

**National Framework Agreement for the Provision of Sterile Services and
Endoscopy Decontamination Facility Solutions**

Project Reference: F/066/SSE/20/MH

SCHEDULE A
FRAMEWORK AGREEMENT SPECIFICATION

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1. INTRODUCTION

Some NHS organisations have out of date in-house Sterile Services and Endoscopy Decontamination Departments (SSD). In order to maintain compliant services, NHS organisations either need to outsource these services or to invest in the development of new in-house facilities.

This Framework Agreement will offer a solution for NHS organisations wishing to invest in the development of new in-house facilities. The Framework Agreement will allow NHS organisations to procure a Supplier who can design, build and equip a SSD and subsequently maintain the facility and its equipment under a managed service contract. The new SSD could be new build, modular or fit out, and could be located on site, or off site depending on client requirements. The Supplier may provide finance to the NHS organisation for the design, build and equip of the SSD. Outsourcing of Sterile Services and Endoscopy Decontamination Services are not within the scope of the proposed Framework Agreement. Outsourcing of services can be contracted for via existing arrangements, including Countess of Chester Hospital Commercial Procurement Services' Dynamic Purchasing System for Provision of Sterile Services.

This Specification is broad in its design to enable application to individual projects. Please note the requirements set out in this Specification are not exhaustive. The scope of each individual project may be refined by the Client to reflect the specific requirements for that project (to the extent permitted and set out in the Framework). These will be detailed at Call Off Contract stage.

The Supplier shall provide the works and services in accordance with the requirements set out in this document, and as may be further detailed in any subsequent specific Call Off Contract.

Specialist requirements for Call Off Contracts will be specified by the Client. For example, such specialist requirements may include, but are not limited to:

- a) Specific security clearances,
- b) Sector specific requirements and/or experience; and
- c) Standards for the works and services specific to the Call Off Contract.

This Framework Agreement includes a range of complementary elements (design, construction, equipment management, finance and facilities management) that will collectively enable Clients to effectively manage the full life cycle requirements of their built asset and associated strategies on the basis of whole life value considerations.

The detailed scope of works and services required for each individual project will be specified at Call Off Contract stage.

The framework will be offered in two Lots

Lot 1 – Design, Build, Equip and Maintain a Sterile Services and Endoscopy Decontamination Facility.

Suppliers appointed to Lot 1 MUST be able to deliver all of the elements within that Lot. Details of the precise elements to be delivered in a Call Off Contract will be specified at Call Off Contract stage.

Lot 2 - Design, Build, Equip and Maintain a Sterile Services and Endoscopy Decontamination Facility with Design, Build, Equipment and ongoing provision of appropriate facilities management financed by the Supplier.

Suppliers appointed to Lot 2 MUST be able to deliver all of the elements within that Lot. Details of the precise elements to be delivered in a Call Off Contract will be specified at Call Off Contract stage.

2. GENERAL REQUIREMENTS (BOTH LOTS)

The following General Requirements may be applicable to any or all elements or phases of a Call Off Contract awarded under this Framework Agreement. The Supplier must therefore be capable of meeting all the requirements outlined below.

The detailed scope of works and services required for each individual project will be specified at Call Off Contract stage.

1. Standards, Legislation and Client Policies

The Supplier shall at all times for the duration of this Framework Agreement, and the term of any individual Call Off Contract, comply with the relevant standards for the scope of the works and services required, including but not limited to, the following:

1. a Quality Management System supported by the International Organisation for Standardisation ISO 9001 Quality Management System, or equivalent;
2. an Environmental Management System supported by the International Organisation for Standardisation ISO 14001 Environmental Management System or equivalent;
3. a FM critical services management system supported by the international organisation for standardisation ISO41001 Critical Services in Healthcare or equivalent;
4. Suppliers must hold (or commit to obtain, prior to commencement of the Framework Agreement if awarded) Cyber Security Essentials accreditation.
5. Business Continuity Plan and Crisis Management Plan.

The Supplier shall ensure that their works and services are at all times compliant with the Law of the United Kingdom, as applicable to the jurisdiction applicable to the Call Off Contract.

Such compliance shall include all relevant primary and secondary legislation relevant to the Framework Agreement Contract Documents and Call Off Contract. The Supplier shall support the Client in ensuring compliance with all regulations, including the implementation of any relevant procedures.

The Supplier shall ensure that all works and services fully comply with all client policies and procedures detailed at Call Off Contract stage.

The Supplier shall ensure full compliance with any estate and asset management strategy detailed in the Call Off Contract in the delivery of the works and services.

The Supplier shall provide information to update the property and asset records, where any changes to the property and assets results from the Call Off Contract.

2. Insurances and Warranties

The Supplier shall ensure that it will have in place and maintain the insurances detailed in the Framework Agreement. Individual projects may require additional levels of insurances, which will be detailed in the Call Off Contract, and the Supplier shall comply with the same.

Individual Call Off Contracts may require the Supplier and Supply Chain to provide warranties and/or Parent Company Guarantees for the works and services delivered. Specific warranty and/or Parent Company Guarantee requirements will be defined for each Call Off Contract.

3. Contract Management

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

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

The Supplier will work closely with the Client and integrate in an adaptive and responsive way with the Client's clinical and management teams as appropriate.

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

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

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

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

Contracts will be delivered in accordance with defined programmes of work to be agreed with each Client for each Contract called off from the Framework Agreement.

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

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

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

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 Client, this element of the cost over-run will be funded by the Client to the extent of its responsibility for such an over-run.

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

- Achievement of Programme Milestones
- Reported non-conformances
- Service improvement initiatives
- Client satisfaction levels
- Cost reductions

4. Programme Management

The Supplier must be capable of preparing and maintaining a master programme for the Client, including all the activities of each phase of the Call Off Contract. This programme will be of sufficient detail to allow control of the activities, to indicate key dates within the overall programme, and show the critical path.

The Supplier may be required to produce further programmes for specific phases of a Call Off Contract. The following list provides examples of the types of programme the client may request:

- Construction Programme
- Procurement Programme
- Commissioning Programme

All programmes supplied under this Framework Agreement and any Call Off Contract will be baselined and provided in electronic format. Progress will then be monitored against the agreed programme.

5. Risk Management

The Supplier shall work with Client and the Supply Chain to proactively identify and manage risk. The Supplier shall deliver the risk management obligations for each project as set out in the individual Call Off Contract.

6. Quality Control

The Supplier shall ensure the works and services delivered for each project meet all the quality requirements as set out in the individual Call Off Contract.

7. Supply Chain

The Supplier is responsible for the selection and management of its Supply Chain. As a minimum, the Supplier will:

- select the Supply Chain through fair, open and transparent competition.
- establish and develop relationships and contractual arrangements with its Supply Chain that are complementary to the relationships and contractual arrangements under the Framework Agreement and Call Off Contract.
- manage its Supply Chain to ensure that the required standards for the delivery of the works and services are consistently achieved.
- ensure the co-ordination of all outputs provided by its Supply Chain in the delivery of the works and services, and shall effectively manage all interface risks to provide a seamless service for all Call Off Contracts..
- have robust performance management and benchmarking processes in place to ensure the objective measurement and assessment of the performance of its Supply Chain. Such processes shall include measurement of the Supply Chain's performance in relation to cost, programme and quality of the works and services delivered.

8. Health and Safety

The Supplier shall fully understand their duties under Construction (Design and Management) Regulations 2015 and must discharge these duties accordingly.

The Supplier shall manage health and safety in line with the requirements for individual Call Off Contracts.

9. Sustainability

The Framework Manager is committed to sustainability and places great importance on ensuring sustainability is considered as part of all Call Off Contracts. The Framework Manager is committed to optimising the positive impact of construction activities and minimising any adverse impacts that construction has on the environment. The Supplier shall support the Client in achieving these goals across the lifecycle of the project through the design process, materials selection, construction techniques and construction methods implemented.

The Supplier shall ensure that it adheres to Government guidance and best practice in all aspects of sustainability. This includes (but is not limited too):

- Greenhouse gas emissions
- Waste generation
- Energy Consumption
- Water consumption
- Use of sustainable and efficient products
- Reuse and responsible recycling of all Information and Communications Technology equipment
- Drainage
- Biodiversity
- Environmental Impact
- Flooding
- BRE Environmental Assessment
- Apprenticeships and sustainable skills development
- Diversity and inclusion

10. Stakeholder Management

The Supplier shall undertake active internal and external stakeholder management throughout the lifetime of each Call Off Contract.

The following list provides examples of the types of internal stakeholders involved in a Call Off Contract under this Framework Agreement:

- Estates/Facilities
- Finance
- Legal
- Commercial/Procurement
- Environment
- Fire

The following list provides examples of the types of external stakeholders involved in a Call Off Contract under this Framework Agreement:

- Councils
- Environment Agency
- Utility Companies
- Professional Consultants
- Developers
- Other building occupiers

11. Working in existing buildings and facilities

Suppliers may be required to work within a client's existing buildings and/or facilities.

Unless stated otherwise in the Call Off Contract specification, the responsibility for the maintenance of the existing building and infrastructure rests with the Client.

Where stated in the Call Off Contract, the Supplier may be requested to manage the supplier appointed by the Client for the maintenance of the existing building and infrastructure services for the period set out in the Call Off Contract. The Supplier shall liaise with such suppliers and share any working area with them to the extent that allows the required maintenance to be completed. In any such circumstances the Supplier shall act as the Principal Supplier/Contractor under the Construction (Design & Management) Regulations 2015 (CDM 2015 Regulations).

The Supplier shall take all reasonable measures to prevent damage or deterioration of the existing building and infrastructure, to prevent any increase in maintenance over and above that which could be reasonably expected.

12. Deliveries

The Supplier shall comply with the transportation, delivery and loading requirements for plant and materials etc. identified in each Call Off Contract.

The Supplier shall provide its Supply Chain with information to ensure that they comply with the relevant requirements in the Call Off Contract.

3. DESIGN (BOTH LOTS)

The Supplier must be capable of the design of a new Sterile Services and Endoscopy Decontamination Unit (SSD). The design must meet all appropriate standards including Health Technical Memoranda and Health Building Notes and all client specific requirements, described in the briefing material for any proposed project.

The detailed scope of works and services required for each individual project will be specified at Call Off Contract stage.

1. Aims of the Design Phase

The objective of this element of the specification is to secure the design of a modern and efficient decontamination and sterilisation unit which complies with all relevant standards, at a competitive and cost effective price. The Design Services comprise the design of a new Sterile Services and Decontamination Unit in accordance with all appropriate industry standards and any client specific requirements.

The specification for the design phase will be agreed for individual projects at call off contract stage. The following sections provide details of overarching general requirements, roles and responsibilities which will form the basis of a detailed specification at Call Off Contract stage.

The output of this phase of any call off contract will be a design proposal that satisfies the Client's stated outcomes and cost benchmark, in accordance with the scope outlined in the call off contract documents. The Supplier is to meet the Client's design and user requirements, whilst taking into consideration value, savings, risk and price as agreed with the Client. The design produced must be capable of being delivered in the Construction Phase.

2. Scope of the Design Phase

The following list details roles and responsibilities which the Supplier must be capable of carrying out:

- The preparation, development and completion of detailed designs. As a minimum, these will include the production of construction drawings and specifications.
- Design Considerations: Ensure all design considerations are taken into account during the design phase. For example, buildability, practicality, clinical safety standards, efficiency, health and safety, material suitability, waste management and reduction.
- Leading the design process in a proactive manner. For example, this may include taking the lead on design progress meetings, design review workshops and any issues that arise during the design phase.
- Design Deliverables: Review and agree the design deliverables with the Client.
- Review of existing documentation: Carry out a detailed review and provide feedback on any existing documents, drawings or specifications which may impact the final design output of this Phase. This may include documents relating to compliance with appropriate standards such as health and safety and environmental regulations.
- Risk: Develop and manage a risk register to cover this Phase of Contract.
- Information Exchange: Facilitate and support the exchange of information between all appropriate parties involved in the project to support the programme.

- Change Management: Proactively manage change throughout the design phase of the contract. Any changes and their potential impacts must be highlighted to the Client at the earliest available opportunity.
- Subcontractor management: Proactively manage any Subcontractor involved in this phase of the contract as agreed with the Client.

The Supplier must be capable of contributing to the development of an agreed construction programme and methodology as required by the Client. The specific role the Supplier will take in this will be defined at Call Off Contract Stage. This may include:

- Overall schedule for the construction phase with consideration for optimum phasing and sequencing
- Logistics planning
- Constructability advice
- Pre-fabrication and pre-assembly planning if required
- Details of operational interfaces and handovers
- Advanced works
- Mobilisation
- Commissioning
- Equipment Validation

3. Design Standards

The Supplier shall at all times for the duration of this Framework Agreement, and the term of any individual Call Off Contract, comply with the relevant standards required of a company carrying out design work.

The Supplier shall complete all design work required under any individual Call Off Contract, in accordance with the relevant design standards for the scope of the works and services required.

4. BUILD (BOTH LOTS)

Following the design of the Sterile Services and Endoscopy Decontamination Unit (SSD), the Supplier must be capable of the construction of the new unit according to the design and specification required by the client.

The detailed scope of works and services required for each individual project will be specified at Call Off Contract stage.

1. Aims of the Build Phase

The overall objective of this element of the specification is to secure the provision of a modern and efficient decontamination and sterilisation unit which complies with all relevant standards, at a competitive and cost effective price. The Build Services comprise the construction of a new Sterile Services and Decontamination Unit in accordance with the requirements identified in the design services delivered under this framework and by the client.

2. Scope of the Build Phase

The specification for the Build Phase will be a product of the Design Phase, and will be mutually agreed between the Client and the Supplier. The list below provides an example of what the specification may cover:

- Foundations
- Structural frame
- Fire protection
- Floor slabs
- Damp proof membrane
- Screed to floor slabs
- Plantroom
- Damp proof course
- Cavity trays
- External walls (masonry)
- Lintels to external walls (masonry)
- Windows
- Curtain walling
- Cillboards
- External doors
- Internal partitions
- Roof
- Internal doorsets
- Wall access panels to service risers and electrical cupboards
- Ironmongery
- Glazed screens
- Emergency breakout panels
- Floor finishes
- Wall finishes
- Suspended ceilings
- Sanitary fittings
- Fitted furniture
- Fixtures and fittings
- Wall and corner protection

- Signposting
- Drainage above ground
- Drainage below ground
- External hard works
- External soft works
- External services
- MEP services

3. Build Standards

The Supplier shall ensure that their works are at all times compliant with all laws, standards and client policies applicable to the scope of the Call Off Contract.

EQUIP (BOTH LOTS)

1. Aims of the Equip Phase

The overall objective of this element of the specification is to secure the provision of a modern and efficient decontamination and sterilisation unit which complies with all relevant standards, at a competitive and cost effective price. The Equip Services comprise the procurement and installation all equipment necessary for the operation of a Sterile Services and Decontamination Unit in accordance with the requirements identified in the design services delivered under this framework and by the client.

Where specified by a Client, the Supplier will procure and install all appropriate equipment to enable the operation of the new unit as a Sterile Services and Endoscopy Decontamination facility. This may include (but is not limited too) decontamination and sterilisation equipment, water treatment (e.g. reverse osmosis plant) and water handling equipment. At Call Off Contract stage, the Client will detail their required level of involvement in the selection of this equipment. Some Clients may want to decide for themselves which equipment is to go into the new facility; where as other Clients may want to leave the selection of equipment to the Supplier. The Client will specify what, if any, equipment owned by them and which is to be transferred from an existing facility to the new facility.

2. Scope of the Equip Phase

The specification for the Equip Phase will be a product of the Design Phase, and will be mutually agreed between the Client and the Supplier. The list below provides a non-exclusive example of what the specification may cover:

- Washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
- Porous Load Steam Sterilisers (Autoclaves)
- Automated Endoscope Reprocessors
- Endoscope Drying Cabinets
- Ultrasonic Baths
- Low Temperature Sterilisers
- Water treatment (e.g. reverse osmosis plant) and water handling equipment

- Instrument tracking and traceability software and systems
- 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.

3. Equip Standards

The Supplier shall ensure that their services are at all times compliant with all laws, standards and Client policies applicable to the scope of the Call Off Contract.

The Supplier must ensure that the equipment is in conformance with the applicable parts of all applicable standards and guidance, in particular but not exclusively the following standards and guidance and to any amendments, revisions and/or superseding standards and guidance:

- Health Technical Memorandum (HTM) 01-01 parts A to E. Management and decontamination of surgical instruments (medical devices) used in acute care
- Health Technical Memorandum (HTM) 01-06 - guidance on the management and decontamination of flexible endoscopes.
- Health Technical Memorandum 07-01 – Safe management of healthcare waste
- BS EN ISO 17665-1:2006. Sterilisation of health care products. Moist heat
- BS EN ISO 13485:2016 or ISO 9001:2015. Quality management systems
- BS EN ISO 11607-1:2017 Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems
- BS EN ISO 14644-1:2015 Cleanrooms and associated controlled environments. Classification of air cleanliness by particle concentration.
- 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.
- BS EN ISO 14971:2012 Medical devices. Application of risk management to medical devices
- BS EN ISO 15883-1:2009+A1:2014 Washer-disinfectors. General requirements, terms and definitions and tests
- 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.
- BS EN 556-1:2001 - Sterilisation of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilised medical devices

It is acknowledged that some of the standards and guidance referenced above are not directly applicable to procurement and installation of all appropriate equipment to enable the operation of the new unit as a Sterile Services and Endoscopy Decontamination facility. Any such standards and guidance are referenced as they are central to the ongoing operation of the new facility.

Proof of conformance to standards will be provided to NHS Organisations and to the Framework 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

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.

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.

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 showing how their services will maintain compliance in their response to a call for further competition and to the Framework Manager on request.

MANAGE EQUIPMENT (BOTH LOTS)

Where specified by a Client, the Supplier will provide a continuing managed service for ongoing maintenance, availability and renewal of the decontamination services machinery, supplementary equipment and supplies.

The detailed scope of services required for each individual project will be specified at Call Off Contract stage.

1. Aims of the Manage Equipment Phase

The overall objective of this element of the specification is to ensure that the new facilities built under this Framework Agreement continually meet 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 this Framework Agreement.

2. Scope of the Manage Equipment Phase

The Supplier must provide a managed service that ensures:

All decontamination processing equipment is maintained and validated in accordance with the relevant applicable European standards (or, where the UK leaves the European Union, an equivalent UK standard), applicable health technical memoranda;

- Planned Preventative Maintenance ("PPM") schedules are in place for all decontamination processing equipment and general departmental equipment, (such schedules being in accordance with the Original Equipment Manufacturer ("OEM") recommendations; and
- Adequate records relating to processing equipment are maintained.

The successful bidder shall ensure that:-

- Steam supply to the autoclaves is in compliance with the relevant applicable European standards, and/or health technical memoranda;
- Alternative sterilisation methods and equipment is tested and maintained in accordance with the relevant applicable European standards, and/or health technical memoranda;
- Production records relating to the sterilization process are maintained and held for a period set out within the Department of Health Records Management Code of Practice for Health and Social Care 2016 or as amended from time to time.

All equipment supplied to enable the operation of the new unit as a Sterile Services and Endoscopy Decontamination facility is maintained, periodically tested and validated in order to perform to the manufacturer's specification and to conform with the relevant Standards, Health Building Notes, Health Technical Memoranda and Medical Devices Regulations.

The managed service may be provided by suitably qualified and trained employees of the Supplier or by suitably qualified and trained sub-contractors. Where services are provided by sub-contractors, the Supplier will retain full responsibility for the delivery of the services at all times.

3. Equipment Management Standards

The Supplier shall be required to comply with all applicable current and future legislation, regulations and guidelines during the period of validity of the Framework Agreement and during the term of any Contract called off from the Framework Agreement where this ends after the period of validity of the Framework Agreement. 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.

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

The Supplier must ensure that the equipment is maintained and tested in conformance with the applicable parts of all applicable standards and guidance, in particular but not exclusively the following standards and guidance and to any amendments, revisions and/or superseding standards and guidance:

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

- Health Technical Memorandum (HTM) 01-06 - guidance on the management and decontamination of flexible endoscopes.
- Health Technical Memorandum 07-01 – Safe management of healthcare waste
- BS EN ISO 17665-1:2006. Sterilisation of health care products. Moist heat
- BS EN ISO 13485:2016 or ISO 9001:2015. Quality management systems
- BS EN ISO 11607-1:2017 Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems
- BS EN 13795:2011+A1:2013: Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical operatives and equipment
- BS EN ISO 14644-1:2015 Cleanrooms and associated controlled environments. Classification of air cleanliness by particle concentration.
- 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.
- BS EN ISO 14971:2012 Medical devices. Application of risk management to medical devices
- BS EN ISO 15883-1:2009+A1:2014 Washer-disinfectors. General requirements, terms and definitions and tests
- 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.
- 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 Framework 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

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.

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.

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 showing how their services will maintain compliance in their response to a call for further competition and to the Framework Manager on request.

5. MANAGE ENVIRONMENT (BOTH LOTS)

Where specified by a Client, the Supplier will provide a continuing managed service for ongoing facilities management of the new unit according to the specification outlined below and any client specific requirements detailed in an individual project Call Off Contract. The managed service will be provided by the Supplier directly or by third party Subcontractors managed by the Supplier.

In exceptional circumstances (i.e. for emergency and/or reasons of patient safety), or for any urgent requirement that may arise, the Client shall be able to contact, liaise and work directly with the relevant third party Subcontractor(s) (an Event) and the Supplier shall not encumber or delay this process. Following an Event or Events the Client will inform the Supplier within a reasonable time and no longer than one Working Day.

The detailed scope of works and services required for each individual project will be specified at Call Off Contract stage.

4. Aims of the Manage Environment Phase

The overall objective of this element of the specification is to secure the provision of an efficient and cost effective facilities management service for the new Sterile Services and Endoscopy Decontamination Unit (SSD).

The Supplier shall provide an integrated Service ensuring a seamless and coordinated delivery and effective synergies with third party suppliers and service providers are delivered at all times. The Supplier shall take advantage of synergies between the different services and the benefits that integration will bring.

The Supplier shall work collaboratively with the Client to identify opportunities for ongoing efficiencies in relation to delivering the services. All opportunities identified that have the potential to deliver performance, economic and social value improvements shall be presented to the Client for consideration.

The Supplier shall undertake billable works Services only with the sanction of the Client.

5. Scope of the Manage Environment Phase

The specification for the Manage Environment Phase will be mutually agreed between the Client and the Supplier for each Contract. Services may include but will not be limited to:

- Contract Management

- Contract Mobilisation
- Maintenance Services
- Horticultural Services
- Catering Services
- Cleaning Services
- Workplace FM Services
- Reception Services
- Security Services
- Waste Services
- Miscellaneous FM Services
- CAFM
- Helpdesk Services
- Management of Billable Works

In particular, and to the extent specified by a Client, the Supplier shall be responsible for:

- The provision of a safe and comfortable environment for all Client users through the provision of a complete building and Asset maintenance management Service for the Client Premises;
- The provision of preventative, cyclical and Reactive Maintenance to the Client Properties to ensure that the Assets provide full operational functionality at all times;
- Provision and maintaining of a Full Asset list of all plant and equipment, kept regularly updated – to a level applicable for performing Planned Preventative Maintenance (PPM) and for also undertaking full condition/ remaining life surveys on all built Assets (in scope);
- Ensuring that buildings and associated engineering services and external works shall be sound and operationally safe;
- Ensuring that the Asset's condition remains commensurate with age and life cycle replacement date;
- Ensuring that maintainable Assets, including non-fixed plant and equipment, within the Client properties and identified from the Asset list and Condition Survey, are maintained to the required '*fit for function*' performance level, and compliant with all statutory/legal and mandatory obligations;
- Ensuring that the maintenance regime is required to suit the built environment (for in use and also mothballing of vacated facilities) taking due regard for the manufacturers and installers recommendations;
- Meeting Reactive Maintenance responsiveness requirements as determined by the Client;
- Provision of Asset listing and Condition Surveys to include plant and equipment. This is to be regularly updated to allow for any additions and /or forward maintenance plans - identifying short, medium and long term maintenance proactive maintenance shall include periodic management inspections of Client Properties (e.g. plant tours, inspections/monitoring);
- Ensuring the management and administration levels to be appropriate to the specific Service Requirements; and

- Tailoring the Service to appropriately maintain the relevant Assets to suit the defined functional use of the built environment over the required period of interest (to fulfil technical, commercial and environmental agendas).
- All statutory requirements and safety practices shall be adhered to in respect to the method of completing the task and the requirements of the specific Acts, Regulations, British Standards and Guidance Notes currently in force and applicable.

Buildings and Asset Maintenance:

The Supplier shall deliver a buildings and Asset maintenance management Service that meets the Client's requirements:

- The Supplier shall deliver a building, installations and Asset maintenance Service that meets, but is not limited, to the following requirements:
- Produce a schedule of programmed maintenance in the form of an annual five (5) Year rolling plan or forward maintenance register with respect to planned maintenance. The schedule of programmed maintenance will be updated annually and on a regular basis as maintenance is undertaken, and as lifecycle maintenance items are brought forward or delayed due to worse or better than expected performance. A general review will be undertaken prior to the end of each Year of the Call-Off Contract and a revised plan presented to the Client in accordance with the Call-Off Contract.
- Provision of a thirty (30) year lifecycle replacement profile for the Client Premises;
- Ensure that all statutory tests and inspections are undertaken within the statutory timescales, together within any repair works arising as a result;
- Maintain full records of work to be undertaken in an order of priority, and subsequently full records of completed work;
- Submit a Monthly report of all works and testing undertaken, whether these be planned or reactive in nature, at the same time as the annual service plan;
- State the expected remaining life (if any) of the key building elements, installations and equipment at the end of the Call-Off Contract;
- Specify minimum redecoration cycles for internal and external elements. The minimum cycles may be split into various areas around the buildings with front of house and all public areas taking precedence. The aim is to ensure that the facilities are maintained in a reasonable decorative standard through the whole Client Premises during the Call-Off Contract;

When carrying out Services the Supplier shall:

- Discuss the proposed works with the Client and Client Representative and seek agreement in relation to timescales;
- Ensure that any reasonable requirements of the Client are taken into account in the proposed works;
- Ensure that the operations of the Client can continue but the extent of maintenance is at the discretion of the Supplier unless governed by statutory requirements;
- Confirm the start and completion dates and hours of working;
- Protect all Client users and their belongings during such works;

- Provide advice and instructions on the use of any new equipment and/or installations;
- Liaise with the Client at the Client Premises or the Client Representative on access issues, including restrictions to areas that may be out of use;
- Maintain and make good any incidental damage caused;
- Remove all rubbish and clean up after completing tasks at the end of each Working Day;
- Carry out all works in accordance with statutory requirements, insurance requirements, Health and Safety requirements, British Standards, manufacturer's instructions and otherwise in compliance with Good Industry Practice.
- Undertake all Portable Appliance Testing for both the Supplier's and the Client's portable appliances, including all ICT equipment, in accordance with the Electrical Regulations Standards, HSE and Statutory Client guidance and all legislative requirements;
- Test and service all plant and equipment within the responsibility of the Supplier, as required by legislation;
- Provide competent Supplier Staff on an ad hoc basis to undertake New Works (not associated with building maintenance) as requested by the Client;
- Survey the Client Premises in accordance with the Client's Service Level Requirements to establish condition, hazards, remaining elemental life etc. of the fabric and building services and record the information which will be provided to the Client on request or by pre-agreed programme. Findings to be incorporated in next annual service plan; and
- Record and periodically update all building development, replacement works and maintenance work undertaken in each in the form of a shared electronic database or any other format agreed with Client.

Planned Maintenance:

The Supplier shall take cognisance of the Client's Planned Preventative Maintenance schedules. The Supplier shall include all building fabric maintenance tasks currently indicated within these documents in addition to any additional Client requirements;

The Supplier shall adopt a proactive approach to preventative and cyclical maintenance and inspections such that breakdowns and failures are minimised. The Supplier shall agree an annual plan of works with the Client that complies with the following requirements;

The forward maintenance register will be developed and submitted for agreement to the Client on an annual basis as part of the Service Delivery Plan at least two (2) months prior to the start of each Year of the Call-Off Contract. Any such agreement will not constitute a limitation on the extent of the maintenance requirement;

Modifications to the schedule of programmed maintenance will also be submitted to the Client for approval, providing at least four (4) weeks term time notice;

The Supplier must comply with the schedule of programmed maintenance which shall be designed to meet SFG20 requirements and ensure compliance with the performance standards;

Access for performing maintenance functions and all other works will be restricted in accordance with the performance standards of the Client (see also Security). The Supplier must comply at all times with these access restrictions and ensure that the

minimum of disruption is caused to the operations of the Client, its staff, Building Users, and the overall Client Premises;

A programme of inspection reports shall be submitted to the Client one (1) month post the Call-Off Contract Commencement Date;

The Supplier shall submit a suggested report format for the reporting of the condition of the Planned Preventative Maintenance activities which shall be agreed with the Client prior to the Call-Off Contract Commencement Date;

The report shall be submitted electronically to the Client within five (5) Working Days of undertaking the inspection;

The Supplier shall report via email within twenty-four (24) hours of the inspection any defects of a Health and Safety nature it finds during the course of its inspection together with a recommendation for remedial action if defects cannot be fixed during the inspection;

The Supplier shall submit by the end of the Mobilisation Period, its Planned Preventative Maintenance (PPM) Programme, which should include (and clearly identify) all statutory and routine tasks; and

All maintenance routines with a frequency:

- (a) Statutory tasks shall be performed on the date required to maintain statutory compliance in accordance with all appropriate legislation;
- (b) of 2 weeks or less shall be performed +/- 1 Working Day of the due date;
- (c) of greater than 2 weeks but no greater than 13 weeks shall be performed +/- 4 Working Days of the due date; and
- (d) of greater than 13 weeks shall be performed +/- 2 weeks of the due date.

Replacement Materials:

The Supplier shall ensure that the programmed replacement of materials and components comply with the requirements of the Client's requirements;

Replacement materials used shall be of the same quality and specification for existing building facilities with an equivalent life span (as detailed elsewhere) and meet Government Buying Standards where applicable, taking into account advancements in materials development and Good Industry Practice and embodied carbon and recycled content at the time of replacement, unless the Client agrees otherwise. External materials will maintain the vernacular of the building;

Reused or reconditioned parts or replacements will only be used where the Supplier can clearly show that the lifecycle and performance of the item is at least equivalent to a new replacement item and performance will not be affected; and

Maintenance and replacement will be affected in accordance with Good Industry Practice, such that at the end of the Call-Off Contract, the remaining life of each element is in line with its anticipated life from new, running from the date of actual replacement.

6. Facilities Management Standards

The Supplier shall at all times ensure that:

The FM operation of the Client Premises and Delivery of the FM Services are undertaken in compliance with all applicable UK legislation and legislation

appropriate to the location of the Client's premises as defined at Call Off, Good Industry Practice, manufacturer's recommendations and where appropriate the requirements specified by the Client as defined at Call-Off stage;

It provides any training required by the procedures and statutory provisions in respect of all Staff (whether Client or Supplier Staff) at the Client Premises;

It operates a Safe System of Work in accordance with their Health and Safety Policy and ensures that all risk assessments are current and accurately reflect the works and risks associated with the Services being undertaken; and

It ensures all activities relating to Statutory Compliance is managed through their CAFM System and that the Client has access to the data, via electronic interface or direct access to the Supplier's CAFM System.

The Supplier shall be responsible for the production, review and update of all risk assessments and written schemes of examination to meet all statutory requirements e.g. SFG20, CIBSE Guide M as required as they apply to the statutory compliance services specified by the Client.

The Supplier shall provide paper copies of all documentation associated with statutory compliance reports or documentation for retention at the Client Premises. These requirements will be defined at Call-Off stage.

The Supplier shall prepare a Service Delivery Plan (SDP) for each Client's requirements, describing its approach to providing the required Services. As a minimum, the SDP shall contain:

- Scope and Services objectives;
- Approach and methodology: Asset management method statement for meeting the Client's requirements, including treatment of any lifecycle / sinking funds (if applicable) and details regarding where such funds will reside, safeguards on early draw down and control of such funds;
- Variation procedures and additional work requests;
- Operational structure including resource proposals;
- Planned maintenance and asset lifecycle replacement schedule and delivery methodology;
- Quality policy / quality statement;
- Third party suppliers / partners;
- Balanced scorecard certification;
- Procurement of Services;
- Procurement of materials taking account of embodied carbon and recycled content;
- Management of energy use including lighting;
- Planned Preventative Maintenance (PPM) methodology / SFG20 methodology / schedules; including Uniclass and NRM classifications for interoperability;
- Computerised Asset management system;
- A single Common Data Environment are for hosting building information models and any associated current state and achieved geometry in line with PAS1192:3;
- Building management system;

- Routine maintenance;
- Formulation of the PPM programme;
- Maintenance management, recording and reporting;
- Critical spares management;
- Inspections;
- Conservation and sustainability;
- Maintenance and renewal;
- Management arrangements;
- Quality management;
- Complaints management processes;
- Operational liaison;
- Reactive maintenance Service; and
- Reactive vandalism maintenance Service.

The Supplier shall manage the Contract in accordance with the personnel and processes as detailed in the Service Delivery Plan as agreed with the Client.

The Supplier shall manage the customer satisfaction, complaint and key performance indicator measurement processes to ensure agreed performance standards are fully met.

The Supplier shall produce and issue the agreed management reports and attend meetings as requested by the Client to maintain the agreed contractual performance standards.

For each Contract, the Supplier shall as a minimum produce and comply with the following documents:

- A forward maintenance register;
- Planned and preventative maintenance schedule;
- Accident/Incident reports (RIDDOR);
- Fire evacuation drill reports;
- Statutory inspection reports, assessments and reviews;
- Risk assessment reports and reviews;
- Compliance certificates;
- Security incident reports;
- Disability discrimination assessments and reports;
- Method statements for meeting the Client's requirements;
- Health and safety policies and procedures; and
- Scope and Services objectives.

The Supplier shall at all times ensure that:

It provides any training required by the procedures and statutory provisions in respect of all staff (whether Client or Supplier Staff) at the Client Premises as well as in emergency response and security procedures;

It produces detailed procedures for a variety of emergency situations in conjunction with Client. These procedures shall be continually updated and reviewed as circumstances demand and at least annually;

It develops and maintains fire and emergency procedures, systems, equipment and staff training in order to produce a safe environment for the designated site and its users. Systems will be unobtrusive where possible to assist in creating a positive building atmosphere for all users;

It shall carry out actions associated with implementation of the procedures routinely as well as in the event of any fire or other emergencies on-site;

It programmes and implements Health and Safety inspections of the Client Premises and Service delivery annually, and provides evidence to the Client on request;

It conducts and reviews all risk assessments relevant to the operation of the Client Premises and the delivery of Services in accordance with current statutory health and safety legislation;

It undertakes a Monthly review of all accidents occurring at the Client Premises whether relating to the Supplier's or Client's staff using the Client Premises or to the Supplier's delivery of Services. The report will detail the cause of each incident and any remedial actions required to prevent reoccurrence, together with timescales for implementation;

It reviews all policies and associated documentation on a regular basis and at least annually and provide evidence of such on request by the Client;

It complies with all health and safety obligations including at all the Client's Properties which are occupied under leasehold arrangements;

It shall at all times provide and maintain the first aid kits and other safety equipment and all related consumables issued to and used by Supplier staff on the Client Properties; and

It provides the required numbers of staff with an appropriate first aid responder qualification and training for emergency responses in accordance with health and safety legislation, as required by legislation and risk assessment (as a minimum) and any Client's specific requirements.

The Supplier shall deliver the Permit to Work systems on behalf of the Client.

The Supplier be responsible for managing compliance of Permit to Work systems on behalf of the Client for all works being undertaken or managed by the Supplier, including hot works, confined spaces, live electrical working, working on or near high voltage, excavations, temporary disconnection of safety systems and working at height.

The Supplier shall be responsible for the provision of all suitably qualified, skilled and accredited Staff to successfully deliver the Permit to Work system for the Client.

The Supplier shall provide professional advice on accessibility, occupational health, disability and safety advice to meet the requirements of the Client.

The Supplier shall provide specialist furniture to meet the requirements of the Client. Cost for the provision of these furniture items will be managed via the Billable Works and Projects process.

The Supplier shall produce and maintain a contact risk register to include contract, maintenance operational service, service continuity, supplier management and staffing risks.

The Supplier shall produce and comply with any and all risk assessments pertaining to all Services undertaken at the designated Client Premises. This includes risk assessments and statutory compliance required by or produced by third parties such as landlords.

The Supplier's CAFM system will be configured to capture all elements of service provision to facilitate the production of the Management Information reporting requirements as requested by the Client.

The Supplier shall be responsible for the provision of all interfaces between their own and third-party CAFM systems to facilitate the real-time transfer of data.

The Client's data contained within the Supplier's CAFM system shall be able to be uploaded to third-party CAFM systems where required by the Client.

The Supplier shall develop the format standard and frequency of reporting with the Client and shall deliver it in accordance with the specific Client requirements in line with the agreed Service Delivery Plan.

The Supplier will deliver services and manage performance in line with the agreed key performance indicator (KPI) model.

The Supplier will manage performance using their own internal performance management systems and processes which shall align with the Client's internal performance monitoring and auditing regimes as agreed within the Service Delivery Plan (SDP).

The Supplier shall provide a system to manage, control and record and report on the delivery of all Services provided as part of any Call-Off Contract.

The Supplier shall also provide a support service available twenty-four (24) hours per day for the Client to request the deployment of the Supplier to rectify any non-provision of accommodation or Service(s) embraced by the scope of the FM Framework Contract and within specified response times.

The Supplier will develop and agree with the Client the management reporting regimes for recording statutory compliance, performance against social value targets and balanced scorecard returns.

The Supplier shall conform to the Client's Business Continuity and Disaster Recovery (BCDR) Plan dealing with recovery from accident and emergency situations, and shall participate fully in the Client's Business Continuity and Disaster Recovery planning for each business unit and as described in the relevant BCDR Plan.

The Supplier's CAFM System shall be able to provide and support any Business Continuity scenario without any degradation in performance.

The Supplier will have its own Business Continuity and Disaster Recovery (BCDR) contingency plan in place to enable continuity of their Services without degradation.

The Supplier's CAFM System facilities will have its own Business Continuity and Disaster Recovery contingency plan in place to enable continuity of the Services without degradation.

FINANCE (LOT 2)

Under this Lot, the Supplier would bring project specific finance for the Design, Build and Equip of a Sterile Services and Endoscopy Decontamination facility, as well as ongoing provision of appropriate facilities management, of the scope and scale required by an NHS acute hospital.

Subject to the Client's requirements, the Supplier should be able bring innovative financing solutions, to facilitate the delivery of land and building based capital projects. The Supplier should be in a position to discuss the impact of a variety of funding mechanisms to the client and assist in helping the client decide on the most appropriate form of financing for the Client's situation, based on appropriateness to the project type, affordability and value for money.

Client's may choose that financing must be secured and be transferrable in the event that a Contract is terminated for Supplier breach.

Suppliers should be in a position to describe the range of funding options they might offer and ensure they are in a position to fund projects, at the point of contract signature.