Commercial Procurement Services

Countess of Chester Hospital NHS
NHS Foundation Trust

DYNAMIC PURCHASING SYSTEM OUTLINE SPECIFICATION

DECONTAMINATION AND STERILISATION SERVICES OF REUSABLE SURGICAL AND MEDICAL INSTRUMENTS, DEVICES AND EQUIPMENT "the Services"

1. Aims of the Services

1.1 The overall objective of the Services is to secure the provision of modern and efficient decontamination and sterilisation services which achieve the national policy for compliance with all of the current and future quality and legislative standards, at a competitive and cost effective price, enabling NHS Organisations to service their current and planned / unplanned growth requirements in a timely manner. The Services will include the comprehensive provision of sterile services and other decontamination services including the cleaning of reusable surgical / medical instruments / devices and equipment within facilities operating to all current relevant Medical Device Directives, Health Technical Memoranda, Health Building Notes and recognised standards used in acute care settings and as may be amended updated, enhanced or superseded at any time during the period of validity of the Dynamic Purchasing System from time to time or to any equivalents to the above that are applicable to Scotland, Wales or Northern Ireland.

1.2 The Services will include but not be limited to:

- Collection of contaminated surgical and/or medical instruments and/or devices and/or equipment from an NHS Organisation site.
- Secure transportation of contaminated surgical and/or medical instruments and/or devices and/or equipment to an appropriate decontamination and sterilisation facility.
- Decontamination and sterilisation of contaminated surgical and/or medical instruments and/or devices and/or equipment to an appropriate standard for the safe reuse by an NHS Organisation.
- Secure transportation of decontaminated and sterilised surgical and/or medical instruments and/or devices and/or equipment to the originating NHS Organisation site.
- Full end-to-end tracking and tracing of surgical and/or medical instruments and/or devices and/or equipment that shall: track and trace all instruments/devices i.e. instrument tray sets containing multiple instruments, and individual supplementary instruments/devices.
- A dedicated contact with responsibility to manage operational issues for all aspects for delivery of the Services to an NHS Organisation.

1.3 The Services and any additional standards will be defined in the Contract Specification for each Call Off Contract under this DPS Agreement, by each participating NHS Organisation in accordance with the Call for Competition Procedure, which is in Section 4 of the template DPS Agreement.

1.4 For each Call Off Contract, the participating NHS Organisation will provide a Contract Specification detailing what is required from the Supplier and the outcome to be achieved. The Supplier shall follow the Call for Competition Procedure.

1.5 The Supplier shall offer coverage on a national, regional and / or local basis within the United Kingdom.

1.6 The Supplier shall provide all staff, equipment and consumables necessary to deliver the Services in accordance with this Outline Specification and with any Contract Specification.

1.7 Additional Services to those outlined in Clause 1.2 of this Specification may be included in a Contract Specification and provided by the Supplier.

Examples of additional Services may include:

- decontamination of High Risk Neurosurgical medical devices in compliance with NICE Guidance IPG196: Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures (and as amended);
- enhanced tracking and tracing to achieve patient association for the total decontamination cycle process to assure the NHS organisation in the event of a look-back process data is available for a robust investigation into an incident;
- low temperature sterilisation of flexible endoscopes;
- repair and maintenance of surgical instruments/medical devices;
- service and maintenance of surgical power tools;
- reprocessing of loan instrument tray sets.

The list above is not exhaustive and other additional Services may be offered providing these services sit within the reasonable scope of the Services as described in this Outline Specification.

2. Contract Management Approach

2.1 The Supplier must operate a defined and documented contract management process.

2.2 The Supplier must operate a defined and documented quality management system.

2.3 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.

2.4 The Supplier will work closely with the NHS Organisation to produce a detailed contract implementation and mobilisation plan which will include interfaces and transfer points to ensure a seamless transition to the Supplier.

2.5 The Supplier will work closely with any outgoing supplier to the NHS Organisation to ensure minimal disruption to the NHS Organisation during any transition. For the avoidance of doubt, this includes managing with the outgoing supplier any issues related to the application of TUPE legislation.

2.6 The Supplier will work closely with the NHS Organisation to produce a detailed exit plan for the end of each Contract called off from the DPS. This will include a plan for managing any issues related to the application of TUPE legislation.

2.7 The Supplier will effectively communicate with and manage the supply chain to deliver the Services for and with NHS Organisations.

2.8 Contracts will be delivered in accordance with defined programmes of work to be agreed with each NHS Organisation for each Contract called off from the DPS.

2.9 The Supplier will ensure that the Services are delivered with minimum disruption to the day-to-day operations of the NHS Organisation.

2.10 The Supplier must ensure that the Services do not negatively impact on patient care.

2.11 The Supplier will effectively performance manage any subcontractors (and their supply chains) in performing the Services.

2.12 The Supplier will effectively manage its costs and budgets to prevent cost over-runs. No further funding will be made available if the Supplier fails to effectively manage its costs and budgets. For the avoidance of doubt, where cost over-runs are partly or wholly due to the actions or inactions of the NHS Organisation, this element of the cost over-run will be funded by the NHS Organisation to the extent of its responsibility for such an over-run.

2.13 The Supplier will achieve value for money and continuous improvement which will be measured by Key Performance Indicators agreed with the NHS Organisation. Key Performance Indicators may include, for example:

- Turn-around time
- Reported non-conformances
- Service improvement initiatives
- Customer satisfaction levels
- Cost reductions

3. Governance Approach

3.1 The Supplier will be responsible for:

- Delivering the Services as described in this Outline Specification and any Contract Specification
- Ensuring that all current and future quality and legislative standards applicable to delivery of the Services are met
- Ensuring that all staff employed and sub-contracted by them in the delivery of the Services are competent to perform all duties that are required of their rôle, including ensuring that all professional registration conditions are met
- Providing access to relevant training and Continuous Professional Development (CPD) for staff employed by them in the delivery of the Services
- Ensuring that any sub-contractors provide access to relevant training and Continuous Professional Development (CPD) for staff employed by sub-contractors in the delivery of the Services
- Providing Human Resources and Occupational Health services for staff employed by them in the delivery of the Services
- Ensuring that any sub-contractors provide access to Human Resources and Occupational Health services for staff employed by sub-contractors in the delivery of the Services
- Leading in audit, service evaluation and service development

3.2 The Supplier will take all reasonable care to engage or employ in and about the provision of the Services only such Staff as are carefully skilled and experienced in their several professions and callings.

3.2 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 PVG certificate, as appropriate, valid for the work that is the subject of any Call Off Contract.

3.3 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 and occupational health checks

3.4 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. The DPS Manager must also be informed to allow relevant and permitted information to be passed to other NHS Organisations to promote safeguarding.

3.5 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 which shall be maintained throughout the life of the DPS and during any Contract whose performance concludes outside the period of the DPS.

3.6 The Supplier will provide details of their policies and procedures for governance to any requesting NHS Organisations and will notify the NHS Organisations that have entered into a Call Off Contract of any changes in these.

3.7 The Supplier shall ensure that all Staff 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.

3.8 The Supplier shall be responsible for ensuring compliance with all relevant HM Revenue and Customs regulations regarding the correct accounting for and payment of tax and National Insurance by and for Staff engaged in the performance of the Services.

3.9 The Supplier will commit to notifying NHS Organisations to whom the Supplier is contracted to perform Services of any Staff changes that could affect the delivery of the Services as soon as they become aware of this.

3.10 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.

3.11 The Supplier must not through its actions or inactions jeopardise any NHS Organisation's compliance with the requirements of The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and related guidance (or equivalent Codes of Practice in Scotland, Wales and Northern Ireland, where applicable), and with those of any future regulatory standards as appropriate throughout the life of the DPS and during any Contract whose performance concludes outside the period of the DPS. The Supplier will use its best endeavours to ensure that the actions or inactions of the Supplier Staff or the staff of any subcontractor do not jeopardise the compliance referred to in this clause 3.11.

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

- Effective performance of the Services at all times including but not limited to periods when equipment is undergoing testing, inspection, maintenance or revalidation and when equipment is out of use for repair or for any other reason;
- All requirements relating to health and safety in the workplace are satisfied;
- Staff are appropriately trained and competent to perform the duties required of their role
- Adherence to the NHS Organisation's guidelines, policies and procedures where applicable throughout the life of the DPS and during any Contract whose performance concludes outside the period of the DPS. Details of applicable guidelines, policies and procedures and the points to which adherence will be required will be will be determined for each Call Off Contract and described in the Contract Specification

3.13 The Supplier must have a defined and documented system in place for reporting safety incidents and reviewing of this data at appropriate levels.

3.14 The Supplier must record within the Supplier's own relevant systems, within two working days, any adverse incidents and supply the NHS Organisation with a summary of any internal enquiry into such incidents.

3.15 The Supplier will undertake to provide information to NHS Organisations to support investigation of any Serious Untoward Incidents and complaints in line with the NHS Organisation's complaints and incident reporting procedures, implementing the NHS Commissioning Board Special Health Authority (formerly NPSA) investigation toolkit (or the procedures of equivalent organisations in Scotland, Wales and Northern Ireland, where applicable).

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

3.17 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

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

3.19 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 DPS and during any Call Off Contracts whose performance concludes outside the period of the DPS.

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

3.21 Any enquiries made by an NHS Organisation to the Supplier will be dealt with in an appropriate and timely manner.

3.22 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.

3.23 The Supplier shall inform the Awarding Authority of any complaints made by any NHS Organisation about services performed under a Contract called off under the DPS and supply copies of all correspondence to the Awarding Authority which relates to complaints or the handling of them.

3.24 In the event that complaints regarding the Services are made by Patients or their representatives to an NHS Organisation, the NHS Organisation will forthwith inform the Supplier and supply relevant correspondence.

3.25 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:

- Appoint a complaints manager or individual with complaints remit
- Provide the Awarding Authority and any NHS Organisation with relevant details of the complaints manager

3.26 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.

3.27 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).

4. Service Standards

4.1 The Supplier shall be required to comply with all applicable current and future legislation, regulations and guidelines during the period of validity of the Dynamic Purchasing System and during the term of any Contract called off from the DPS where this ends after the period of validity of the Dynamic Purchasing System. NHS Organisations recognise that legislative and regulative compliance from the Supplier does not absolve them from their own specific responsibility to comply with legislation and regulations. NHS Organisations shall work with their contracted Supplier to ensure that jointly both parties notify and advise with regard to all relevant current and future legislation, regulation and guidelines to ensure each party meet their individual statutory obligations.

4.2 The Supplier must ensure that its quality management system maintains compliance at all times with all applicable parts of the Medical Devices Directive (MDD) 2007/47 EC

4.3 The Supplier must comply with the applicable parts of all following standards and guidance and to any amendments, revisions and/or superseding standards and guidance:

4.3.1 Health Technical Memorandum (HTM) 01-01 parts A to E. Management and decontamination of surgical instruments (medical devices) used in acute care

4.3.2 Health Technical Memorandum (HTM) 01-06 - guidance on the management and decontamination of flexible endoscopes.

4.3.3 Health Technical Memorandum 07-01 – Safe management of healthcare waste

4.3.4 BS EN ISO 17665-1:2006. Sterilisation of health care products. Moist heat

4.3.5 BS EN ISO 13485:2016 or ISO 9001:2015. Quality management systems

4.3.6 BS EN ISO 11607-1:2017 Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems

4.3.7 BS EN 13795:2011+A1:2013: Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical operatives and equipment

4.3.8 BS EN ISO 14644-1:2015 Cleanrooms and associated controlled environments. Classification of air cleanliness by particle concentration.

4.3.9 BS EN ISO 14644-2:2015 Cleanrooms and associated controlled environments. Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration.

4.3.10 BS EN ISO 14971:2012 Medical devices. Application of risk management to medical devices

4.3.11 BS EN ISO 15883-1:2009+A1:2014 Washer-disinfectors. General requirements, terms and definitions and tests

4.3.12 BS EN ISO 15883-2:2009 Washer-disinfectors. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

4.3.13 BS EN 556-1:2001 - Sterilisation of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilised medical devices

Proof of conformance to standards will be provided to NHS Organisations and to the DPS Manager on request.

Conformance with additional standards and guidance may be required and will be detailed in a Call Off Contract Specification issued with a call for further competition. This may include, but not be limited to NICE IPG 196 Guidance: Patient safety and reduction of risk of transmission of Creutzfeldt–Jakob disease (CJD) via interventional procedures

4.4 Contracted Suppliers must include in their response to a call for further competition a method statement or statements clearly demonstrating how the Supplier will comply with applicable current and future legislation, regulations and guidelines to achieve Best Practice standard.

4.5 The delivery of the Services by the Supplier is expected to meet the operational requirements set out in a Call Off Contract Specification at all times. The Supplier shall nominate a named individual responsible for maintaining quality standards for each Call Off Contract awarded for the contract period.

4.6 All items decontaminated, sterilised and disinfected should be subjected to properly validated and documented procedures, tracking/traceability and auditable systems, supported by authorised records. Standard Operating Procedures shall comply and be in accordance with BS EN ISO 13485:2016. The Supplier will provide evidence of compliance in their response to a call for further competition and to the DPS Manager on request.

4.7 All items must be processed to a consistently high quality.

4.8 All vehicles, equipment, storage containers, trolleys and any other equipment used to transport surgical and/or medical instruments and/or devices to and from an NHS Organisation site must be fit for the intended purpose and fully compliant with all relevant and applicable parts of the ADR Regulations and The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (2015). The Supplier must provide details of vehicles, equipment, storage containers, trolleys and any other equipment used in their response to a call for further competition and to the DPS Manager on request.

4.9 All vehicles, equipment, storage containers, trolleys and any other equipment used to transport surgical and/or medical instruments and/or devices to and from an NHS Organisation site must be decontaminated in accordance with applicable Best Practice. The Supplier will provide evidence of the decontamination process and frequency in their response to a call for further competition and to the DPS Manager on request.

4.10 The Supplier must ensure that all vehicles, equipment, storage containers, trolleys and any other equipment used to transport surgical and/or medical instruments and/or devices to and from an NHS Organisation site are maintained at manufacturer recommended intervals to ensure continual compliance with all relevant and applicable parts of the ADR Regulations and The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (2015).

4.11 Turn-around times will set out in each Call Off Contract Specification and must be adhered to at all times. The Supplier must have processes and contingencies to ensure compliance with agreed turn-around times as part of the Supplier's quality management system.