National Framework Agreement for Intraoperative Neuromonitoring Services and Equipment

Project Reference: F/048/IONM/18/IB

SCHEDULE A

FRAMEWORK AGREEMENT SPECIFICATION

LOT 1

PROVISION OF INTRAOPERATIVE NEUROMONITORING SERVICES ("the Services")

1. Overview

1.1 Suppliers appointed to Lot 1 of the Framework agreement will:

1.1.1 Provide multi-modal intraoperative neuromonitoring (IOM) services to NHS Organisations.

1.1.2 Provide high quality support to NHS Organisations that can be called upon at relatively short notice.

1.1.3 Provide a professional monitoring service to support surgeons aiming to optimise patient treatment and minimise risks during complex surgery.

1.1.4 Have an excellent record of safe performance.

1.1.5 Have an excellent record of accuracy and effectiveness in the delivery of IOM services.

1.1.4 Establish a positive working relationship between NHS Organisations who use the Framework Agreement and the Supplier to facilitate and maximise service delivery, the emphasis being on timely, quality, cost effective, evidence-based care, with appropriate clinical protocols and audit where possible.

1.2 Responsibility for obtaining patient consent for the use of IOM during treatment will be retained at all times by the contracting NHS Organisation.

2. Supplier responsibilities

2.1 The Supplier will provide, for each instance where they are contracted to provide the Services:

2.1.1 A fully qualified and trained monitoring physiologist, capable of monitoring and interpreting any and all of the modalities required by the surgeon with overall responsibility for the care of the patient.

2.1.2 An IOM complete system for neurosurgery including any and all of the modalities required by the surgeon with overall responsibility for the care of the patient.

2.1.3 Any consumables required for the case, including but not limited to electrodes, corkscrews and stimulation probes

2.2 Monitoring physiologists must hold as a minimum a degree-level qualification in a relevant subject, have documented evidence of at least 100 cases independently monitored and be able to show evidence of continuous professional development. Evidence of monitoring physiologist qualifications and experience will be provided on request to NHS Organisations.

2.3 All equipment used for IOM must be maintained to the standards determined by the manufacturer of the equipment.

2.4 All equipment used for IOM must be running the latest version of any software released by the manufacturer. The Supplier is responsible for ensuring that software updates are implemented promptly on release by the manufacturer.

2.5 All consumables used for IOM must be single-use and matched to the Supplier's intraoperative neuromonitoring equipment.

2.6 The Supplier will work closely with the NHS Organisation and integrate in an adaptive and responsive way with the NHS Organisation's clinical and management teams.

2.7 The Supplier shall take all reasonable care to engage or employ in and about the provision of the Services only such monitoring physiologists as are carefully skilled and experienced in their profession and calling. The Supplier will be responsible for ensuring that all monitoring physiologists are competent to perform all duties that are required of their rôle.

2.8 The Supplier will be responsible for ensuring that all of their monitoring physiologists are fully trained on the intraoperative neuromonitoring equipment supplied to perform the Services. The Supplier will provide evidence of training on request to NHS Organisations.

2.9 The Supplier will be responsible for ensuring access to relevant training and Continuous Professional Development (CPD) for their monitoring physiologists

2.10 The Supplier will ensure that all monitoring physiologists engaged to undertake any of the Services fulfil all statutory requirements of employment including but not limited to the right to work in the UK.

2.11 The Supplier will commit to notifying the NHS Organisation of any relevant staff changes as soon as they become aware of this.

2.12 All persons employed by or subcontracted by the Supplier who may come into contact with Patients during the course of their duties must hold a current enhanced Disclosure and Barring Service (DBS) certificate or Disclosure Scotland Protection of Vulnerable Groups (PVG) certificate, as appropriate, valid for the work that is the subject of any Call Off Contract.

2.13 All DBS or PVG checks undertaken must have been completed to include all information pertaining to children and vulnerable adults and will cover induction, all mandatory training, occupational health checks, and all appropriate General Medical Council (GMC), Health and Care Professions Council (HCPC) and/or Nursing and Midwifery Council (NMC) checks

2.14 The Supplier must ensure that the NHS Organisation is informed directly should convictions be received regarding them or their employees or subcontractors after the date of the DBS or PVG check. Appropriate action will be taken if necessary. In the event that any person in any of the groups referred to previously are substantively employed by the NHS Organisation concerned, that organisation will continue to retain full responsibility for this for those employees. The Awarding Authority will also be informed to allow relevant and permitted information to be passed to other NHS Organisations to promote safeguarding.

2.15 The Supplier must ensure that the NHS Organisation is informed directly of any relevant suspension from service proceedings conducted by the GMC, HCPC and/or NMC or disciplinary matters concerning their employees or subcontractors.

2.16 The Supplier must work within Care Quality Commission (CQC) (or equivalent organisations in Scotland, Wales and Northern Ireland, where applicable) compliance either using the NHS Organisation's own certification or the Supplier's certification for each individual service throughout the life of the Framework Agreement and during any Contract whose performance concludes outside the period of the Framework Agreement. The Supplier must have robust, auditable management and corporate governance procedures including clear responsibilities for all staff and appropriate employment policies and procedures, insurances and indemnities and, where relevant, clear written agreements with sub-contractors.

2.17 The Supplier will commit to provide any information as reasonably required by the Awarding Authority for the purposes of monitoring the Framework Agreement.

2.18 The Supplier will be responsible for ensuring that all applicable clinical negligence insurances are in place prior to the performance of any Service under a Contract called off under the Framework Agreement.

2.19 The Supplier must ensure that it retains all appropriate public liability, professional liability and employer liability insurance at all times throughout the life of the Framework Agreement and during any treatments whose performance concludes outside the period of the Framework Agreement.

2.20 The Supplier shall produce to the Awarding Authority or to any NHS Organisation on request documentary evidence that the insurance required is properly maintained.

2.21 Where the Supplier employees or subcontractors deployed under a Call Off Contract are responsible for procuring and maintaining their own professional indemnity insurance cover, the Supplier shall procure that any such employees or subcontractors maintains such cover in an amount adequate to cover potential liabilities for the minimum insurance period specified in a Call Off Contract and exhibits details of the relevant policy with confirmation from the insurers if required that the professional responsibilities performed in connection with the provision of Services are covered by such insurance.

2.22 Any patient enquiries to the Supplier will be dealt with in an appropriate and timely manner.

2.23 The Supplier will maintain a complaints procedure in line with applicable law and provide as and when necessary details of such a procedure to the Awarding Authority or to any NHS Organisation.

2.24 The Supplier shall inform the Awarding Authority of any complaints made by any NHS Organisation and supply copies of all correspondence to the Awarding Authority which relates to complaints or the handling of them.

2.25 In the event that complaints regarding the Services are made by patients to an NHS Organisation, the NHS Organisation will forthwith inform the Supplier and supply relevant correspondence.

2.26 The Supplier will co-operate as required with any statutory and regulatory bodies in relation to the complaints procedure and with any independent investigation of complaints. Accordingly, the Supplier will:

2.26.1 Appoint a complaints manager or individual with complaints remit

2.26.2 Provide the Awarding Authority and any NHS Organisation with relevant details of the complaints manager

2.27 The Supplier will undertake to provide information to the NHS Organisation to support the NHS Organisation's adherence to national or local frameworks for performance reporting.

2.28 The collection of data to assess Patient Reported Outcome Measures will remain the responsibility of the NHS Organisation. The Supplier will provide assistance to the NHS Organisation where the Supplier can help in gathering additional information

2.29 The NHS Organisation shall on reasonable notice in writing be entitled to request additional information from the Supplier covering the provision of the Services if such information is reasonably required by the NHS Organisation and to comply with any written requests under the Freedom of Information Act 2000 (as amended) or under the Freedom of Information (Scotland) Act 2002 (as amended) or under the Environmental Information Regulations 2004 (as amended) or under the Environmental Information Regulations (Scotland) 2004 (as amended).

2.30 The Supplier must commit to comply with any NHS Organisation's policies and procedures appropriate to the performance of the Services, including but not restricted to clinical governance policies and risk management strategies. NHS Organisations will provide these to the Supplier as necessary or upon written request

2.31 The Supplier must not through its actions or inactions jeopardise the NHS Organisation's compliance with Care Quality Commission (or equivalent organisations in Scotland, Wales and Northern Ireland, where applicable) standards, and with those of any future regulatory bodies as appropriate throughout the life of the Framework Agreement and during any Contract whose performance concludes outside the period of the Framework Agreement. The Supplier will use best endeavours to ensure that the actions or inactions of its staff do not jeopardise the compliance referred to in this clause 2.31.

2.32 The Supplier must maintain a defined and documented quality assurance system which will ensure:

2.32.1 Adherence to the NHS Organisation's policies and procedures appropriate to the performance of the Services

2.32.2 Effective measures of infection prevention and control are used including, where relevant, decontamination and/or sterilisation of surgical and medical equipment;

2.32.3 All requirements relating to health and safety in the workplace are satisfied;

2.32.4 Professionals are appropriately trained and competent to perform duties required of their rôle

Details of this quality assurance system will be made available to NHS Organisations on request.

2.33 The Supplier will implement specific audit arrangements and submit evaluation of audits to the Awarding Authority or to any NHS Organisation on request.

2.34 Topics for audit will be agreed between the NHS Organisation and the Supplier and will be detailed in tailored agendas for review meetings. The Supplier will ensure attendance at such meetings by an appropriately senior office of the Supplier who will be named within the Call Off Contract

2.35 The Supplier will have access to the NHS Organisation's full range of clinical and non-clinical risk assessments, including written policies on business continuity, and will use them as agreed with the NHS Organisation for each Call Off Contract.

2.36 The Supplier must have a robust system in place for reporting patient safety incidents and reviewing of this data at appropriate levels. Details of this system will be made available to NHS Organisations on request.

2.37 The Supplier will assist the NHS Organisation with any investigation and management of Serious Untoward Incidents and complaints relating to the Service in line with the NHS Organisation's complaints and incident reporting procedures.

2.38 The Supplier will be responsible for ensuring that the monitoring physiologist removes all electrodes from the patient prior to emergence from anaesthesia.

2.39 The Supplier will be responsible for ensuring that the monitoring physiologist correctly disposes of all single use items, using the NHS Organisation's waste management facilities.

2.40 The Supplier will be responsible for ensuring that the monitoring physiologist cleans all reusable items of neuromonitoring equipment before its removal from the NHS Organisation's premises. The Supplier will provide the monitoring physiologist with appropriate cleaning equipment for this purpose.

2.41 The Supplier will be responsible for ensuring the safe and effective decontamination of all reusable items of neuromonitoring equipment before its next use.

3. Standards

3.1 Services must follow British Society for Clinical Neurophysiology (BSCN) Guidelines for Intraoperative Monitoring (and as amended). The guidelines can be seen here http://www.bscn.org.uk/content.aspx?Group=guidelines&Page=guidelines_iom

3.2 The Supplier must have well defined systems and processes to ensure that the standards referred to in these guidelines are met. Details of these systems and processes will be made available to NHS Organisations on request.

3.3 The Supplier must operate a defined quality management system for the management of its service delivery. Details of this quality management system will be made available to NHS Organisations on request.

3.4 The Supplier will be accredited to the IQIPS (Improving Quality in Physiological Services) Standard for neurophysiology or will commit to work towards accreditation during the term of the Framework Agreement

3.5 All products provided by the Supplier and used for the delivery of the Services under the Framework Agreement will be CE certified under the relevant directive.

LOT 2

SUPPLY OF INTRAOPERATIVE NEUROMONITORING EQUIPMENT

1. Overview

1.1 Suppliers appointed to Lot 2 of the Framework agreement will:

1.1.1 Supply state of the art intraoperative neuromonitoring equipment to NHS Organisations.

1.1.2 Supply intraoperative neuromonitoring equipment with an excellent record of safe performance.

1.1.3 Supply intraoperative neuromonitoring equipment with an excellent record of accuracy and effectiveness.

1.1.4 Supply intraoperative neuromonitoring equipment that is versatile, user-friendly and that provides uninterrupted information in easy to read and interpreted formats that can be varied according to user need.

1.1.5 Supply intraoperative neuromonitoring equipment that is capable of intermittent and continuous monitoring of any and all of the modalities required by NHS Organisations. Suppliers may offer a range of intraoperative neuromonitoring equipment to ensure that NHS Organisations have a choice of equipment and modalities suitable to their requirements.

1.1.6 In the event that one or more of the Supplier's items of intraoperative neuromonitoring equipment is withdrawn from sale and contraindicated for further use by NHS Organisations due to product safety concerns, the Supplier will replaced each item of neuromonitoring equipment purchased by NHS Organisations with neuromonitoring equipment of equivalent functionality at no charge to the NHS Organisation. If different consumables are required for any replacement neuromonitoring equipment provided to NHS Organisations in line with provisions of this clause 1.1.6, these consumables will be supplied at the same price as the equivalent consumable previously supplied. For the avoidance of doubt, this clause will not apply where product safety concerns have arisen directly as the result of the actions or inactions of the NHS Organisation. This clause will apply where product safety concerns have arisen directly as the result of the actions or inactions of the Supplier in relation to failure to correctly carry out maintenance, inspections and/or software update services.

1.1.7 Supply a range of single-use consumables, matched to the Supplier's intraoperative neuromonitoring equipment, including but not limited to electrodes, corkscrews and stimulation probes.

1.1.8 Supply the range of single-use consumables described in clause 1.1.7 that is fully compatible with any intraoperative neuromonitoring equipment that is withdrawn from sale for a period of seven (7) years after the withdrawal from sale date. For the avoidance of doubt, this provision will not apply to intraoperative neuromonitoring equipment that is withdrawn from sale and contraindicated for further use by NHS Organisations due to product safety concerns.

1.1.9 Supply intraoperative neuromonitoring equipment and consumables that are highly reliable and consistent in performance. Equipment uptime percentage and mean time between failures should be high.

1.1.10 Provide advice to NHS Organisations on the most appropriate intraoperative neuromonitoring equipment for the organisation's requirements.

1.1.11 Provide comprehensive training in the use of their intraoperative neuromonitoring equipment to appropriate clinical staff of NHS Organisations.

1.1.12 Provide instructions for NHS Organisations on the safe, efficient and effective decontamination of their intraoperative neuromonitoring equipment.

1.1.13 Supply all certification, documentation and support necessary for an NHS Organisation's Medical Engineering, Electronics & Bio-Medical Engineering (EBME) or provider of such services to conduct such engineering safety checks on the intraoperative neuromonitoring equipment that are required by the NHS Organisation.

1.1.14 Provide a comprehensive warranty of at least 12 months duration from the date of delivery or acceptance, whichever is later, covering all intraoperative neuromonitoring equipment, consumables and parts.

1.1.15 Provide maintenance, inspections and software update services to ensure optimal equipment performance and minimise equipment downtime. Software updates will be included at no additional cost in all levels of maintenance plan.

1.1.16 Provide maintenance, inspections and software update services for any intraoperative neuromonitoring equipment that is withdrawn from sale for a period of seven (7) years after the withdrawal from sale date. For the avoidance of doubt, this provision will not apply to intraoperative neuromonitoring equipment that is withdrawn from sale and contraindicated for further use by NHS Organisations due to product safety concerns.

1.1.17 Provide a detailed maintenance schedule to each NHS Organisation purchasing intraoperative neuromonitoring equipment.

1.1.18 Provide remote diagnostic and fault rectification for the intraoperative neuromonitoring equipment with rapid response times and availability during NHS operating hours.

1.1.19 Provide an experienced, multi-person UK based service organisation available for maintenance and support.

1.1.20 Provide guaranteed minimum response times for the attendance of a service engineer on site if required by an NHS Organisation.

1.1.21 Provide the means to ensure continuity of service for NHS Organisations carrying out IOM during planned or unplanned equipment downtime.

1.1.22 Provide training and supply parts to an NHS Organisation's Medical Engineering, Electronics & Bio-Medical Engineering (EBME) or provider of such services to allow first-line maintenance of the intraoperative neuromonitoring equipment, where possible and appropriate.

1.1.23 Provide technical support services to enable the most efficient and effective use of the intraoperative neuromonitoring equipment.

1.1.24 Have short lead times for the delivery of intraoperative neuromonitoring equipment and consumables. The Supplier's On Time In Full (OTIF) percentage for consumable delivery should be high and may be included as a Key Performance Indicator by an NHS Organisation for their Call Off Contract.

1.1.25 Have short lead times for the delivery of parts to an NHS Organisation's Medical Engineering, Electronics & Bio-Medical Engineering (EBME) or provider of such services to allow first-line maintenance of the intraoperative neuromonitoring equipment, where applicable. The Supplier's On Time In Full (OTIF) percentage for parts delivery, where applicable, should be high and may be included as a Key Performance Indicator by an NHS Organisation for their Call Off Contract.

2. Standards

2.1 All products supplied under the Framework Agreement must be CE certified under the relevant directive.

2.2 The Supplier must operate a defined quality management system for the design, development, manufacture, service, installation and distribution of its intraoperative neuromonitoring equipment and its intraoperative neuromonitoring consumables to the standard of ISO 13485 or operate a system to an equivalent level. Details of this quality management system will be made available to NHS Organisations on request.

2.3 The Supplier must operate a defined quality management system for its training, servicing and technical support services. Details of this quality management system will be made available to NHS Organisations on request.