

DOCUMENT 3

SPECIFICATION

**FRAMEWORK FOR** **FUNCTIONAL ELECTRICAL STIMULATORS (FES) AND ACCESSORIES FOR BIRMINGHAM COMMUNITY HEALTHCARE NHS FOUNDATION TRUST (BCHC)**

Tender Reference: BCHC-16-0010

Dated: 15 September 2016

Emma Leach - Procurement Manager

Birmingham Community Healthcare NHS Foundation Trust

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# **Glossary**

BCHC

CE European Conformity

CFT Community Foundation Trust

CQC Care Quality Commission

FES Functional Electrical Stimulation

FT Foundation Trust

HCP Health Care Professionals

ITB Intrathecal Baclofen

MDD Medical Devices Directive

MS Multiple Sclerosis

MHRA Medicines and Healthcare products Regulatory Agency

NHSLA National Health Service Litigation Authority

T12 12th Thoracic Vertebra

TRUST Birmingham Community Health Care NHS Trust (BCHC)

SABS Services Awareness Bulletins

WMRC West Midlands Rehabilitation Centre

# **Introduction**

* 1. Birmingham Community Healthcare (BCHC) delivers more than two million patient interactions each year across a broad range of community and specialist services, including community nursing and health visiting. The organisation was formed in 2010 to create a single community services provider across the city of Birmingham.
  2. BCHC has more than 5,000 staff working across Birmingham and the West Midlands in a wide range of community nursing and specialist healthcare roles.
  3. BCHC provides over 100 clinical services, in people's homes, health centres, clinics and inpatient facilities for children and adults, It also provides community services, two community hospitals and services for people with learning disabilities.
  4. BCHC also operates some services for the West Midlands region including the internationally recognised West Midlands Rehabilitation Centre and one of Europe’s leading Dental Hospitals and School of Dentistry
  5. The 2014 Care Quality Commission (CQC) inspection found BCHC to be well led, effective, responsive, caring and safe, rating the Trust as ‘good’ overall. Employees were praised for their caring and compassionate nature.
  6. Birmingham Community Healthcare was officially confirmed as an NHS Foundation Trust (FT) on 1 April, 2016.
  7. Following in-depth assessment from the regulatory body, Monitor, BCHC has proved itself ready and able to lead and govern itself as a Foundation Trust (FT). Becoming a Foundation Trust will:
     1. **Allow BCHC to become closer to its communities** so they can influence BCHC more and make BCHC more accountable – helping services to become more responsive to people’s needs.
     2. **Empower BCHC staff:** membership of the organisation will create an increased sense of ownership so as to inspire staff to contribute further to BCHC decision making and plans.
     3. **Strengthen BCHC governing processes:** the role of the council of governors, which will now move out of shadow form, is to challenge BCHC practice and continually evaluate BCHC business on behalf of it’s 15,000-strong membership.
     4. **Allow for more financial and commercial freedom:** increased independence will allow BCHC to further innovate – and to act in a more flexible and timely manner – to develop services in line with local priorities and feedback from its members.
  8. BCHC continues to focus on its core purpose - the delivery of high quality, accessible and responsive community healthcare.

# **Background**

* 1. The Trust is seeking to establish a Framework Agreement for Functional Electrical Stimulation Treatment (FES).

# **Contract Period**

* 1. The framework contract period will cover a four (4) year period.

# **Scope**

* 1. This framework agreement includes:
     1. FES equipment (functional stimulators, exercise stimulators &

consumables)

* + 1. Future development of the technology
    2. Maintenance of equipment in and out of warranty period
  1. This framework agreement excludes:
     1. Medical devices not associated with FES
     2. Implanted FES Devices

# **TUPE**

* 1. Not applicable under this contract.

# **Functional Electrical Stimulation Treatment (FES)**

* 1. FES is used widely in general rehabilitation to complement therapy interventions and to facilitate, maintain and restore function. FES uses small electrical impulses to activate muscles by exciting the nerve endings to the muscles.
  2. The most common problem treated by FES is dropped foot. Drop foot is the inability to lift the foot and toes when walking. It can result from conditions such as stroke, multiple sclerosis or spinal cord injury. Functional electrical stimulation involves stimulation of the peripheral nerves that supply the paralysed muscle using electrodes that may be implanted or placed on the surface of the skin. The aim is to restore neurological muscular function:
  3. Other problems treated by FES are upper, lower & trunk weakness, spasticity, dystonia, constipation, sensory problems, poor knee control, pain, shoulder subluxation, reduced range of movements, inattention and neglect. (Please note that this list not exhaustive).
  4. Referrers include:
     1. Consultants
     2. General Practitioners
     3. Health Care Professionals (HCP)
     4. Specialist Nurses
     5. Self referrals must have Medical or HCP support

# **FES Inclusion Criteria**

* 1. **Neurological Conditions** 
     1. Upper motor neurone lesions e.g. Strokes, Multiple Sclerosis, Cerebral Palsy, Traumatic Brain Injury, Parkinson Disease, Dystonia, Partial spinal injuries – lesions above T12
     2. Muscle imbalance rather than peripheral nerve damage eg: spastic dropped foot
     3. Sensory/proprioceptive deficits such as neglect and inattention
     4. Loss of function which is disproportionate to diagnosis
     5. Patients must have receptive cognitive abilities
  2. **Orthopaedic Conditions** 
     1. Muscle wasting/loss of function through dis-use
     2. Joint replacement surgery e.g. Total Knee Replacement
     3. Amputees : particularly around shoulder and knees
     4. Children less than 5 years old are referred on a case by case basis. There is no upper age limit for FES provision.
     5. In most cases patients need to be able to physically apply the stimulator with minimal assistance to reduce carer burden.

# **FES Exclusion Criteria**

* 1. Fixed contractures of joints associated with muscles to be stimulated
  2. Broken or poor condition of skin
  3. Chronic oedema at site of stimulation
  4. Diagnosis of deep vein thrombosis
  5. Receptive dysphasia (unable to understand instructions)
  6. Anxious patients
  7. Complete peripheral nerve damage
  8. Pacemaker or defibrillator in situ
  9. Pregnancy or intention to become pregnant
  10. Active cancer
  11. Uncontrolled epilepsy
  12. Metal in region of stimulation eg: pin and plate
  13. Ataxic and polio patients are generally poor responders although there are exceptions.

# **Examples of Clinical Reasons for FES**

* 1. Patients who are at risk of tripping and falling whilst walking (whether or not they use an orthosis.)
  2. Combined with another intervention eg: Botulinum toxin, Intrathecal Baclofen (ITB)
  3. Maintain joint range, increase muscle strength and improve mobility
  4. Reduce pain and improve quality of life and participation
  5. Prevent, reduce and maintain spasticity levels
  6. Facilitate/re-educate muscle activity

# **Types Of Stimulators**

* 1. Function (walking) and exercise
  2. Function only
  3. Exercise only

# **Uses of Stimulators & External Surface Electrode Application of FES**

* 1. Wireless footswitch, single channel for function (e.g. walking)
  2. Single channel for function (e.g. walking)
  3. Two (2) Channel (e.g. bilateral dropped foot)
  4. Two (2) channel exercise – preparation for treatment (e.g. walking)
  5. Patients may need more than one stimulator as:
     1. preparation for walking or
     2. when they need a stimulator for each leg.

# **Regulations**

* 1. A Managed Service to provide and maintain Functional Electrical Stimulation (FES) Devices and associated management to support compliance in line with national regulatory and statutory bodies which include, but not limited to:
     1. Managing Medical Devices Guidelines for Healthcare & Social Service Organisations[[1]](#footnote-1)
     2. Medical Devices Regulations 2002[[2]](#footnote-2)
     3. The Care Quality Commission (CQC) audits against regulations approved by the UK government e.g.: [[3]](#footnote-3)
        1. CQC outcome 15 - Premises and equipment
        2. All other appropriate standards subsequently added or amended.
     4. [NHS Litigation Authority](http://www.nhsla.com/safety/Documents/Issue%201.pdf) (NHSLA) Standard No. 5 e.g. [[4]](#footnote-4)
        1. Criterion No. 4 Maintenance of Medical Devices & Equipment
        2. Criterion No. 5 Medical Devices Training
        3. All other appropriate standards subsequently added or amended.
     5. ISO 14385:2016 Medical Device – Quality management systems requirements for regulatory purposes.[[5]](#footnote-5)
     6. Medical Devices Directive (MDD) for Class IIa Devices.[[6]](#footnote-6)
  2. All devices must meet appropriate European and UK national safety standards prior to procurement.
  3. The successful Contractor(s) shall provide the following services:
     1. Manage all maintenance elements associated within this agreement and provide the Trust with monthly reports detailing associated activity.
     2. Carry out all repairs in conjunction with manufacturer's specifications and regulatory body's guidance, ensuring compliance and service is provided in a cost effective manner.
     3. Advise on any MHRA / Medical Device Alerts and Field Safety Notices that may be relevant to the Commissioners medical device inventory.
     4. Monthly reports of purchases and stimulator serial numbers where appropriate
     5. Provide training to staff on new products as appropriate (Train the Trainer).
     6. Helpdesk support as required for clinical & technical queries including maintenance
     7. Warranty period for all new stimulators and footswitches (non-wireless or wireless)

# **Key Aims and Objectives**

* 1. Bidders can bid for the **any or all** of the following lots:
     1. Lot 1
        1. Functional Only Stimulators (Clause 16)
        2. Functional and Exercise Stimulators (Clause 16)
     2. Lot 3 Exercise Only Stimulators (Clause 17)
     3. Lot 4 FES Consumables (Clause 18)

# **Lot 1 Functional and Exercise Electrical Stimulation Equipment**

* 1. **Lot 1 Equipment** shall include:
     1. Functional only stimulators
     2. Functional and Exercise Stimulators
  2. Accessories for 15.1.1 and **Error! Reference source not found.** shall include:
     1. Instruction Manual (full and quick guide)
     2. Storage Bag
     3. Knee Straps
     4. Case
     5. Belt Clip
     6. Insoles
     7. Wireless Insoles
     8. Wireless footswitches
     9. Knee cuff
     10. Electrodes
     11. Electrode leads
     12. Footswitch leads
     13. Footswitches
     14. Battery charger
     15. Rechargeable batteries
     16. Non-rechargeable e.g. CR2430 or 9v

# **Lot 2 Exercise Only Electrical Stimulation Equipment**

* 1. Equipment shall include:
     1. Exercise only units
  2. **Accessories** shall include:
     1. Instruction Manual (full and quick guide)
     2. Storage Bag
     3. Case
     4. Belt Clip
     5. Electrodes
     6. Leads and footswitches (including variable length)
     7. Batteries (rechargeable or other)
     8. Battery charger (if appropriate)

# **Lot 3 Consumables**

* + 1. Electrodes range of sizes & properties for skin care
    2. Leads range of lengths for attachment to electrodes and footswitches
    3. Batteries – all types as appropriate

# **Contractor(s) Requirements**

* 1. The Trust will be awarding the framework to the successful Contractor(s) who can demonstrate they have the appropriate attributes in the following key areas:
     1. Quality (70%)
     2. Price (30 %)

# **Repairs**

* 1. Repairs work includes but is not limited to the following list:
     1. Display
     2. Controls
     3. Output
     4. Power
     5. Software Upgrade
     6. Service
     7. Battery connectors
     8. Overhaul
        1. Replace damaged stimulator body if necessary and ensure device is fit for purpose
        2. Check for all defects and ensure device meets manufacturers specification
     9. Sounder
     10. Wire Connection
     11. Wireless footswitch
  2. The successful Contractor(s) shall carry out repairs occurring outside the warranty period at a flat rate. The successful Contractor(s) may also offer an extended warranty.
  3. The successful Contractor(s) shall carry out all repairs in conjunction with manufacturer’s recommendations, equipment specifications and regulatory body’s guidance. All repair work will be carried out subject to Trust approval
  4. The successful Contractor(s) shall ensure repairs are carried out by qualified personnel. (The successful Contractor(s) shall provide records on request.)
  5. The successful Contractor(s) shall fit only manufacturer approved quality replacement parts and carry out all tests as per the manufacturers' recommendations.

# **Insurance**

* 1. The successful Contractor(s) must ensure that adequate levels of insurance are in place. The following are the minimum levels required, this is not intended to be an exhaustive list:
     1. Public Liability = £10m
     2. Employers Liability = £5m
  2. Where these levels are not currently held at point of tendering, the successful Contractor(s) will be required to have them in place at time of award.

# **Incident Reporting**

* 1. As soon as the successful Contractor(s) becomes aware, it shall immediately report any incident to the designated Trust Authorised Officer[[7]](#footnote-7). The successful Contractor(s) shall undertake an immediate investigation and shall provide feedback on findings, including corrective actions required and trends observed, to the Trust within forty-eight (48) hours of the incident being reported by telephone/e-mail.
  2. Serious incidents can be categorised as any of the following. This list is indicative only and not exhaustive:
     1. Malfunctioning software
     2. Substandard hardwire
     3. Missing instruction handbook
  3. In the event of an incident the Trust will immediately follow its own organisational health and safety procedures. This will include the following, this list is not exhaustive;
     1. Tending to the injured party.
     2. Reporting the incident on the Trust’s incident reporting system (Datix)
     3. Report as necessary to MHRA (or member state competent authority)
  4. The successful Contractor(s) shall, in the event of a serious incident;
     1. Provide from within Senior Management, a single point of contact person within one (1) hour of notification. It shall be the responsibility of the contact person to pursue the investigation and mitigation of the incident to the satisfaction of the Trust and shall be required to provide progress updates to the Trust on request.
     2. Arrange an immediate visit to investigate and provide additional services if required to ensure patient safety that all information has been recorded accurately.
     3. Notify their insurers. Should the injured party raise a claim as a result of the incident;
     4. Any claims made against the successful Contractor(s) for alleged failure in the service will be addressed by their insurers.
  5. Full written responses to incidents will be provided to the Trust within five (5) working days of the initial notification.

# **Contract Management**

* 1. **Account Manager**
     1. The successful Contractor(s) shall appoint and provide contact details for an Account Manager upon award of the Contract. In the event of unsatisfactory performance the Trust reserves the right to stipulate that the Account Manager must be changed.
     2. The Account Manager tasks are envisioned, but not limited to:
        1. Liaising with the Trust Contact Management Team.
        2. Acting as an escalation point for queries, advice and issues.
        3. Identification of opportunities for cost savings and improvements.
        4. Recording and agreeing changes to improve the service.
        5. Trend analysis.
        6. Preparation for review meetings including the provision of Management Information (MI)
        7. Fulfilling requests for information from the Trust.
        8. Information security & governance.
        9. Incident Handling and responses.
     3. Category Review meetings shall include, but not be restricted to the following topics:-
        1. Overall performance against key performance indicators (KPI’s).
        2. Volume and expenditure trends.
        3. Compliance and satisfaction levels.
        4. Sustainability strategy and performance.
        5. Business Continuity issues and updates.
        6. Proposals for improvements on any area of the contract.
        7. Review of market conditions/ intelligence.
        8. Trading Conditions and Financial Stability.
        9. Review of risk assessment.
        10. Consideration of security incidents and trends, other security issues and review of Security Plan.
     4. The Trust may make ad hoc requests to the Account Manager for management information and support for Freedom of Information requests, all of which shall be provided at no additional cost. The successful Contractor(s) shall note that such responses are often required urgently and shall be prepared to work to whatever deadline the Trust proposes/stipulates.
     5. The Account Manager shall ensure that all relevant staff in the successful contractor’s organisation will be fully briefed on the nature and details of the service provision and any changes as a result of any improvements identified.
     6. The successful Contractor(s) shall bear all of their costs associated with Category Management including attendance at meetings, which may be held at either the Trust’s or the successful contractor’s premises.

# **Management Information**

* 1. The primary contract management activity from both parties shall be to monitor service performance.
  2. After Contract commencement the successful Contractor(s) shall attend performance review meetings with the Trust to review the progress of the contract, discuss the management information and to review any operational issues that have arisen in the preceding months.
  3. The Trust reserves the right to conduct site audits as part of the contract management activity.
  4. The successful Contractor(s) shall offer access to any part of their premises to representatives from the Trust for the purpose of commercial assurance, risk assessment, security assurance, familiarisation on procedures etc.
  5. Monthly Service Review Meetings between Trust and successful contractor, reviewed after three (3) months.
  6. The successful Contractor(s) must provide monthly MI reports[[8]](#footnote-8) (by ten (10) working days from the beginning of each month) including the following, this list is not exhaustive:
  7. Monthly attendance summary report listing all work carried out at each of the sites.
  8. A summary of all incidents, problems and changes.
  9. Any information required to support the KPI’s (see clause 24).

# **Key Performance Indicators (KPI’s)**

* 1. The successful Contractor(s) must provide all KPI statistics (by ten (10) working days from the beginning of each month) at the end of each Service Monitoring Period to be reviewed at the Service Review Meeting.
  2. The successful Contractor(s) shall provide robust processes to ensure they achieve their Key Performance Indicators (KPIs). Key Performance Indicators by example may include, but not exclusive to, the following:
     1. Delivery within agreed timeframe – 100%
     2. Communication on delivery process – 100%
        1. delays
        2. all goods at once or separate
        3. expected time frame for delivery
     3. Repairs right first time – 100%. Within agreed timeframe
     4. Trust Contract Management Team notified of any incidents in line within defined timescales (clause 21) – 100%
     5. Successful Contractor(s) to ensure MI is delivered within defined timeframe – 100%

# **Staff**

* 1. The successful Contractor(s) shall employ a sufficient number of trained and competent staff at all times and in all respects to ensure the continuous provision of services to meet this specification (as a minimum).
  2. The Successful Contractor(s) must have a transparent and accountable recruitment process. Where applicable ensures all staff hold clean licenses and/or have less than six (6) points none of which to be accumulated by cautions / offences described by the Road Safety Act 2006.
  3. The successful Contractor(s) will be required to demonstrate that all staff have gained appropriate occupational health clearance prior to the commencement of employment.
  4. The successful Contractor(s) will be expected to deal with any breach of conduct, failure of performance or other disciplinary matter using an appropriate disciplinary procedure.
  5. The Successful Contractor(s) shall ensure an identity badge is provided to all staff assigned to work on Trust premises, which must include an up to date photograph and a contact telephone number to enable the identity of the Successful Contractor(s) staff to be confirmed. This identity card must be provided to personnel on commencement of working on the contract. The costs of identity badges will be borne by the Successful Contractor. This must be worn at all times by the staff when working on this contract.
  6. The successful Contractor(s) will recruit competent technical trained staff, in order to comply with the successful contractor’s obligations. All successful contractors’ staff will have on-going training reviews, and the successful Contractor(s) will develop its staff, to meet any current or future regulatory requirements.
  7. The successful Contractor(s) shall not access Trust property without due and appropriate reason confining activity to the locality of the work tasked and shall cause as little interference as possible with the personnel, patients and work proceeding in and around the Trusts premises.
  8. The Trust Authorised Officer may exclude from the contract any employee of the successful Contractor(s) who persistently fails to meet the required standards of competence and behavior and request that the successful Contractor(s) ensures that he/she is not involved in the provision of this service for the remainder of the contract (and any extensions).
  9. The successful Contractor(s) shall ensure that every member of staff to work on this contract, including temporary staff and any Sub-Contractors and their staff can confirm as a minimum, all of the following:
     1. Name, date of birth and address.
     2. National Insurance number or other unique personal identifying number where appropriate.
     3. Full details of previous employers (name, address and dates), for a minimum of the past three (3) years.
     4. Confirmation of any necessary qualifications/licenses.
     5. Educational details and references where someone is new to the workforce when these are considered necessary.
     6. Confirmation of permission to work in the UK, if appropriate.
     7. A Criminal record declaration form.
  10. The successful Contractor(s) must hold validated references for their staff, including documentary evidence.
  11. To establish the bona fide status of the staff.
      1. Their permission to work within the UK prior to the commencement of working with the Trust.
      2. The successful Contractor(s) must ensure that their personnel comply with the Trust’s policies in respect of;
         1. Manual Handling.
         2. Equality and Diversity.
         3. Safeguarding of Adults and Children / PREVENT Awareness. (minimum standard the Trust Baseline level information leaflets must be available to staff)[[9]](#footnote-9)
         4. Control of Substances Hazardous to Health (COSHH).
      3. It is a requirement that, at the successful contractor’s own cost, all staff, including Sub-Contractors and their staff, working on this contract must be fully trained in respect of the Trusts’ Policies for the items listed in clause 25.11.1.
  12. The Trust employs a diverse workforce and the successful Contractor(s) must ensure that personnel engaging with the Trust’s staff act in a nondiscriminatory manner.
  13. The Trust requires that employees who fail to satisfy vetting procedures, or who refuse to be vetted, be removed from all tasks involved in the delivery of the service. The Trust shall not give reasons for this requirement and the successful Contractor(s) must comply with such a direction.
  14. **Training**
      1. All operatives of the successful Contractor(s) will attend a Trust Estates induction on an annual basis prior to the commencement of the winter period. The induction process takes approximately fifteen (15) minutes and provides a general overview of Health and Safety guidance along with guidance of the Trusts expectations of the successful contractor’s staff behaviour whilst on site.
      2. The successful contractor’s staff that will be involved in the provision of the services required under this contract are to be demonstrate on-going competence to the Trust standards in the areas listed in 25.11.1.
         1. Please note that the areas listed in 25.11.1 are not exhaustive and may be updated from time to time over the contract period.
      3. The successful Contractor(s) will ensure all manual handling complies with Manual Handling Regulations 1992 including where required a dynamic risk assessment in accordance with TILE (Task, Individual, Load, and Environment) protocols.
      4. Where required the successful Contractor(s) will seek the advice and support of the Trust Risk Management Team to resolve issues from any Risk Assessment undertaken.
  15. **Smoking**
      1. The successful Contractor(s) shall ensure that all of its staff member(s) used in the provision of the services shall abide by the Trust’s smoke free zones. Smoking by any person is strictly prohibited whether prior, during or after the provision of Services whilst within a Trust smoke free zone.
      2. The Trust reserve the right to require the replacement of any of the successful contractor’s staff member(s) observed or otherwise reasonably suspected of smoking within a Trust smoke free zone whilst performing the Services.
  16. **Alcohol and Illegal Drugs**
      1. The successful Contractor(s) shall ensure that its staff member(s) do not perform any services whilst under the influence of either alcohol or illegal drugs.
      2. The Trust may if it suspects that any staff member(s) is under the influence of either alcohol or illegal drugs:
         1. Suspend/terminate the staff member(s) from providing services under this Agreement.
         2. Inform the Police of any suspected offence.
      3. The successful Contractor(s) shall not be entitled to any payment from the Trust nor shall it be entitled to make any claim for any losses or expenses whatsoever or howsoever incurred as a result of, or any period of suspension of the staff member(s) from this Agreement.
      4. The Trust may at any time during the Term of this Agreement introduce a system for testing staff member(s) for alcohol and illegal drugs. The Trust shall provide the successful Contractor(s) with fourteen (14) days prior notice in writing of the intention to commence a testing program together with details of the Trust’s requirements in relation to any such program.
  17. **Prescribed and non-prescribed medication**
      1. The successful Contractor(s) shall ensure that it implements procedures for monitoring the taking of medication by their staff member(s) to ensure that the recommendations of their doctor, or, for over the counter remedies, the manufacturer in relation to driving / operating machinery, are appropriately followed.

# **Uniforms**

* 1. The successful contractor’s staff engaged with activates relating to this contract on Trust premises must be easily identifiable and wear the appropriate Personal Protection Equipment (PPE) when entering any of the Trust’s sites.
  2. Where the successful Contractor(s) intends to use Sub-Contractors, the Sub-Contractors employees engaged with activates relating to this contract on Trust premises must be easily identifiable and wear the appropriate Personal Protection Equipment (PPE) when entering any of the Trust’s sites.
  3. As a minimum the Contractor(s) will ensure that all operatives undertaking work as part of this service will wear safety shoes, high visibility (hi-vis) jacket and any other PPE deemed necessary identified from a task specific risk assessment and in compliance with the Personal Protective Equipment and Work Regulations 2002.

# **Complaints**

* 1. The successful Contractor(s) shall notify the Trust Authorised Officer[[10]](#footnote-10) of any complaints lodged concerning the service with a copy of any relevant documentation. A written response to complaints must be submitted within ten (10) working days.
  2. Complaints about the service must as a matter of routine be reported to the Trust Authorised Officer. The Trust Authorised Officer shall immediately investigate the matter and if the complaint appears justified he/she shall contact the successful contractor’s Contract Manager in writing in order to resolve the problem. The Contract Manager shall investigate the matter and reply to the Trust Authorised Officer in writing in accordance with the Trust’s Complaints Procedure.
  3. The Contract Manager and the Trust Authorised Officer shall review the complaints made regarding the service provided at their review meetings.

# **Quality Standards**

* 1. From the commencement[[11]](#footnote-11) of the contract, the successful Contractor(s) shall be required to hold accreditation and comply with any and all subsequent revisions throughout the length of the contract, of the following (or latest relevant version) standards:
  2. **ISO 13485:2016 Medical Devices**
     1. ISO 13485:2016 specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). ISO 13485:2016 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organisations.
     2. Requirements of ISO 13485:2016 are applicable to organisations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organisation.
  3. **ISO 9001:2015 – Quality management systems**
     1. ISO 9001:2015 specifies requirements for a quality management system where an organisation needs to demonstrate its ability to consistently provide products that meet Trust and applicable statutory and regulatory requirements, and aims to enhance Trust satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to Trust and applicable statutory and regulatory requirements.
     2. All requirements of ISO 9001:2015 are generic and are intended to be applicable to all organisations, regardless of type, size and product provided.
  4. **ISO 14001:2015 – Environmental Management**
     1. The ISO 14000 family of standards provides practical tools for companies and organizations of all kinds looking to manage their environmental responsibilities.
     2. ISO 14001:2015 and its supporting standards such as ISO 14006:2011 focus on environmental systems to achieve this. The other standards in the family focus on specific approaches such as audits, communications, labeling and life cycle analysis, as well as environmental challenges such as climate change.
  5. **BS OHSAS 18001 - Occupational Health and Safety Management**
     1. BS OHSAS 18001 sets out the minimum requirements for occupational health and safety management best practice. IT is a framework for an occupational health and safety management system. Ensuring policies, procedures and controls needed for an organisation to achieve the best possible working conditions, aligned to internationally recognised best practice.
  6. **Safety Schemes In Procurement (SSIP)**
     1. SSIP activity has increasingly been able to cut pre-qualification costs and bureaucracy in the supply chain. SSIP is a key route to health and safety pre-qualification concentrating on making cross-recognition of member schemes as effective as possible, and on highlighting the resulting savings to the supply chain.
     2. Holding a valid accreditation, throughout this contract period, to a recognised SSIP member scheme will identify that a recognised independent health & Safety assessment of the successful Contractor(s) has been undertaken.

# **Legislation**

* 1. The successful Contractor(s) shall comply with all relevant legislation associated with the services required under this contract and shall bear the cost of any changes that need to be made to comply with amendments / new legislation as required.
  2. **Health and Safety at Work Act 1974 (as amended)**
     1. The successful Contractor(s) shall ensure that their employees are instructed as to their duties and responsibilities in relation to the Health and Safety at Work Act etc 1974 and that they comply with the requirements at all times.
     2. The successful Contractor(s) shall be required to provide evidence that they regularly instruct their staff in the requirements of the Health and Safety at Work Act etc 1974.
     3. It is a requirement that the successful Contractor(s) fully notifies the Trust of any Risk Assessment carried out in relation to providing the service, and clearly details any findings or conclusions.
  3. **Managing Health and Safety at work regulations 1999 (as amended) (HSAWA)**
     1. The successful Contractor(s) shall ensure that the services provided and the staff used shall at all times be aligned to the provisions of the Managing Health and Safety at work regulations.
     2. The successful Contractor(s) must ensure that the essential health and safety requirements[4] of the Machinery Directive, concerning hazards from the mobility of machinery (as implemented by the Supply of Machinery (Safety) Regulations 2008[[6]) are adhered to at all times.
        1. These essential health and safety requirements must be met by the manufacturer when designing and constructing mobile machinery. This means that end users should not need to further modify new [CE marked](http://www.hse.gov.uk/work-equipment-machinery/ce-mark-summary.htm)[7] mobile work equipment in order for it to comply with PUWER.
        2. Where mobile work equipment is designed primarily for travel on public roads, compliance with the [Road Vehicles (Construction and Use) Regulations](http://www.legislation.gov.uk/uksi/1986/1078/contents/made) [8] will normally be sufficient in complying with the main mobile equipment aspects of PUWER.
        3. Purchases and maintains equipment conforming to Schedule 2 HSAWA 1974 the Supply of Machinery (Safety) Regulations 2008 and the requirements of the DVSLA regarding the [Road Vehicles (Construction and Use) Regulations](http://www.legislation.gov.uk/uksi/1986/1078/contents/made)  for mobile equipment.
  4. **Working Time Regulations Act (1998) (as amended)**
     1. The successful Contractor(s) shall ensure that staff shall not exceed safe and/or statutory guidelines/requirements described in the above act with respect to their working hours, breaks and intervals between shifts.
  5. **Equality Act 2010 (as amended)**
     1. The successful Contractor(s) must comply with the Trust’s Equal Opportunities policy, demonstrate a commitment to equal opportunities and diversity in their staff and demonstrate that their staff is treated under the same principles of fairness as NHS staff. In respect of all persons employed or seeking to be employed by the successful Contractor(s) in and about the provision of the services, the successful Contractor(s) shall comply with each and every part of the provision of law which prohibits discrimination in relation to employment on the grounds of sex, colour, race, ethnic or national origin or religion, and disability.
  6. **Control of Substances Hazardous to Health Regulations 2002 (COSHH) (as amended)**
     1. COSHH is the law that requires employers to control substances that are hazardous to health.
  7. **Late Payment of Commercial Debts (Interest) Act 1998 (as amended)**
     1. The successful Contractor(s) shall refer to the Late Payments of Commercial Debts (interest) Act 1998, for instances of failure by the Trust to make any payment of any charges for the Service within 28 days of receipt of a valid invoice , then the Successful Contractor(s) shall be entitled to interest on the payment overdue.
  8. **Data Protection Act 1998 (as amended)**
     1. The successful Contractor(s) must ensure that the service being provided throughout the full contract period is fully compliant with the Data Protection Act at all times throughout this contract.
  9. **Freedom of Information Act 2000 (as amended)**
     1. The successful Contractor(s) must provide the support to Trust Authorised Officer to gain access to the relevant data. This is to support the Trust in meeting its statutory requirements in responding to any requests received under the Freedom of Information Act at all times throughout this contract.
  10. **The Computer Misuse Act (CMA) 1990 (as amended)**
      1. The successful Contractor(s) must provide the support to Trust Authorised Officer to gain access to the relevant data. This is to support the Trust in meeting its statutory requirements to make provision for securing computer material against unauthorised access or modification; and for connected purposes.

# **Information Governance**

* 1. The successful Contractor(s) must ensure all processes and policies align to requirements within the NHS Information Governance Toolkit.
  2. All of the successful contractors staff with access to Trust data MUST have a signed a confidentiality agreement.
  3. The successful Contractor(s) must provide assurance of data protection and information security compliance in line with the Data Protection Act 1998 and Information Commissioner's Office (ICO) guidance at all times throughout the lifetime of the contract.

# **Business Continuity**

* 1. The successful Contractor(s) shall use reasonable endeavors to ensure its Business Continuity Plan operates effectively alongside the Trust’s business continuity plan where relevant to the provision of the services.
  2. Where “Business Continuity Plan” means the successful contractor’s business continuity plan which includes its plans for continuity of the Services during a Business Continuity Event.
  3. Where “Business Continuity Event” means any event or issue that could impact on the operations of the successful Contractor(s) and its ability to provide the Services including influenza pandemic and any Force Majeure Event.
  4. Throughout the Term, the successful Contractor(s) shall need to ensure its Business Continuity Plan provides for continuity during a Business Continuity Event. The successful Contractor(s) shall be required to confirm and agree such Business Continuity Plan details and shall continue to detail robust arrangements that are reasonable and proportionate to:
     1. the criticality of this Contract to the Trust,
     2. and the size and scope of the successful Contractor’s business operations,
     3. regarding continuity of the provision of the Services during and following a Business Continuity Event.
  5. The successful Contractor(s) shall need to conduct a Business Continuity Programme over a twelve month period which shall actively document action based learning from any arising Incident, training or exercising completed. The Plan; programme and learning documents shall be open to inspection and report as part of the Trusts Core Standards assurance process.
  6. The successful Contractor(s) shall need to provide to the Trust a copy of any updated or revised Business Continuity Plan within fourteen (14) Business Days of any material update or revision to the Business Continuity Plan.
  7. The Trust may suggest reasonable and proportionate amendments to the successful Contractor(s) regarding the Business Continuity Plan at any time. Where the successful Contractor, acting reasonably, deems such suggestions made by the Trust to be relevant and appropriate, the successful Contractor(s) shall incorporate into the Business Continuity Plan all such suggestions made by the Trust in respect of such Business Continuity Plan. Shall the successful Contractor(s) not incorporate any suggestion made by the Trust into such Business Continuity Plan it shall explain the reasons for not doing so to the Trust in writing to the named authorised officer.
  8. Shall a Business Continuity Event occur at any time, the successful Contractor(s) shall implement and comply with its Business Continuity Plan and provide regular written reports to the Trust’s authorised officer on such implementation.
  9. During and following a Business Continuity Event, the successful Contractor(s) shall use reasonable endeavors to continue to provide the Services in accordance with the contract.

# **Exit Plan**

* 1. The successful Contractor(s) will be required to create and maintain an exit plan throughout the length of the contract period, in line with the following timescales;
     1. On implementation, an indicative exit plan will be provided to the Trust by the successful contractor.
     2. After the first six (6) months a finalised exit plan will be provided to the Trust by the successful contractor.
     3. At the annual contract review meeting the exit plan will be updated by the successful Contractor(s) and provided to the Trust.
  2. On cessation of the contract, all electronic information shall be provided to the Trust at no cost. This must include all data relevant to the trust, as per the Trusts Terms & Conditions, all data belongs to the Trust and must be provided to the trust in a reasonable timescale and format.
  3. Any exit plan must have clear timescales and confirmation of resource commitments required by the supplier to ensure that any handover of data to a new provider shall be in a reasonable and timely manner, in agreement with the Trust and the new provider’s implementation plan.

# **Sustainability**

* 1. The successful Contractor(s) shall operate the service having due care for the environment and must have an Environmental Policy. This policy shall cover as a minimum:
     1. Waste disposal e.g. batteries etc. If this function is contracted to a third party, the successful Contractor(s) shall be able to provide evidence that correct procedures are in place.

# **Social Economic Responsibility**

* 1. The Trust is committed to its Social Economic Responsibilities and ensuring it is a Good Corporate Citizen[[12]](#footnote-12) (GCC). It is imperative that the successful Contractor(s) ensures that its supply chain is monitored and that there is zero tolerance of Modern Slavery within their supply chain.
  2. The successful Contractor(s) must ensure that at no point, throughout the delivery of this agreement, that any materials used to deliver this agreement are created through the use of bonded labour or infringement of human rights.
  3. Where any such issues arise within the extended supply chain, the successful Contractor(s) shall act to remove these items from entering the Trusts extended supply chain and implement ethical sourcing programs and supply chain audits to prevent any repetition.

# **Payment**

* 1. Any liquidated damages shall be deducted from payments due to the successful Contractor(s) on a monthly basis.
  2. The successful Contractor(s) shall endeavor to absorb fuel price increases where possible.
  3. The successful Contractor(s) shall submit an invoice to the Trust for payment in line with the payment profile and form of invoicing agreed between the Trust and the successful Contractor(s) for the Service or parts thereof that have been completed to the satisfaction of the Trust during that particular period. Invoices shall be transferred in written form on a monthly basis. A detailed transaction summary shall also be transferred to the Trust in electronic form.
  4. Within twenty-eight (28) days of receipt of a valid invoice[[13]](#footnote-13), the Trust shall pay to the successful Contractor(s) the sum due in accordance with the Contract unless the Trust does not accept part of an invoice, in which instance the element under dispute shall be withheld. The Trust shall inform the successful Contractor(s) within two (2) working days of any disputed areas, and shall endeavor to resolve the dispute with the successful Contractor(s) within one (1) month.
  5. As per regulation 113(6) of the Public Contracts Regulations 2015, where the successful Contractor(s) enters into a Sub-Contract[[14]](#footnote-14) in the delivery of this contract, the successful Contractor(s) shall include in that sub-contract14 provisions having the same effect as the clauses 35.3 to 35.5 inclusive and a provision requiring the counterparty to that sub-contract to include in any sub-contract which it awards provisions having the same effect as clauses 35.3 to 35.5 inclusive.
  6. Any credit or other payments due to the Trust from the successful Contractor(s) for whatever reason shall be shown separately on monthly invoices and may be recoverable by deduction from any sum or sums then due, or which at any time thereafter may become due to the successful Contractor(s) under the Contract or any other contract with the Trust.
  7. The successful Contractor(s) must state whether prompt payment for this service shall qualify for a reduction in charges, and if so how this would be structured and applied. Any discount for prompt payment shall be applicable to the date of receipt of the correct and valid invoice.
  8. Any delay as a result of failure by the successful Contractor(s) to provide a correctly completed and valid invoice shall not jeopardise the receipt by the Trust of prompt payment discount.
  9. No debt incurred in the delivery of this Contract may be assigned without the prior permission of the Trust.
  10. All Prices must be quoted in Great British Pounds (GBP) and all payments shall be made in GBP.
  11. In line with the Department of Health Combating Inflation Guidance Document (March 2014), there shall be no pricing uplift for inflation made throughout the length of this contract. This guidance of a zero inflation policy shall be seen as a minimum target, In order for the Trust to keep a balanced budget and to continue to provide a quality service for patients by protecting it’s front-line.
  12. Where the successful Contractor(s) is able to introduce initiatives to help the Trust reduce costs over the length of the Contract, they are to be ratified through the Contract Review Meetings and agreed in writing by the Trust Contract Manager.
  13. VAT shall be shown separately on all invoices.

1. <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/421028/Managing_medical_devices_-_Apr_2015.pdf> [↑](#footnote-ref-1)
2. http://www.legislation.gov.uk/uksi/2002/618/introduction/made [↑](#footnote-ref-2)
3. http://www.cqc.org.uk/content/regulations-service-providers-and-managers [↑](#footnote-ref-3)
4. http://www.nhsla.com/safety/Documents/NHS%20LA%20Risk%20Management%20Standards%202013-14.pdf [↑](#footnote-ref-4)
5. http://www.iso.org/iso/home/store/catalogue\_ics/catalogue\_detail\_ics.htm?csnumber=59752 [↑](#footnote-ref-5)
6. https://www.gov.uk/guidance/medical-devices-conformity-assessment-and-the-ce-mark [↑](#footnote-ref-6)
7. Available at Mini-Competition Stage [↑](#footnote-ref-7)
8. Available at Mini-Competition Stage [↑](#footnote-ref-8)
9. Whilst the Trust understands that the successful contractor(s)’s staff will not come in contact with patients on a regular basis, the Trust has the Social Responsibility to ensure that all staff and contractors are trained in the Safeguarding of Adults and Children. [↑](#footnote-ref-9)
10. Available at Mini-Competition Stage [↑](#footnote-ref-10)
11. Where a standard is not currently in place, or an equivalent, the successful Contractor(s) shall be required to work to the principles of the standard from contract commencement and work towards accreditation during the contract period. [↑](#footnote-ref-11)
12. <http://www.sduhealth.org.uk/delivery/evaluate.aspx> [↑](#footnote-ref-12)
13. The Trust uses an outsourced financial services supplier, ELFS Shared Services. Appendix E explains what is required to ensure prompt payment of your invoices. [↑](#footnote-ref-13)
14. “Sub-Contract” means a contract between two or more suppliers, at any stage of remoteness from the Trust in a subcontracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of this contract. [↑](#footnote-ref-14)