the Ministry, in relation to future sales, to take account of inflation.
3. Should the Contractor grant a licence to manufacture Contract Articles, the Contractor shall pay to the Ministry a levy calculated at 33.3 per cent of the gross receipts of the Contractor in money by way of royalties, licence fees or otherwise in respect thereof:

Provided that:

- a. where the consideration consists wholly or in part of some benefit other than money the levy shall, in lieu of or in addition to such payments (as the case may be), consist of or include a sum representing ■ per cent of what may reasonably be regarded as the value of the said benefit; and
 - b. the Contractor shall not grant any licence for which there is no consideration, or only nominal consideration, without first agreeing with the Ministry what levy if any should reasonably be paid to the Ministry in respect of such licence; and
 - c. where the licensee pays for parts supplied in addition to paying its licence fee for manufacturing Contract Articles, levy on such parts shall be due in accordance with Clause 2 above in addition to the rate due under this clause. The receipts by the Contractor in respect of such parts shall not be regarded as receipts in respect of the licence on which the levy of ■ per cent is charged.
4. Payment of levy is deemed to include payment for the use of any industrial property rights owned by the Ministry in connection with a sale or other transaction giving rise to levy under this Agreement.
5. No levy shall be payable in respect of:
 - a. purchases by the Ministry;
 - b. sales to another UK Government Contractor or sub-contractor when the Contract Articles concerned can be clearly identified as being supplied to meet the requirements of the Ministry;
 - c. substantial individual equipment not developed at UK Government expense.
6. In the case of sales to the Government of Australia, whether directly or under a sub-contract, of Contract Articles which are Guided Weapons or other items which have been developed with the aid of the Joint Project facilities at the Weapons Research Establishment, Woomera, and of

spares for elements of such systems, the levy shall be restricted to a charge for the use of Government-funded tooling in accordance with Clause 2.b.

Sales of or Licensing of Spares or Parts

7. The sale of or licence to manufacture spares or parts of Contract Articles shall attract levy in accordance with this Agreement unless the Ministry agrees that an allowance may be made for any elements of the design of any such spare or part that were not developed at UK Government expense or a reduced rate of levy shall apply on all such spares and parts where there are practical difficulties in distinguishing between those which attract the full rate of levy, those which attract a reduced rate of levy and those on which no levy is due.

Derivatives

8. Should the Contractor sell, refurnish, recondition, maintain, lend, hire, or grant a licence to manufacture any articles in any further stage of development or articles based on the design of, or using design features of, or being a scaled version of, the Contract Article, levy calculated in accordance with this Agreement shall be due to the Ministry only to such extent as shall be reasonable in the circumstances. Subject to this the provisions of this Agreement shall apply.

Refurbishing or Reconditioning

9. Should the Contractor for resale or otherwise refurbish or recondition any Contract Articles (except at no charge to the customer under defects liability obligations) the Contractor shall pay to the Ministry a levy consisting of:
 - a. a sum calculated in accordance with this Agreement on the selling price of any new sub-assemblies, components and spare parts embodied in the reconditioned or refurbished Contract Articles; and
 - b. a sum for any use of Government-funded tooling (other than any used only in the manufacture of the said new sub-assemblies, components and spare parts) calculated as in Clause 2.b on the Contractor's selling price of the said reconditioned or refurbished Contract Articles after deduction of the selling price of any new sub-assemblies, components and spare parts embodied in the reconditioned or refurbished Contract Articles.

Maintenance Agreements

10. Where an agreement for the maintenance of Contract Articles between the Contractor and another party for a fee includes the provision of parts and spares of such Contract Articles not separately invoiced, a levy calculated in accordance with this Agreement will be due on that proportion of the maintenance fee which represents a reasonable estimate for the provision of such parts and spares.

Loan or Hire of Contract Articles

11. Should the Contractor enter into any Agreement for lending any Contract Articles or for otherwise making such Articles available to a third party except by way of sale, the Contractor shall pay to the Ministry a levy calculated as specified under Clause 2 hereof of the gross receipts of the Contractor.

Provided that:

- a. where the consideration consists wholly or in part of some benefit other than money the levy shall, in lieu of or in addition to such payment (as the case may be), consist of or include a sum calculated in accordance with Clause 2 hereof and based on what may be reasonably regarded as the value of the said benefit; and
 - b. the Contractor shall not enter into any Agreement (as set out in this clause) for which there is no consideration, or only nominal consideration, unless the Ministry has agreed what levy, if any, should reasonably be paid to the Ministry in respect of such Agreement.
12. Unless the Contract Article is subsequently sold, no levy shall be due where the Contractor makes a Contract Article solely for its own research or development purposes or for its own demonstration or sales promotion purposes, except in respect of use of Government-funded tooling. Contract Articles made and used by the Contractor for any other purpose shall attract levy at normal rates in accordance with Clause 2.

Abatement of Levy

13. Where, in the circumstances of an individual sale, the Contractor considers that the effect upon its selling price of inclusion of levy rates calculated in accordance with Clause 2 would be such as to prejudice its chances of completing the sale, or would result in an unreasonably low profit, it shall be open to the Contractor before the sale contract is entered into to seek the approval of the Ministry to an abatement scheme in accordance with the provisions of Clauses 14 and 15 herein. Provided that the Contractor's cost accounting system is adequate in the opinion of the Ministry to provide the statements of allowable costs necessary to implement the scheme such approval will not be unreasonably withheld.
14. The abatement scheme shall generally determine levy on the basis of outturn profitability of the sale in question expressed as a percentage on the allowable costs as prescribed for this purpose by the Ministry and shall apply as follows:
 - a. where Government-funded tooling is used, the first half percent of profit on cost shall be payable to the Ministry;
 - b. the next ■ of profit on cost (or the initial ■ where sub-clause 14.a does not apply) shall be retained by the Contractor;
 - c. the remaining profit, without upper limit, shall be shared between the Ministry and the Contractor in the ratio of 1:1 until a total profit of ■ on cost has been reached, and thereafter in the ratio of X:1.

Note: X should be one-fifth of the total normal unabated levy rates, but never less than 1.

15. Once a request to apply the abatement scheme has been approved by the Ministry it shall not thereafter be revoked by either party for the sale in question. The Contractor shall provide on request and in a specified form a certified statement of costs and profitability and such facilities as may be necessary for the Ministry, if it so desires, to verify the statements. Where the value of the sale is less than £■ any abatement of levy may at the discretion of the Ministry, be settled (before the sale contract entered into is concluded) on the basis of the expected outturn profitability provided the request for abatement is supported by adequate evidence and reasonable notice is given to the Ministry.

Notification of Leviable Transactions

16. The Contractor shall notify details including, where appropriate, the expected value of the sale, to the Ministry Delivery Team named in the Contract quoting the number of the Contract / CEL Agreement No.:
 - a. in respect of a sale of any Contract Articles or of a development or derivation thereof:
 - (1) as soon as it becomes apparent that a sale (or contemporaneous sales of the same equipment to the same customer) above £█ in value (or such higher value as may be notified by the Ministry from time to time) may arise;
 - (2) immediately a first sale of lesser value is entered into;
 - b. immediately any negotiations for the grant of a licence for the manufacture of any Contract Articles, or of a development or derivation thereof, is entered into (the Ministry reserves the right in this connection to be supplied with a copy of the terms of the licence agreement); or
 - c. in respect of any leviable transaction other than a sale or licence relating to any Contract Articles, or to a development or derivation thereof:
 - (1) immediately the transaction is entered into where the rate of levy is laid down in this Agreement;
 - (2) immediately negotiations are entered into where the appropriate rate of levy has not been agreed;
 - d. when any proposed extension or alteration to the transactions set out in a.(1), b. or c.(2) is considered.

Cancelled Orders

17. Where a sale is cancelled after some work in aid of the sale involving the use of Government-funded tooling has been undertaken, a levy shall be due in respect of such use calculated on a fair and reasonable basis. Where the Contractor has received any payments, whether from its customer or otherwise which it is entitled to retain, in respect of work done or in hand, or in respect of any claim arising out of the cancellation, levy shall also be due on a fair and reasonable basis having regard to the reasonable costs and claims which the Contractor may have to meet therefrom. The Contractor shall notify any such cancellation to the Ministry Delivery Team named in the Contract and shall provide such information as may reasonably be required for the determination of the levies payable under this Clause. Should any Contract Article (or article falling under Clause 8) manufactured or in course of manufacture prior to cancellation subsequently be re-sold levy will again be due on the normal basis.
18. The liability of the Contractor to the Ministry for any sum due under this Agreement shall accrue:
 - a. in respect of sales, on the date of delivery ex-Contractor's works or, where the sale contract so prescribes, upon shipment;
 - b. in respect of cancelled sales, six months after the date of cancellation or such longer period as may be agreed;
 - c. in the case of licences, and in any other case in which levy is based on gross receipts by the Contractor in respect of an agreement relating to Contract Articles, on the date of receipt by the Contractor of each payment;
 - d. in respect of the use of Government-funded tooling where no other liability for levy arises, upon completion of the work in question, except that if the work takes longer than a year

interim payments of levy will accrue as deliveries take place. In the event of cancellation of the sale liability will accrue six months thereafter;

- e. in respect of any Variation of Price settlements on receipt of payment by the Contractor.

Payment of levy shall be in accordance with the Accounting provisions at Clauses 21-24 below.

19. Where an abatement scheme has been approved in accordance with Clauses 13-15 the Contractor shall be liable for interim payment of levy in accordance with the provisions of Clause 18 at one half the appropriate unabated levy rate unless the Ministry agrees otherwise. A final adjustment to or from the Ministry shall be made as soon as it is practicable after completion of the sale. The Ministry reserves the right to review and alter interim rates of levy from time to time and agrees to carry out such a review upon request by the Contractor.
20. Should the Contractor fail to provide statements under Clause 22 within a reasonable time the Ministry reserves the right to assess the levy payable and to recover the same.

Accounting

21. The Contractor shall supply to Defence Business Services Finance-Commercial Exploitation Agreement Team, 1st Floor, Walker House, Exchange Flags, Liverpool L2 3YL, two copies of a statement (see Clause 22) at quarterly intervals commencing with first sale or licensing arrangements (see Clause 16).
22. The statement shall contain information concerning every sale, licence or other transaction in respect of which levy accruing during the period to which the statement relates is payable, and in particular shall specify:
- a. the nature of the transaction (making clear under which of the Clauses 2-12 hereof it falls) and the date thereof and the name and address of the other party or parties thereto;
 - b. in the case of a sale, the quantity and type of equipment sold, the selling price, and in any other case, the gross receipts in money in respect thereof and the nature and value of any consideration other than money;
 - c. any other matters relevant to determining the levy payable;
 - d. the sum (to the nearest pound) computed to be payable by the Contractor to the Ministry in respect of each transactions (including a provisional sum in any case in which the sum depends upon a reasonable figure yet to be agreed with the Ministry).
23. The statement shall be provided not later than two months after the close of the period to which it relates once a first sale or licensing has been agreed and 'nil' statements shall thereafter be provided whenever appropriate. Where there are NIL returns over a number of years and no evident prospect of a future leviable activity or receipt the contractor should approach the Ministry Delivery Team commercial officer regarding future reporting and future CEL arrangements.
24. Each statement shall be accompanied by a payment covering the accrued levy calculated by the Contractor to be due and set out in the statement (plus VAT where applicable). Invoices in respect of any other accrued levy will be issued to the Contractor by Defence Business Services Finance-Commercial Exploitation Arrangement Team (DBSFin-CEA-Team@mod.uk). Payments (including VAT where applicable) shall be made to the Secretary of State for Defence at the address to which statements are to be supplied, or at the address stated on the invoice, as appropriate.

25. Two copies of an annual certificate that the sums reported on the statements are correct and complete and in accordance with the Contractor's books of account and records or that no sales have been made or licences granted or other leviable transactions entered into, shall be obtained by the Contractor from its Auditors and shall be forwarded to Defence Business Services Finance-Commercial Exploitation Arrangement Team (DBSFin-CEA-Team@mod.uk) not later than six months after the end of the Contractor's financial year.
26. For the purpose of verifying the statements the Contractor shall maintain proper books of account and records at its premises and shall make them available for inspection at all reasonable times by the representatives of the Ministry and of the National Audit Office.

Recovery of Sums Due

27. Whenever under this Agreement any sum of money shall be recoverable from or payable by the Contractor, the same may be deducted from any sum then due, or which at any time thereafter may become due, to the Contractor under any contract with the Ministry or with any Department or Office of Her Majesty's Government.

Arbitration etc

28. This Agreement shall be considered as an agreement made in England and subject to English Law.
29. All disputes, differences or questions between the parties to this Agreement with respect to any matter arising out of or relating to this Agreement shall be referred to the arbitration of two persons (one to be appointed by the Ministry and one by the Contractor) or their Umpire, in accordance with the provisions of the Arbitration Act 1996.**

(** Amend as necessary should Scots Law apply - the revision should be modelled on DEFCONs 529A and 530A, omitting from the latter references to other conditions and matters on which the MOD's decision is final.)

30. Nothing in this Agreement shall be construed as relieving the Contractor from responsibility for:
 - a. obtaining the necessary export licence as applicable to any overseas sale;
 - b. obtaining any necessary release from security restrictions in force for the Contract Articles.
31. Contractors are advised to consult the Exports Team, Security Policy and Operations, MOD, 4.C, Whitehall, London SW1A 2HB, on a case by case basis before making offers to sell Contract Articles overseas.

Signed:
(MOD Commercial)

Signed:
(Contractor)

Date:

Date

Commercial Exploitation - Profit-Sharing Agreement

CEL AGREEMENT No.

CONTRACT No: CBRN/00276

1. This Agreement is made the [.....] day of [.....] 20[.] between the Secretary of State for Defence (the 'Ministry') and [.....] (the 'Contractor'), and is supplemental to the Agreement dated [.....] and made between the parties hereto (the 'Main Agreement') and it is agreed that the levy payable to the Ministry in respect of the sale of [.....] to the [.....] Government (the 'customer') under contract(s) [.....] shall be determined in accordance with the Conditions herein on the basis of the outturn profitability of the sale, expressed as a percentage on the allowable costs as prescribed for this purpose by the Ministry.
2. The outturn profitability of the sale shall be determined by deducting from the gross selling price, i.e. the price for which the Contractor invoices its customer, the allowable costs as prescribed by the Ministry for this purpose and expressing the difference as a percentage on such allowable costs. The outturn profit so determined shall be shared between the Contractor and the Ministry as below, but in no circumstances will any loss be shared:
 - a. The first [.....] per cent shall be retained by the Contractor;
 - b. The next [.....] per cent shall be shared between the Contractor and the Ministry in the ratio of [.....];
 - c. The remaining profit shall be shared between the Contractor and the Ministry in the ratio of [.....].
3. Except as provided for at paragraph f below, in lieu of the provisions in Clauses 21, 22, 23, 24 and 25 of the Main Agreement the following provisions shall apply to this Agreement:
 - a. The Contractor shall provide as soon as possible after delivery of the sale articles a statement, in a form prescribed by the Ministry, of the outturn profitability showing the gross selling price and a summary of the allowable costs together with a certificate from its statutory auditors that the statement is correct and complete and that it complies with the accounting conventions agreed by the Ministry for the purpose.
 - b. The Contractor shall provide such facilities as may be necessary for the Ministry, if it so desires, to verify the statements and for this purpose the Contractor shall maintain proper books of accounts and records at its premises and shall make them available for inspection at all reasonable times by representatives of the Ministry.
 - c. The liability of the Contractor to the Ministry for any sum due under this Agreement including interim payment of levy as prescribed in paragraph d below shall accrue on the date of delivery ex-Contractor's works or, where the sale contract so prescribes, upon shipment.
 - d. Pending determination of the outturn profitability of the sales in accordance with the above provisions, an interim payment of levy shall accrue in accordance with paragraph c above at the rate of [.....] per cent of the gross selling price in respect of individual deliveries. A final adjustment to or from the Ministry shall be made as soon as it is practicable after completion of the sale. The Ministry reserves the right to

Annex L to Contract CBRN/00276

review and alter interim rates of levy from time to time and agrees to carry out such a review upon request by the Contractor.

- e. Should the Contractor fail to provide the statement and certificate under paragraph a above within a reasonable time the Ministry reserves the right to assess the levy payable and to recover the same.
 - f. Interim levy accruing under paragraph c above shall be reported as part of the statements of accrued levy required to be submitted under Clause 21 of the main Agreement and shall be paid in accordance with the procedures in the Main Agreement applying to accrued levies reported in such statements.
4. This Agreement shall be read and construed as if it were part of the Main Agreement and the terms and conditions of the Main Agreement other than those referred to in Clause 3 thereof shall as far as the same are relevant be applicable to this Agreement. However, in the case of conflict between the provisions of the Main Agreement and this Agreement, for the purpose of this Agreement, the provisions herein set out shall prevail.

Signed:
(MOD Contracts)
Date:

Signed:
(Contractor)
Date:

* Delete words in parentheses as appropriate.

Commercial Exploitation - Abatement Agreement

CEL AGREEMENT No.

CONTRACT No: CBRN/00276

1. This Agreement is made the [.....] day of [.....] 20[] between the Secretary of State for Defence (the 'Ministry') and [.....] (the 'Contractor'), and is supplemental to the Agreement dated [.....] and made between the parties hereto (the 'Main Agreement') and it is agreed that the levy payable to the Ministry in respect of the sale of [.....] to the [.....] Government (the 'customer') under contract(s) [.....] shall be determined in accordance with the Conditions herein on the basis of the outturn profitability of the sale, expressed as a percentage on the allowable costs as prescribed for this purpose by the Ministry.
2. The outturn profitability of the sale shall be determined by deducting from the selling price as defined at Clause 1.f of the main Agreement, the allowable costs as prescribed by the Ministry for this purpose and expressing the difference as a percentage on such allowable costs. The outturn profit so determined shall be shared between the Contractor and the Ministry as below, but in no circumstances will any loss be shared:
 - a. The first [.....] per cent shall be retained by the Contractor;
 - b. The next [.....] per cent shall be shared between the Contractor and the Ministry in the ratio of [.....];
 - c. The remaining profit shall be shared between the Contractor and the Ministry in the ratio of [.....].
3. Except as provided for at paragraph f below, in lieu of the provisions in Clauses 21, 22, 23, 24 and 25 of the Main Agreement the following provisions shall apply to this Agreement:
 - a. The Contractor shall provide as soon as possible after delivery of the sale articles a statement, in a form prescribed by the Ministry, of the outturn profitability showing the gross selling price and a summary of the allowable costs together with a certificate from its statutory auditors that the statement is correct and complete and that it complies with the accounting conventions agreed by the Ministry for the purpose.
 - b. The Contractor shall provide such facilities as may be necessary for the Ministry, if it so desires, to verify the statements and for this purpose the Contractor shall maintain proper books of accounts and records at its premises and shall make them available for inspection at all reasonable times by representatives of the Ministry.
 - c. The liability of the Contractor to the Ministry for any sum due under this Agreement including interim payment of levy as prescribed in paragraph d below shall accrue on the date of delivery ex-Contractor's works or, when Pending determination of the outturn profitability of the sales in accordance with the above provisions, an interim payment of levy shall accrue in accordance with paragraph c above at the rate of [.....] per cent of the gross selling price in respect of individual deliveries. A final adjustment to or from the Ministry shall be made as soon as it is practicable after completion of the sale. The Ministry reserves the right to review and alter interim rates of levy from time to time and agrees to carry out such a review upon request by the Contractor.

Annex M to Contract CBRN/00276

- d. Should the Contractor fail to provide the statement and certificate under paragraph a above within a reasonable time the Ministry reserves the right to assess the levy payable and to recover the same.
 - e. Interim levy accruing under paragraph c above shall be reported as part of the statements of accrued levy required to be submitted under Clause 21 of the main Agreement and shall be paid in accordance with the procedures in the Main Agreement applying to accrued levies reported in such statements.
4. This Agreement shall be read and construed as if it were part of the Main Agreement and the terms and conditions of the Main Agreement other than those referred to in Clause 3 thereof shall as far as the same are relevant be applicable to this Agreement. However, in the case of conflict between the provisions of the Main Agreement and this Agreement, for the purpose of this Agreement, the provisions herein set out shall prevail.

Signed:
(MOD Contracts)

Signed:
(Contractor)

Date:
* Delete words in parentheses as appropriate

Date:

Target Cost Incentivised Fee (TCIF) Arrangement

- 1) The total amount to be paid by the Authority to the Contractor in respect of carrying out the work under the Contract shall be calculated in accordance with the provisions of this Annex.
- 2) The Target Price for the performance of work under the Contract shall be the agreed Target Cost plus the Target Fee, exclusive of VAT. The contract price shall be subject to an overall Maximum Price, exclusive of VAT, which is not to be exceeded.
- 3) Definition and Interpretation
 - a) **‘Actual Cost’** means charges and costs attributable to the carrying out the works in accordance with this Contract, but not including any items included in the Target Fee or any cost associated with the resolution of disputes under Clause 40. Actual cost is deemed to include the following items:
 - i) Labour – all personnel listed under the Schedule of Labour Rates shall be recoverable under ‘Actual Cost’ and will be recovered using the agreed rates listed under the Schedule of Labour Rates. These rates are Firm and are not subject to variation. The Schedule of Labour rates shall be agreed on a case by case basis for all future options in a format prescribed by the Authority.
 - ii) Materials and goods purchased by the Contractor from stockists or manufactures that are purchased in accordance with the Statement of Works. Any invoice for materials and goods may include:
 - (1) the components of the Auto-injector device;
 - (2) Any packaging and labelling of the Auto-injector device;
 - (3) Any materials and components of the Active Pharmaceutical Ingredient; and
 - (4) The cost of delivery.

Equipment – the Authority does not expect to cover the cost of any equipment or facility construction costs in this contract. Should the Contractor require any additional equipment to be purchased in the performance of this Contract. The Contractor may submit to the Authority a proposal, detailing what equipment is required and the reasoning for purchasing the equipment. The Authority shall review any proposal and may choose to vary the target cost to cover these costs and / or allow the Contractor to recover these costs as part of their Actual Cost.

- b) **‘Disallowed Cost’** means any cost which the Authority’s Representative decides:
 - i) Is not justified by the Contractor’s accounts and records,
 - ii) Should not have been paid to any sub-contractor or supplier in accordance with this Contract,
 - iii) Was incurred only because the Contractor did not:
 - (1) Follow an acceptance or procurement procedure stated in this Contract; or
 - (2) Give any notification of to the Authority in accordance with the change procedure under this Contract,
 - iv) Is a cost for correcting, amending, rectification or making good defective works carried out by the Contractor and any sub-contractors or suppliers;
 - v) Is a cost caused by the Contractor for not complying with the Statement of Work;
 - vi) Is a cost for resources, materials and / or equipment that was not used to perform this Contract;
 - vii) Is a cost for the preparation for and conduct of legal proceedings or any other form of dispute resolution;
 - viii) Is any cost due to negligence on the part of the Contractor in his compliance with any of his obligations under the Contract.

- c) **'Maximum Target Price'** – means the sum agreed between the Authority and the Contractor which is calculated as the Target Cost plus the Target Fee and the total additional sum that the Contractor is entitled to recover under the Sharing Formula. The Maximum Target Price is not to be exceeded and no sum will be due to be paid to the Contractor by the Authority should the Contractor exceed the Maximum Target Price.
- d) **'Sharing Formula'** - determines how the excess cost (over-spend) or savings in cost (under-spend) as measured against the Target Cost shall be shared between the Authority and the Contractor. The Sharing Formula will be based on the following Differential Percentage Bands which will be applied proportionally to the over-spend or under-spend based on the level applicable:

Underspend / Overspend by Contractor	Differential Percentage Band	Share Percentage of Underspend or Overspend paid by Authority	Share Percentage of Underspend or Overspend paid by Contractor
Underspend	Lower than 80%	50%	50%
Underspend	80% to 100%	25%	75%
On Target	100%	Not applicable	Not applicable
Overspend	100% to 110%	50%	50%
Overspend	110% to 120%	25%	75%
Overspend	Higher than 120%	0%	100%

- e) **'Target Cost'** means the sum agreed between the Authority and the Contractor including any amendment or adjustment to the Contract requirements (as applicable to each Schedule of Requirements) but excluding the Fee for carrying out the Services in accordance with the Contract. All sums which are not included in the Target Cost are deemed to be included in the Fee. The Contractor shall propose the Target Cost using a breakdown of their costings under the Schedule of Requirements. A new Schedule of Requirements template shall be drafted by the Authority and submitted to the Contractor, as required, for future works or Options.
- f) **'Target Fee'** means a fixed percentage of the Target Cost. The Target Fee is deemed to include but not limited to such items as:
- i) All elements of over-head cost;
 - ii) Site-set up and office running costs;
 - iii) Profit;
 - iv) All costs associated with the following personnel and services:
 - (1) Legal and company secretariat
 - (2) Senior management
 - (3) Finance, commercial, accounts and purchasing
 - (4) Health and safety, environmental and quality assurance – except for those service specifically defined under the Statement of Work.
 - (5) Administration
 - (6) IT
- g) **'Total Actual Cost'** means all cost (excluding Disallowed Cost and items recovered by the Fee) incurred by the Contractor for carrying out the works in accordance with this Contract.
- h) **'Target Price'** means the total Target Cost plus the Target Fee.
- 4) Calculation of Payment

- a) If the Total Actual Cost exceeds the Target Cost, the Contractor is paid any cost defined as Actual Cost plus the Target Fee less a proportion of the over-spend in accordance with the Sharing Formula.
- b) If the Total Actual Cost is less than the Target Cost the Contractor shall recover any cost defined as Actual Cost plus Target Fee plus a proportion of the under-spend in accordance with the Sharing Formula.
- c) The Sharing Formula is expressed as a percentage ratio depending on which Differential Percentage Band the Total Actual Cost is applied to. For example, if the Contractor's total Actual Cost is 85% of the Target Cost, then the Contractor shall be entitled to receive 50% of the difference or 'savings' between the total Actual Cost and the Total Target Cost.
- d) The fee is assessed and recovered using the agreed Target Fee percentage. This percentage is applied to the Total Actual Cost up to the agreed Target Cost. Fee shall not be applicable to any Actual Cost over and above the Target Cost.
- e) Please find below a worked example of how the sharing formula shall be implemented should the Contractor under-spend or over-spend:

Worked Example 1 – The Contractor Underspends

- The Authority and Contractor agree a total Target Cost of £10 million and a Target Fee of 16%.
- The Contractor under-spends against the target, with a total Actual Cost of £8.5 million, resulting in an under-spend of £1.5m.
- The Contractor is entitled to be paid the following:
 - £8.5 million of Actual Cost;
 - The Fee, which is calculated as 16% of the Actual Cost ($£8,500,000 \times 16\% = £1,360,000$); and
 - An element of gain share under the sharing formula. The total difference between the Actual Cost and the Target Cost is £1.5 million and so the Contractor will be entitled to 25% of this sum ($£1,500,000 \times 25\% = £375,000$)
 - In total, the Contractor will be entitled to payment of the following sum: £ 10,235,000

Worked Example 2 – The Contractor Overspends

- The Authority and Contractor agree a total Target Cost of £10 million and a Target Fee of 16%.
- The Contractor incurs a total Actual Cost of £11.5 million, resulting in an over-spend of £1.5m
- The Contractor is entitled to be paid the following:
 - £10 million of Actual Cost;
 - The Fee, which is calculated as 16% of the Total Target Cost (£1,600,000)
 - A percentage of the overspend as defined by the Sharing Formula noting the proportion approach being applied to the overspend.

Differential Percentage Band	Share Percentage paid by Authority	Over-spend	Total Cost recoverable against the Share Percentage
100% to 110%	50%	£1,000,000	£500,000
From 110% to 120%	25%	£500,000	£125,000
			£625,000

- In total, the Contractor will be entitled to payment of the following sum **£12,225,000** (£10,000,000 plus £1,600,000 plus £625,000)
- f) The intention is that the Target Cost is an accurate reflection of the Total Actual Cost and that the Contractor is efficient in his performance of the contract, and therefore the Maximum Price will not come into operation.
- g) The Target Cost may be adjusted (increased or decreased) in accordance with any amendment or change to the contract. The Target Fee will also be adjusted in accordance with any agreed adjustment to the Target Cost.

5) Payment

- a) The Contractor shall submit to the Project Manager at the intervals agreed under the Payment Plan a cost statement including:
- i) The Total Actual Cost of the Works carried out up to date of the invoice together with the proportion of Target Fee applicable to that Total Actual Cost. This breakdown shall show the labour and material charges that are attributable to each relevant deliverable specified under the Schedule of Requirements;
 - ii) The Contractor's forecast of Total Actual Cost for the completed works; and
- b) The Project Manager shall certify the amount in respect of the Total Actual Cost which in his opinion and based on the statement is due to the Contractor for the Works carried out up to the end of that period.
- c) The Project Manager may request substantiation for any of the Actual Cost included within the cost statement. Such substantiation may be in the form of invoices, receipts of any other proof of payment of works undertaken.

- d) The Project Manager will have power to omit from any certificate any cost which he may for the time being considered to be a Disallowed Cost.
- e) A separate invoice shall be required for any agreed options and future works. Accordingly, the Contractor shall issue an invoice for the main contract works and a separate invoice for each and any option price.

6) Final Cost Statement

- a) Once the requirements in the Schedule of Requirements have been completed to the satisfaction of the Authority, the Contractor will issue a Final Cost Statement to the Authority.
- b) A separate Final Cost Statement shall be required for each separate Target Price agreed under this contract.
- c) The Final Cost Statement must include the following:
 - i) The total agreed Target Cost, inclusive of any agreed adjustments.
 - ii) The Total Actual Cost;
 - iii) The total Fee due;
 - iv) Any gain share or additional cost due under the Sharing Formula in accordance with the terms of this Annex; and
 - v) a certified cost statement of the total Actual Cost of the work to completion using DEFFORM 812 (At Annex I to the Contract).
- d) On completion of the relevant Schedule of Requirements, the Contractor must submit their Final Cost statement within three months from the date of completion or three months from the date of the last invoice period.
- e) The Authority may request substantiation for any of the Actual Cost included within the Final Cost Statement. Such substantiation may be in the form of invoices, receipts of any other proof of payment of works undertaken.
- f) If the Contractor does not submit their Final Statement within the timescales stated within clause 6(d) of this annex, the Authority may submit a Final Cost Statement to the Contractor, stating the total sums the Authority assesses to be due in accordance with the terms of this Contract.

FUTURE AUTO-INJECTOR REQUIREMENTS

Introduction

The Authority has a requirement for an Auto Injector Delivery Partner to replace the existing capability in a staged approach. ■.

In addition, the Authority expects to have a frequent demand to source various types of Auto-Injector over the 15 year duration of this contract. Accordingly, and in accordance with the terms of this contract, the Authority may choose to instruct the Contractor to undertake the design, development, filling and supply of any new Auto-Injector device that is required by the Authority ('Future Requirement/s'). For any new Future Requirement, the Contractor will have the first opportunity to provide a proposal to the Authority, which will include a price and schedule for completing the works.

The Authority is under no obligation to award any and all Future Requirements to the Contractor. The Authority may choose to award the works to an alternative Contractor should the Authority consider that the Contractor's proposal does not present Value for Money.

The purpose of this Annex is to outline how the Authority will engage with the Contractor to instruct any Future Requirement.

1. Defining the Future Requirement (The Statement of Work)

- 1.1. The Authority will define the requirements for the new Auto-Injector via a Statement of Work.
- 1.2. The Authority may approach the Contractor before the Statement of Work has been finalised if a joint approach to defining the requirements is considered to provide a more favourable outcome.
- 1.3. It is therefore possible, that the Contractor will have an active role in agreeing how the Auto-injector will be developed and how that device will be supplied in batch form in the future.

2. The Price (the Schedule of Requirements)

The Authority will issue a Request for Quotation (RFQ) with a separate Schedule of Requirements to the Contractor. This document will be used to assess the price for the Future Requirement. The price will be built up using an Auto-Injector 'Device Price' and potentially a mix of Target Cost prices and Firm prices for the purchase and / or development of the Active Pharmaceutical Ingredient (API).

2.1. Auto-Injector Device Price – the Tiers

The new Auto-Injector requirement will fall into one of three different Tiers of Auto-injector Device, which are explained in more detailed in Annex P to this Contract.

The Tiers cover three different types of Auto-injector device, which range in complexity: Tier 1 is the simplest form of Auto-injector device and Tier 3 is the most complex. A brief description of each of these Tiers is as follows:

- Tier 1 - A basic single chamber device which would hold one or more API (if more than one must be formulated). This device does not require any technical changes to the device or mechanism to activate. The assumption is that the entire device is a standard device or 'off-the-shelf' product that requires the fill and finish requirement only.
- Tier 2 - A dual chamber device, cartridge comprising of two chambers which would hold various APIs either on their own or formulated, this would require the device to have a mechanism within the device to mix APIs from one chamber into the next and subsequently administered in a single process at point of activation. The assumption is that the main body and common functional aspects of the device are a standard 'off-the-shelf' procurement.

- Tier 3 - A Dual or Triple chamber device, cartridge comprising of a number of chambers which would hold various APIs, the most complex being dry based API. This would require the device to have a mechanism to activate within the device, that mixes the dry with the wet API, the dry API to be fully dissolved at the point of activation. This may include some filtering process built into the devices and activated at the point of activation of device. It is assumed that the main body and main functional aspects of the device will be a standard device or 'off-the-shelf' product.

A full specification of each of these Tiers is detailed at Annex P of this Contract. The Authority and the Contractor will have agreed a 'Unit Price' for each of these Auto-injector device Tiers at contract award for the Auto Injector Partner (stated under Annex P). These Unit Prices cover the cost of the Auto-injector device only, and so the requirement to fill the device (including the cost of the API) will be priced separately.

The Authority may also require a specific quantity of Auto-Injector 'Training Devices'. The Unit Price and specification for Training Devices are also detailed at Annex P.

The Authority will specify the relevant Tier of the Auto-Injector Device in the new Schedule of Requirements to be priced, as well as, the total quantity of Auto-injectors that is required (the 'Specified Quantity').

The Contractor will then calculate a 'Device Price' by multiplying the agreed Tier Unit Price by the Specified Quantity.

The process to calculate a Device Price will also be applicable to any Training Devices that may be required.

The Tier Unit Prices originally agreed in Annex P are Firm and are therefore not subject to variance. However, the Unit Prices will be subject to a review by the Authority and the Contractor every 36 months and will be highlighted in the RFQ. At this review, the Authority may agree to amend the Unit Prices, should it be clear that the current rates are no longer reflective of the actual cost involved in purchase and / or manufacturing the auto-injector device.

Should there be any technical changes to the specification of a particular Tier, then the Authority may agree a variance to the Device Price with the Contractor, and this will be detailed in the RFQ. Any variance will be specified in the Schedule of Requirements.

2.2. Pricing the API

The Authority will also require the Contractor to provide a price for filling the auto-injector device with the specified active pharmaceutical ingredients. This will also be detailed in the RFQ. The purchase of the APIs may fall into one or more of the following scenarios:

- The Contractor may be required to undertake the development of a new API;
- The Contractor may be required to purchase an API that is already in commercial circulation and requires no additional development work or formulation (an 'off-the-shelf' product); or
- the Authority may free-issue an API to the Contractor.

The new specific Schedule of Requirements and Statement of Work will state the API that is required, any requirements for development / formulation and the technical parameters for filling the auto-injector device.

The new specific Schedule of Requirements will also state the method of pricing. The Authority may require that any of the following pricing methods be used for a particular requirement:

- i. Target Cost Incentivised Fee – any Target Price that is sought will be calculated and administered in accordance with the Target Cost Incentivised Fee Arrangement detailed at

Annex N of this Contract. Any Target Price agreed for any Future Requirement will be administered and paid separately to any other agreed Target Price under this contract;

- ii. Firm Prices – these will be not be subject to variance; and / or
- iii. Maximum Prices – these are indicative prices that are not to be exceeded. A maximum price will be requested if the requirements are not sufficiently known at the proposal stage. A maximum price will then be reviewed at a specified review point, at which time, the Authority and Contractor may then choose to revise and agree this price as a 'Firm Price'.

The Authority may further ask the Contractor to provide an Option Price for any requirements that cannot be specified at that particular stage. An Option price may be subject to any of the pricing methods noted above. The Authority will specify which pricing method is to be used and the date by which that option will need to be 'exercised'.

3. Other Documents

The Authority will also issue the following other documents with the RFQ, which will need to be agreed with the Contractor as part of any proposal for a Future Requirement:

- **Key Performance Indicators (KPIs)** that are relevant to the requirements;
- A suitable **Payment Plan** to reflect the specified pricing method;
- An agreed **Schedule** or **Programme** to undertake the Works;
- Any **additional Terms and Conditions** and **Contract Data Record** and **Intellectual Property** requirements; and
- Details of any **Government Furnished Assets**.

4. Timescales

Once the Authority has issued the RFQ (and 'Other Documents'), the Contractor will have 30 days to respond to the Authority with their proposal and price to undertake the works.

The Authority and Contractor may agree an extended timeline to return the proposal should the Contractor be involved in scoping the requirements.

5. Amending the Contract

Once and if any proposal is agreed with the Contractor, the Authority will issue an amendment to the Contract. The Contract Amendment will consist of the following agreed documents:

- Statement of Work;
- Price (Schedule of Requirements) and Payment Plan;
- KPIs;
- Schedule; and
- Terms and Conditions, if applicable.

The Contract Amendment will be made in accordance with the change procedure under this contract.

Unless specified and agreed otherwise as part of the Contract Amendment, all other terms under this Contract will apply to the Future Requirement instructed under the Contract Amendment.

Auto-Injector Device Pricing (Tiers 1 – 3)

The Prices stated in this Annex are representative of several 'Unit Prices' for different types of Auto-Injector Device. The Authority deems that any requirement under this Contract will fall into one of the following categories of Auto-Injector Device: Tier 1, Tier 2 or Tier 3. The Tiers cover three different and standard types of Auto-injector device which range in complexity: Tier 1 is the simplest form of Auto-injector device and Tier 3 is the most complex.

These Unit Prices are agreed as 'Firm' Unit Prices under this Contract, and therefore will not be subject to variance, unless the Authority agrees a variance is admissible.

The following pricing conditions apply to each Tier Auto-injector Unit Price:

1. These Unit Prices cover the purchase or manufacture of commercially available off the shelf Auto-injector devices only. A price for filling the device and supply of the Active Pharmaceutical Ingredient ('API') must be priced separately.
2. The Unit Price is based on a rate per single auto-injector device. This Unit Price will be multiplied by the total quantity of Auto-injector devices required for any supply requirement.
3. These Unit Prices will also be used to calculate prices for any Future Requirements (as set out in Annex O to this Contract)
4. The Authority will hold a review with the Contractor every 36 months (starting from the date of Contract Award) to undertake a review of these rates. If the Authority and the Contractor agree that the Unit Price is no longer reflective of the costs involved in purchasing this type of device, then the Authority may agree to vary the rate accordingly.

The Auto-injector Unit Price for each Tier is deemed to **include** the following:

1. The cost of purchasing the device as an 'off-the-shelf' product (if applicable), including any management cost involved in purchasing that product;
2. The cost of manufacturing the device (if applicable) – this will include any design and management costs of the manufacturing process;
3. The cost of tertiary packaging;
4. The cost of standard labelling and markings on the device;
5. The cost of the needle, the cartridge and the chamber; and
6. The cost of the safety mechanism.

The Unit Price for each Tier is deemed to **exclude** the following:

1. The cost of filling the device;
2. The cost of developing or purchasing the API;
3. The cost of producing the Auto-injector training device and any associated training manuals (see section below on 'Auto-Injector Training Devices'); and
4. The cost of alternative or specific labelling and markings on the device.

Auto-injector Training Devices

A separate Unit Price will be applicable to any quantity of Auto-injector Training Device that is required in accordance with this contract. Any agreed Unit Prices for Training Devices are set out in this Annex.

Training Devices may be required for a Tier 1, Tier 2 or Tier 3 Auto-injector.


The Training Device will be identical to the active Auto-injector Tier, except for those parts of the device that must be specifically constructed for training purposes.

Auto-injector TIER 1 UNIT PRICE			
ID	Parameter	Limits / guidance	Unit Price
T1-01	Auto-Injector Tier 1	The specification of a Tier 1 Device is set out below. This Unit Price is per single Auto-Injector.	£ ■
TIER 1 AUTO-INJECTOR DEVICE SPECIFICATION			
<p>Description: A Tier 1 Auto-injector Device is the most basic model, in comparison to Tier 2-3 this device does not have additional complexity or technical aspects, a basic single chamber device of which would hold 1 or more API (if more than one must be formulated). This device does not require any technical changes to the device or mechanism to activate. Assumption would be for entire device to be standard device off the shelf procurement, fill and finish requirement only.</p> <p>Length. The active auto-injector device (secondary packaging) shall be between 150 and 180 mm long.</p> <p>Diameter. The diameter of the active auto-injector device (secondary packaging) shall be between 18 and 29mm. (Ergonomic modifications that take the diameter outside of this constraint may be considered on a case-by-case basis).</p> <p>Weight. The active auto-injector device shall be as light as practicable and preferably less than 80g.</p> <p>Tertiary Packaging. A container, such as a box, sleeve etc that protects the active auto-injector device from contaminants such as dust and moisture until it is required for use.</p> <p>Safety Mechanisms:</p> <ul style="list-style-type: none">• At least one safety mechanism to stop accidental reconstitution (priming). As part of this mechanism, it should be immediately obvious to the user if accidental priming has occurred.• At least one safety mechanism to stop accidental exposure of needle (in both 'live' and 'discharged' states).• At least one safety mechanism to stop accidental 'firing'. As part of this mechanism, it should be immediately obvious to the user if accidental firing has occurred.• An indication that the device has been used so as to prevent any attempt to re-use.• At least one approach to prevent dust or other extraneous material from contaminating the functional components of the active auto-injector. <p>Intramuscular delivery by needle: Gauge. 21 to 23 Length. >19-25 mm (to allow depth of penetration into muscle) Sterility. As per ISO 7864</p>			

Construction materials:

- Primary packaging. Remark – Only those materials previously approved for medical device and small volume parenteral products should be used.
- Robustness and rough handling. The active auto-injector device shall remain operational after suitable robustness tests. For example, the device should be able to function after being subjected to a drop test (drop device 4 feet onto a hard (concrete backed tiles) surface three times) or a steel ball test (drop a 2 inch steel ball or weight 1.18 lb onto the device from 4 feet) – ISO 116083. Methods of sterilisation must not negatively impact materials used in manufacture.

Ease of Use:


- Activation force. The required force is to be derived from published standards (ISO 116083) and device.
 - Administration time. The auto-injector should be able to be held against the thigh, in a stable position, for as long as required to complete the full administration of triple therapy (ie c. 10 seconds).
- 

Auto-injector TIER 2 UNIT PRICE			
ID	Parameter	Limits / guidance	£ Unit Price
T2-01	Auto-Injector Tier 2	The specification of a Tier 2 Device is set out below. This Unit Price is per single Auto-Injector.	£ ■
TIER 2 AUTO-INJECTOR DEVICE SPECIFICATION			
<p>Description: The Tier 2 Auto-injector device is a dual chamber device, cartridge comprising of two chambers of which would hold various APIs either on their own or formulated, this would require the device in having a mechanism within the device to mix APIs from one chamber into the next and subsequently administered in a single process at point of activation, mixing the APIs into one chamber at the point of activation allowing API to flow without hinderance through the device and into the needle at point of administering drug. The API mix upon activation must not hinder the flow of drug product through the device or flow through the needle to the injection site. Assumption would be for the main body and common functional aspects of the device to be standard off the shelf procurement.</p> <p>Length. The active auto-injector device (secondary packaging) shall be between 150 and 180 mm long.</p> <p>Diameter. The diameter of the active auto-injector device (secondary packaging) shall be between 18 and 29mm. (Ergonomic modifications that take the diameter outside of this constraint may be considered on a case-by-case basis).</p> <p>Weight. The active auto-injector device shall be as light as practicable and preferably less than 80g.</p> <p>Tertiary Packaging. A container, such as a box, sleeve etc that protects the active auto-injector device from contaminants such as dust and moisture until it is required for use.</p> <p>Safety Mechanisms:</p> <ul style="list-style-type: none"> • At least one safety mechanism to stop accidental reconstitution (priming). As part of this mechanism, it should be immediately obvious to the user if accidental priming has occurred. • At least one safety mechanism to stop accidental exposure of needle (in both 'live' and 'discharged' states). • At least one safety mechanism to stop accidental 'firing'. As part of this mechanism, it should be immediately obvious to the user if accidental firing has occurred. • An indication that the device has been used so as to prevent any attempt to re-use. • At least one approach to prevent dust or other extraneous material from contaminating the functional components of the active auto-injector. <p>Intramuscular delivery by needle: Gauge. 21 to 23 Length. >19-25 mm (to allow depth of penetration into muscle) Sterility. As per ISO 7864</p>			

Construction materials:

- Primary packaging. Remark – Only those materials previously approved for medical device and small volume parenteral products should be used.
- Robustness and rough handling. The active auto-injector device shall remain operational after suitable robustness tests. For example, the device should be able to function after being subjected to a drop test (drop device 4 feet onto a hard (concrete backed tiles) surface three times) or a steel ball test (drop a 2 inch steel ball or weight 1.18 lb onto the device from 4 feet) – ISO 116083. Methods of sterilisation must not negatively impact materials used in manufacture.

Ease of Use:

- Activation force. The required force is to be derived from published standards (ISO 116083) and device.
 - Administration time. The auto-injector should be able to be held against the thigh, in a stable position, for as long as required to complete the full administration of triple therapy (ie c. 10 seconds).
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Auto-injector TIER 3 UNIT PRICE			
ID	Parameter	Limits / guidance	£ UNIT PRICE
T3-01	Auto-Injector Tier 3	The specification of a Tier 3 Device is set out below. This Unit Price is per single Auto-Injector.	£ ■
TIER 3 AUTO-INJECTOR DEVICE SPECIFICATION			
<p>Description: The Tier 3 Auto-injector version is the most complex and technical, with a potential for Dual or Triple chamber device, cartridge comprising of a number of chambers of which would hold various APIs, the most complex being dry based API. This would require the device to have a mechanism to activate within the device, that mixes the dry with the wet API, the dry API to be fully dissolved at the point of activation. This may include some filtering process built into the devices and activated at the point of activation of device. Some system or process in place to ensure undissolved matter is retained within the device so not to be injected. All API whether wet or dry upon activation and dissolution must not hinder the flow of drug product through the device and flowing through the needle to the injection site. Assumption would be for the main body and main functional aspects of the device to be standard device off the shelf procurement.</p> <p>Length. The active auto-injector device (secondary packaging) shall be between 150 and 180 mm long.</p> <p>Diameter. The diameter of the active auto-injector device (secondary packaging) shall be between 18 and 29mm. (Ergonomic modifications that take the diameter outside of this constraint may be considered on a case-by-case basis).</p> <p>Weight. The active auto-injector device shall be as light as practicable and preferably less than 80g.</p> <p>Tertiary Packaging. A container, such as a box, sleeve etc that protects the active auto-injector device from contaminants such as dust and moisture until it is required for use.</p> <p>Safety Mechanisms:</p> <ul style="list-style-type: none"> • At least one safety mechanism to stop accidental reconstitution (priming). As part of this mechanism, it should be immediately obvious to the user if accidental priming has occurred. • At least one safety mechanism to stop accidental exposure of needle (in both 'live' and 'discharged' states). • At least one safety mechanism to stop accidental 'firing'. As part of this mechanism, it should be immediately obvious to the user if accidental firing has occurred. • An indication that the device has been used so as to prevent any attempt to re-use. • At least one approach to prevent dust or other extraneous material from contaminating the functional components of the active auto-injector. <p>Intramuscular delivery by needle: Gauge. 21 to 23 Length. >19-25 mm (to allow depth of penetration into muscle)</p>			

Sterility. As per ISO 7864

Construction materials:

- Primary packaging. Remark – Only those materials previously approved for medical device and small volume parenteral products should be used.
- Robustness and rough handling. The active auto-injector device shall remain operational after suitable robustness tests. For example, the device should be able to function after being subjected to a drop test (drop device 4 feet onto a hard (concrete backed tiles) surface three times) or a steel ball test (drop a 2 inch steel ball or weight 1.18 lb onto the device from 4 feet) – ISO 116083. Methods of sterilisation must not negatively impact materials used in manufacture.

Ease of Use:

- Activation force. The required force is to be derived from published standards (ISO 116083) and device.
- Administration time. The auto-injector should be able to be held against the thigh, in a stable position, for as long as required to complete the full administration of triple therapy (ie c. 10 seconds).

Auto-injector Training Device – TIER 2 UNIT PRICE			
ID	Parameter	Limits / guidance	£ UNIT PRICE
TD-01	Auto-Injector Training Device – Tier 2	The specification of a Tier 2 Auto-injector Training Device is set out below. This Unit Price is per single Auto-Injector, and should reflect the specifications of the Tier 2 Auto-Injector Device (see specification for Tier 2 Auto-injector device in ID 'T2-01' above), except for those specifications that are specific to Training devices, and as set out below in the device specification.	£ ■
TIER 2 - AUTO-INJECTOR TRAINING DEVICE SPECIFICATION			
<p>The Training auto-injector device shall be safe, i.e. with no needle, nor medicinal products. It shall be representative of the active device and is to be supplied in any tertiary packaging planned for the active auto-injector device.</p> <p>The training auto-injector device should be able to be re-set.</p> <p>The training manual shall indicate how the device shall be used. A decision on the acceptance of the deliverable will be communicated by the Authority's representative Project Manager within four weeks of receipt of both the training auto-injector device and the training manual. The training device and instructions shall be available at the point of active device supply.</p>			

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